AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

114TH CONGRESS
1st Session

COMMITTEE PRINT

S. PRT.
114–20

THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTH CARE SYSTEM

PART 1 OF 2

PREPARED BY THE STAFFS OF RANKING MEMBER RON WYDEN AND COMMITTEE MEMBER CHARLES E. GRASSLEY

COMMITTEE ON FINANCE
UNITED STATES SENATE

ORRIN G. HATCH, *Chairman*
RON WYDEN, *Ranking Member*

DECEMBER 2015

Printed for the use of the Committee on Finance

THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTH CARE SYSTEM—PART 1 OF 2

114TH CONGRESS
1st Session

COMMITTEE PRINT

S. PRT.
114–20

THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTH CARE SYSTEM

PART 1 OF 2

PREPARED BY THE STAFFS OF RANKING MEMBER RON WYDEN AND COMMITTEE MEMBER CHARLES E. GRASSLEY

COMMITTEE ON FINANCE
UNITED STATES SENATE

ORRIN G. HATCH, *Chairman*
RON WYDEN, *Ranking Member*

DECEMBER 2015

Printed for the use of the Committee on Finance

U.S. GOVERNMENT PUBLISHING OFFICE
97–329—PDF WASHINGTON : 2015

For sale by the Superintendent of Documents, U.S. Government Publishing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2104 Mail: Stop IDCC, Washington, DC 20402–0001

COMMITTEE ON FINANCE

ORRIN G. HATCH, Utah, *Chairman*

CHARLES E. GRASSLEY, Iowa
MIKE CRAPO, Idaho
PAT ROBERTS, Kansas
MICHAEL B. ENZI, Wyoming
JOHN CORNYN, Texas
JOHN THUNE, South Dakota
RICHARD BURR, North Carolina
JOHNNY ISAKSON, Georgia
ROB PORTMAN, Ohio
PATRICK J. TOOMEY, Pennsylvania
DANIEL COATS, Indiana
DEAN HELLER, Nevada
TIM SCOTT, South Carolina

RON WYDEN, Oregon
CHARLES E. SCHUMER, New York
DEBBIE STABENOW, Michigan
MARIA CANTWELL, Washington
BILL NELSON, Florida
ROBERT MENENDEZ, New Jersey
THOMAS R. CARPER, Delaware
BENJAMIN L. CARDIN, Maryland
SHERROD BROWN, Ohio
MICHAEL F. BENNET, Colorado
ROBERT P. CASEY, Jr., Pennsylvania
MARK R. WARNER, Virginia

CHRIS CAMPBELL, *Staff Director*
JOSHUA SHEINKMAN, *Democratic Staff Director*

INVESTIGATIVE STAFF

Senate Finance Committee Minority Staff
PETER T. GARTRELL, Investigator
DAVID M. BERICK, Chief Investigator
ELIZABETH M. JURINKA, Chief Health Policy Advisor
IAN M. NICHOLSON, Assistant to the Democratic Staff Director
MATTHEW A. KAZAN, Senior Health Advisor
ANNE M. DWYER, Health Counsel
DOUGLASS V. CALIDAS, Legislative Fellow
JAMES P. WEISMULLER, Law Clerk
ADAM L. CARASSO, Senior Tax and Economic Advisor
JOSHUA L. SHEINKMAN, Democratic Staff Director
MICHAEL W. EVANS, Democratic Chief Counsel

Senator Charles E. Grassley's Staff
JASON FOSTER, Chief Investigative Counsel
RODNEY L. WHITLOCK, Health Policy Director
JOSHUA FLYNN-BROWN, Investigative Counsel
JANET TEMKO-BLINDER, Investigative Counsel-Detailee
KATHERINE NIKAS, Investigative Counsel
SAMANTHA BRENNAN, Legal Fellow

CONTENTS

	Page
Note on the report	1
Introduction	1
Section 1: Hepatitis C, its Human Toll, Treatment, and the Effect of "Warehousing" on Pharmaceutical Markets	5
Section 2: Gilead's Acquisition of Pharmasset and the Final Approval Phase for Sovaldi	13
Section 3: The Pricing of Sovaldi	29
Section 4: The Financial Burden of Treating HCV and Resulting Access Restrictions	79
Section 5: Patients' and Payers' Reactions to the Price of Sovaldi	99
Section 6: A Competitor Drug Enters the Market	112
Section 7: Conclusions and Questions	117
Timeline of Key Events	123
Glossary of Key Terms	126
Letter from Senators Wyden and Grassley to John Martin, CEO, Gilead Sciences, Inc. (July 11, 2014)	129
Appendix A: Medicaid Spending Data	135
Appendix B: Medicaid Prior Authorization Data Compiled by Oregon Health and Science University	153
Appendix C: Medicare Spending Data	267
Appendix D: Correspondence	273
Exhibit 1: Email from Ann Walker-Jenkins, Director, Federal Government Affairs, CVS Health Corp., to Peter Gartrell (Mar. 9, 2015), attaching written response to investigative staff	274
Exhibit 2: Letter from Darin J. Gordon and Thomas J. Betlach, National Association of Medicaid Directors, to Congress (Oct. 28, 2014)	283
Exhibit 3: Email from Eric Kimelblatt to Christopher J. Andrews and William Dozier, Re: Sovaldi Data (Apr. 15, 2014)	292
Exhibit 4: Letter from Lynne Saxton to the Honorable Ron Wyden and the Honorable Chuck Grassley (Oct. 19, 2015)	297
Exhibit 5: Letter from MaryAnne Lindeblad to the Honorable Ron Wyden and the Honorable Chuck Grassley (Sept. 23, 2015)	301
Exhibit 6: Letter from Theodore Dallas to the Honorable Ronald L. Wyden and the Honorable Charles E. Grassley (Oct. 2, 2015)	305
Exhibit 7: Letter from Charles M. Palmer to Peter Gartrell (Feb. 9, 2015)	310
Exhibit 8: Letter from Thomas J. Betlach to Peter Gartrell (July 17, 2015)	313
Exhibit 9: Letter from Justin M. Senior to the Honorable Orrin G. Hatch and the Honorable Ron Wyden (Oct. 19, 2015)	316
Exhibit 10: Letter from Samantha McKinley to the Honorable Charles E. Grassley and the Honorable Ron Wyden (Oct. 21, 2015)	319

Page

Appendix D—Continued
Exhibit 11: Letter from Andy Vasquez to the Honorable Ron Wyden and the Honorable Charles E. Grassley (Aug. 14, 2015) 322
Exhibit 12: Letter from Coy Stout, Vice President, Managed Markets, Gilead Sciences, Inc., to Community Partner (July 1, 2015) 330
Exhibit 13: Meeting Agenda, HCV Fair Pricing Coalition Meeting (Oct. 3, 2013) (prepared by Cara Miller, Gilead Sciences, Inc.) 333
Exhibit 14: Meeting Agenda, "FPC Gilead 10–3–13 Meeting Agenda (FOR FPC ONLY)" (Oct. 3, 2013) (prepared by Lynda Dee, Fair Pricing Coalition) 335
Exhibit 15: "Gilead 12–6–13 Call Notes" (prepared by Lynda Dee, Fair Pricing Coalition) 337
Exhibit 16: Letter from Murray Penner, Fair Pricing Coalition, to Coy Stout, Vice President, Managed Markets, Kristie Banks, Senior Director, Business Operations & Contract Compliance, Jim Drew, Director, Business Operations and Contract Compliance, Amy Flood, Vice President, Public Affairs, and Michele Rest, Director, Public Affairs, Gilead Sciences, Inc. (Apr. 14, 2014) 341
Exhibit 17: Email from William Dozier, Senior Manager, National Accounts, Gilead Sciences, Inc., to Douglas M. Brown, Senior Director, Pharmacy Pricing & Value Based Solutions, Magellan Health Services (May 11, 2014) 344
Exhibit 18: Email from Douglas M. Brown, Senior Director, Pharmacy Pricing & Value Based Solutions, Magellan Health Services, to Matthew D. Lennertz, Magellan Health Services (May 19, 2014) 347
Exhibit 19: Email from Douglas M. Brown, Senior Director, Pharmacy Pricing & Value Based Solutions, Magellan Health Services, to William Dozier, Senior Manager, National Accounts, Gilead Sciences, Inc. (June 5, 2014) 350
Exhibit 20: Letter from John B. McCarthy, Director, Ohio Department of Medicaid, to Peter Gartrell (Aug. 7, 2015) 353
Exhibit 21: Email from Janet Zachary-Elkind to Kacy Hutchison, Gilead Sciences, Inc. (Sept. 9, 2014) (attaching Sovaldi projections chart) 355
Exhibit 22: Letter from Hon. Henry A. Waxman et al., to Dr. John C. Martin, Chief Executive Officer, Gilead Sciences, Inc. (Mar. 20, 2014) 358
Exhibit 23: Troyen A. Brennan et al., CVS Health Corp., Analysis of "Real World" Sovaldi® (sofosbuvir) Use and Discontinuation Rates, September 2014 362
Exhibit 24: Letter from Diana S. Dooley to the Honorable Ron Wyden and the Honorable Charles E. Grassley (Oct. 14, 2015) 369
Appendix E: Documents Produced by Gilead Sciences, Inc. 373
Exhibit 1: Gilead Sciences, Inc., Gilead Liver Disease Therapeutics Strategy Overview: October 2011 Board of Directors Review (2011) (GS–0019261—GS–0019274) 374
Exhibit 2: Email from John McHutchison to Matthew Young, Re: Bristol-Inhibitex (Jan. 7, 2012) (GS–0010634—GS–0010635) 389
Exhibit 3: Pharmasset, Inc., Board of Directors Meeting, Princeton, NJ (July 21, 2011) (GS–0004488—GS–0004612) 392
Exhibit 4: Gilead Sciences, Inc., Gilead to Acquire Harry (Nov. 19, 2011) (GS–0009179—GS–0009209) 518
Exhibit 5: Gilead Sciences, Inc., Miscellaneous powerpoint slides (2014) (GS–0019034—GS–0019057) 550
Exhibit 6: Pharmasset, Inc., Board of Directors meeting packet (July 21, 2010) (GS–0014970—GS–0015065) 575
Exhibit 7: Pharmasset, Inc., Board of Directors Memorandum (Sept. 16, 2011) (GS–0017760—GS–0017760) 672
Exhibit 8: Pharmasset, Inc., Global Commercialization Strategy Update to Pharmasset Board of Directors (2011) (GS–0003852—GS–0003857) ... 674

Page

Appendix E—Continued
Exhibit 9: Pharmasset, Inc., PSI–7977 Phase II Clinical Trial Data Review (Oct. 3, 2011) (GS–0011638—GS–0011734) 681
Exhibit 10: Gilead Sciences, Inc., Introduction to Project Harry (July 21, 2011) (GS–0019211—GS–0019233) 779
Exhibit 11: Barclays Capital, Description of Fairness Opinion (Nov. 13, 2011) (GS–0011877—GS–0011900) 803
Exhibit 12: Gilead Sciences, Inc., Gilead Liver Disease Franchise: BOD Strategic Review (Oct. 2011) (GS–0019275—GS–0019298) 828
Exhibit 13: Gilead Sciences, Inc., Harry Update (Oct. 7, 2011) (GS–0019236—GS–0019250) 853
Exhibit 14: Email from Schaefer Price to Herb Conrad, et al., "FW: Forecast Assumptions" (Nov. 18, 2011) (GS–0018378—GS–0018378) 869
Exhibit 15: Pharmasset, Inc., "Adjustments to Forecast Assumptions, Based on Learnings from AASLD" (Nov. 18, 2011) (GS–0018379—GS–0018380) 871
Exhibit 16: Morgan Stanley, Project Royal Discussion Materials (Nov. 18, 2011) (GS–0018382—GS–0018403) 874
Exhibit 17: Morgan Stanley, Project Royal Discussion Materials (Oct. 6, 2011) (GS–0002762—GS–0002773) 897
Exhibit 18: Pharmasset, Inc., Untitled Presentation by Pharmasset Executives (Sept. 2011) (GS–0011557—GS–0011636) 910
Exhibit 19: Barclays Capital, Revenue/Valuation Models: Project Harry (Nov. 13, 2011) (GS–0013466—GS–0013479) 991
Exhibit 20: Email from John McHutchison to Jonathan Piazza, Re: Project Pyramid Assumptions (June 21, 2011) (GS–0004809—GS–0004814) 1006
Exhibit 21: Gilead Sciences, Inc., Project Harry—Model Discussion (Aug. 16, 2011) (GS–0005511—GS–0005549) 1013
Exhibit 22: Gilead Sciences, Inc., Project Harry—Barclays Deck Backgrounder (July 20, 2011) (GS–0000207—GS–0000228) 1053
Exhibit 23: Gilead Sciences, Inc., Hepatitis C and GS–7977 Development Update (Nov. 5, 2012) (GS–0019442—GS–0019506) 1076
Exhibit 24: Gilead Sciences, Inc., 2012–2018 Financial Forecast (Nov. 2012) (GS–0019394—GS–0019413) 1142
Exhibit 25: Pharmasset, Inc., Board of Directors Packet (Oct. 11, 2011) (GS–0017925—GS–0017991) 1163
Exhibit 26: Gilead Sciences, Inc., Harry Update: Board Meeting (Oct. 24, 2011) (GS–0019309—GS–0019319) 1231
Exhibit 27: Email from Cara Miller to Gregg Alton (Nov. 22, 2013) (GS–0020826—GS–0020827) 1243
Exhibit 28: Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Assessment, Final Recommendations—July 31st, 2013 (July 31, 2013) (GS–0014018—GS–0014058) 1246
Exhibit 29: Gilead Sciences, Inc., Gilead HCV US BPOA (Oct. 2012) (GS–0013489—GS–0013502) 1288
Exhibit 30: Gilead Sciences, Inc., Sofosbuvir US Pricing & Contracting Strategy, SVP Briefing (March 25, 2013) (GS–0019128—GS–0019184) .. 1303
Exhibit 31: Gilead Sciences, Inc., U.S. HCV Launch Update to Board of Directors (Aug. 1, 2013) (GS–0014059—GS–0014078) 1361
Exhibit 32: Gilead Sciences, Inc., 2013–2015 HCV Launch Commercial Plan (April 4, 2013) (GS–0013503—GS–0013546) 1382
Exhibit 33: Email from Jim Myers to David L. Johnson, et al., Characterization of SOF pricing at Launch (Nov. 8, 2013) (GS–0020772—GS–0020773) 1427
Exhibit 34: Gilead Sciences, Inc., Sofosbuvir Pricing & Contracting Strategy Working Team, SVP Check-in II (May 10, 2013) (GS–0013972—GS–0014017) 1430

Page

Appendix E—Continued
Exhibit 35: Gilead Sciences, Inc., Minutes of Regular Meeting of Board of Directors (Aug. 1, 2013) (GS–0019671—GS–0019674) 1477
Exhibit 36: Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Assessment: Response to Follow Up Questions (Aug. 26, 2013) (GS–0013857—GS–0013887) 1482
Exhibit 37: Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Recommendation (Nov. 2013) (GS–0014079—GS–0014082) 1514
Exhibit 38: Email from Kevin Young to John Martin, et al., Re: COMPANY CONFIDENTIAL (Nov. 18, 2013) (GS–0020800—GS–0020800) ... 1519
Exhibit 39: Email from John Martin to Kevin Young, Re: CONFIDENTIAL (Nov. 24, 2013) (GS–0020946—GS–0020947) 1522
Exhibit 40: Email from Kevin Young to Jim Meyers et al., Re: ADAP and Sofosbuvir (Nov. 19, 2013) (GS–0020802—GS–0020804) 1525
Exhibit 41: Gilead Sciences, Inc., "EAME SOF Price Recommendations" (Sept. 11, 2013) (GS–0019913—GS–0019919) 1529
Exhibit 42: Email from Kevin Young to Jim Meyers and Derrell Porter (Oct. 19, 2013) (GS–0020285—GS–0020288) 1537
Exhibit 43: Email from Paul Carter to Cara Miller (Oct. 11, 2013) (GS–0020212—GS–0020213) 1542
Exhibit 44: Gilead Sciences, Inc., Canadian Sofosbuvir Pricing Considerations (Sept. 30, 2013) (GS–0020086—GS–0020094) 1545
Exhibit 45: Gilead Sciences, Inc., 2015–2016 HCV Commercial Plan (April 22, 2014) (GS–0014083—GS–0014110) 1555
Exhibit 46: Gilead Sciences, Inc., Topics for Discussion—LDV/SOF US Pricing (Aug. 4, 2014) (GS–0019000—GS–0019033) 1584
Exhibit 47: Gilead Sciences, Inc., US HCV Pricing Update, SVP Update Meeting (July 21, 2014) (GS–0018861—GS–0018953) 1619
Exhibit 48: Gilead Sciences, Inc., 2014–2015 US HCV Franchise BPOA (Draft) (June 2014) (GS–0014143—GS–0014171) 1713
Exhibit 49: Gilead Sciences, Inc., Updated Slides—Wave 2 Pricing (GS–0018965—GS–0018999) 1743
Exhibit 50: Gilead Sciences, Inc., Managed Markets Hepatitis C Virus (HCV) Payer Advisory Board Final Report (Oct. 14, 2014) (GS–0018760—GS–0018814) 1779
Exhibit 51: Email from Mark Schoenebaum to Robin Washington, FINAL data from gild/bmy (and sort of MRK/ROG) buy-side survey (Oct. 31, 2013) (GS–0020496—GS–0020512) 1835
Exhibit 52: Gilead Sciences, Inc., HCV Wave 2 Contracting Recommendations (Sept. 9, 2014) (GS–0019058—GS–0019127) 1853
Exhibit 53: Email from Cara Miller to Gregg Alton, FW: FPC Ad Board Feedback (Oct. 4, 2013) (GS–0020133—GS–0020135) 1924
Exhibit 54: Email from Jim Meyers to David L. Johnson, et al., Synopsis of feedback from top HCV advisors at AASLD (Nov. 5, 2013) (GS–0020776—GS–0020780) 1928
Exhibit 55: Email from Jim Meyers to John Milligan, Synopsis of feedback from top HCV advisors at AASLD (Nov. 8, 2013) (GS–0020765—GS–0020769) 1934
Exhibit 56: Email from Jim Meyers to Norbert Bischofberger, Synopsis of feedback from top HCV advisors at AASLD (Nov. 7, 2013) (GS–0020753—GS–0020759) 1940
Appendix F: Narrative answers from Gilead Sciences, Inc., in response to questions in the July 11, 2014 letter from Senators Wyden and Grassley 1949

THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTH CARE SYSTEM

Note

This inquiry began as a Senate Committee on Finance investigation when Senator Wyden was Chairman and Senator Grassley was a member of the Committee's Minority. During the course of the investigation, leadership on the Committee changed in January 2015. Both senators instructed their staffs to continue the investigation and produce a staff report to the Finance Committee. All references to "investigative staff" or "staff" refer to the current Minority staff of the Finance Committee and the staff of Senator Grassley.

Introduction

Hepatitis C (HCV) is the most common blood-borne virus in the United States, affecting as many as 5.2 million people.[1] The virus attacks the liver, resulting in inflammation, scarring and cirrhosis, while increasing the risk of liver cancer. Left untreated, HCV can cause serious illness; the disease is the leading cause of liver transplants in the United States. The aggressiveness of the virus makes it a potent public health issue in the United States. The virus is disproportionally concentrated among Americans who are likely to receive health coverage from public payers including Medicaid, Medicare, the Veterans Administration, and the State and Federal prison system.[2] The high cost of HCV drugs sold by Gilead Sciences, Inc., continues to put tremendous strain on these public payer systems, creating difficult decisions about how to provide medically necessary drugs to patients while staying within budgets. As a result of the high cost of these drugs, many public and private payers adopted access restrictions to control HCV treatment costs, which reduced the number of patients eligible for treatment.

Gilead brought two drugs to market in recent years, Sovaldi and Harvoni, which have improved therapies to cure HCV. Sofosbuvir—the drug that would ultimately reach the market as Sovaldi and used in combination with ledispavir to create Harvoni—was largely developed by Pharmasset, Inc., a pharmaceutical company that was based in Princeton, New Jersey. Gilead acquired Pharmasset in January 2012.

---

[1] Eric Chak et al., *Hepatitis C Virus Infection in USA: An Estimate of True Prevalence,* 31 Liver Int'l 1090, 1090–1101 (Sept. 2011), *available at* http://www.ncbi.nlm.nih.gov/pubmed/21745274.

[2] *Id.* at 1096, Table 6.

Sovaldi and Harvoni have reduced the time needed for treatment to a fraction of what it was five years ago. In addition, the effectiveness of treatment, that is, the probability that a patient will be cured, has increased. The new drugs have resulted in more patients being able to receive HCV therapy with limited or no use of interferon, an injectable drug that complicates treatment because it typically requires visits to a health care provider, and is often accompanied by difficult side effects.

Progress in therapeutics has come at a high cost for both the public and private sectors. Concurrent with drug price increases, greater numbers of providers and patients have been drawn to these new drugs, leading to increased outlays for HCV treatment. In the run-up to launching Sovaldi, Gilead estimated that worldwide spending on HCV treatment in 2008 totaled $2.4 billion.[3] By 2014, Gilead alone reported net product sales of $12.4 billion for its HCV drugs, primarily from sales in the United States and Europe.[4] A competitor drug developed by Johnson & Johnson, known as simeprevir, or Olysio, generated sales of $2.3 billion in 2014,[5] primarily due to "off label"[6] co-prescriptions with Sovaldi.[7]

Gilead's recent financial results show that the company has generated an additional $14.3 billion in net product sales from its HCV drugs through the first nine months of 2015, bringing its 21-month total for its HCV drugs to $26.6 billion, $20.6 billion of which was from sales to U.S. consumers.[8]

An analysis by the consulting firm IMS Institute for Healthcare Informatics (IMS Institute) showed that U.S. spending on Sovaldi in 2014 was $7.9 billion, and from 2010 to 2013 U.S. spending on all HCV drugs totaled $7.8 billion. Sovaldi alone accounted for 64% of U.S. HCV drug spending in 2014, which totaled $12.3 billion, and more than a third of the $20.3 billion spent that year on new pharmaceutical treatments.[9] HCV treatments also caused a jump in spending for "specialty therapies," which the IMS Institute defines in part as "mostly used by specialists and include treatment for cancer and other serious conditions."[10] According to the IMS Institute, U.S. "specialty medicine spending increased by 26.5% to

---

[3] Appendix E, Ex. 1, Gilead Sciences, Inc., *Gilead Liver Disease Therapeutics Strategy Overview: Board of Directors Review* (2011), GS–0019261, at GS–0019265—GS–0019266 (2011).

[4] Gilead Sciences, Inc., Annual Report (Form 10-K), at 59 (Feb. 25, 2015), *available at* http://www.sec.gov/Archives/edgar/data/882095/000088209515000008/a2014form10-k.htm.

[5] Johnson & Johnson, Annual Report (Form 10-K), Exhibit 13, at 5 (Feb. 23, 2015), *available at* http://www.sec.gov/Archives/edgar/data/200406/000020040615000004/ex13-form10xk20141228.htm.

[6] The practice of a health care provider prescribing a drug or combination of drugs in a manner outside of what has been officially approved (in the U.S., by the Food and Drug Administration).

[7] Chris Hepp, *Drug Sales Bolster J&J's Bottom Line,* Phila. Inquirer (Apr. 21, 2014), *available at* http://articles.philly.com/2014-04-21/business/49268459_1_olysio-gilead-sciences-sovaldi.

[8] Gilead Sciences, Inc., Third Quarter 2015 Financial Results (Form 8–K,), Exhibit 99.1) (October 28, 2015), *available at* http://www.sec.gov/Archives/edgar/data/882095/000088209515000031/exhibit991earningspressrel.htm; Gilead Sciences, Inc., Fourth Quarter and Full Year 2014 Financial Results (Form 8–K), Exhibit 99.1 (Feb. 3, 2015), *available at* http://www.sec.gov/Archives/edgar/data/882095/000088209515000003/exhibit991earningspressrel.htm.

[9] IMS Institute for Healthcare Informatics, *Medicines Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014,* at 1, 8 (2015) [hereinafter IMS Institute for Healthcare Informatics, *Medicines Use and Spending Shifts*].

[10] *Id.* at 8.

$124.1 billion in 2014; the increase was 16.3% excluding hepatitis C treatments." [11]

After the introduction of Sovaldi at end of 2013, millions of Americans had a potentially viable path to a cure, but the price and cumulative cost on the health care system caused roadblocks for many. In response to treatment access and cost issues, Senators Ron Wyden and Charles Grassley sent a letter to Gilead on July 11, 2014, requesting documents and information about how the company determined the price for Sovaldi, the first of its two HCV drugs.

For over a year, investigative staff reviewed more than 20,000 pages of internal company documents provided by Gilead, as well as documents obtained from the Federal Trade Commission (FTC), Food and Drug Administration (FDA), state Medicaid programs, the Centers for Medicare and Medicaid Services (CMS), the Federal Bureau of Prisons (BOP), and other companies. In addition, investigative staff interviewed more than 100 people with expertise in HCV, or who had interacted with Gilead regarding Sovaldi and/or Harvoni. Lastly, investigative staff collected data from Medicaid programs in 50 states and the District of Columbia that provide important information about the breadth of HCV infection for one segment of public payers, and the cost that states faced in order to treat the disease.

Based on all of the information reviewed, it appears that in pricing its line of HCV drugs Gilead may have underestimated the warnings of patient groups, insurers, health care providers, and other organizations about the potential impact that price would have on access. Such warnings were made not only through the media, but directly to company officials, both in private correspondence and various public forums. While publicly saying it prioritized patient access, Gilead set Sovaldi's price at a level where ultimately many patients would not receive treatment. Sovaldi was on the market for almost a year without serious competitors, allowing Gilead to maintain a high effective price despite efforts by many payers to negotiate volume or treatment discounts or rebates.

The costs incurred by Gilead to bring the drugs to market included its $11.2 billion purchase of Pharmasset in 2011. Pharmasset performed the initial development of the drug and began the process of FDA approval, which Gilead then completed following the acquisition. Several months after Gilead agreed to buy Pharmasset, a Gilead executive described the acquisition as a "bargain." [12] The company failed to provide sufficient information to determine how much additional cost it incurred to complete the development, finish the FDA approval process, and bring the drug to market.

This report describes how Gilead set the price for Sovaldi and its follow-on drug, Harvoni. In addition, this report discusses and analyzes the financial and budgetary impacts of Gilead's pricing decisions on payers—public and private—as well as the resulting access restrictions imposed due to Sovaldi's cost. And finally, the re-

[11] *Id.*

[12] Appendix E, Ex. 2, Email from John McHutchison to Matthew Young, Re: Bristol-Inhibitex (Jan. 7, 2012), GS–0010634.

port describes Gilead's response to resultant market forces, including payer access restrictions and competition.

Appendices

Several appendices to the report provide additional information and documents related to the investigation.

Appendix A contains data collected by investigative staff from state Medicaid programs showing the amount of money spent on Sovaldi and Harvoni in 50 states and the District of Columbia, as well as the estimated number of Medicaid clients with HCV in states where the information was available.

Appendix B presents a review of prior authorization restrictions put in place by state Medicaid programs for Sovaldi and Harvoni, as well as a sample of other payers. The study was completed by researchers at the Oregon Health and Sciences University.

Appendix C presents data provided by the Centers for Medicare & Medicaid Services (CMS) on Medicare spending on Sovaldi, Harvoni, and other HCV drugs.

Appendix D contains correspondence and other documents received by the Senators or investigative staff regarding Sovaldi or Harvoni.

Appendix E contains all Gilead documents cited in this report.

Appendix F contains all narrative answers cited in this report from Gilead in response to questions in the July 11, 2014 letter from Senators Wyden and Grassley.

Section 1: Hepatitis C, its Human Toll, Treatment, and the Effect of "Warehousing" on Pharmaceutical Markets

Hepatitis C and Its Human Toll

In 2013, HCV was listed as the cause of death for 19,368 people in the United States.[13] This number likely underestimates the number of HCV deaths. CDC researchers have found that fewer than 20% of HCV-infected decedents have HCV listed on their death certificates, even though at least 75% of HCV-infected decedents had pre-mortem evidence of serious liver disease.[14] Despite the likely undercounting, a 2012 study reported that the number of HCV-associated deaths was greater than the number of human immunodeficiency virus (HIV)-associated deaths in the United States between 1999 and 2007.[15] This trend has continued in recent years. The virus is a killer not just in the United States, but across the world. Globally, between 130 million and 150 million people have chronic HCV; annually, the virus and related liver disease kill 704,000 people worldwide.[16] In comparison, the World Health Organization (WHO) estimated that in 2010, malaria caused 660,000 deaths, and that in 2011, tuberculosis caused 1.4 million deaths and HIV caused 1.7 million deaths.[17]

Prior to the virus's identification in 1989, HCV was frequently spread through unscreened blood transfusions.[18] The virus is disproportionately concentrated among baby boomers born from 1945 through 1965. In 2011, about 75% of HCV deaths in the United States were among forty-five to sixty-four-year-olds.[19] The CDC estimates that 3.2% of baby boomers are positive for HCV, five times higher than people born prior to 1945 or after 1965. Consequently, in 2012 and 2013, the CDC and the U.S. Preventative Services Task Force recommended that all people born from 1945 through 1965—more than 60 million people—be tested for the virus.[20] The virus is most commonly transmitted in the United States through the use of unsanitary needles, leaving intravenous drug users at

---

[13] Centers for Disease Control and Prevention (CDC), *Surveillance for Viral Hepatitis—United States, 2013,* Table 4.5, at 58, *available at* http://www.cdc.gov/hepatitis/statistics/2013surveillance/commentary.htm.

[14] Reena Mahajan et al., *Mortality Among Persons in Care With Hepatitis C Virus Infection: The Chronic Hepatitis Cohort Study (CHeCS), 2006–2010,* 58 Clinical Infectious Diseases 1055, 1055–61 (2014).

[15] Kathleen N. Ly et al., *The Increasing Burden of Mortality From Viral Hepatitis in the United States Between 1999 and 2007,* 156 Annals of Internal Medicine 271, 271–78 (2012).

[16] GBD 2013 Mortality and Causes of Death Collaborators, *Global, regional, and national age-sex specific all-cause and cause-specific mortality for 240 causes of death, 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013,* 385 Lancet 9963, 117–71 (2015).

[17] World Health Organization, *Global Policy Report on the Prevention and Control of Viral Hepatitis in WHO Member States* (2013), *available at* http://apps.who.int/iris/bitstream/10665/85397/1/9789241564632_eng.pdf?ua=1.

[18] Q.L. Choo et al., *Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome,* 244 Science 359, 359–62 (1989).

[19] CDC, Number and Rate* of Deaths with Hepatitis C Listed as a Cause of Death, by Demographic Characteristic and Year—United States, 2007–2011, *available at* http://www.cdc.gov/hepatitis/Statistics/2012Surveillance/Table4.4.htm.

[20] Bryce D. Smith et al., CDC, *Recommendations for the Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945–1965* (2012), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6104a1.htm; U.S. Preventative Services Task Force, Hepatitis C: Screening, (June 2013), *available at* http://www.uspreventiveservicestaskforce.org/Page/Topic/recommendation-summary/hepatitis-c-screening.

high risk for contracting the disease.[21] With a growing number of people who inject intravenous drugs, such as heroin or other opiates, rates of HCV infection are increasing, as the recent HCV outbreak reported in Indiana illustrates.[22]

Distinct Genotypes Across the World Create Distinct Markets

There are seven different genotypes of HCV and within each genotype, there are sub-genotypes.[23] Each genotype and sub-genotype reacts differently to treatment, and the FDA has approved drug regimens for specific HCV genotypes and sub-genotypes, rather than the entire spectrum of HCV. The current generation of HCV drugs, including Sovaldi and Harvoni, are not "full spectrum" drugs that can treat all genotypes, and they are not an equally effective treatment against all sub-genotypes.

The prevalence of specific genotypes and sub-genotypes varies among different regions of the world. About 70% of HCV cases in the United States are genotype 1, the majority of which are sub-genotypes 1a and 1b. Genotypes 2 and 3 are estimated to account for 16% and 12% of cases in the United States, respectively, while genotypes 4, 5 and 6, in total, account for fewer than 4% of cases in the United States.[24] Conversely, in many Middle Eastern and African countries, genotype 4 accounts for more than 90% of HCV infections.[25] Genotype 5 is almost entirely contained within South Africa and select countries in Europe and the Middle East.[26] Drug manufacturers have concentrated their focus on selling HCV drugs that treat genotypes with prevalence in developed countries.[27]

HCV Symptoms

A major challenge associated with HCV is its tendency to go undiagnosed, due to its slow progression and tendency to remain asymptomatic for years. These attributes have earned HCV the moniker "the silent killer," and have contributed to poor surveil-

---

[21] Centers for Disease Control and Prevention, *Viral Hepatitis Surveillance, United States, 2013,* at 6 (last updated Oct. 19, 2015), *available at* http://www.cdc.gov/hepatitis/statistics/2013surveillance/pdfs/2013hepsurveillancerpt.pdf ("HCV is transmitted primarily through percutaneous (parenteral) exposure that can result from injection drug use, needle stick injuries, and inadequate infection control in health-care settings."); *id.* at 52 ("Of the 955 case-reports that had information about injection drug use, 61.6% (n=588) indicated use of injection drugs.").

[22] Centers for Disease Control and Prevention, CDC Health Alert Network, *Outbreak of Recent HIV and HCV Infections Among Persons Who Inject Drugs* (Apr. 24, 2015), *available at* http://www.bt.cdc.gov/han/han00377.asp.

[23] Donald G. Murphy et al., *Hepatitis C Virus Genotype 7, a New Genotype Originating from Central Africa,* 53 J. Clinical Microbiology 967, 967–72 (2015).

[24] *See e.g.,* Jane P. Messina et al., *Global Distribution and Prevalence of Hepatitis C Virus Genotypes,* 61 Hepatology 77, 77–87 (2015); M. Michele Manos et al., *Distribution of Hepatitis C Virus Genotypes in a Diverse U.S. Integrated Health Care Population,* 84 J. Med. Virology 1744, 1744–1750 (2012), *available at* http://www.ncbi.nlm.nih.gov/pubmed/22997077.

[25] Sanaa M. Kamal & Imad A. Nasser, *Hepatitis C Genotype 4: What We Know and What We Don't Yet Know,* 47 Hepatology 1371, 1371 (2008), *available at* http://webhome.weizmann.ac.il/home/liorg/HCV.pdf.

[26] N. Antaki et al., *HCV Genotype 5: An Orphan Virus,* 18 Antiviral Therapy 263, 263–69 (2012), *available at* http://www.ncbi.nlm.nih.gov/pubmed/23111702.

[27] Appendix E, Ex. 3, Pharmasset, Board of Directors Meeting, Princeton, NJ (July 21, 2011), GS–0004488; Appendix E, Ex. 4, Gilead Sciences, Inc., Gilead to Acquire Harry (Nov. 19, 2011), GS–0009179, at GS–0009187; Jane P. Messina et al., *Global Distribution and Prevalence of Hepatitis C Virus Genotypes,* 61 Hepatology 77, 77–87 (2014), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4303918/.

lance of the disease.[28] A recent study estimated that half of people in the U.S. with chronic HCV are aware they are infected.[29] When HCV symptoms do develop, they include easily bleeding or bruising, itchy skin, fluid accumulation in the abdomen (ascites), swelling in the legs, weight loss, confusion, drowsiness, slurred speech (hepatic encephalopathy), and development of spider-like blood vessels on the skin (spider angiomas).[30] Approximately 20% of chronic HCV patients, if untreated, will develop cirrhosis.[31]

Hepatitis C remains the leading primary indication for people receiving or waiting for liver transplants.[32] The most recent available federal data show that 1,402 patients received transplants in 2012, and 4,612 patients were on waiting lists.[33]

Advancing Treatment for Hepatitis C

There is no vaccine for HCV, unlike for Hepatitis A and Hepatitis B. However, in recent years, significant progress has been made in improving standards of care (SOC). The effectiveness of a drug is primarily measured by the speed of viral reduction (early virologic response, or EVR, and rapid virologic response, or RVR) and the percentage of cured patients. A patient is considered cured when blood tests do not detect the virus twelve or twenty-four weeks after treatment, which is called sustained virologic response (SVR).[34] Each successive SOC has simplified and shortened treatment regimens, increased effectiveness, and minimized side effects.

HCV treatment relied on interferon for nearly twenty-five years. It is a naturally occurring protein that cells secrete when they are attacked by a virus and was first identified in 1957. Interferon exists in three different forms—alpha, beta, and gamma—and each is used to treat numerous diseases, including cancer, multiple sclerosis, AIDS, and genital warts.[35] Interferon works by boosting the immune system to effectively block new cell sites to which a virus could attach. However, interferon has drawbacks, especially when used for prolonged treatment. Interferon treatment requires injections, necessitating weekly or semi-weekly visits to a provider's office or regular access to other health care services. Additionally, interferon causes side effects, including flu-like symptoms, such as

---

[28] Patrick Strudwick, *Hepatitis C: Hunting the Silent Killer,* The Guardian (Feb. 25, 2015), *available at* http://www.theguardian.com/society/2015/feb/25/hepatitis-c-hunting-the-silent-killer.

[29] Baligh R. Yehia et al., *The Treatment Cascade for Chronic Hepatitis C Virus Infection in the United States: A Systematic Review and Meta-Analysis,* PLoS ONE (July 2, 2014), *available at* http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0101554.

[30] Mayo Clinic, *Diseases and Conditions: Hepatitis C* (Jan. 15, 2015), http://www.mayoclinic.org/diseases-conditions/hepatitis-c/basics/definition/con-20030618?p=1.

[31] David H. Spach, *HCV Epidemiology in the United States,* University of Washington, Hepatitis C Online (June 16, 2014), *available at* http://www.hepatitisc.uw.edu/go/screening-diagnosis/epidemiology-us/core-concept/all#hcv-incidence-prevalence.

[32] United States Department of Health & Human Services, Organ Procurement & Transplantation Network, Scientific Registry of Transplant Recipients, 2012 Annual Data Report: Liver, at 69, 75 (Table 1.3) and 81 (Table 4.7), *available at* http://srtr.transplant.hrsa.gov/annual_reports/2012/flash/03_liver_13/v2files/assets/downloads/publication.pdf.

[33] *Id.*

[34] H. Nina Kim & David H. Spach, *Virologic Responses During Treatment of Hepatitis C,* University of Washington, Hepatitis Web Study, (last updated Oct. 1, 2012), *available at* http://depts.washington.edu/hepstudy/hepC/mgmt/viroresponse/discussion.html (last updated Oct. 1, 2012).

[35] *Interferon,* Encyclopedia Britannica Online (Aug. 7, 2009), *available at* http://www.britannica.com/EBchecked/topic/290230/interferon.

fever, fatigue, muscle aches, and myalgia.[36] Patients have likened the side effects to having the flu throughout treatment. Many patients cannot tolerate interferon, and thus did not have a viable treatment option.[37]

Researchers began testing the effectiveness of interferon-alpha (interferon) therapies for HCV in the mid-1980s before the virus was identified and was still known as non-A-non-B hepatitis.[38] After the virus' identification in 1989, interferon became the first SOC for those that could tolerate it. Interferon, as a standalone SOC, has a poor SVR rate. A twenty-four-week regimen has an SVR of only 6%, and a forty-eight-week regimen increases the SVR to 16%.[39] In 1998, the FDA approved ribavirin, an antiviral drug, for use in combination with interferon for treatment of HCV.[40] The combination improved the effectiveness of treatment; a twenty-four-week regimen resulted in an SVR of 34%, and a forty-eight-week regimen resulted in an SVR of 42%. Ribavirin further increased the SVR to 54% when combined with pegylated interferon, which combines polyethylene glycol (PEG) with interferon.[41]

The next major advance in treatment was the development of direct-acting antiviral (DAA) drugs, which work by attacking specific viral proteins encoded within the virus's RNA. These viral proteins include enzymes such as the NS5B polymerase and NS3/4A protease, as well as the NS5A protein, which is involved in the HCV replication complex. In 2011, the FDA approved two DAAs, boceprevir (Victrelis) and telaprevir (Incivek).[42] In 2013, the FDA approved two additional DAAs, simeprevir (Olysio) and sofosbuvir (Sovaldi).[43] Each successive DAA advanced HCV treatment by maintaining or improving SVR, while also reducing treatment time for most patients, thereby reducing the use of interferon.

The introduction of drugs that could treat patients without interferon critically advanced HCV treatment. Although the FDA approved Sovaldi for use without interferon for genotype 2 and genotype 3 patients, the primary cohort of genotype 1 patients still required the use of interferon and ribavirin with Sovaldi. However,

---

[36] Mary L. Filipi et al., *Nurses' Perspective on Approaches to Limit Flu-Like Symptoms During Interferon Therapy for Multiple Sclerosis,* 16 Int'l J. of MS Care 55, 59 (2014), *available at* http://ijmsc.org/doi/pdf/10.7224/1537-2073.2013-006.

[37] *Id.*

[38] Jay H. Hoofnagle et al., *Treatment of Chronic Non-A, Non-B Hepatitis with Recombinant Human Alpha Interferon: A Preliminary Report,* 315 New Eng. J. Med. 1575, 1575–1578 (1986), *available at* http://www.ncbi.nlm.nih.gov/pubmed/3097544.

[39] Doris B. Strader & Leonard B. Seef, *A Brief History of the Treatment of Viral Hepatitis C,* 1 Clinical Liver Disease 6, 6 (2012), *available at* http://onlinelibrary.wiley.com/doi/10.1002/cld.1/epdf [hereinafter Strader & Seef, A Brief History of the Treatment of Hepatitis C].

[40] Press Release, Schering-Plough Corp., Schering-Plough Announces FDA Approval of Rebetron(TM) Combination Therapy for Previously Untreated Hepatitis C Patients; Rebetron Combination Therapy Now Approved for Use in Both Previously Untreated and Relapse Hepatitis C Patients (Dec. 9, 1998). Ribavirin was discovered in 1972 and, in addition to treating HCV, treats other RNA viruses. Shane Crotty et al., *Ribavarin's Antiviral Mechanism of Action: Lethal Mutagenesis?,* 80 J. Molecular Med. 86, 86 (2001), *available at* http://www.liai.org/files/Ribavirin-Crotty.pdf. Ribavirin does not effectively treat HCV as a monotherapy because it does not reduce the production of HCV RNA, although it does significantly reduce liver damage. *Id.* at 91.

[41] Strader & Seef, *A Brief History of the Treatment of Hepatitis C,* at 6.

[42] VICTRELIS Prescribing Information (2011), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/202258lbl.pdf; INCIVEK Prescribing Information (2011), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/201917lbl.pdf.

[43] OLYSIO Prescribing Information (2013), *available at* http://www.accessdata.fda.gov/drugsatfda—docs/label/2013/205123s001lbl.pdf; SOVALDI Prescribing Information (2013), *available at* http://www.accessdata.fda.gov/spl/data/24e7ec0a-9f1b-4b63-8e48-53a63cd7c46f/24e7ec0a-9f1b-4b63-8e48-53a63cd7c46f.xml.

in January 2014, the American Association for the Study of Liver Disease (AASLD) recommended that providers combine Sovaldi with Olysio for patients who could not tolerate interferon-based therapies. This off-label combination comprised approximately one-third of all Sovaldi-based treatments by the second quarter of 2014.[44] The off-label drug combination further increased the cost of treatment for a portion of the patient population, primarily genotype 1 patients who could not tolerate interferon.

In October 2014, nine months after the AASLD recommendation, the FDA approved Gilead's ledipasvir-sofosbuvir (Harvoni), the first FDA-approved interferon-free HCV therapy for genotype 1 patients.[45] In November 2014, the FDA approved Johnson & Johnson's application for the AASLD-recommended Olysio-Sovaldi combination,[46] but use of these drugs and their combination has fallen due to market competition from Viekira Pak and Harvoni[47] (see slide below).[48] In December 2014, the FDA approved another interferon-free regimen, consisting of a combination of drugs—ombitasvir, paritaprevir, ritonavir, and dasabuvir (Viekira Pak).[49] Notably, Harvoni is a single-tablet therapy, whereas Viekira Pak is a multi-tablet therapy.

[44] Appendix E, Ex. 5, Gilead Sciences, Inc., Miscellaneous powerpoint slides (2014), GS–0019034, at GS–0019036.

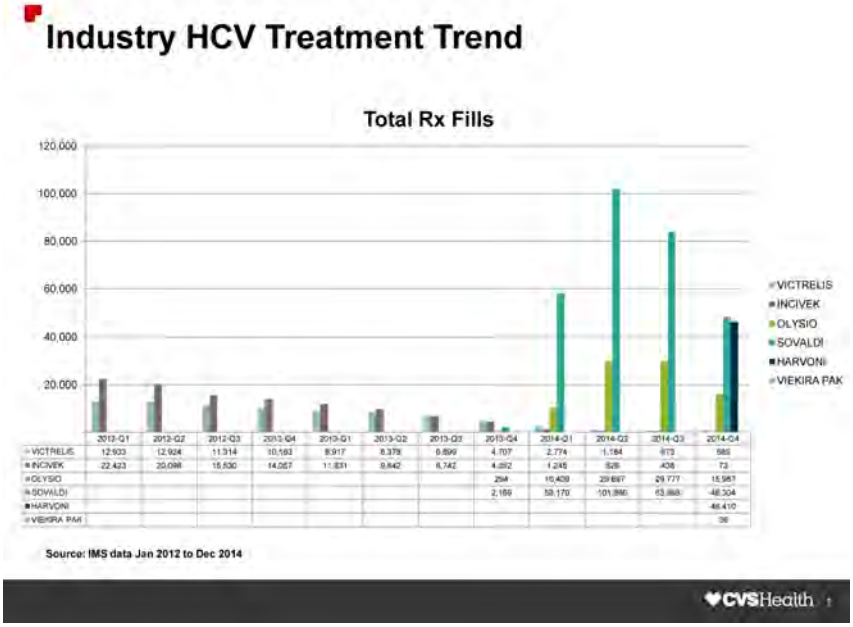
[45] HARVONI Prescribing Information (2014), *available at* http://www.accessdata.fda.gov/spl/data/a3f06ce8-e0c0-4d41-9126-c43c94e4c87c/a3f06ce8-e0c0-4d41-9126-c43c94e4c87c.xml.

[46] Anna Edney, *J&J Wins U.S. Approval for Hepatitis C Combo with Gilead,* Bloomberg (Nov. 5, 2014), *available at* http://www.bloomberg.com/news/articles/2014-11-05/j-j-wins-u-s-approval-for-hepatitis-c-combo-with-gilead.

[47] Olysio generated revenue of $234 million during the first three months of 2015, an annualized pace of $936 million, compared to $2.3 billion in sales during the full year 2014.

[48] Appendix D, Ex. 1, Email from Ann Walker-Jenkins, Director, Federal Government Affairs, CVS Health Corp., to Peter Gartrell (Mar. 9, 2015), attaching written response to investigative staff, at 6.

[49] VIEKIRA PAK Prescribing Information (2014), *available at* http://www.accessdata.fda.gov/spl/data/045ddc2b-403e-7db2-b3e1-9627632ab3d7/045ddc2b-403e-7db2-b3e1-9627632ab3d7.xml.



Even after competition entered the genotype 1 market, Sovaldi was the only drug that the FDA had approved to treat genotypes other than genotype 1—its label included indications for the treatment of genotypes 1, 2, 3, and 4 patients. Consequently, Gilead did not face significant competition in the U.S. for genotype 2 or 3 treatments besides the interferon-ribavirin combination, which has significantly worse side effects and, in some genotypes, worse outcomes. On July 24, 2015, the FDA approved daclatasvir (Daklinza) for treatment of genotype 3; however, its label indicates that it should be used in combination with Sovaldi,[50] which means there remains no standalone competitor. The AASLD has added the Daklinza-Sovaldi combination to its recommended treatment regimens for genotype 1 and 2 patients. In addition, the FDA has approved a combination of ombitasvir, paritaprevir, and ritonavir (Technivie) for genotype 4 patients without cirrhosis.[51]

Fibrosis and Patient "Warehousing"

The severe side effects of interferon-based regimens coupled with the anticipation of new, more tolerable treatment regimens, and the slow progression of HCV, caused many providers to advise their HCV patients to wait until more tolerable and effective therapies came to market. This practice is known as "warehousing." Providers warehoused patients based in part on fibrosis scores, which correspond with declining liver function and range from 0 (no fibro-

[50] DAKLINZA Prescribing Information (2015), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/206843Orig1s000lbl.pdf.
[51] TECHNIVIE Prescribing Information (2015), *available at* http://www.accessdata.fda.gov/drugsatfda—docs/label/2015/207931Orig1s000lbl.pdf.

sis) to 4 (severe fibrosis or cirrhosis).[52] Warehousing can result in sharply increased demand when an anticipated treatment comes to market. Fibrosis scores played two key roles in the recent debate over HCV treatment in part because low fibrosis scores are an indicator of a patient's ability to forestall treatment. Patients with early stages of the disease (fibrosis scores of 0, 1 or 2) were frequently advised to wait until new drugs were released before beginning treatment. The rationale was that there would be better outcomes for patients who could medically afford to wait on new treatments with shorter durations, higher cure rates, and fewer side effects.

Warehousing had previously occurred in 2000, in anticipation of the FDA's approval of pegylated interferon, and again in 2010, leading up to the approval of DAA medications. Warehousing has been a focus of pharmaceutical makers, Wall Street analysts, and the financial press because pent up demand materially affects revenue when regulatory approvals for improved treatments are anticipated. Such warehousing with HCV medications was noted in 2000 ahead of regulatory approval of pegylated interferon:

> One issue is a study released in late October showing that Schering-Plough Corp.'s experimental hepatitis drug Peg-Intron is more effective than the standard treatment for hepatitis C when the drug is combined with ICN's ribavirin. The study compared the combination to the standard therapy of ribavirin and Intron A, a combination sold by Schering-Plough as Rebetron. The study results "have led to some speculation that doctors may be warehousing their patients instead of giving them Rebetron now as they wait for approval of Peg-Intron and ribavirin," Smith said. If that's true, that could lead to a temporary weakness in ribavirin sales, Smith said.[53]

Again in 2010, warehousing occurred leading up to approval of the first DAA medications:

> At Fred Poordad's bustling hepatitis C clinic in the heart of Los Angeles, one in every five patients receives no treatment. They are waiting for a wave of new drugs, expected in the next 18 months, that may boost their chance at a cure by as much as 10-fold. The medicines also may bolster the prospects of Merck & Co., Vertex Pharmaceuticals Inc. and Johnson & Johnson, the companies in a race to get the first new treatment to the market in a decade. About half of patients can't tolerate the side effects of existing therapies, which generate $2 billion annually in sales. The new drugs could expand the market to $10 billion in five years,

[52] Marc G. Ghany et al., *Diagnosis, Management, and Treatment of Hepatitis C: An Update,* 49 Hepatology 1335 (2009), *available at* http://onlinelibrary.wiley.com/doi/10.1002/hep.22759/abstract.

[53] Karen Fessler, *Panic Abandons Plan to Sell 50,000 ICN Shares,* L.A. Times (Dec. 14, 2000), *available at* http://articles.latimes.com/2000/dec/14/business/fi-47.

> said Geoff Porges, an analyst for Sanford C. Bernstein & Co. in New York.[54]

With the expected introduction of new, more effective HCV drugs, Pharmasset noted the projected effect of warehousing on the market in financial filings after Gilead announced its intention to buy the company: "Warehousing in 2012 and 2013 results in the 2011 treatment rate being halved for these years. The treatment rate then accelerates in 2014 to twice the 2011 treatment rate and remains stable through the end of the forecast period."[55] In a 2013 New York Times article, Dr. Scott Friedman explained the rationale behind the patient warehousing that occurred in anticipation of Sovaldi:

> Many doctors are now "warehousing" their hepatitis C patients—urging them to forgo treatment until the new drugs are approved. "There's no way I'm going to put them on an interferon regimen when we're a year away from having interferon-free regimens," said Dr. Scott Friedman, the chief of liver diseases at the Icahn School of Medicine at Mount Sinai. "It's rare you have to pull the trigger and get them on treatment in that period of time." Gilead estimates that only 58,000 Americans with hepatitis C are now undergoing treatment, a small fraction even of those who know they are infected. Wanting to avoid interferon's side effects, some patients without symptoms try to monitor their liver and start treatment only if it shows signs of deterioration. But with the new more tolerable treatments, some experts say, it makes sense to treat early-stage disease to prevent cirrhosis and the accompanying risk of liver cancer.[56]

---

[54] Michelle Cortez & Naomi Kresge, *Warehoused Hepatitis C Patients May Boost Merck, J&J,* Bloomberg (Apr. 19, 2010), *available at* http://www.bloomberg.com/news/articles/2010-04-18/-warehoused-hepatitis-c-patients-may-boost-sales-for-merck-j-j-vertex.

[55] Pharmasset, Inc. Amendment No. 2 to Solicitation/Recommendation Statement Under Section 14(d)(4) of the Securities Exchange Act of 1934 (Schedule 14D–9), at 9 (Dec. 20, 2011), *available at* http://www.sec.gov/Archives/edgar/data/1301081/000119312511347237/d270458dsc14d9a.htm.

[56] Andrew Pollack, *Hepatitis C, A Silent Killer, Meets Its Match,* N.Y. Times (Nov. 4, 2013), *available at* http://www.nytimes.com/2013/11/05/health/hepatitis-c-a-silent-killer-meets-its-match.html?pagewanted=all&_r=0.

Section 2: Gilead's Acquisition of Pharmasset and the Final Approval Phase for Sovaldi

Pharmasset's Path From University Labs to Hepatitis C Front-Runner

Pharmasset was launched by four medical researchers in 1998, with its first headquarters in a suburb of Atlanta. Soon thereafter, the company signed licensing agreements for drug candidates discovered during university-based research and signed additional agreements with several pharmaceutical companies.[57]

As Pharmasset prepared to become a publicly traded company in 2006, it focused on the clinical development of drugs to treat HIV, Hepatitis B, and HCV.[58] By 2008, Pharmasset's financial filings showed that it began spending money on pre-clinical studies for PSI–7977, which Gilead would eventually market as Sovaldi, and include as a component of Harvoni.[59] Between 2008 and 2011, Pharmasset spent $62.4 million researching and developing PSI–7977.[60] Those research funds included a federal grant of $244,479.25 awarded under the Qualifying Therapeutic Discovery Program for development of PSI–7977.[61]

Pharmasset executives understood PSI–7977's potential as a drug candidate. More than a year before acquisition talks began with Gilead, Pharmasset executives informed their board of directors that the drug's safety and efficacy profile proved promising in clinical trials, and that PSI–7977 "is less risky than other drugs at this stage of development."[62] Pharmasset received unsolicited buyout offers from other pharmaceutical companies, prompting the company to engage Morgan Stanley as an advisor.[63]

Pharmasset executives also continued to press the board for supplemental budget approvals to carry on development of PSI–7977.[64] Executives discussed and explored ways to turn a small firm focused on research into a company that sold HCV drugs internationally.[65] According to an internal slide presentation, the FDA told the company on August 18, 2011 that PSI–7977 "could enable [a] rapid transition away from interferon AND ribavirin," and that agency officials "were supportive of a rapid move to monotherapy in order to eliminate both interferon and ribavirin."[66] On November 6,

---

[57] Pharmasset, Inc., Registration Statement (Form S–1), at F–21 (May 8, 2006), *available at* http://www.sec.gov/Archives/edgar/data/1301081/000119312506103750/ds1.htm.

[58] *Id.*

[59] Appendix F, Gilead Sciences, Inc., Response to Chairman Wyden/Senator Grassley letter dated July 11, 2014, narrative answer to question 6a (Sept. 9, 2014).

[60] *Id.*

[61] *Qualifying Therapeutic Discovery Project Grants for the State of New Jersey,* Internal Revenue Service (May 7, 2015), *available at* http://www.irs.gov/Affordable-Care-Act/Affordable-Care-Act-Tax-Provisions.

[62] Appendix E, Ex. 6, Pharmasset, Board of Directors meeting packet (July 21, 2010), GS–0014970 at GS–0015031—GS–0015039.

[63] Pharmasset, Inc. Solicitation/Recommendation Statement Under Section 14(d)(4) of the Securities and Exchange Act of 1934 (Schedule 14D–9) (Dec. 6, 2011), at 8–12, *available at* http://www.sec.gov/Archives/edgar/data/1301081/000119312511331226/d265035dsc14d9.htm.

[64] Appendix E, Ex. 7, Pharmasset, Board of Directors Memorandum (Sept. 16, 2011), GS–0017760.

[65] Appendix E, Ex. 8, *Global Commercialization Strategy Update to Pharmasset Board of Directors* (2011), GS–0003852.

[66] Appendix E, Ex. 9, PSI–7977 Phase II Clinical Trial Data Review (Oct. 3, 2011), GS–0011638, at GS–0011640.

2011, just two weeks before announcing its acquisition by Gilead, Pharmasset publicly unveiled the results of a Phase 2 FDA trial dubbed "ELECTRON," which showed that PSI–7977 effectively cured all 40 of the genotype 2 and 3 participants, including 10 who had not used interferon.[67]

Jim Meyers, Gilead vice president of North American commercial operations, told investigative staff that the data release was better than Gilead expected. It provided a better view and a more bullish view of all of the variables that came into play, including assumptions about the drug's launch year, its eventual market penetration, overall disease prevalence and geographic distribution.[68]

Pharmasset's Phase 2 success with PSI–7977 came against a backdrop of stiff competition. In 2011, the first drugs that directly attacked HCV had been released, and a herd of pharmaceutical companies was racing to be the first with an interferon-free therapy, as described in a 2010 memo from Pharmasset's executives to its board:

> [M]ost big pharmaceutical companies with antiviral franchises are expecting HCV to be the next big antiviral market and are placing a strong emphasis on quickly establishing market leadership through the use of direct acting antivirals to improve the efficacy of current therapy with the hope of decreasing the duration of interferon therapy. This will be quickly followed by combinations of direct acting antivirals in hopes of eliminating interferon therapy.[69]

Given the promising data from clinical trials and the potential market for improved HCV therapies, Pharmasset's PSI–7977 was well-positioned to be a market leader. Gilead was aware of this potential.

Gilead's Concern About a Weak Product Pipeline

Gilead was not only concerned about ensuring it could acquire Pharmasset's promising molecule, it was aware that it could move too slowly and miss the chance to purchase the company in a highly competitive industry. Gilead and its bankers code-named the acquisition "Project Harry," with the companies named after characters from the children's novel *Harry Potter*—Pharmasset was referred to as "Harry" and Gilead was "Gryffindor." In a presentation titled "Introduction to Project Harry" on July 21, 2011, Gilead COO John Milligan stated that "Harry is the best, and most timely, way to bring a nucleotide to Gilead's portfolio," and the company was "unlikely to be available a year from now" because it is an "[a]ttractive acquisition for several companies."[70]

Presentations to Gilead's board suggest that absent its own promising drug compounds, the purchase of Pharmasset was the

---

[67] *Twelve Weeks Interferon-Free PSI–7977 Regimen Cures 100 Percent Hep C Genotype 2/3,* Hep Mag (Nov. 6, 2011), *available at* http://www.hepmag.com/articles/psi7977_svr_hcv_2501_21405.shtml.

[68] Interview with Jim Meyers, Senior Vice President, North America Commercial Organization, Gilead Sciences, Washington, D.C. (Dec. 1, 2014).

[69] Appendix E, Ex. 6, Pharmasset, Board of Directors meeting packet (July 15, 2010), GS–0014970, at GS–0015031—0015042.

[70] Appendix E, Ex. 10, Gilead Sciences, Inc., *Introduction to Project Harry* (July 21, 2011), GS–0019211, at GS–0019214.

primary route for the company to compete in the HCV market. Barclays summarized the strategic rationale in the days before the acquisition was announced:

- Diversifies Gryffindor's business outside of **HIV** while leveraging Gryffindor's area of expertise
- Harry acquisition accelerates Gryffindor's development program in the treatment of **HCV**
- Harry's nucleotide analog PSI–7977 and portfolio of nucs have demonstrated potency and effectiveness in 700+ patients without safety or resistance concerns
- Gryffindor's expertise in anti-viral therapies positions it as the company uniquely capable of maximizing Harry's **HCV** commercial opportunity [71]

More than a year before acquisition talks began, Pharmasset executives presented a case study to the company's board that succinctly summarized their view of Gilead's difficulties in HCV drug development:

> Today, Gilead is left wondering what to do in HCV. As a result of their lack of success in HCV, they hired John McHutchison to head their Hepatitis development efforts in June 2010. The very clear signals from Gilead and John are that they will be making some strategic moves in HCV.[72]

The expectation of a strategic move was partially due to Gilead's own difficulties in developing an HCV drug. As negotiations with Pharmasset began in September 2011, Gilead announced another setback for one of its HCV drugs, GS–9190, forcing the company to alter study protocols after patients in two studies reported adverse side effects.[73] A presentation to Gilead's board of trustees in October 2011 showed that as late as 2010, Gilead had been aiming for a "broad genotypic oral antiviral" in 2020, but that "the competitive nature of the field and speed of development has now compacted the timelines" to within just a few years.[74] Another presentation showed that Gilead's advisory board expected an all-oral therapy "very soon," that "[development] [t]imelines are shrinking rapidly," and that the "[f]ield is moving very fast; faster than anyone anticipated." [75] The presentation stated that Pharmasset was recruiting patients to its clinical trials faster than any other company, and concluded that the company "has established the fastest pathway forward with the simplest regimen that is furthest along." [76] These presentations made clear that Gilead's lack of success in its HCV

---

[71] Appendix E, Ex. 11, Barclays, Description of Fairness Opinion (Nov. 13, 2011), GS–0011877, at GS–0011880 (emphasis in original).

[72] Appendix E, Ex. 6, Pharmasset, Board of Directors meeting packet (July 15, 2010), GS–0014970, at GS–0015031—0015061.

[73] Press Release, Gilead Sciences, Inc., Gilead Amends Study Design for Ongoing Hepatitis C Clinical Trials That Include GS 9190, Pegylated Interferon and Ribavirin, and Another Direct-Acting Antiviral Agent (Sept. 4, 2011), *available at* http://www.gilead.com/news/press-releases/2011/9/gilead-amends-study-design-for-ongoing-hepatitis-c-clinical-trials--that-include-gs-9190-pegylated-interferon-and-ribavirin-and-another--directacting-antiviral-agent.

[74] Appendix E, Ex. 12, Gilead Sciences, Inc., *Gilead Liver Disease Franchise: BOD Strategic Review* (2011), GS–0019275, at GS–0019285—0019286.

[75] Appendix E, Ex. 13, Gilead Sciences, Inc., *Harry Update* (Oct. 7, 2011), GS–0019236, at GS–0019239.

[76] *Id.* at GS–0019246.

pipeline and its desire to remain competitive increased both the value and importance of acquiring Pharmasset's promising therapies.

The $11.2 Billion Acquisition of Pharmasset

On January 17, 2012, Gilead Sciences, Inc., announced the completion of its $11.2 billion purchase of Pharmasset, Inc. Gilead executives were confident in Pharmasset's HCV drug candidate, which was entering the final phase of testing for regulatory approval. However, when the acquisition was first announced on November 21, 2011, it triggered a selloff of Gilead stock, and was panned by financial analysts who deemed the deal as extremely risky:

> Investors balked at the deal on Monday, with shares of Gilead falling 9 percent on the announcement. "For Gilead to give up effectively one-third of their value for an unproven asset still subject to significant ongoing clinical risk seems remarkable," Geoffrey Porges, biotechnology analyst at Sanford C. Bernstein & Company, wrote in a note Monday. Thomas Wei of Jefferies & Company estimated that Gilead's sales of hepatitis C drugs would have to reach $4 billion a year—difficult, but not impossible—to justify the purchase price.[77]

Despite doubts among analysts and investors, Gilead executives were confident that Pharmasset was developing a molecule that would revolutionize HCV treatment by potentially removing interferon from therapy in the future. Furthermore, executives were willing to pay a premium because, as noted above, Gilead's own efforts at developing HCV drugs were not succeeding and were not progressing as quickly as needed to keep up with competitor companies.

Although a company executive told investigative staff that Gilead was taking an extraordinary risk in buying Pharmasset,[78] documents provided by the company suggest that executives were very confident in sofosbuvir's ability to gain FDA approval. Gilead slides highlighted an "[e]xcellent safety profile (no measureable side effects in any patients to date)" headed into Phase 3 testing as well as high cure and response rates for genotype 1 patients with and without interferon.[79] The confidence stemmed from months that Gilead, in conjunction with advisors from Barclays and Bank of America, had spent studying the global HCV market and potential revenue streams from a hypothetical "Harry-Gryffindor" acquisition. The acquisition team had studied proprietary financial and research data provided by Pharmasset under non-disclosure agreements, and provided regular reports to executives and the Board of Directors at Gilead.

---

[77] Andrew Pollack & Michael J. De La Merced, *Gilead to Buy Pharmasset for $11 Billion,* N.Y. Times (Nov. 21, 2011), *available at* http://dealbook.nytimes.com/2011/11/21/gilead-to-buy-pharmasset-for-11-billion/?_r=0.

[78] Interview with Jim Meyers, Senior Vice President, North America Commercial Organization, Gilead Sciences, Inc., in Washington, D.C. (Oct. 30, 2014).

[79] Appendix E, Ex. 13, Gilead Sciences, Inc., *Harry Update* (Oct. 7, 2011), GS–0019236 at GS–0019240.

The information left Gilead's leadership sufficiently convinced of PSI–7977's promise, that the company increased its offer 37% during the 11 weeks spent negotiating the deal—from $100 per share to the final offer price of $137 per share.[80] That was a 59% premium to the all-time high price for Pharmasset stock.[81]

John McHutchison, who would be an important player in the eventual pricing of Sovaldi, was deeply involved in the acquisition process. A medical doctor and well-known HCV researcher, McHutchison had been a consultant to Pharmasset before joining Gilead as senior vice president, liver disease therapeutics, and a member of the company's executive team.[82] Shortly before the deal closed, McHutchison described the purchase of Pharmasset as a "bargain" in an email to Matthew Young at Barclays, which served as Gilead's acquisition advisor. In the same email, dated January 7, 2012, McHutchison wrote that Bristol-Meyers Squibb acted in "desperation" when the company paid $2.5 billion to purchase another small biotechnology firm developing a different HCV drug.[83]

In 2014, the first year that Gilead marketed Sovaldi and Harvoni, the company reported $12.4 billion in worldwide HCV sales,[84] more than three times the amount that Jefferies & Company projected being needed to justify the purchase of Pharmasset. The company expects sales of its HCV drugs to grow in 2015, having reported net product sales of $14.3 billion during the year's first nine months.[85]

Pharmasset Expected 12-Week HCV Treatment to Cost $36,000

Gilead's eventual selling price for Sovaldi was substantially higher than what Pharmasset expected to charge. Specifically, after the acquisition was announced, Pharmasset filed with the Securities and Exchange Commission on December 6, 2011, showing it projected to sell PSI–7977 for $36,000 per treatment regimen in the United States, with discounted prices in the European Union.[86] Gilead ultimately set the price of Sovaldi at $84,000 for a single 12-week treatment course, more than twice as high as Pharmasset's public projection at the time the acquisition was announced.

Gilead claims that Pharmasset actually projected a higher selling price than $36,000. In particular, Gilead's outside counsel directed

---

[80] Pharmasset, Inc. Solicitation/Recommendation Statement Under Section 14(d)(4) of the Securities and Exchange Act of 1934 (Schedule 14D-9) (Dec. 6, 2011), at 8–12, *available at* http://www.sec.gov/Archives/edgar/data/1301081/000119312511331226/d265035dsc14d9.htm.

[81] Press Release, Gilead Sciences, Inc., Pharmasset, Inc., Gilead Sciences to Acquire Pharmasset, Inc. for $11 Billion (Nov. 21, 2011), *available at* http://www.sec.gov/Archives/edgar/data/882095/000119312511317734/d259746dex991.htm.

[82] Press Release, Gilead Sciences, Inc., John G. McHutchison, MD, to Join Gilead Sciences as Senior Vice President, Liver Disease Therapeutics (June 8, 2010), *available at* http://investors.gilead.com/phoenix.zhtml?c=69964&p=irol-newsArticle&ID=1436018.

[83] Appendix E, Ex. 2, Gilead Sciences, Inc., Emails between Matthew Young, Barclays Capital, and John McHutchison (Jan. 7, 2012), GS–0010634.

[84] Gilead Sciences, Inc. Annual Report (Form 10-K) (Feb. 25, 2015), *available at* http://www.sec.gov/Archives/edgar/data/882095/000088209515000008/a2014form10-k.htm.

[85] Press Release, Gilead Science, Inc., Gilead Sciences Announces Second Quarter 2015 Financial Results (July 28, 2015), *available at* http://www.sec.gov/Archives/edgar/data/882095/000088209515000022/exhibit991earningspressrel.htm.

[86] Pharmasset, Inc. Solicitation/Recommendation Statement Under Section 14(d)(4) of the Securities and Exchange Act of 1934 (Schedule 14D–9) (Dec. 6, 2011) at 32, *available at* http://www.sec.gov/Archives/edgar/data/1301081/000119312511331226/d265035dsc14d9.htm.

investigative staff to Pharmasset's amended 14–D filing, which projects a price range of $36,000 to $72,000 for U.S. customers, filed on December 20, 2011.[87] Investigative staff's review of documents provided during the course of the investigation show that Pharmasset's executives and board of directors were presented with this price range immediately before the acquisition was announced, but the $72,000 price did not appear to play a role as the company considered selling to Gilead.

Documents show that the $72,000 price for PSI–7977 first appeared on November 18, 2011, three days before the acquisition was announced. That day, Pharmasset CEO Schaefer Price emailed a presentation to the company's board of directors. The presentation states that the "price for 7977 + RBV ranges from $36,000 (Victrelis only) to $72K (Incivek + SOC). This does not reflect any price premium or cost savings to payers."[88] The presentation also states that the then-current cost to treat patients with protease inhibitors ranged from "$65K to $74K based on length" of treatment. Importantly, though, the price increases were not included in the presentation's forecast model.[89]

On the same day as the Price email, Morgan Stanley presented slides to the Pharmasset board containing a matrix titled "Pricing Sensitivity—Mgmt. Case."[90] In this matrix, unit pricing of $72,000 translates to a price of $290 per share.[91] This amount per share is more than twice the purchase price the board approved from Gilead less than 72 hours later. This suggests that Pharmasset did not view $72,000 as a realistic price. Moreover, in that presentation, all of the management cases—downside, base, and upside—used $36,000 as the price for PSI–7977. The management case "represents management's view of the most probable scenario in light of recent developments in the Hepatitis C landscape."[92]

Other documents from earlier in the year further demonstrate that Pharmasset had not contemplated pricing PSI–7977 nearly as high as Gilead would eventually price Sovaldi. One document contains a presentation prepared by Morgan Stanley with financial analysis prepared in its advisory role to Pharmasset. These presentations contained a matrix like the one below estimating the per-

---

[87] Pharmasset, Inc., Amendment No. 2 to Solicitation/Recommendation Statement Under Section 14(d)(4) of the Securities Exchange Act of 1934 (Schedule 14D–9) (Dec. 20, 2011), *available at* http://www.sec.gov/Archives/edgar/data/1301081/000119312511347237/d270458dsc14d9a.htm.

[88] Appendix E, Ex. 14, Email from Schaefer Price to Herb Conrad, et al., "FW: Forecast Assumptions," November 18, 2011, GS–0018378; Appendix E, Ex. 15, Pharmasset, Inc., "Adjustments to Forecast Assumptions, Based on Learnings from AASLD" (Nov. 18, 2011), GS–0018379 at GS–0018380. At the time, clinical guidelines recommended using Victrelis (boceprevir) in combination with peg-interferon/ribavirin for 24 to 44 weeks; guidelines recommended that Incivek be used for 12 weeks in combination with peg-interferon/ribavirin, with an additional 12 to 36 weeks of peg-interferon/ribavirin. See Table 2 in Mark G. Ghany et al., *An Update on Treatment of Genotype 1 Chronic Hepatitis C Virus Infection: 2011 Practice Guideline by the American Association for the Study of Liver Diseases,* 54 Hepatology 1433, 1433–44 (Oct. 2011), *available at* http://doi.org/10.1002/hep.24641.

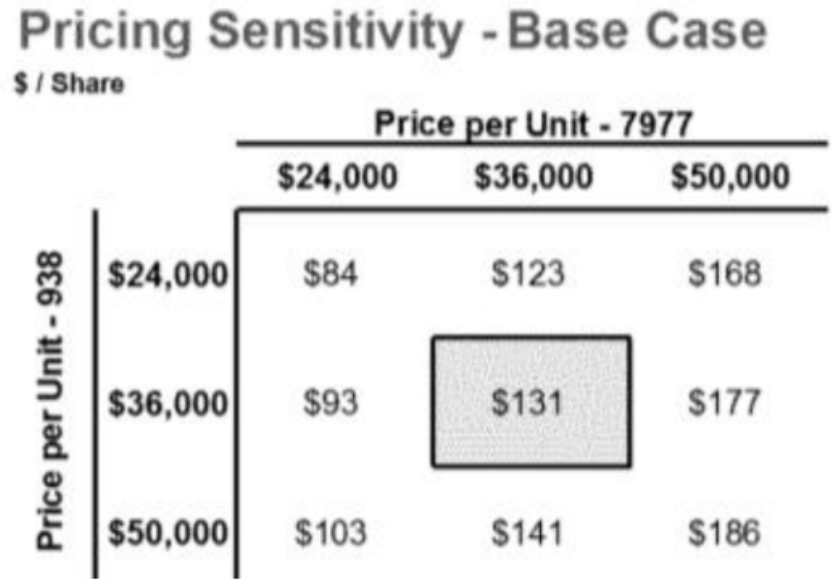
[89] Appendix E, Ex. 15, Pharmasset, Inc., "Adjustments to Forecast Assumptions, Based on Learnings from AASLD" (Nov. 18, 2011), GS–0018379, at GS–0018380.

[90] A management case is typically the financial model that executives believe is most likely reflective of a company's business on a go-forward basis or the model that management is using to make planning decisions.

[91] Appendix E, Ex. 16, Morgan Stanley, Project Royal Discussion Materials (Nov. 18, 2011), GS–0018382, at GS–0018396.

[92] *Id.* at GS–0018393.

share value of Pharmasset correlated with the expected prices for PSI–7977 and another drug candidate, PSI–938:[93]



The above pricing sensitivity matrix suggests that if Pharmasset expected PSI–7977 to sell for $50,000, the company would have expected its market value to range from $13.7 billion to $15.2 billion—between 22.6% and 35.7% higher than the price that was actually garnered from Gilead.[94] Similarly, presentations in May 2011 and July 2011 show that the highest price points being discussed in modeling were $24,000 and $36,000, the latter of which was dubbed the "management case."

Lastly, a presentation from September 2011 shows the price of manufacturing PSI–7977 in relation to the price of therapy. While the drug was being manufactured for testing, Pharmasset calculated the production cost to be $32,000 per kilogram, or $1 per 1,200-milligram caplet.[95] Pharmasset expected production costs to be cut by almost two-thirds to $11,000 per kilogram when commercial-scale operations began.[96] The presentation shows that manufacturing costs for Pharmasset would be de minimis compared to

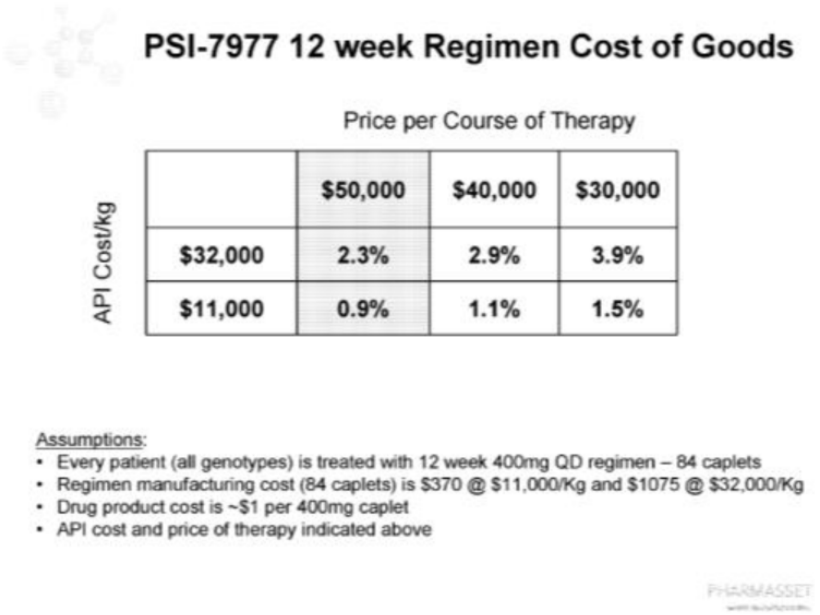
[93] Appendix E, Ex. 17, Morgan Stanley, Project Royal Discussion Materials (Oct. 6, 2011), GS–0002762.

[94] To determine this estimate, investigative staff compared the tender price Gilead offered Pharmasset shareholders when the 2011 transaction took place ($137/share) with the Morgan Stanley pricing sensitivity matrix. *Id.* The matrix projected different share prices for Pharmasset based on prices for PSI–7977 and PSI–938. The column in which PSI–7977 was priced at $50,000 had a range of share prices as low as $168 (with PSI–938 at $24,000) and $186 (with PSI–938 at $50,000), which are 122.6% and 135.7% of the tender price. Staff used those percentage differences to multiply the final purchase Gilead paid for Pharmasset ($11.2 billion) to arrive at a range of $13.7 billion and $15.2 billion.

[95] Appendix E, Ex. 18, Pharmasset, Untitled Presentation by Pharmasset Executives (Sept. 2011), GS–0011557 at GS–0011588.

[96] *Id.* at GS–0011581.

the revenue each course of therapy would generate—ranging from 0.9% for a $50,000 course to 1.5% for a $30,000 course:[97]



PSI-7977 12 week Regimen Cost of Goods

Price per Course of Therapy

API Cost/kg	$50,000	$40,000	$30,000
$32,000	2.3%	2.9%	3.9%
$11,000	0.9%	1.1%	1.5%

Assumptions:
- Every patient (all genotypes) is treated with 12 week 400mg QD regimen – 84 caplets
- Regimen manufacturing cost (84 caplets) is $370 @ $11,000/Kg and $1075 @ $32,000/Kg
- Drug product cost is ~$1 per 400mg caplet
- API cost and price of therapy indicated above

PHARMASSET

Thus, it appears that, based on internal presentations given between five months and three days before the announcement of Gilead's acquisition of Pharmasset, Pharmasset did not intend to sell PSI–7977 for prices exceeding $50,000. In particular, the range that was presented to the board while the acquisition was in its final stages indicate that the financial impacts of the higher end of the drug price range would have meant Pharmasset was substantially undervaluing itself.

Gilead Did Not Contemplate a Price Above $75,000 Leading up to Acquisition

On November 13, 2011, less than two weeks before the deal was announced, Barclays gave a presentation to Gilead that suggests Gilead was considering a price range of $55,000 to $75,000 for Sovaldi treatment to ensure suitable financial returns. The presentation referenced a gross price per patient in the United States of $65,000 and included sensitivity analysis showing the revenue effect of increasing or decreasing the price by $10,000 (resulting in the $55,000 to $75,000 range).[98] It is important to recognize that the figures in the presentation were projected gross prices, which is the price point before discounting to payers which results in a net price.

[97] *Id.* at GS–0011590.
[98] Appendix E, Ex. 19, Barclays Capital, *Revenue/Valuation Models: Project Harry* (Nov.13, 2011), GS–0013466, at GS–0013467, GS–00013474.

These figures were developed over the course of several months by Barclays in close partnership with a Gilead project team. Emails show that the pricing model had been through numerous iterations with Gilead's employees studying the model for market assumptions with respect to infection rates, cure rates, market share and other data points related to the HCV population domestically and abroad.[99]

Jim Meyers told investigative staff that the molecule's ultimate price was not a major consideration during the run-up to the purchase of Pharmasset.[100] Gilead had a rough but conservative estimate for drug prices, primarily based on the Barclays model.[101] Treatment rates, flow of patients and flow of diagnosis were the company's primary concern at that point.[102] Price was not unimportant, but the number of patients was more important to making the deal acceptable.[103]

Meyers referred investigative staff to the last page of a presentation from July 20, 2011, and a summary of assumptions, including an $80,000 "price-per-cure" (the total cost of prescribing drugs divided by the number of cured patients results in an average price per cured patient), which was based on the price of telaprevir and boceprevir.[104] Price per cure is higher than the price of these drugs because some number of patients taking the drug would not be cured, and the initial treatment regimen required the use of interferon and/or ribavirin to also be administered.[105] That presentation assumed that the gross price of DAA drugs would start at $63,500, equaling a price per cure of $80,000.[106] The pricing assumption model showed that the cost-per-cure was projected to increase 3% annually, and assumes an 8% "convenience bump" in pricing when an all-oral, single-tablet drug came to market.[107] This appears similar to the strategy, detailed later in this report, which Gilead employed when it priced Sovaldi and Harvoni. Lastly, Barclays expected that American patients would be charged a premium for HCV treatments, compared to patients in Japan and Europe (see slide below).[108]

---

[99] Appendix E, Ex. 20, Email from John McHutchison to Jonathan Piazza, Re: Project Pyramid Assumptions (June 21, 2011), GS–0004809; Appendix E, Ex. 21, Gilead Sciences, Inc., *Project Harry—Model Discussion* (Aug 16, 2011), GS–0005511.

[100] Interview with Jim Meyers, Senior Vice President, North America Commercial Organization, Gilead Sciences, Inc., in Washington, D.C. (Dec. 1, 2014).

[101] *Id.*

[102] *Id.*

[103] *Id.*

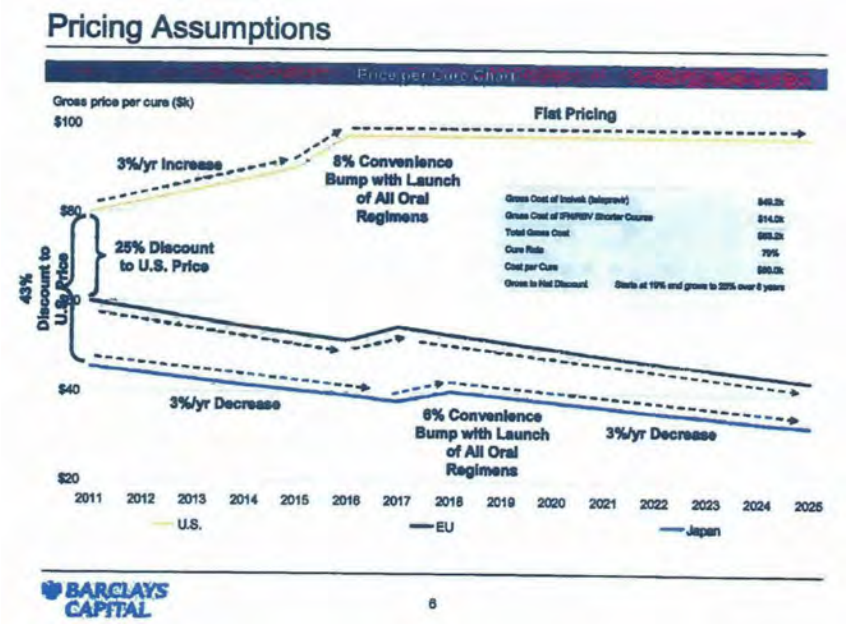
[104] Appendix E, Ex. 22, Gilead Sciences, Inc., *Project Harry—Barclays Deck Backgrounder* (July 20, 2011), GS–0000207, at GS–0000228.

[105] *Id.* at GS–0000214.

[106] *Id.* at GS–0000219.

[107] *Id.*

[108] *Id.*



In sum, as the deal between Pharmasset and Gilead entered its final phase, Gilead executives believed that the purchase of Pharmasset would be profitable if the drug were sold for a gross price ranging from $55,000 to $75,000 before sales discounts were applied. A presentation one year after the sale suggests the company expected prices to be at the midpoint—i.e., $65,000.[109] This was approximately $20,000 less than what Gilead ultimately chose as the selling price.

Complete R&D Costs for Gilead's Completion of the Approval Process for Sovaldi Were Not Provided

Gilead provided R&D spending data for "sofosbuvir-based regimens," which include "any compound in R&D that uses sofosbuvir or is combined in development with sofosbuvir."[110] Thus, the spending data may overstate the R&D costs associated with bringing Sovaldi to market because the data includes three compounds in addition to sofosbuvir as a single-agent drug.[111] Gilead failed to provide costs attributable solely to the development of Sovaldi, despite repeated requests to do so.

---

[109] Appendix E, Ex. 23, Gilead Sciences, Inc., *Hepatitis C and GS–7977 Development Update,* "HCV Strategy Review," November 5, 2012, GS–0019442, at GS–0019461—GS–0019462.

[110] Appendix F, Gilead Sciences, Inc., Response to Chairman Wyden/Senator Grassley letter dated July 11, 2014, narrative answer to question 12 (Sept. 9, 2014).

[111] These four combinations were GS–7977 (sofosbuvir as a single-agent drug); GS–7977 in combination with GS–5885 (which would eventually become Harvoni); GS–7977 in combination with GS–5816; and GS–7977 in combination with GS–9813. Appendix E, Ex. 24, Gilead Sciences, Inc., *2012–2018 Financial Forecast* (Nov. 2012), GS–0019394 at GS–0019413.

Gilead said that its estimated R&D costs for sofosbuvir-based regimens would be $880.3 million between 2012 and 2014.[112] The R&D costs that Gilead provided are detailed in table 1 below:

Table 1—Gilead Sciences' Research and Development Costs for Sofosbuvir-based Drug Regimens

	2012	2013	2014 (estimated)
Personnel Costs*	$45,195,000	$51,770,600	$74,765,423
Clinical Studies/Contract Research Organization Costs**	$136,942,698	$238,986,739	$242,830,400
Milestones/Licenses	–	$4,117,281	($2,907,678)
Overhead Allocations/Facilities Costs/ Materials and Supplies	$27,859,182	$29,339,061	$31,367,638
Total	$209,996,871	$324,213,681	$346,055,782
Total 2012–2014			**$880,266,334**

Source: Gilead Sciences, Inc.

*Gilead does not track expenses related to personnel costs, overhead allocation, facilities costs, and materials and supplies by therapeutic product candidate. Gilead estimated expenses by allocating based on a percentage of total employee headcount.

** Section 14.1 of Sovaldi's FDA label states "The safety and efficacy of SOVALDI was evaluated in five Phase 3 trials in a total of 1724 HCV mono-infected subjects with genotypes 1 to 6 chronic hepatitis C (CHC) and one Phase 3 trial in 223 HCV/HIV–1 co-infected subjects with genotype 1, 2 or 3 CHC."[113]

As noted above, Pharmasset spent $62.4 million between 2008 and 2011 researching and developing PSI–7977. Combined, this totals $942.4 million. Gilead did note in its response to the senators' letter that additional costs were expected for post-market release studies, but Gilead failed to detail those costs.[114]

By comparison, while negotiating its eventual sale to Gilead, executives for Pharmasset presented the company's expected drug development costs for fiscal year 2012 (which began October 1, 2011):

> Our budgeted development program expenses are $125.0 million for fiscal 2012, up $72.7 million from $52.3 million in fiscal 2011. The main drivers of this substantial increase in our development expenses is the advancement of PSI–7977 into four Phase 2b studies (including the Phase 2b QUANTUM study), as well as 3 Phase 3 studies, and the advancement of PSI-938 into the QUANTUM study.[115]

[112] Appendix F, Gilead Sciences, Inc., Response to Chairman Wyden/Senator Grassley letter dated July 11, 2014, narrative answer to question 12 (Sept. 9, 2014).

[113] SOVALDI Prescribing Information, Section 14.1 (2013), *available at* http://www.accessdata.fda.gov/spl/data/24e7ec0a-9f1b-4b63-8e48-53a63cd7c46f/24e7ec0a-9f1b-4b63-8e48-53a63cd7c46f.xml.

[114] Appendix F, Gilead Sciences, Inc., Response to Chairman Wyden/Senator Grassley letter dated July 11, 2014, narrative answer to question 12 (Sept. 9, 2014).

[115] Appendix E, Ex. 25, Pharmasset, Inc., Board of Directors Packet (Oct. 11, 2011), GS–0017925, at GS–0017956.

Specifically, development costs for PSI–7977 were budgeted by Pharmasset to be $90.5 million.[116] In the same presentation, Pharmasset executives projected that the Phase 3 studies for PSI–7977—the final clinical development needed for regulatory approval that Gilead was primarily engaged in after the merger—would total $125.6 million.[117]

The spreadsheet on the following page provides specific, quarterly costs that Pharmasset budgeted for these studies.

[116] *Id.*
[117] *Id.* at GS–0017966.

Development Programs	FQ1 '12 Budget	FQ2 '12 Budget	FQ3 '12 Budget	FQ4 '12 Budget	F '12 Budget	F '11 Actuals	Diff Ov (Und)	Total Study Costs
PSI-7977								
DMPK, Tox & Other	$ 963	$ 943	$ 766	$ 587	$ 3,259	$ 3,117	$ 142	
Phase 1 & Clin Pharm	2,339	1,101	1,288	900	5,628	4,765	863	
Phase 2b - early studies	1,185	754	534	330	2,803	9,215	(6,412)	
Phase 2b - ATOMIC	2,615	1,670	1,156	693	6,134	9,465	(3,331)	
Phase 3 - Study 1	3,769	7,102	7,492	8,094	26,457	743	25,714	$ 54,077
Phase 3 - Study 2	428	3,124	5,624	6,588	15,764	-	15,764	$ 36,286
Phase 3 - Study 3		428	3,672	7,146	11,246	-	11,246	$ 35,278
Phase 3b - Rollover				500	500	-	500	
Phase 3b - Health Economics				500	500	-	500	
API	7,251	4,088	5,137	1,729	18,205	10,339	7,866	
	18,550	19,210	25,669	27,067	90,496	37,644	52,852	
PSI-938								
DMPK, Tox & Other	792	303	418	616	2,129	2,145	(16)	
Phase 1 & Clin Pharm	2,540	2,223	3,669	2,911	11,343	5,035	6,308	
Phase 2b - QUANTUM	3,421	4,541	4,205	5,678	17,845	2,251	15,594	$ 49,480
API	1,557	1,605	31	31	3,224	3,966	(742)	
	8,310	8,672	8,323	9,236	34,541	13,397	21,144	
PSI-661	-	-	-	-	-	1,289	(1,289)	
Total	$ 26,860	$ 27,882	$ 33,992	$ 36,303	$ 125,037	$ 52,330	$ 72,707	

Gilead's Development Timeline Benefited from FDA Policies

Sovaldi was one in a series of HCV therapies that benefited from FDA policies designed to shorten the R&D process and broaden access to potentially lifesaving therapies (See Table 2). In the case of Sovaldi, the compressed timeline meant Gilead was afforded an opportunity to sell its therapy in the U.S. with minimal competition in the genotype 1 market for nearly a year.

Little more than a month before acquiring Pharmasset in 2011, Gilead executives reported to the board that changes to FDA standards regarding HCV testing protocols would benefit the purchase of Pharmasset and speed up the eventual approval of sofosbuvir. The agency would no longer require SVR to be tested 24 weeks after treatment ended. Instead, it would require an SVR follow-up at just 12 weeks.[118] Furthermore, studies using placebo-controlled trials would be accepted. As a result, Phase 3 studies would be "simpler and faster."[119] Gilead executives believed that the probability of successfully reaching the market increased along with the "truncated timelines for approval."[120]

By November 2012, McHutchison reiterated to the board that "the timelines have shortened considerably for both GS–7977 as a single agent and GS–7977 combinations," in a presentation that referred to additional conversations with the FDA (when Gilead acquired Pharmasset, the PSI–7977 became GS–7977). A presentation made on the same day first referenced the company's expectation that a new drug approval (NDA) for GS–7977 would be submitted by April 2013, and approval achieved by December of that year.[121]

In 2013, the FDA granted GS–7977 both "breakthrough therapy designation"[122] and GS–7977 "priority review"[123] status. The priority review, granted in June 2013, expedited the approval of Sovaldi.[124] The breakthrough status broadened the label's treatment indication, as Martin explained in a memo that was drafted for the board of directors:

> As highlighted by John McHutchison and Bill Symonds during our meeting last month/earlier this month, the FDA granted Sovaldi a Breakthrough Designation, which

---

[118] Appendix E, Ex. 26, Gilead Sciences, Inc., *Harry Update: Board Meeting* (Oct. 24, 2011), GS–0019309, at GS–0019311.

[119] *Id.*

[120] Appendix E, Ex. 13, Gilead Sciences, Inc., *Harry Update: Board Meeting* (Oct. 7, 2011), GS–0019236, at GS–0019244.

[121] Appendix E, Ex. 23, Gilead Sciences, Inc., *Hepatitis C and GS–7977 Development Update,* November 5, 2012, GS–0019442, at GS–0019443, GS–0019469.

[122] The agency implemented the process based on instruction in the Food and Drug Administration Safety and Innovation Act of 2012 to "implement more broadly effective processes for the expedited development and review of innovative new medicines intended to address unmet medical needs for serious or life-threatening diseases," Pub. L. No. 112–144, § 901(a)(1)(C), 126 Stat. 993.

[123] Authorized by the Prescription Drug User Act (PDUFA) of 1992, Pub. L. No. 102–571, priority review allows the FDA to act on an NDA within six months of submission, as opposed to the standard 10-month period. The FDA can grant priority review status if the NDA "treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness." Food and Drug Administration, *Guidance for Industry: Expedited Programs for Serious Conditions—Drugs and Biologics,* at 7 (2014), *available at* http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.

[124] Press Release, Gilead Sciences, Inc., Gilead Announces U.S. FDA Priority Review Designation for Sofosbuvir for the Treatment of Hepatitis C (June 7, 2013), *available at* http://www.gilead.com/news/press-releases/2013/6/gilead-announces-us-fda-priority-review-designation-for-sofosbuvir-for-the-treatment-of-hepatitis-c.

> allowed us to submit data from two additional Phase 3 studies beyond the four Phase 3 trials submitted with the initial New Drug Application.[125]

Martin appeared to be referring to the VALENCE and PHOTON-1 studies.[126] The FDA's summary review explained, "VALENCE provided data to support a 24-week treatment duration for GT3 subjects to improve relapse rates and PHOTON–1 provided data to support regimens for HCV/HIV–1 co-infected subjects along with an interferon-free regimen for GT1 subjects." [127]

Under section 506(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended, breakthrough designation is provided:

> if the drug is intended, alone or in combination with 1 or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on 1 or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.[128]

When considering a breakthrough therapy designation request, the FDA evaluates the quantity and quality of the clinical evidence submitted, available alternative therapies to that drug, and magnitude of treatment effects shown.[129] For Gilead, expanding the label's indication meant that Sovaldi would be a viable therapy for more patients, expanding the market for the drug.

Financial documents filed a month after the Gilead-Pharmasset acquisition was announced show that Pharmasset's management expected that the drug would be launched in the U.S. sometime between the fourth quarter of 2013 and the second quarter of 2015.[130] The actual December 2013 FDA approval was at the front-end of these projections. The importance of this timing shift is underscored in pricing documents discussed in detail later in this report showing that Gilead officials believed a lack of competition would inform the eventual price for Sovaldi.

Table 2 shows the HCV drugs that received FDA approval.

---

[125] Appendix E, Ex. 27, Gilead Sciences, Inc., Email from Cara Miller to Gregg Alton (Nov. 22, 2013), GS–0020826.

[126] Food and Drug Administration Center for Drug Evaluation and Research, Clinical Pharmacology and Biopharmaceutics Review(s): Application Number: 204671Orig1s000, at 2 (Nov. 22, 2013), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204671Orig1s000ClinPharmR.pdf.

[127] *Id.* at 8.

[128] Food and Drug Administration Safety and Innovation Act Pub. L. No. 112–114, § 902(a)(3), 126 Stat. 995 (2012).

[129] Center for Health Policy at Brookings, *Breakthrough Therapy Designation: Exploring the Qualifying Criteria* (2015) [hereinafter Brookings, *Breakthrough Therapy Designation*], *available at* http://www.brookings.edu/~/media/events/2015/04/24-fda-breakthrough-therapy-designation/breakthrough-therapy-designation_final.pdf.

[130] Pharmasset, Inc., Amendment No. 2 to Solicitation/Recommendation Statement Under Section 14(d)(4) of the Securities Exchange Act of 1934 (Schedule 14D–9) (Dec. 20, 2011), *available at* http://www.sec.gov/Archives/edgar/data/1301081/000119312511347237/d270458dsc14d9a.htm. Pharmasset, Inc.

Table 2—HCV Drugs That Received FDA Approval

Drug	Approval Date	Breakthrough Therapy Designation for Approved Indication(s)	Priority Review (Y/N)	Indication(s) Approved
Daklinza (daclatasvir) NDA 206843.	July 24, 2015	No	Yes	For the treatment of hepatitis C virus (HCV) genotype 3 in combination with sofosbuvir.
Technivie (ombitasvir, paritaprevir, and ritonavir) NDA 207931.	July 24, 2015	Yes	Yes	For use in combination with ribavirin for the treatment of hepatitis C virus (HCV) genotype 4 infections in patients without cirrhosis.
Viekira Pak (ombitasvir, paritaprevir, and ritonavir; dasabuvir) NDA 206619.	December 19, 2014	Yes	Yes	For use with or without ribavirin to treat patients with chronic hepatitis C virus (HCV) genotype 1 infection.
Harvoni (ledipasvir and sofosbuvir) NDA 205834.	October 10, 2014	Yes	Yes	For the treatment of chronic hepatitis C (CHC) genotype 1 infection.
Sovaldi (sofosbuvir) NDA 204671	December 6, 2013	Yes	Yes	For the treatment of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen. [Labeling specifies efficacy established in genotype 1, 2, 3 or 4]
Olysio (simeprevir) NDA 205123	November 22, 2013	No	Yes	For the treatment of chronic hepatitis C (CHC) genotype 1 infection as a component of a combination antiviral treatment regimen.
Incivek (telaprevir) NDA 201917	May 13, 2011	No *	Yes	In combination with peginterferon alfa and ribavirin, the treatment of genotype 1 chronic hepatitis C (CHC) in adult patients with compensated liver disease, including cirrhosis.
Victrelis (boceprevir) NDA 202258.	May 13, 2011	No *	Yes	For the treatment of chronic hepatitis C (CHC) genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients with compensated liver disease, including cirrhosis.

Source: FDA.
Note: * Prior to Food and Drug Administration Safety and Innovation Act and creation of the Breakthrough Therapy designation.

Section 3: The Pricing of Sovaldi

Shortly after Gilead bought Pharmasset, the company's senior officials began to prepare for the release of what they expected to be a blockbuster drug. The documentation reviewed shows that Gilead considered a number of factors in determining a price point for Sovaldi, including costs for the existing standard of care for HCV treatment and setting a high baseline for the next wave of HCV drugs. In addition, during the pricing process, Gilead looked at a range of impacting factors to gauge the likelihood of various "softer issues" at different pricing points, ranging from professional societies including price "asterisks" in their therapy recommendations, to protests from the AIDS Health Foundation or Fair Pricing Coalition, to losing "key opinion leader" endorsements, and even the likelihood of congressional hearings or letters concerning the price of Sovaldi.[131] (See slide below)

The Gilead pricing team concluded that while pricing Sovaldi at $80,000 to $85,000 would generate an outcry from advocacy groups and payers, "[t]his price will allow Gilead to capture value for the product without going to a price where the combination of external factors and payer dynamics could hinder patient access to uncomfortable levels."[132] Ultimately, Gilead was mistaken in some of its key assumptions as many public and private payers quickly reacted and adopted access restrictions.

Gilead did not produce all relevant documents and supporting materials related to pricing as requested, despite the company's assurances of cooperation. Therefore, the staff's analysis of pricing decisions and strategies that follows is necessarily based only on the documents and interviews that were provided by the company and from outside sources.

[131] Appendix E, Ex. 28, Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Assessment, Final Recommendations—July 31st, 2013, GS–0014018, at GS–0014047.
[132] *Id.* at GS–0014044, GS–0014047—GS–0014050, GS–0014053.

Early Pricing Strategy

By October 2012, the company had Phase 3 trials well underway, and was turning its attention to how it would market Sovaldi. That same month, Gilead laid out objectives for its commercial launch in a working document titled "Gilead HCV U.S. BPOA."[133] The document detailed potential customer groups, advertising strategies to reach baby boomers, and "critical success factors for

[133] Appendix E, Ex. 29, Gilead Sciences, Inc., Gilead HCV U.S. BPOA (Oct. 2012), GS–0013489, at GS–0013489.

launch."[134] As it would for the next 14 months, the company was largely focused on expanding the patient pool that would be treated with sofosbuvir.

In a November 2012 a presentation titled "HCV Strategy Review," Kevin Young, the company's executive vice president for commercial operations, referenced a U.S. price of "$58k vs. $65k (likely at parity for launch)."[135] The price in the EU would be "discount to U.S. $\simeq$ 25%."[136]

On March 25, 2013, Gilead management met and reviewed the results of market data that had been collected in a senior vice president briefing titled "Sofosbuvir U.S. Pricing & Contracting Strategy."[137] This meeting was the first of eight scheduled meetings leading to a recommendation to a group of senior executives known as the "global pricing committee" or GPC.[138]

Gilead's key pricing considerations at this time, as reflected in the documents provided, were comparisons to the costs of existing HCV SOCs, the impact of expected competition on the market for HCV therapies, the increased cost for SOCs longer than the 12-week regimen for genotype 1 patients, and an initial discussion of contracting strategies. The slide on the following page indicates Gilead's contracting and pricing timeline.

---

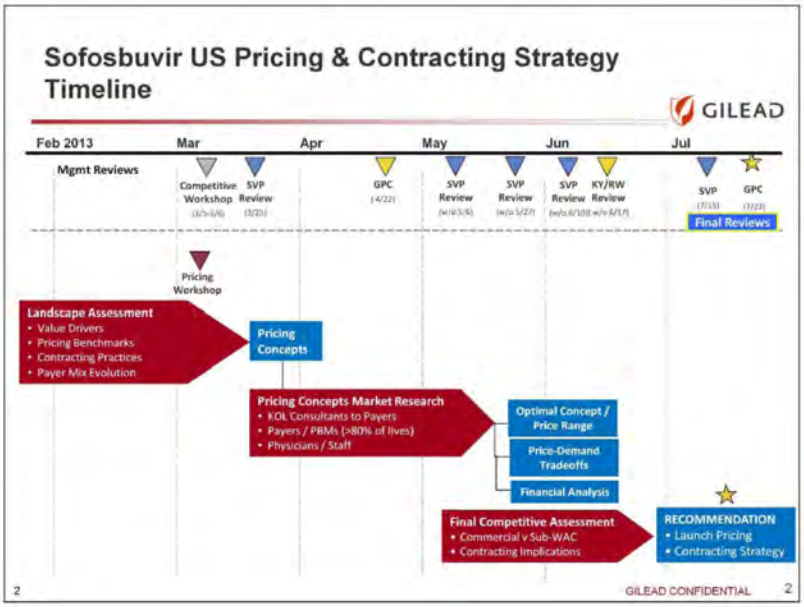
[134] *Id.* at GS–0013492—GS–0013502.

[135] Appendix E, Ex. 23, Gilead Sciences, Inc., *Hepatitis C and GS–7977 Development Update,* "HCV Strategy Review," November 5, 2012, GS–0019442, at GS–0019460, GS–0019462.

[136] *Id.* at GS–0019462.

[137] Appendix E, Ex. 30, Gilead Sciences, Inc., Sofosbuvir U.S. Pricing & Contracting Strategy, SVP Briefing, March 25, 2013, GS–0019128.

[138] Gilead failed to provide documents related to the GPC meeting scheduled for April 22 or July 21. Only one SVP review was provided for the month of May, and none in June. The "KY/RW Review," which stands for Kevin Young and Robin Washington, both senior officials at the company, is referred to on page GS–0019129 of Exhibit 30, but was not provided. *See id.* at GS–0019129. In a letter dated September 30, 2014, Senators Grassley and Wyden asked Gilead's outside counsel, Mark R. Paoletta, to certify all documents related to these meetings had been provided. Gilead's counsel failed to certify that the document production had been completed, indicating that many documents remained, and that the request would likely "incorporate hundreds of thousands of emails and documents." Gilead also failed to provide any documentation of a "SOF Launch Meeting" that the HCV Sales Team was scheduled to convene in November 2013 (referred to in Appendix E, Ex. 31, Gilead Sciences, Inc., U.S. HCV Launch Update, August 1, 2013, GS–0014059, at GS–0014068).



According to Meyers, the GPC is a critical intra-corporate body that determined the final price of Sovaldi and other drugs.[139] The committee typically meets when a material product, such as Sovaldi, is being priced. The GPC is made up of top executives at the company including:

- John Martin, CEO
- Robin Washington, CFO
- John Milligan, COO
- Jim Meyers, Senior Vice President for Commercial Operations, North America
- Kevin Young, Executive Vice President, Commercial Operations (now retired)
- Norbert Bischofberger, Executive Vice President, Research and Development Chief Scientific Officer
- John McHutchison, Executive Vice President for Clinical Research.[140]

By the time of the March 2013 presentation, the company had Phase 3 testing data and had begun taking steps to understand the drug's place in the market.[141] The company was gathering data relevant for pricing determinations taking into consideration what was currently being paid for similar drugs, discounting, and the concentration of the payer market share. The pricing process was based on four different factors: clinical attributes, value determination, market research with payers, and the cost of current product

[139] Interview with Jim Meyers, Senior Vice President, North America Commercial Organization, Gilead Sciences, Inc., in Washington, D.C. (Dec. 1, 2014).
[140] *Id.*
[141] *Id.*

regimens.[142] The 58-page slide deck prepared for management touched on all of these points and data, while noting that "sofosbuvir will likely rank among the largest launches ever (year 1 sales), driving a doubling in payers' HCV class expenditures in 2014."[143]

As part of pricing considerations, Gilead aimed to gain a thorough understanding of how similar drugs on the market were priced.[144] Gilead focused on the genotype 1 market because it makes up roughly 70% of HCV patients in the United States and was a focal point for competing drug companies. As discussed in Section 1 of this report, two protease inhibitors, telaprevir (Incivek developed by Vertex) and boceprevir (Victrelis developed by Merck), had already received FDA approval in 2011. However, Sovaldi was expected to have an edge because clinical studies showed it would provide faster, more effective treatment and reduced time on, or outright elimination of, interferon injections.[145]

Gilead used the prices of Incivek and Victrelis as a baseline and evaluated how to price sofosbuvir at a premium to existing therapies.[146] Company officials surmised that its drug had a "value premium" because of increased efficacy and tolerability, shorter treatment duration, and its potential to ultimately be part of an all-oral regimen (as it ultimately would be in combination with ledipasvir in Harvoni).

In a slide titled "Premium Based on Explicit Savings from P/R Duration," the company used the approximate price of Incivek ($55,275) as a pricing baseline. Incivek required using interferon/ribavirin for 24 to 48 weeks. Gilead calculated Incivek's average Wholesale Acquisition Cost (WAC) based on 36 weeks of interferon/ribavirin would be $82,496.[147] Using this model, Gilead's clinical and projected "real world" cure rates could justify prices ranging between $82,000 and $121,000 for a 12-week course of the drug.[148]

The next step was to evaluate competition. Because Incivek and Victrelis would be sidelined by next generation drugs, Gilead anticipated two primary competitors, simeprevir (Olysio) and the "second wave" all-oral drug combination being developed by AbbVie (later launched as Viekira Pak).[149]

Another key concern was the timing and order of competitor drug release dates. For example, AbbVie's all-oral regimen could affect uptake for sofosbuvir, which still relied on interferon and ribavirin, if Gilead's all-oral offering, Harvoni, had not yet received approval. The presentation also left open the question about what weight Gilead should give to "actual or assumed competitive pricing."[150] Importantly, the group also weighed how Harvoni's eventual pricing should affect pricing for the launch of Sovaldi.[151]

---

[142] *Id.*
[143] Appendix E, Ex. 30, Gilead Sciences, Inc., Sofosbuvir U.S. Pricing & Contracting Strategy, SVP Briefing, March 25, 2013, GS–0019128, at GS–0019156.
[144] *Id.* at GS–0019143.
[145] *Id.* at GS–0019133.
[146] *Id.* at GS–0019172, GS–0019173.
[147] *Id.* at GS–0019143.
[148] *Id.* at GS–0019174—GS–0019175.
[149] *Id.* at GS–0019133.
[150] *Id.* at GS–0019136.
[151] *Id.*

The clinical data that was included in the presentation showed that Sovaldi would perform better clinically in genotype 1 patients than Olysio, which would be Sovaldi's primary head-to-head advantage until the FDA approved interferon-free regimens.[152] Looking ahead to competition, Gilead recognized that AbbVie's yet-to-be-approved Viekira Pak had shown similar clinical efficacy as Gilead's interferon-free Harvoni (which also was in clinical trials). However, Gilead was confident that the simplicity of its eventual drug—Harvoni would require taking only a single pill per day whereas Viekira Pak required multiple pills—would be more popular with providers and payers.[153]

Gilead surmised that "price and/or contracting may be an important competitive differentiator" for Olysio and Viekira Pak.[154] The company planned to focus on a series of strategic questions over the coming months:

- Is our objective to maximize revenue or volume/share?
- What nominal price range for sofosbuvir should we consider? Are today's PIs [protease inhibitors] a valid reference point?
- How should we think about articulating sofosbuvir's price—in terms of price per cure? Other more or less sophisticated metrics?
- How can we best manage value perceptions of sofosbuvir for those patient groups for which SVR% is lower? Should we evaluate strategies that offer guarantees, e.g., price-per-cure, blended pricing maximum across genotypes? [155]

The last of these questions touched in part on the treatment of people with genotype 2 and 3, for which sofosbuvir would be the only DAA to gain FDA approval until the July 2015 approval of Daklinza. The FDA label that was eventually issued recommended that genotype 3 patients use the drug for twice as long as for genotype 1 patients—24 weeks.[156] Using the drug longer meant paying twice as much—a $168,000 WAC price before additional costs for ribavirin—and an increased likelihood of side effects such as pruritus and asthenia.[157] The March 2013 presentation shows that Gilead anticipated that the headline number for cures—more than 90%—would set a higher expectation for many patients whose actual outcomes were significantly more uncertain.[158] Some patients taking Sovaldi would pay more for a drug that had a lower probability of curing their particular HCV genotype or sub-genotype.[159]

Gilead's clinical data showed that the outcomes for genotype 3 patients, particularly those with cirrhosis or who had undergone

---

[152] *Id.* at GS–0019167, GS–0019168.
[153] *Id.* at GS–0019166.
[154] *Id.* at GS–0019135.
[155] *Id.* at GS–0019178.
[156] SOVALDI Prescribing Information (2013), *available at* http://www.accessdata.fda.gov/spl/data/24e7ec0a-9f1b-4b63-8e48-53a63cd7c46f/24e7ec0a-9f1b-4b63-8e48-53a63cd7c46f.xml.
[157] *Id.* at Table 3.
[158] Appendix E, Ex. 30, Gilead Sciences, Inc., Sofosbuvir U.S. Pricing & Contracting Strategy, SVP Briefing, March 25, 2013, GS–0019128, at GS–0019167, GS–0019178, GS–0019182.
[159] One of the company's strategic questions in the presentation was: "How can we best manage value perceptions of sofosbuvir for those patient groups for which SVR% is lower? Should we evaluate strategies that offer guarantees, e.g., price-per-cure, blended pricing maximum across genotypes?" *Id.* at GS–0019178.

previous treatment for HCV ("treatment experienced" or "TE") were far less certain than, for example, patients with genotype 1 who were non-cirrhotic and had never received treatment ("treatment naive" or "TN").[160] The concerns about treating genotype 3 patients was especially true in March 2013, when Gilead's pricing team only appeared to be evaluating results for 12 weeks of treatment, which had an SVR of just 56% for genotype 3 patients who were treatment-naive.[161] Treatment-experienced genotype 3 patients showed an even lower SVR for 12 weeks—30%—and just 62% for 16 weeks.[162]

Gilead also would have been aware that its drug faced shortfalls in other patient populations. People with subtype genotype1b and cirrhosis had lower SVR rates (82% and 80%, respectively) than those with subtype gentoype1a and non-cirrhotic (both at 92%).[163] For patients facing a liver transplant, the FDA label recommended using Sovaldi with ribavirin for 48 weeks. However, clinical trials showed SVR of just 64% following a transplant.[164] The cost of Sovaldi for those patients alone would be $336,000 at wholesale prices.[165]

Gilead considered adjusting the price downward for patients with genotypes 2 and 3, but ultimately set a single price, regardless of genotype or clinical effectiveness. Meyers would raise this issue with senior executives less than a month before sofosbuvir received FDA approval:

> It will be important for us to have a coordinated cross-functional characterization of the price of SOF at launch, regardless of who we're speaking to (advocacy groups, physicians, payers, Wall Street, etc.). Part of that characterization (not by any means all of it) will be addressing concerns about patients who may require 24 weeks of SOF and thus be subjected to 2X the cost (GT–3 patients, HIV/HCV co-infected patients, etc.). If not handled effectively, this concern could dominate the narrative at launch.
>
> As you know, I raised this concern proactively with some of our closest advisors at AASLD. Below was the helpful advice from Nid Afdhal (which was very similar to that of Ira Jacobson) on how to speak to the fact that some patients may need 24 weeks [sic]
>
> SOF has been developed for a therapy duration of 12 weeks or less, now and in the future. For the first year of launch, there are some patient segments that may benefit from 24 weeks of SOF. We are hopeful that having an FDA approved indication for a longer duration of therapy in

[160] Appendix E, Ex. 32, Gilead Sciences, Inc., 2013–2015 HCV Launch Commercial Plan, April 4, 2013, GS–0013503, at GS–0013509.

[161] Appendix E, Ex. 30, Gilead Sciences, Inc., Sofosbuvir U.S. Pricing & Contracting Strategy, SVP Briefing, March 25, 2013, GS–0019128, at GS–0019176.

[162] Appendix E, Ex. 32, Gilead Sciences, Inc., 2013–2015 HCV Launch Commercial Plan, April 4, 2013, GS–0013503, at GS–0013508. The FDA ultimately approved using Sovaldi for 24 weeks in genotype 3 patients.

[163] SOVALDI Prescribing Information (2013), *available at* http://www.accessdata.fda.gov/spl/data/24e7ec0a-9f1b-4b63-8e48-53a63cd7c46f/24e7ec0a-9f1b-4b63-8e48-53a63cd7c46f.xml.

[164] *Id.*

[165] The wholesale price for Sovaldi is $84,000 for 12 weeks, and a 48-week prescription would cost four times as much, excluding additional costs for interferon and/or ribavirin.

> these subgroups will induce payers to cover SOF and leave a modest cost burden to the patient (that Gilead can cover) [sic] [166]

In addition to the wholesale price, the presentation showed the company beginning to consider the question of its contracting strategy with private and public payers. Gilead's data showed that commercial payers accounted for 52% of Victrelis payments and 63% of Incivek payments during the fourth quarter of 2012, with the remaining split among various public payers.[167] Furthermore, as Gilead observed of Incivek and Victrelis: "[t]hough PIs have been widely contracted, discounts have been relatively small and geared mostly to provide access rather than preferred status." [168] That led Gilead to ask additional strategic questions:

- Do payers anticipate historic increases in HCV expenditures? If so, how do they intend to control them?
- What should Gilead do to assuage payers' concerns?
- Is contracting a cost of entry in HCV? Should we contract from "day one"? Should our contracting strategy be proactive or reactive? Do we think it's going to be a nominal contract?
- Should we make any "guarantees" to create greater predictability of expenditures for payers? [169]

Just as importantly, Gilead recognized that because the Affordable Care Act (ACA) substantially expanded the number of people who qualify for Medicaid, "the percentage of HCV-infected [individuals] with public coverage, specifically Medicare and VA, will grow substantially." [170] Even at that early stage, Gilead viewed the shift to public payers "as important targets for policy engagement and contracting." [171] The company also was concerned that its average sales price could face "significant downward pressure" due to the Medicaid expansion and transition of baby boomers onto Medicare.[172] The company questioned whether the WAC should incorporate the expectation that prices would be subject to pressure, and whether Gilead would need to engage in "more proactive in contracting with government payers." [173]

May 2013: The Second Pricing Check-in

Gilead continued its pricing discussions on May 10, 2013, when the Sofosbuvir Pricing & Contracting Strategy Working Team met for "SVP Check-in II." The meeting was scheduled to last 90 minutes, and included presentations from Abby Ginsberg, a senior manager of marketing sciences at Gilead, and three representatives

---

[166] Appendix E, Ex. 33, Email from Jim Myers to David L. Johnson, et al., Characterization of SOF pricing at Launch (Nov. 8, 2013), GS–0020772, at GS–0020772—GS–0020773.
[167] Appendix E, Ex. 30, Gilead Sciences, Inc., Sofosbuvir U.S. Pricing & Contracting Strategy, SVP Briefing, March 25, 2013, GS–0019128, at GS–0019159–60.
[168] *Id.* at GS–0019156.
[169] *Id.* at GS–0019157.
[170] *Id.* at GS–0019161.
[171] *Id.*
[172] *Id.* at GS–0019163.
[173] *Id.*

from the consulting firm IMS—Steve Swanson, Tom Baker, and Kevin O'Leary.[174]

Based on the documentation reviewed, this pricing check-in was dominated by the results of a study conducted by IMS that was intended to determine an access-optimizing pricing strategy for the drug. The significant themes from this presentation involved Sovaldi's ability to influence the price of future HCV products; that a price point of $80,000—$90,000 would be acceptable in terms of access, even without significant contracting; and pricing concerns for genotype 3 patients and non-standard SOC regimes.

By the time of the May 10 meeting, a strong sentiment had emerged within the company that there was a "clinically justified reason for premium pricing," according to internal interviews that were highlighted in the presentation.[175] Other views discussed internally included:

- Optimize price for G1 and develop strategies for dealing with G2/3
- Penetrate the market upfront to maximize sofo experience
- Exploring price per cure messaging is critical
- Leave plenty of room in the gross to net assumptions for Wave 2[176]

Several anonymous quotes from company officials were included in the presentation slide, such as "Vertex moved the conversation with managed to care [sic] to pricing per cure and I think that we can make that argument better."[177] That statement likely reflects that until the introduction of protease inhibitors to the market, there had not been a sufficiently effective cure against which a reasonable pricing method could be justified. Now that Gilead was on the cusp of introducing a more effective cure for genotype 1 patients than had previously been introduced, the internal view was that Gilead should follow other companies in using a price-per-cure method (rather than a price-per-regimen method), which would ultimately justify higher unit pricing.

To further pinpoint a price for the product's market introduction, IMS was hired to "determine the access-optimizing price point for its novel HCV therapy sofosbuvir in support of the brand's U.S. launch," with a goal "to anticipate payer access and management strategies for sofosbuvir in order to determine the access-optimizing pricing strategy."[178] It was charged with gauging the product's value for providers and payers, developing the expected mix of private and public payers with which Gilead would interact, and prioritizing the most important accounts, both for market access and contracting strategies.[179]

---

[174] Appendix E, Ex. 34, Gilead Sciences, Inc., Sofosbuvir Pricing & Contracting Strategy Working Team, SVP Check-in II, May 10, 2013, GS–0013972, at GS–0013973.
[175] *Id.* at GS–0013976.
[176] *Id.*
[177] *Id.*
[178] *Id.* at GS–0013981.
[179] *Id.*

Meyers told investigative staff that IMS contacted over 90 payers and asked them what value they saw in the proposed label.[180] The communications were made in a double-blind fashion—the client was not aware of the payers' identities, and vice-versa.[181] Payers were presented with clinical attributes and other information about a given drug, but were not provided the name or company developing it.[182]

IMS began its portion of the presentation by highlighting an Express Scripts report that showed drugs used to treat HCV made up less than 1% of Express Scripts' PMPY (per-member-per-year) drug spending in 2012. With a PMPY of $7.82, HCV was behind the four most expensive therapy classes—inflammatory conditions ($50.62), multiple sclerosis ($37.98), cancer ($31.93), and HIV ($20.78).[183] The relatively low spending on HCV drugs fit into Gilead's view that HCV was being undertreated and was a potent commercial opportunity. Express Scripts was a bellwether because it is the largest pharmacy benefit manager, as measured by market share.

IMS asked payers not only about Sovaldi, but also anticipated products, Harvoni and AbbVie's Viekira Pak. In the presentation, IMS described Sovaldi as the first wave of a two-step drug release strategy for Gilead. The second wave would be Harvoni, which would be interferon-free and would compete with Viekira Pak.[184] In the executive summary, IMS laid out top level results of the surveys, first from a clinical point of view:

- Wave 1 sofosbuvir was seen to be a clear winner over the current standard of care in GT–1 and GT–2, while GT–3 was generally not well-received (at least in treatment naive patients)
- AbbVie's regimen was highly valued, despite the complicated regimen burden, and was favored by payers over IFN-containing regimens, including sofosbuvir Wave 1
- Wave 2 was the unanimously preferred regimen over all profiles tested and was driven by a multitude of clinical factors, including co-infected data, limited side effects, once daily oral dosing, and SVR[185]

IMS noted that Managed Medicaid payers "did appear slightly less enthusiastic" about Sovaldi's clinical attributes.[186] Likewise, while payers recognized a "significant step for advancing HCV treatment," the expectation of a high price was flagged by three payers that "immediately cited their **concerns** that **the product would be expensive** due to all the improvements relative to the current treatment options."[187]

The executive summary then laid out "Wave 1 Pricing Strategy," for Sovaldi:

---

[180] Interview with Jim Meyers, Senior Vice President, North America Commercial Organization, Gilead Sciences, Inc., in Washington, D.C. (Dec. 1, 2014).
[181] *Id.*
[182] *Id.*
[183] Appendix E, Ex. 34, Gilead Sciences, Inc., Sofosbuvir Pricing & Contracting Strategy Working Team, SVP Check-in II, May 10, 2013, GS–0013972, at GS–0013979—GS–0013980.
[184] *Id.* at GS–0013983.
[185] *Id.*
[186] *Id.* at GS–0013985.
[187] *Id.* at GS–0013986 (emphasis in original).

- Pricing potential varied across payer segments although acceptable pricing with equal access was widely achievable at up to $80-90K; access will always have a PA [prior authorization] to the label in HCV and a hard step through current products was seen to be quite difficult
- Gilead could feasibly influence AbbVie's pricing by capturing a high price with Wave 1, which is most likely to be the price reference for AbbVie at the time of their launch [188]

IMS suggested that pricing at "$80–90K" was "acceptable" and would provide "equal access." [189] IMS also assumed that AbbVie would enter the market at a high price and that Gilead could capture that price point by entering high as well.[190] The potential price point for AbbVie appears to be a building block for the price Gilead ultimately would use for Sovaldi:

- If AbbVie launches before Wave 2, it will become the new price reference and drive payer reactions to Wave 2 list prices
- Despite the significantly better clinical perception, Wave 2 will likely need to be within a 10–15% price range to AbbVie's regimen to avoid being disadvantaged on access because of equal SVR
- For Wave 2, contracting could be valuable with payers who might prefer AbbVie's 3-DAA based on a lower price; the goal would be to allow Gilead to have equal market access and compete among docs [191]

The presentation then turned its attention to "Wave 2 Pricing Strategy," for what would eventually be called Harvoni. IMS was even more explicit about the opportunity Gilead had to set a high price if Sovaldi was brought to the market first, and the pricing downside the company faced if it was beaten to the market by AbbVie:

- Gilead's [drug] has the first mover advantage with Wave 1, which gives the possibility to set a higher price reference for the market
- If AbbVie's 3-DAA comes to the market before Wave 2, it will become SoC and Wave 2 will not be able to command a premium over it if equal market access is the goal [192]

These suggested strategies show the importance that market competition likely had on Gilead's approach to pricing and contracting its HCV drugs. The presentation also delved into cost issues regarding non-genotype 1 patients. Although genotype 2, 3, and 4 patients make up a minority (20-25%) of HCV patients in the United States, treatment costs would be much higher given the additional amount of time needed for treatment. For example, at the time, the only other FDA-approved treatment for genotype 3 pa-

[188] *Id.* at GS–0013983.
[189] *Id.*
[190] *Id.*
[191] *Id.*
[192] *Id.* at GS–0013992.

tients was 24 weeks of pegylated interferon and ribavirin, which had a wholesale cost of $18,150; whereas Sovaldi plus pegylated interferon and ribavirin for genotype 3 patients required 24 weeks, pushing the wholesale cost of treatment above $168,000—more than nine times the previous SOC. This price increase was in the face of concern from payers that genotype 3 trials demonstrated only slight improvements to the then-current standard of care, interferon and ribavirin; the slide characterized the data from trials as "seen to be **weak relative to IFN/Ribavirin alone.**" [193]

IMS added additional detail to its preliminary conclusions regarding how Gilead should engage in a contracting strategy throughout 2014. First, IMS said that "contracting was not seen to be mandatory for sofosbuvir in Wave 1," and that "access will likely be achieved without active payer engagement via contracting." [194] Contracting also should only be undertaken as a "sign of good faith." [195] It suggested a potential contracting approach in which Gilead "[c]ontract only with the high level of control payers that may block Wave 1 at high prices and only implement traditional rebate +/- performance kickers." [196]

Furthermore, for Wave 2, i.e. Harvoni, the potential contract approach was to "[c]ontract selectively only with payers preferring AbbVie to gain equal access and compete for physicians, who will likely prefer Gilead's easier regimen." [197] IMS told Gilead that "[p]layers expect significant contracting opportunities when both AbbVie and Wave 2 are on the market due to comparable SVR, which drives payers to see interchangeability," although "[p]layers would, however, expect Gilead to have to offer less given the improved pill burden." [198]

The IMS consultation may have reinforced the internal view that Gilead's line of drugs should be sold at a premium price. IMS reported that payers evaluating SVR data had a "very **strong perception of GT–2** data . . . **GT–1** was also well-received to nearly all payers though **slightly less so than the GT–2 data,**" and that the "improved dosing/duration" were "very favorable drivers of value." [199] IMS also reinforced the company's expectation that it would not compete on price, but instead on its ability to treat patients. Lastly, it shows that Gilead expected the price it set for Sovaldi to be a benchmark from which per-unit prices could increase.

IMS also presented analyses of how Gilead could approach setting a price from a "regimen pricing argument" similar to Gilead's first SVP Check-In two months earlier. For genotype 1 patients using Incivek, the FDA called for up to 48 weeks of pegylated interferon/ribavirin. The new sofosbuvir regimen would only require 12 weeks—a potential savings of more than $27,000 at wholesale costs. Instead of passing the potential savings onto payers, IMS suggested an approach in which the savings would be added to sofosbuvir's topline revenue. IMS calculated that the Incivek reg-

[193] *Id.* at GS–0013993 (emphasis in original).
[194] *Id.*
[195] *Id.*
[196] *Id.*
[197] *Id.*
[198] *Id.*
[199] *Id.* at GS–0013985 (emphasis in original).

imen would cost $95,766[200] of which roughly $35,000 could be attributed to interferon and ribavirin. That left roughly $25,000 of "potential savings capture" from the shorter regimen of interferon and ribavirin that could be added to sofosbuvir's price. On the slide, IMS noted:

- Sofosbuvir will clearly benefit from **comparison to the current triple regimen cost** because of shorter duration and less INF/ribavarin [sic]
- Payer price sensitivity toward regimen costs **compels a choice** of pricing strategy **that maximizes revenue for a single regimen**
- Generally, payers will look at the **cost of single agents** in terms of PMPM[201] **for underwriting purposes,** but the **P&T**[202] will certainly consider course of therapy[203]

The potential $85,000 price was included in tables with three other price benchmarks—less than $67,000, $100,000, and more than $120,000—showing how commercial, Medicaid, and Medicare payers might restrict access at different price points. Across each of the payer categories, access for genotype 1 patients became increasingly restrictive as the price rose. However, IMS concluded that "most payers are willing to accept at least $85k for GT-1 before considering additional access restrictions over the current PIs."[204] Payers were more reluctant to accept that cost for genotype 2 and 3 patients where data showed relatively minor improvements in terms of cure rates.[205] As IMS summarized, "GT–2/3 posed more difficulties to payers at the tested price points, and GT–3 in particular pushed many payers to look for heavy restrictions or block sofosbuvir completely."[206]

In a third table summarizing potential prices for Harvoni's eventual release, IMS concluded "[s]ofosbuvir in Wave 2 was widely seen as achieving a $100K price point although the competitive implications of AbbVie pricing will clearly influence achievable pricing."[207]

The IMS view on pricing strategy was built at least partly on the experience that other drug companies had in introducing earlier HCV treatments, which IMS used as a case study.[208] For example, in 1998 the Schering Corporation introduced Rebetron, which combined interferon and ribavirin in a single package.[209] IMS observed that "through aggressive price increases, Schering doubled the cost

---

[200] IMS used 12 weeks of Incivek plus 48 weeks of ribavirin and interferon as a reference. *See id.* at GS–0014017.

[201] "Per Member Per Month" is a calculation of the monthly average cost of services provided to individuals.

[202] "Pharmacy and Therapeutics Committees" are made up of physicians, pharmacists, and other health professionals, who together manage and update a provider's formulary, and set policies for use of different drugs.

[203] Appendix E, Ex. 34, Gilead Sciences, Inc., Sofosbuvir Pricing & Contracting Strategy Working Team, SVP Check-In II, May 10, 2013, GS–0013972, at GS–0013988 (emphasis in original).

[204] *Id.* at GS–0013989.

[205] *Id.* at GS–0013990.

[206] *Id.* at GS–0013990.

[207] *Id.* at GS–0013991.

[208] *Id.* at GS–0013995—GS–0013999.

[209] Lauran Neergaard, *FDA Approves Potent Hepatitis C Drug,* Associated Press (June 3, 1998).

of HCV therapy over 3–4 years following Rebetron launch."[210] Rebetron was reported to cost between $15,600 and $17,300 for a yearlong therapy, or $1,300 to $1,440 a month.[211]

July 2013: The Final Pricing and Access Recommendations

On July 31, 2013, Gilead's pricing team gave Meyers final pricing and access recommendations. The documentation from the July timeframe indicated a belief that price sensitivity would begin at $90,000 and a recognition of potential public payer restrictions. There were also deep concerns about wave 2 pricing because of prospective competition and a continued confidence in the clinical efficacy of the drug in comparison to the prices for existing regimens and other factors justifying a higher price. At the time, the contracting strategy began to take more detailed shape.

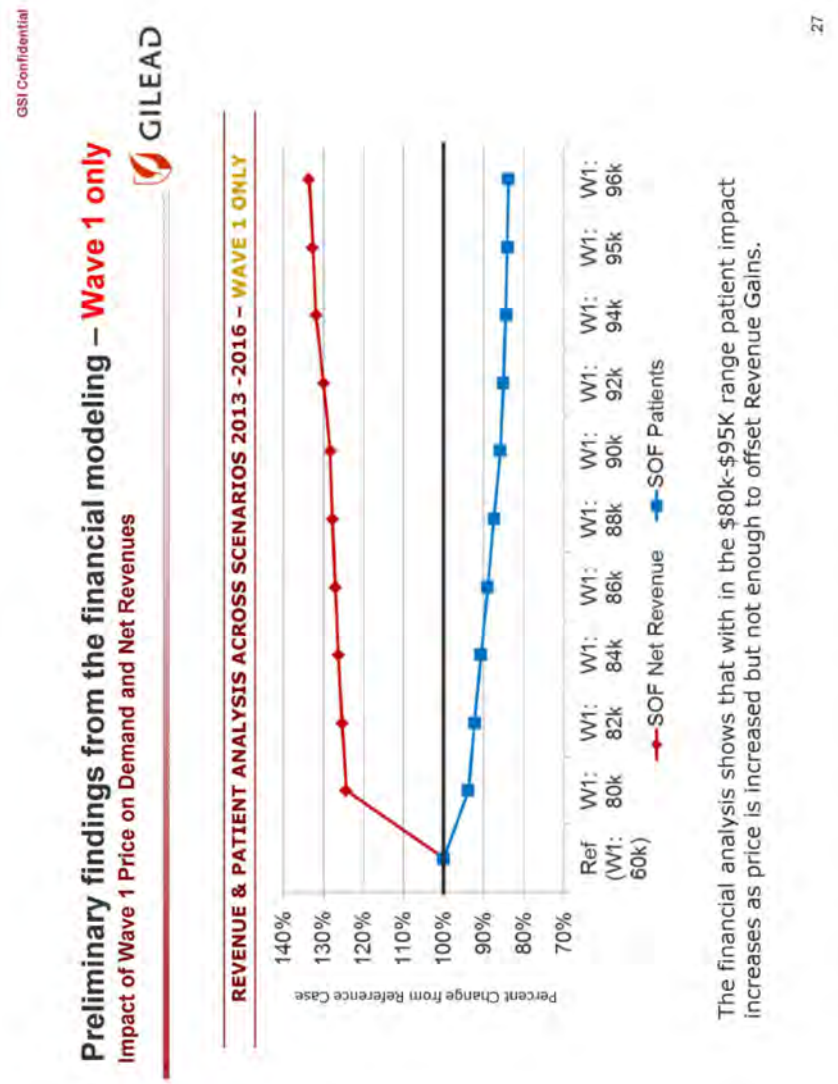
The slide presentation included analysis of the expected tradeoffs of increasing the price of Sovaldi—revenue would rise but the number of patients receiving the drug would decline. (See slide below). It also showed that Gilead was aware it was in a position to create clear savings for payers, but chose to pursue a "regimen neutral" price justified by "cost-per-cure" calculations that resulted in greater revenue per treatment than previous DAAs. The company had received feedback from payers that "[g]iven the significant improvements in efficacy and tolerability and high level of physician demand, SOF enjoys substantial pricing freedom in Wave 1," that "price sensitivity begins at $90k for subset of payers [sic]," and "that even at a high price differential it is unlikely they would impose step edits through inferior regimens (PIs or simeprevir)."[212]

---

[210] Appendix E, Ex. 34, Gilead Sciences, Inc., Sofosbuvir Pricing & Contracting Strategy Working Team, SVP Check-In II, May 10, 2013, GS–0013972, at GS–0013996.

[211] Denis Grady, *Group Finds a Way to Offer a Hepatitis C Drug for Less,* N.Y. Times (June 30, 1999), *available at* http://www.nytimes.com/1999/06/30/us/group-finds-a-way-to-offer-a-hepatitis-c-drug-for-less.html.

[212] Appendix E, Ex. 28, Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Assessment, Final Recommendations—July 31st, 2013, GS–0014018, at GS–0014026.



The presentation predicted that 24% of the payers it had surveyed would institute access restrictions of some sort for genotype 1 patients if Sovaldi were priced at $75,000, and that 47% would institute restrictions at $90,000.[213] For genotype 2 patients, 33% of payers were predicted to institute restrictions at a price of $75,000, and 43% at $90,000; for genotype 3 patients, restrictions at the two price points were expected to be 37% and 51%, respectively.[214]

[213] *Id.* at GS–0014029.
[214] *Id.* at GS–0014029—GS–0014030.

The presentation concluded that "[t]he optimal range for Wave 1 pricing based on revenue/uptake trade-offs is likely $85–$95K, though other softer factors must be considered," and ultimately recommended that the price be "between $80K to $85K per course of therapy."[215] The presentation picked up on other themes that had been discussed and analyzed in previous presentations, including:

1. Gilead has **considerable pricing potential with sofosbuvir in Wave 1** without major access consequences, but the pricing potential for future launches will be constrained by competition
2. Long term sofosbuvir franchise value will be driven by **a high price capture opportunity in Wave 1** and a **volume capture in Wave 2 and beyond**[216]

As noted above, one of Gilead's considerations for Wave 1 prices, i.e., Sovaldi, was the potential to achieve a high price for Wave 2, i.e., Harvoni. The "value capture opportunity is in Wave 1," the presentation stated, and "Wave 2 access will be enhanced with a high Wave 1 price."[217] It went on to say that "[a]t any price, access for Wave 2 improves as the price for Wave 1 is increased, suggesting that Wave 1 will set a price benchmark against which Wave 2 will ultimately be evaluated."[218] It also noted that the introduction of market competition would change the pricing environment. The "[c]ompetitive threat from AbbVie and [Bristol-Myers Squibb] will be critical factors for the Wave 2 market access strategy as these regimens could drive payers to disadvantage sofosbuvir under select scenarios, especially if efficacy is comparable among all the regimens and there is a large price differential."[219]

There was particular concern about competition posed by Bristol-Myers Squibb's drug candidate, daclatasvir, "being used to break up the sofosbuvir [single tablet regimen]."[220] Bristol-Myers was singled out several times in the presentation as a constraining factor for the eventual pricing of Harvoni, underscoring the need that it was important Sovaldi "[e]stablishes high benchmark for Wave 2."[221] Gilead believed the Bristol-Myers Squibb combinations, with fewer pills, could pose a market share risk to AbbVie, and "could be a threat to Gilead depending on price,"[222] limiting Gilead's ability to charge a premium for Harvoni. The presentation stated, "[w]ave 1 pricing will impact the imputed sub-WAC value of ledipasvir, therefore determining the value capture opportunity for a sofosbuvir + daclatasvir combination" and "[t]hese considerations re-enforce the limitations on taking a premium in Wave 2, as a large difference between the two regimens would make NS5A substitution significantly more appealing to payers."[223] As noted above, the FDA approved a Daklinza-Sovaldi combination for geno-

[215] *Id.* at GS–0014053.
[216] *Id.* at GS–0014053 (emphasis in original).
[217] *Id.* at GS–0014026.
[218] *Id.*
[219] *Id.*
[220] *Id.* at GS–0014027.
[221] *Id.* at GS–0014052.
[222] *Id.* at GS–0014027.
[223] *Id.*

type 3 patients on July 24, 2015 that was submitted by Bristol-Myers Squibb.

The presentation sought to assure executives that Gilead would have ample justification to price its HCV drug at a premium level. Gilead had weathered criticism for pricing decisions in the recent past, coming under scrutiny for its decision to charge $28,500 for the AIDS drug Stribild. One activist derided Stribild's price at the time of FDA approval as "shockingly irresponsible," [224] and 13 congressmen expressed concern in a letter to CEO John Martin about the effects of Gilead's drug-pricing decisions on the AIDS Drug Assistance Program.[225] The presentation stated "HCV is very much unlike HIV and, while exercising caution based on the Stribild launch is understandable, sofosbuvir is quite different." [226] It went on to detail the "sofosbuvir opportunity relative to Stribild," with the following lists:

Sofosbuvir Wave 1 is . . .	Implications
1. Substantially better than standard of care across metrics.	• Market access in **HIV is significantly different** than market access in HCV
2. In a therapy area where there is significant unmet need.	• Prescribing **physicians are comfortable with prior authorizations** and recognize that they are part of ''standard operating procedures''
3. In a therapy area where prior authorizations are the norm.	• **Stribild** is not viewed by payers as having substantially better efficacy than current products and view it largely as a **convenience value story**
4. Being researched with more rigor than the Stribild launch.	• **Sofosbuvir** demonstrates substantially better data in both efficacy and convenience as well as other metrics that are important to payers and represents **significant clinical value** [227]

Gilead remained confident that Sovaldi's ability to increase SVR for most patients, coupled with reduced time on interferon and ribavirin, was ample justification for increased pricing: "A price of $80–$85K does represent >30% premium to Incivek on a molecule price [sic], however, the product is delivering better outcomes for those dollars." [228] The presentation touched on how payers might end up justifying paying for multiple rounds of treatment with some patients: "[p]ayers are currently paying significantly more than the price of Incivek to achieve an outcome, so regimen cost is critical." [229] The company also included "future market considerations" justifying their pricing:

- Healthcare reform has incentives to pay for value, which aligns with what sofosbuvir will deliver (even if it is not the least expensive agent)
- While it is true that budgets are not infinite, higher cost products can be preferred if actually demonstrating strong real world outcomes [230]

[224] Andrew Pollack, *F.D.A. Approves Once-A-Day Pill for H.I.V.,* N.Y. Times (Aug. 27, 2012), *available at* http://www.nytimes.com/2012/08/28/business/fda-approves-once-a-day-pill-for-hiv.html? r=0.

[225] Press Release, Office of U.S. Representative Alcee Hastings, Hastings Expresses Concern over HIV Drug Price Increases, ADAP (Aug. 1, 2012), *available at* http://alceehastings.house.gov/news/documentsingle.aspx?DocumentID=327935.

[226] Appendix E, Ex. 28, Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Assessment, Final Recommendations—July 31st, 2013, GS–0014018, at GS–0014021.

[227] *Id.* (emphasis in original).

[228] *Id.* at GS–0014022.

[229] *Id.*

[230] *Id.*

Gilead presented multiple pricing scenarios for Sovaldi, numbered one through five—$50,000, $60,000, $80,000, $95,000, and $115,000 (the company assumed each would have an additional $10,000 worth of interferon/ribavirin).[231] Those prices were compared to the price for Incivek plus interferon/ribavirin "at launch" ($81,000) and "today" ($99,000).[232] The company concluded that "[r]elative to the current cost of Incivek, sofosbuvir would most likely provide *savings* to payers at molecule prices <$80k."[233] The company relied on a cost-per-cure justification for a higher price—"[s]avings are still likely at a sofosbuvir product cost of $95K, especially considering sofosbuvir's superior SVR and the significant rates of treatment failure/abandonment associated with Incivek."[234]

The company also considered the effect of selling to substantial government payers, such as Medicaid, 340B, and the VA, which it termed "sub-WAC channels," where pricing would be "substantially lower than the Commercial market."[235] The company expected the payer mix for treatment of HCV to be heavily weighted toward various public payer insurance programs, growing from 34% in 2012 to as much as 58% by 2016.[236]

Like their commercial counterparts, Gilead expected most Medicaid and Medicare payers would likely provide "preferred access" to Sovaldi if the drug were priced below $80,000. Above that price, all three payer categories were expected to begin implementing some sort of restrictions on access, particularly for patients with genotype 2 or genotype 3.[237]

For other payer groups, Gilead recognized that "[n]on-traditional segments widely vary in price sensitivity and some degree of contracting is likely required regardless of price" to secure access.[238] For the VA, that meant "discount for access."[239] For integrated delivery networks (IDN) such as Kaiser Permanente, "these price levels will likely not provide access and demand contracts."[240] For Departments of Corrections, "possible discount for access, though may not be a Gilead target."[241] A key consideration for the company was that Gilead would be "generally pushing the upper comfort level for IDN payers."[242]

This presentation was the first in which Gilead discussed contracting strategy in detail and its unwillingness to discount from the WAC price to gain access on payers' formularies and/or preferred drug lists. The company planned to limit its contracting because "[r]eactive contracting with low rebates should be sufficient in many channels although proactive strategies will be required elsewhere."[243]

---

[231] *Id.* at GS–0014024.
[232] *Id.*
[233] *Id.* (emphasis in the original).
[234] *Id.*
[235] *Id.* at GS–0014025.
[236] *Id.* at GS–0014028.
[237] *Id.* at GS–0014033—GS–0014035.
[238] *Id.* at GS–0014036.
[239] *Id.*
[240] *Id.*
[241] *Id.*
[242] *Id.*
[243] *Id.* at GS–0014037.

To determine where to contract, Gilead identified "market influencers" in different payer categories that were tightly managing access to HCV drugs already on the market.[244] In the commercial space the market influencers included companies like Aetna, Regence, and Blue Cross Blue Shield Michigan; in Medicare Part D, Coventry and Emblem Health; and in managed Medicaid states, such as Missouri, Illinois, Louisiana, and California.[245] For Department of Corrections and Medicaid fee-for-service payers, the primary target was California, which represented "~12% of the overall DOC payer segment," and "~10% of channel," respectively.[246] Gilead planned to use a "proactive approach" with Kaiser Permanente and the VA.[247] In all cases, the company planned to offer 5% to 10% discounts off the WAC price.[248]

The company examined the implications of pricing Sovaldi at various levels, and how different prices would affect the company's standing amongst stakeholders, the value to shareholders and reputational risks. The lowest prices posed the least risk, but the least financial upside.[249] Gilead determined that "[w]hile pricing at $50–60K would promote preferred status, it will result in significant unrealized revenue."[250] It continued:

- Pricing at $50K
  - PROS: Gilead could build substantial "good will" with the payer community and will gain widespread "preferred" market access across nearly every payer segment in the market
  - CONS: What Gilead could achieve at $50K would also be achievable at much higher prices, suggesting significant foregone revenue; despite pricing at this level, activists are still likely to voice dissatisfaction with the strategy
- Pricing at $60K
  - PROS: Gilead very unlikely to face any access issues from the major market segments and will be enabling payers to pay substantially less per patient on a regimen basis relative to incumbent products
  - CONS: Gilead not realizing a substantial revenue amount and Wave 1 price would fall below the access-optimizing price; furthermore, achieving more than an $80K Wave 2 price will be unlikely, eroding shareholder value[251]

At the next price level, $80,000, the company identified "external considerations" to be the primary risk, that is, how consumer groups would react to the price.[252] Gilead concluded "[a]t $80K, widespread parity access will be the norm, with strong physician

[244] *Id.* at GS–0014031—GS–0014037.
[245] *Id.* at GS–0014033, GS–0014035.
[246] *Id.* at GS–0014037.
[247] *Id.*
[248] *Id.* at GS–0014031—GS–0014037.
[249] *Id.* at GS–0014047.
[250] *Id.* at GS–0014048.
[251] *Id.*
[252] *Id.* at GS–0014049.

and patient preferences driving significant uptake."[253] It then considered the effects on four different groups:[254]

- Payer Considerations
  - Given that SOF will be cheaper than most PIs on a regimen basis, payers are highly unlikely to manage access at $80K (beyond PA to label), instead placing it at parity to current treatments and leaving the decision to physicians
- Physician/Patient Considerations
  - SOF will be the clear favorite of physicians and patients considering its equivalent (or cheaper) total cost, significantly improved SVR, decreased duration, and reduced side effect burden relative to PIs
- Competitive Considerations
  - An aggressive pricing strategy for [simeprevir] could create some challenges for SOF in some high control accounts, but a low price strategy would be value-destroying for Janssen
- External Considerations
  - As with all prices, advocacy groups will criticize pricing, likely focusing on the product cost without accounting for the total regimen discount
  - While a select subset of KOLs (key opinion leaders) will be vocal about their concerns, a change in guidelines is highly unlikely at this price[255]

At $95,000, which the company had identified earlier in the document as an "inflection point," risks from physicians, patients, and competing companies increased. Gilead summarized the landscape: "[p]layer pushback is more likely . . . but strict management will remain difficult to the significantly improved clinical profile." More specific considerations included:[256]

- Payer Considerations
  - The majority of payers are still unlikely to impose anything above a soft step at $95K, although certain high-control plans such as the VA and Kaiser may require additional contracting or cost-effectiveness data to ensure access
- Physician/Patient Considerations
  - Given the strength of the profile and modest premium to PIs, physician preferences will remain largely unchanged
  - Patients will continue to prefer sofosbuvir, with most OOP (out-of-pocket) issues easily addressable via co-pay programs

---

[253] *Id.*

[254] The abbreviations include PA (prior authorization, which payers can use to restrict access), PIs (protease inhibitors), SIM (simeprevir, a.k.a. Olysio), and KOLs (key opinion leaders). "Janssen" refers to Johnson & Johnson's pharmaceutical arm that developed Olysio.

[255] Appendix E, Ex. 28, Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Assessment, Final Recommendations—July 31st, 2013, GS–0014018, at GS–0014049.

[256] OOP is Out of Pocket expenses; 3–DAA is triple direct-acting antiviral; BMS is Bristol-Myers Squibb.

- Competitive Considerations
  - At this price, an AbbVie premium for 3–DAA would break the $100K threshold, which they may elect to avoid
  - Irrespective of Wave 2 price, as Wave 1 price rises, the capturable [sic] opportunity for BMS expands [257]
- External Considerations
  - Advocacy group criticism will intensify but overall impact will be similar
  - While increasing numbers of KOLs may voice concern, guideline modification remains unlikely given the modest premium to PI regimens vs. the significant clinical improvements [258]

Finally, the company considered the highest end of its proposed price range—$115K. At that point, external risks were considered to be at their highest (as denoted by a circle filled with red).[259] Other factors registered high risk, but their respective circles were only two-thirds red, indicating less concern.[260] Gilead expected "[s]trict management and guideline restrictions may appear at $115K, with usage in GT–2 and GT–3 presenting a potential target for payers." [261] More specifically:

- Payer Considerations
  - At $115K, many payers will attempt to disadvantage sofosbuvir through tier differentials and soft steps; while hard steps are possible, it will remain extremely difficult to step patients through an inferior regimen
- Physician/Patient Considerations
  - Physicians will still prefer sofosbuvir to PI regimens, but a limited number may reduce usage or consider warehousing
  - Usage in GT–3 and, to a lesser extent, GT–2 will become increasingly difficult to justify, particularly for TN patients
- Competitive Considerations
  - Competitor pricing would be informed by Gilead's access experience, and risks of discounts rise
  - This price translates into $38K reduction in SOF costs if Wave 2 is only 8 weeks, heightening price pressure from BMS
- External Considerations
  - High levels of advocacy group criticism and negative PR/competitive messaging could be expected at $115K and it would be increasingly difficult to manage at these levels

---

[257] This observation refers to Gilead's concern about daclatasvir being paired with other companies' drugs, including sofosbuvir.

[258] Appendix E, Ex. 28, Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Assessment, Final Recommendations—July 31st, 2013, GS–0014018, at GS–0014050.

[259] *Id.* at GS–0014051.

[260] *Id.*

[261] *Id.*

- Select KOLs may intensify their push for guideline modification [262]

With a price range established for senior management to consider, the company's pricing team summarized what Gilead should expect if the drug were priced at $80,000 to $85,000, including the expectation that certain patients would have problems accessing the drug, and that contracting would be necessary for certain payers:

- Sofosbuvir will have a PA to the label, which will mean very limited, if any, access for treatment experienced patients; naives will be accessible
- Gilead will need to contract with the VA, Kaiser, and likely additional plans on the fringes who may restrict sofosbuvir
- Advocacy groups will be vocal at any price and a minority of KOLs may voice concern [263]

It also set an action plan with priorities for Gilead:

- While restrictions based on fibrosis score are unlikely, Gilead needs to be prepared to answer questions about which patients and why
- It will be critically important to communicate to payers the clinical value that SOF creates and to be prepared in advance to answer questions regarding in which patients SOF should be used
- Gilead should proactively identify key accounts and develop a plan for messaging to them immediately following launch to ensure access
- Ensure that payers understand the population Gilead is aiming to treat and to reinforce that the population is not in the millions, as some believe [264]

This presentation shows that Gilead set a price as high as it thought acceptable before significant access restrictions would be imposed. Its analysis indicated that pricing in the $80,000 to $85,000 range would deliver this result for the majority of genotype 1 patients, though not for other patient groups. As discussed later in this report, Gilead's analyses were ultimately incorrect on this point as many payers adopted access restrictions at the final price of $84,000. Even when the scope of these restrictions became manifest in mid-2014, Gilead did not alter its approach.

The presentation's final slide was devoted to patient support programs such as co-pay coupon programs, donations to two independent non-profit patient assistance foundations, and patient assistance programs (PAP). These programs were designed to "ensure there is no gap in coverage and impact from pricing & contracting decisions." [265]

In its April 2015 report, *Medicines Use and Spending Shifts,* the IMS Institute states "[m]anufacturers commonly provide coupons when their brand is not covered on a formulary," and

[262] *Id.* at GS–0014051.
[263] *Id.* at GS–0014054.
[264] *Id.*
[265] *Id.* at GS–0014058.

"[i]ncreasingly, coupons are being used around the launch of an innovative brand to eliminate barriers to patients considering new medicines."[266] Any loss on co-payment (typically a small percentage of a drug's price) is made up by the insurance company's portion. Industrywide, co-pay coupons were used for 8% of total prescriptions in 2014 compared to 3% in 2011, 5% in 2012 and 6% in 2013.[267] However, co-pay coupons may not be used for federally funded health care programs.[268]

The copay coupons, used to pay the deductibles or coinsurance for commercial customers, were expected to cost the company between $10 million and $15 million, depending on the WAC price ($60,000 to $100,000).[269] The Foundation support would cost $100 million at $60,000, with costs growing about $5 million for every incremental price increase of $10,000.[270] The PAP did not add additional costs, but instead was foregone revenue—it was a cost of goods sold for 6,000 uninsured patients and 6,000 pre-transplant patients.[271] Although this presentation outlined the company's initial approach to its patient support programs, the strategy of providing such benefits evolved as payer access restrictions began to be imposed, as discussed in section 4 of this report.

The timeline in the March presentation discussed above indicates that the pricing and access recommendations would next have been provided to the GPC for a final review. However, interviews and documents that Gilead provided to investigative staff do not clearly indicate whether the GPC was involved in a final review.

August 2013: The Board is Briefed on Sovaldi's Launch and Pricing

On August 1, 2013, the day after the final pricing team recommendation, Meyers and Bill Symonds, Gilead's vice president for liver diseases, presented "an update on the status of the clinical trials involving sofosbuvir and . . . the preparations taken for the anticipated U.S. launch of sofosbuvir."[272] Meyers' presentation, "U.S. HCV Launch Update," gave a high-level overview of the market, pricing and Gilead's launch timeline to the board of directors.[273] During the meeting, members of the board "asked a number of questions that were answered by management."[274] After Meyers and Symonds left the room, the board and Kevin Young, the executive vice president for commercial operations, "further discussed the anticipated launch of sofosbuvir."[275]

---

[266] IMS Institute for Healthcare Informatics, *Medicines Use and Spending Shift,* at 25.
[267] *Id.*
[268] Office of the Inspector General, U.S. Department of Health and Human Services, *Special Advisory Bulletin: Pharmaceutical Manufacturer Copayment Coupons,* September 2014, *available at* http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf.
[269] Appendix E, Ex. 28, Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Assessment, Final Recommendations—July 31st, 2013, GS–0014018, at GS–0014058.
[270] *Id.*
[271] *Id.*
[272] Appendix E, Ex. 35, Gilead Sciences, Inc., Minutes of Regular Meeting of Board of Directors, August 1, 2013, GS–0019671, at GS–0019672.
[273] Appendix E, Ex. 31, Gilead Sciences, Inc., U.S. HCV Launch Update, August 1, 2013, GS–0014059.
[274] Appendix E, Ex. 35, Gilead Sciences, Inc., Minutes of Regular Meeting of Board of Directors, August 1, 2013, GS–0019671, at GS–0019672.
[275] *Id.*

The presentation by Meyers and Symonds began with a review of the market, specifically, Gilead's estimate that there were 4.1 million people in the United States with HCV, but that only 1.7 million were diagnosed. In addition, the presentation noted that of the 1.7 million diagnosed with HCV, 381,000 were being cared for by a health provider, and just 73,000 were currently being treated with drugs.[276] The presentation underscored the need to boost marketing efforts around HCV and disease awareness; "HCV-infected patients account for only ~17% of the patient volume of HCV treaters," which "[i]ncreases the importance of implementing a broad disease awareness/medical education platform and of increasing patient awareness of new treatment options."[277]

Meyers reiterated the need for sofosbuvir to be established as the SOC and "backbone of HCV therapy at initial launch," because the more that physicians waited for interferon-free therapies for genotype 1 patients, "the less established SOF will be at the time of competitive IFN-free launches."[278] Broad market access, growing the pool of patients seeking therapy, and deploying disease awareness advertising were also deemed "critical success factors."[279] The board also was guided through disease awareness and branded marketing materials that would accompany Sovaldi at launch, and was informed that Gilead's U.S. sales force of 144 people was 30% larger than the next closest competitor, Vertex.[280]

The next topic for Myers was payer access restrictions and pricing comparisons, emphasizing the need to set a high price for Sovaldi in order to set a price platform from which to launch Harvoni. The presentation stated that Gilead would be "[b]etter off pricing SOF at initial launch for GT–1 patients, as there will be varying degrees of access restrictions for GT–2/3 patients regardless of where we price," and that "[w]herever we want to end up in terms of pricing for SOF/LDV, we have to get most of the way there in the initial pricing of SOF."[281] The "[l]argest incremental gain in SVR is at initial launch, and this is what payers value."[282] The company would "need to keep prescribing in the hands of physicians, not payers, and to contract for open/parity access only when necessary."[283]

August 2013: Answering Follow-up Questions

On August 26, 2013, a presentation was given entitled "Sofosbuvir Pricing and Market Access Assessment: Response to Follow Up Question." The presentation built on the July 31st presentation where Meyers was provided a final recommendation from Gilead's pricing team to senior management.[284]

---

[276] Appendix E, Ex. 31, Gilead Sciences, Inc., U.S. HCV Launch Update, August 1, 2013, GS–0014059, at GS–0014061.
[277] *Id.* at GS–0014063.
[278] *Id.* at GS–0014067.
[279] *Id.* at GS–0014067.
[280] *Id.* at GS–0014069—GS–0014071.
[281] *Id.* at GS–0014076.
[282] *Id.*
[283] *Id.* at GS–0014076.
[284] Appendix E, Ex. 36, Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Assessment: Response to Follow Up Question, August 26, 2013, GS–0013857.

The presentation delved into "the potential impact of discounting on demand into the financial modeling."[285] It studied payer, patient, and provider reactions to a gross-to-net price that reflect contracted discounts.[286] The impact of discounting did "not change the overall conclusion from the financial analysis: [w]ithin a $70K–$95K SOF price range patient impact increases as price is increased but not enough to offset revenue gains."[287] It continued, "[a]ssuming a gross SOF price between $75K and $90K the current budgeted level of mandatory and supplemental discounting could theoretically support enough contracting to regain the majority of the predicted patient losses."[288] But, "[g]iven the competitive timing executing these contracts in a timely manner may be challenging . . . assum[ing] supplemental discounts could be in place by Q3."[289]

Gilead assumed its discounts for HCV drugs would be lower than for other product lines—17% for HCV drugs versus a range of 20% to 41% for its other units.[290] The presentation assumed that supplemental discounts would be offered only to "the most price sensitive accounts" in Medicare, Medicaid, and commercial payer segments.[291] The presentation used several percentages for projected discounts for each payer segment.[292] Subsequent tables and graphs show that the patient impact, i.e., lost patient starts, would be reduced by discounting across all price levels, and that revenue would increase during Wave 1. "Incorporating the impact of discounting on patients [sic] demand increases the forecast and reduces estimated patient loss significantly," the presentation states.[293] At an $85,000 price point, with a 6% supplemental discount applied, Gilead projected patient losses of 10% in 2014, 8% in 2015, and 11% in 2016 compared to a $65,000 price point.[294] An "alternative version" at the end of the presentation shows that implementing 15% supplemental discount for commercial payers would have reduced patient start at a WAC price of $85,000 to 5% in 2014, 2% in 2015, and 3% in 2016; revenue in each of those years was expected to remain higher than without discounting.[295]

However, as detailed in Sections 4 and 5 of this report, very few payers agreed to Gilead's discount offers for Sovaldi. The discount offers were viewed negatively because of their small size and because they were tied to loosening access restrictions to treatment that would have increased patient volume, offsetting any cost savings for the payer.

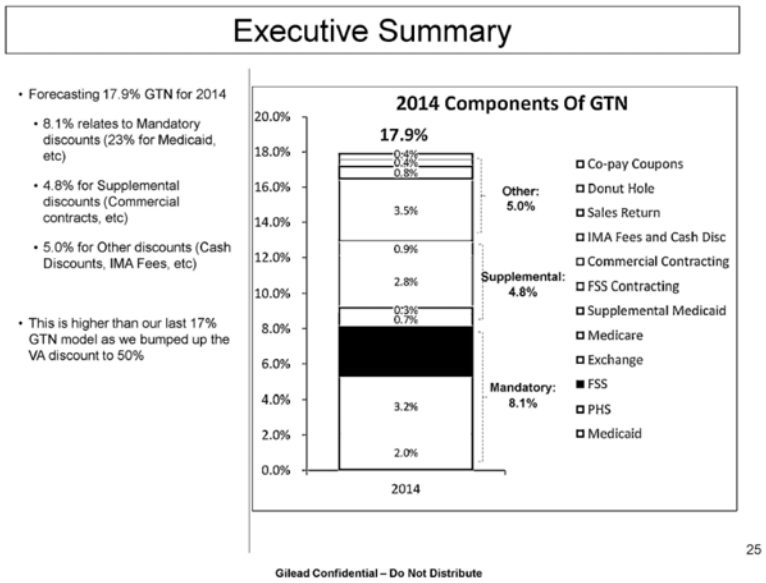
A note at the bottom of the page appears to show how the company's assumptions about discounting had evolved from the "June Forecast" price of $60,000. Discounts appear to be lower, meaning a greater share of the gross price would be captured in the net price:

---

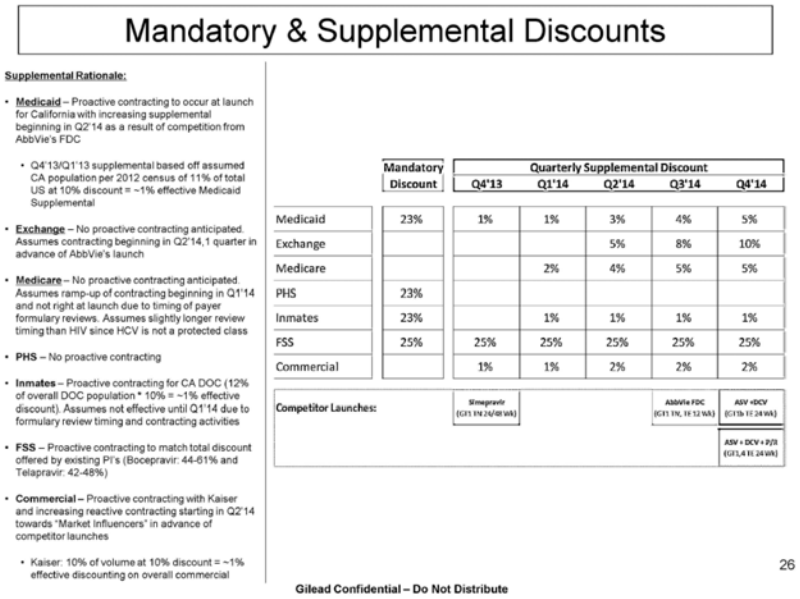
[285] *Id.* at GS–0013858.
[286] *Id.* at GS–0013860.
[287] *Id.* at GS–0013859.
[288] *Id.*
[289] *Id.* at GS–0013859.
[290] *Id.* at GS–0013880.
[291] *Id.* at GS–0013861.
[292] *Id.*
[293] *Id.* at GS–0013862.
[294] *Id.* at GS–0013861, GS–0013863.
[295] *Id.* at GS–0013887.

> Gross to Net in June forecast was ~22% in 2014; updated gross-to-net assumptions of ~13% in 2014 are used for all scenarios with Wave 1 pricing at or below $60K and ~17% for all scenarios with Wave 1 pricing about $60K[296]

Two slides in the presentation's appendix (see below) further detail how Gilead calculated its gross-to-net assumptions.[297] Mandatory discounting for government programs would account for the majority of the discounts (8.1%). Supplemental discounts to commercial payers and others would account for 4.8%, and other discounts (for example, cash discounts and inventory management agreements, which are referred to as IMAs) would account for 5% of the discounting. References to FSS apply to the Federal Supply Schedule, the contracting system for the VA, Department of Defense, and other federal agencies such as the Bureau of Prisons (see Section 4).[298] The slides also reinforce that Gilead planned to limit supplemental discounting except with certain key accounts.



[296] *Id.* at GS–0013862.
[297] *Id.* at GS–0013881 and GS–0013882.
[298] U.S. Department of Veterans Affairs, *available at VA Federal Supply Schedule Service: General FAQs*, http://www.fss.va.gov/faqs/general.asp#q001 (last visited Sept. 1, 2015).



Mandatory & Supplemental Discounts

Supplemental Rationale:

- **Medicaid** – Proactive contracting to occur at launch for California with increasing supplemental beginning in Q2'14 as a result of competition from AbbVie's FDC
  - Q4'13/Q1'13 supplemental based off assumed CA population per 2012 census of 11% of total US at 10% discount = ~1% effective Medicaid Supplemental
- **Exchange** – No proactive contracting anticipated. Assumes contracting beginning in Q2'14,1 quarter in advance of AbbVie's launch
- **Medicare** – No proactive contracting anticipated. Assumes ramp-up of contracting beginning in Q1'14 and not right at launch due to timing of payer formulary reviews. Assumes slightly longer review timing than HIV since HCV is not a protected class
- **PHS** – No proactive contracting
- **Inmates** – Proactive contracting for CA DOC (12% of overall DOC population * 10% = ~1% effective discount). Assumes not effective until Q1'14 due to formulary review timing and contracting activities
- **FSS** – Proactive contracting to match total discount offered by existing PI's (Bocepravir: 44-61% and Telapravir: 42-48%)
- **Commercial** – Proactive contracting with Kaiser and increasing reactive contracting starting in Q2'14 towards "Market Influencers" in advance of competitor launches
  - Kaiser: 10% of volume at 10% discount = ~1% effective discounting on overall commercial

	Mandatory Discount	Quarterly Supplemental Discount				
		Q4'13	Q1'14	Q2'14	Q3'14	Q4'14
Medicaid	23%	1%	1%	3%	4%	5%
Exchange				5%	8%	10%
Medicare			2%	4%	5%	5%
PHS	23%					
Inmates	23%		1%	1%	1%	1%
FSS	25%	25%	25%	25%	25%	25%
Commercial		1%	1%	2%	2%	2%

Competitor Launches: Simeprevir (GT1 IFN 24/48 Wk) | AbbVie FDC (GT1 1N, 1F 12 Wk) | ASV +DCV (GT1b 1F 24 Wk) | ASV + DCV + PJ/I (GT1,4 IL 24 Wk)

26

Gilead Confidential – Do Not Distribute

The presentation examined what it considered the "highly unlikely" scenario of Johnson & Johnson pricing simeprevir at $20,000 per course of treatment, its impact on Gilead's revenue from Sovaldi, and how it "would put negative attention on SOF at the recommended price."[299] Focusing on Sovaldi's price, the presentation concluded that if simeprevir were priced at $20,000, Gilead would need to triple the number of patient starts in 2014 to 37,500 people in order to achieve the same revenue as it would if simeprevir were priced at $60,000.[300] Similarly, the presentation concluded that "[o]ur Wave 1 goal of a high price remains consistent"—and Harvoni "Wave 2 strategy may require more caution."[301]

November 2013: Sovaldi's Price is Set by Top Executives

One of the final pricing documents provided by Gilead is the "Sofosbuvir Pricing and Market Access Recommendation," dated November 15, 2013. This presentation recommended that Sovaldi be priced at $81,000 or $27,000 per bottle.[302] This is the price that Meyers and Young would provide to the company's senior management three days later for final approval.

This presentation is light on details compared to previous presentations, and very little new information is presented, save for the following:

---

[299] Appendix E, Ex. 36, Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Assessment: Response to Follow Up Question, August 26, 2013, GS–0013857, at GS–0013865.
[300] *Id.* at GS–0013866.
[301] *Id.* at GS–0013867.
[302] Appendix E, Ex. 37, Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Recommendation, November 2013, GS–0014079, at GS–0014079.

- The optimal range for Wave 1 pricing based on revenue/uptake trade-offs is likely $85–$95K, though other softer factors must be considered
- If we price lower it opens up a window for competitors to pair up with SOF and come in at a lower regimen cost than our FDC
- Even if we priced lower, such as $70k, it would not mitigate the high cost of a 24 week regimen (message points being developed), and therefore we recommend we address this on a case by case basis on a sub-WAC level [303]

It is clear that Gilead was concerned about competition. The threat of competition worked in two ways—the efficacy of AbbVie's drug combination complicated the decision-making process to price the product and the potential of a daclatasvir-sofosbuvir combination put upward pressure on the price. Lastly, the company recognized the weakness of its drug in treating genotype 3 patients versus the interferon/ribavirin SOC.

The final pricing recommendation was addressed as follows:

- We recommend pricing sofosbuvir Wave 1 at $81K ($27k/bottle) per course of 12 week therapy and contract selectively for access at target payers:
- For the VA we recommend negotiating up to a 50% discount on their volume (vs the original 40% discount) to make up for the higher cost of treating co-infected and IFN-ineligible patients which account for about 60% of their population
- For Kaiser we recommend negotiating up to a 10% discount for access
- Other plans will be evaluated on a one off basis [304]

On November 18, 2013, Young received a slide from Meyers and forwarded it to company officers later that night (see slide below). In the body of the email, Young stated, "[o]ur recommendation for your discussion and approval is $27,000 per 28 tablet bottle" ($81,000 for 12W).[305]

[303] *Id.*
[304] *Id.*
[305] Appendix E, Ex. 38, Email from Kevin Young to John Martin et al., Re: COMPANY CONFIDENTIAL (Nov. 18, 2013), GS–0020800.

Sofosbuvir (SOF) Pricing

Target Price	SOF price per bottle ($)	SOF price per pill ($)	Cost of 12 weeks of SOF ($)	Cost of 24 weeks of SOF ($)	Cost of SOF + PEG/RBV for 12 weeks	Cost of SOF + RBV for 12 weeks	Cost of SOF + RBV for 24 weeks
$70,000	$23,333	$833	$70,000	$140,000	$79,640	$70,990	$141,980
$75,000	$25,000	$893	$75,000	$150,000	$84,640	$75,990	$151,980
$80,000	$26,666	$952	$80,000	$160,000	$89,640	$80,990	$161,980
$85,000	$28,333	$1,012	$85,000	$170,000	$94,640	$85,990	$171,980
$90,000	$30,000	$1,071	$90,000	$180,000	$99,640	$90,990	$181,980

Assumes SOF priced at $80,000 for 12 weeks

Genotype / Patient type	SOF-based regimen	Cost of SOF-based regimen ($)	Cost of current SOC ($)
GT-1 (Option A)	SOF + PEG/RBV for 12 weeks	$89,640	$95,074*
GT-1 (Option B)	SOF + RBV for 24 weeks	$161,980	$95,074*
GT-2	SOF + RBV for 12 weeks	$80,990	$19,279
GT-3	SOF + RBV for 24 weeks	$161,980	$19,279
HIV/HCV co-infection	SOF + RBV for 24 weeks	$161,980	n/a

GILEAD CONFIDENTIAL

1

* Range from $85,435 to $104,714

Business Proprietary Information – Confidential Treatment Requested

GS-0020801

On November 23, 2013, less than two weeks before Sovaldi received FDA approval and went on the market in the U.S., Young sent an email to Cara Miller, the company's senior director for public affairs stating, "The amount to drop into the U.S. Sovaldi press release, when you do final review is '$28,000.'" [306] The price appears to have been set during an offsite meeting held in the days prior with the company's leadership team—CEO John Martin, President and COO John Milligan, Chief Scientific Officer Norbert Bischofberger, CFO Robin Washington, Executive Vice President for Corporate and Medical Affairs Gregg Alton, and Young.[307] No notes or further record of this meeting has been provided.

On November 24, 2013, Young was in Tokyo, Japan and exchanged emails with Martin, who noted the per-bottle price of $28,000 would be "be easy from the press release, from 28 days and $28,000." [308] Young responded, "I think $28,000 is right. Its [sic] where I wanted to be and I think we all collectively circled this price point. What I've really appreciated is how we have stepped carefully through this with the Board and [the leadership team] over two years." [309] Martin ended the back-and-forth saying "I'm pleased where we are too." [310]

---

[306] Appendix E, Ex. 39, Email from Kevin Young to Cara Miller, Re: CONFIDENTIAL (Nov. 24, 2013), GS–0020946, at GS–0020947.

[307] *Id.*; Appendix E, Ex. 38, email from Kevin Young to John Martin et al., COMPANY CONFIDENTIAL (Nov. 18, 2013), attaching Sofosbuvir (SOF) Pricing chart, GS–0020800, GS–0020801.

[308] Appendix E, Ex. 39, Email from Kevin Young to Cara Miller, Re: CONFIDENTIAL (Nov. 24, 2013), GS–0020946.

[309] *Id.*

[310] *Id.*

Those emails appear to be the final decision points in a pricing process. During that time, company officials engaged in a series of presentations that examined a complex matrix of tradeoffs regarding revenue, volume, marketing, reactions from payers, patients, and advocates, potential market competition, and how Sovaldi's price ultimately would affect pricing of Gilead's successor drug, Harvoni. Staff repeatedly requested documentation regarding the final pricing decision, but Gilead refused such requests. Accordingly, it was not clear what factors ultimately influenced the final decision to increase the price from the final recommendation of $27,000 per bottle to $28,000 per bottle.

However, it was clear that as senior leadership finalized the price for Sovaldi, the company was already anticipating protests over the price. "Let's not fold to advocacy pressure in 2014," Young wrote in an email on November 19, 2014, to Meyers, the company's chief spokesman, Coy Stout, and Kristie Banks, a senior director for business development and contract compliance.[311] "Let's hold our position whatever competitors do or whatever the headlines."[312]

International Pricing of Sovaldi Was Significantly Lower Than in the United States

As noted in the senators' July 2014 letter to Gilead, the pricing strategy for Sovaldi in non-U.S. markets contemplated significant lower prices than what would be set for U.S. consumers. For example, the senators noted that Gilead had reportedly reached an agreement with Egypt to sell Sovaldi for roughly $900 per course of treatment.

In a written response to the senators, Gilead explained that it engaged in separate pricing approaches for developed- and less-developed countries. In developed countries, Gilead negotiated with individual countries and payers. Based on information provided by Gilead, Table 3 shows the wholesale price for Sovaldi in those developed countries was at significant discount to the U.S. price (per 12-week course of treatment).[313]

---

[311] Appendix E, Ex. 40, Email from Kevin Young to Jim Meyers et al., Re: ADAP and Sofosbuvir (Nov. 19, 2013), GS–0020802, at GS–0020802.

[312] *Id.*

[313] Appendix F, Gilead Sciences, Inc., Response to Chairman Wyden/Senator Grassley letter dated July 11, 2014, narrative answer to question 21 (Sept. 9, 2014).

Table 3—Wholesale Price of Sovaldi in Developed Countries Outside the United States

Country	Price
Austria	$63,189.70
Canada	$50,525.00
Denmark	$56,449.40
Finland	$54,381.20
France	$72,508.00
Germany	$63,198.70
Luxembourg	$62,149.90
Norway	$53,043.90
Sweden	$51,453.60
Switzerland	$59,594.80
United Kingdom	$57,100.20

Source: *Gilead Sciences, Inc.,* Response to Chairman Wyden/Senator Grassley letter dated July 11, 2014, narrative answer to question 21, September 9, 2014 (Appendix F)

In formulating its strategy for pricing for European countries, Gilead's commercial pricing team sought to achieve "the highest price we can get accepted in early launch markets (UK, Germany, France)."[314] At the time, the team expected the United Kingdom to set the European price floor and Germany to set the ceiling,[315] although Gilead put great weight on negotiating an early European price point with the French Temporary Authorization of Use (ATU) program at $74,000 in October 2013.[316] This program allows access to drugs for serious illness prior to final marketing authorization approval,[317] and was seen as an important benchmark for European negotiations.[318] Under this program, companies are granted a price premium, averaging 12%.[319] However, even at this price, a senior Gilead official cautioned that ". . . we should be careful saying that the price is comparable with existing treatment. It's actually at a significant premium (although entirely justifiable on its merits.)"[320]

In less-developed countries, Gilead employed a different set of strategies. Initially, it followed a "tiered pricing structure based on a country's health care and other resources and the severity of the HCV prevalence within that country."[321] How these factors were weighted was not explained, but Gilead confirmed that it had signed a treatment agreement with the Egyptian government in

[314] Appendix E, Ex. 41, Gilead Sciences, Inc., "EAME SOF Price Recommendations" (Gilead slide presentation), September 11, 2013, GS–0019913, at GS–0019914.
[315] *Id.*
[316] Appendix E, Ex. 42, Email from Kevin Young to Jim Meyers and Derrell Porter (Oct. 19, 2013), GS–0020285, at GS–0020285.
[317] A. Degrassat-Theas et al., Abstract, *Temporary authorization for use: does the French patient access programme for unlicensed medicines impact market access after formal licensing?,* 31 PharmacoEconomics 335, 335–43 (April 2013), *available at* http://www.ncbi.nlm.nih.gov/pubmed/23529210.
[318] Appendix E, Ex. 42, Email from Kevin Young to Jim Meyers and Derrell Porter (Oct. 19, 2013), GS–0020285, at GS–0020285—GS–0020287.
[319] A. Degrassat-Theas et al., Abstract, *Temporary authorization for use: does the French patient access programme for unlicensed medicines impact market access after formal licensing?,* 31 PharmacoEconomics 335, 335–43 (April 2013), *available at* http://www.ncbi.nlm.nih.gov/pubmed/23529210.
[320] Appendix E, Ex. 43, Email from Paul Carter to Cara Miller (Oct. 11, 2013), GS–0020212, at GS–0020212—GS–00200213.
[321] Appendix F, Gilead Sciences, Inc., Response to Chairman Wyden/Senator Grassley letter dated July 11, 2014, narrative answer to question 21 (Sept. 9, 2014).

July 2014 at a list price equivalent to $908.04 per course of treatment.[322]

As Gilead noted in its written response, it also was pursuing a parallel strategy for these same less-developed-country markets based on the licensing of generic production and marketing of sofosbuvir-based drugs. Indeed, shortly after the response was provided, Gilead entered into licensing agreements with seven Indian pharmaceutical companies to produce and market sofosbuvir (Sovaldi) and ledipasvir/sofosbuvir single tablet regimen (Harvoni) in 91 developing countries.[323] As explained by Meyers and Andy Rittenberg, corporate counsel for Gilead, in the October 30th interview, this model also has been used by Gilead for HIV/AIDS drugs. According to Mr. Rittenberg, these generic manufacturers would be licensed to manufacture and sell these drugs even in countries in which Gilead had previously reached pricing agreements.[324]

The generic manufacturers would set their own prices even to the point of undercutting Gilead's own country-specific price agreement—a point reiterated in the company's fact sheet, which states that "(t)he generic drug companies may set their own prices. . . ."[325] The license agreement for these generic manufacturing arrangements posted by Gilead on its website establishes a 7% royalty to be paid to Gilead Sciences Limited, an Irish corporation, on net sales of products in these 91 countries.[326] According to the most recent version of the company's fact sheet, these generic licensing agreements have now been expanded to include 11 Indian companies for distribution in 101 developing countries.[327]

The cost of these drugs outside of the U.S. is significantly below the U.S. price—a fact that was actively considered by Gilead in pricing them in Canada. In a presentation prepared by the Gilead Sciences Canada, the company concluded that the expected Canadian wholesale price of $55,000 would not draw cross border patients and that the structure of the Gilead distribution system would limit the risk of mail order arbitrage.[328] Gilead concluded that U.S. patients would not cross the border to incur a final expected out-of-pocket expense of some $64,000.[329]

---

[322] *Id.*

[323] Press Release, Gilead Sciences, Inc., Gilead Announces Generic Licensing Agreements to Increase Access to Hepatitis C Treatments in Developing Countries, (Sept. 15, 2014), *available at* http://www.gilead.com/news/press-releases/2014/9/gilead-announces-generic-licensing-agreements-to-increase-access-to-hepatitis-c-treatments-in-developing-countries.

[324] Interview with Jim Meyers, Senior Vice President, North America Commercial Organization, Gilead Sciences, Inc., in Washington, D.C. (Oct. 30, 2014).

[325] Gilead Sciences, Inc., Fact Sheet, Chronic Hepatitis C Treatment Expansion: Generic Manufacturing for Developing Countries, August 2015, *available at* http://www.gilead.com/~/media/files/pdfs/other/hcvgenericagreementfactsheet.pdf?la=en.

[326] Gilead Sciences, Inc., License Agreement, Execution Copy, September 15, 2014, (Section 4.1, page 8), *available at* http://gilead.com/~/media/files/pdfs/other/2014_original_hcv_licensing_agreement.pdf?la=en.

[327] Gilead Sciences, Inc., Fact Sheet, Chronic Hepatitis C Treatment Expansion: Generic Manufacturing for Developing Countries, August 2015, *available at* http://www.gilead.com/~/media/files/pdfs/other/hcvgenericagreementfactsheet.pdf?la=en.

[328] Appendix E, Ex. 44, Gilead Sciences, Inc., Canadian Sofosbuvir Pricing Considerations, September 30, 2013, GS–0020086, at GS–0020087.

[329] *Id.* at GS–0020091.

Sticking to the Plan: Harvoni Builds on the Price Set for Sovaldi

After the successful launch of Sovaldi, Gilead turned its attention to pricing Harvoni, the second wave of HCV drugs involving sofosbuvir. In a series of presentations, Gilead described how it would "[s]ecure market share leadership, while growing the market," through "[e]ffective portfolio management/prioritization in wake of successive launches, [r]esponding to competitors' attempts to fragment the market *through scientific dialogue* with prescribers, [e]nsuring parity access in a payer environment that desires market fragmentation," and "[a]ccelerating Market Development efforts to grow the market."[330] The ultimate goal for the time period was to *"[m]aximize [t]otal [f]ranchise [v]alue."*[331]

As it considered pricing Harvoni at $96,000 for a 12-week course of therapy, which the majority of patients was expected to need, the company projected that its HCV drugs would generate more than $30 billion in net revenue between 2015 and 2018.[332] The company ultimately set Harvoni's price at $94,500.[333]

Harvoni was expected to face competition that would make large price jumps difficult. One of the challenges was to "[p]rotect against price erosion from Wave 1➔2, and 2➔3."[334] As it set out to price Harvoni, the company viewed its position as one of "modest pricing power for the LDV/SOF, although avoiding restrictions with all accounts will be difficult to achieve."[335] The company also was loath to offer broad discounts, because they "do not offer offsetting share benefits for Gilead; however, this does not mean there are not some payers where discounting will be profitable."[336]

Gilead's main selling point for Harvoni has been that for certain patients—specifically, those who were treatment-naive and free of cirrhosis—it would be a single-pill, interferon-free therapy that could be curative in eight weeks. However, Gilead expected that just 21% to 46% of patients using its drugs would fit in that category and receive the eight-week therapy.[337] Gilead expected 14% to 32% of its Harvoni revenue to come from eight-week patients.[338] The remainder would be on 12 weeks (45% to 70%) or in the case of treatment experienced patients with cirrhosis, 24 weeks (9%).[339] Gilead has repeatedly said that Harvoni lowered the cost of treatment, but it did so only for the least sick, i.e., those with the lowest viral load counts and the healthiest livers.[340] In terms of sticker prices, Gilead would now be charging $94,500 for a 12-week treat-

---

[330] Appendix E, Ex. 45, Gilead Sciences, Inc., 2015–2016 HCV Commercial Plan, April 22, 2014, GS–0014083, at GS–0014085 (emphasis in original).
[331] *Id.* at GS–0014086 (emphasis in original).
[332] Appendix E, Ex. 46, Gilead Sciences, Inc., Topics for Discussion—LDV/SOF U.S. Pricing, August 4, 2014, GS–0019000, at GS–0019026.
[333] Stephanie M. Lee, *Is $1,125 Hepatitis Pill from Bay Area Drugmaker Worth It?*, San Francisco Chronicle (Oct. 11, 2014), *available at* http://www.sfgate.com/health/article/Is-1-125-hepatitis-pill-from-Bay-Area-drugmaker-5815341.php.
[334] Appendix E, Ex. 45, Gilead Sciences, Inc., 2015–2016 HCV Commercial Plan, April 22, 2014, GS–0014083, at GS–0014097.
[335] Appendix E, Ex. 47, Gilead Sciences, Inc., U.S. HCV Pricing Update, SVP Update Meeting, July 21, 2014, GS–0018861, at GS–0018862.
[336] *Id.*
[337] *Id.* at GS–0018878.
[338] *Id.* at GS–0018894—GS–0018895.
[339] *Id.* at GS–0018878.
[340] *Id.*

ment, up from $84,000 for Sovaldi, and more than 30% higher than the price of Incivek.

In addition to boosting awareness of sofosbuvir and gaining access to payers' formularies, the company would seek to "*[e]ducate governments about economic advantages of* investments in HCV cure and of HCV budget increases in 2015–2016," and "[a]ccelerate patient flow through the HCV waterfall."[341] In other words, ensure patients were tested and received treatment at an earlier disease stage, "to drive longer term sustainable growth."[342] Specifically, the company was seeking to "[e]ncourage a shift towards more patients being candidates for treatment" to "drive rapid SOF uptake across all indicated patient types."[343]

Gilead was aware of "[n]egative noise regarding price and potential access limitations."[344] It also knew that "[b]udget impact" would "shape reimbursement decisions in certain markets, with growing desire to prioritize care" amongst patients.[345] Gilead singled out Medicaid, noting that "[w]hile this will grow to ~15% of the treated population, coverage may continue to be challenging based on state-level budget constraints," and that the program was "[h]ighly cost constrained and predominately cost-focused."[346] Gilead expected HCV treatment "to drive a significant increase in 2015 federal Medicare Part D spending and annual individual beneficiary premiums."[347] It also was aware that "[t]he Wave 2 launches will add significantly to the total spend on HCV," with its projections topping $15 billion in 2015, alone, compared to less than $2 billion in 2013 (see slide below).[348] Gilead stated in a slide titled "PR Considerations" presented in July that "[g]iven that the LDV/SOF is >$1000/pill for all scenarios under consideration, negative stakeholder reactions and media scrutiny can be expected to continue in the months prior to AbbVie's launch."[349] Similar to its approach with Sovaldi, Gilead examined how different prices would affect "soft" factors ranging from negotiations with insurers, to the possibility that "[d]iscussions of U.S. government price controls gain traction."[350]

---

[341] Appendix E, Ex. 45, Gilead Sciences, Inc., 2015–2016 HCV Commercial Plan, April 22, 2014, GS–0014083, at GS–0014095 (emphasis in original).

[342] *Id.*

[343] Appendix E, Ex. 48, Gilead Sciences, Inc., 2014-2015 U.S. HCV Franchise BPOA (Draft), GS–0014143 at GS–0014146.

[344] *Id.*

[345] Appendix E, Ex. 45, Gilead Sciences, Inc., 2015–2016 HCV Commercial Plan, April 22, 2014, GS–0014083, at GS–0014088.

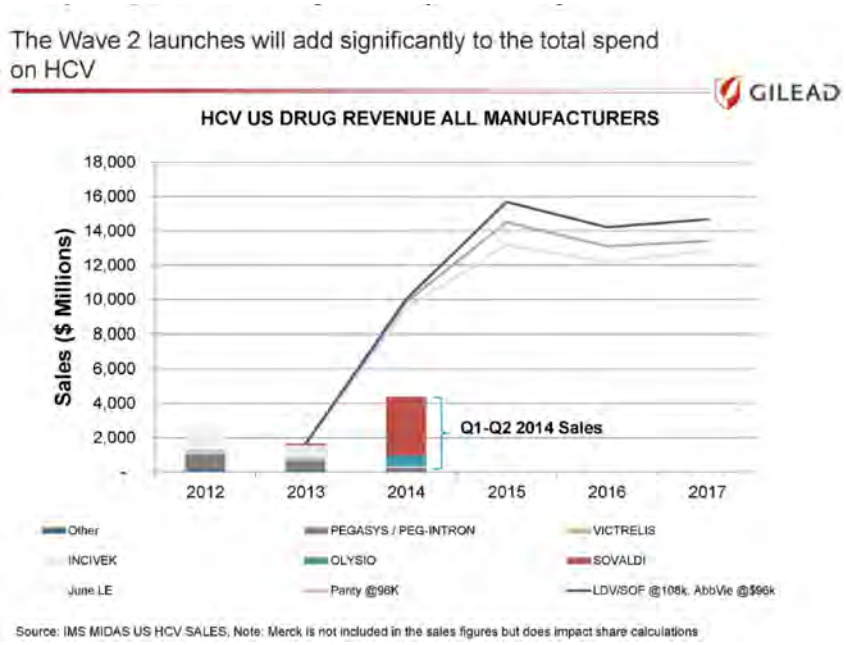
[346] Appendix E, Ex. 48, Gilead Sciences, Inc., 2014–2015 U.S. HCV Franchise BPOA (Draft), GS–0014143 at GS–0014157.

[347] Appendix E, Ex. 49, Gilead Sciences, Inc., Updated Slides—Wave 2 Pricing, GS–0018965, at GS–0018992.

[348] Appendix E, Ex. 47, Gilead Sciences, Inc., U.S. HCV Pricing Update, SVP Update Meeting, July 21, 2014, GS–0018861, at GS–0018891.

[349] *Id.* at GS–0018906 (emphasis omitted).

[350] Appendix E, Ex. 46, Gilead Sciences, Inc., Topics for Discussion—LDV/SOF U.S. Pricing, August 4, 2014, GS–0019000, at GS–0019013.



Source: IMS MIDAS US HCV SALES, Note: Merck is not included in the sales figures but does impact share calculations

In addition, Gilead received direct feedback from payers such as CVS/Caremark, Molina Healthcare, Atrius Health, California Medicaid, UnitedHealth Group, and Blue Cross Blue Shield of Michigan, all of which had representatives on Gilead's payer advisory board.[351] In October 2014, "[a]dvisors found Sovaldi and LDV/SOF's clinical profile compelling; however, the cost per population and impact on the plan's budgets [sic] are large concerns for advisors," which the presentation listed under "similarities" with previous advisory boards.[352] And as Gilead was seeking to expand the number of patients, Joel Brill, the CEO of Predictive Health LLC, warned "[t]here is a need to narrow the patient population, because if you tell us that all patients need to be treated, our budgets cannot afford that," which was put under a category in the presentation of "budget sustainability."[353]

Gilead recognized that Sovaldi had fundamentally changed the HCV market in 2014. It estimated that, based on 120,000 new patients and an average treatment cost of $89,300, "[o]verall additional spending on HCV treatments in the U.S. in 2014 is estimated $10.7 [billion]," which "[r]eflects a 280% increase in national HCV [per member per month] spending from $0.87 in 2013 to $4.2 in 2014," while "[a]nnual increases in PMPM have typically ranged from 3% to 4%."[354] In addition, the company expected HCV spending to push down earnings-per-share by double-digit percentages

[351] Appendix E, Ex. 50, Gilead Sciences, Inc., Managed Markets Hepatitis C Virus (HCV) Payer Advisory Board Final Report, October 3, 2014, GS–0018760, at GS–0018768—GS–0018769.
[352] *Id.* at GS–0018774.
[353] *Id.* at GS–0018777.
[354] Appendix E, Ex. 47, Gilead Sciences, Inc., U.S. HCV Pricing Update, SVP Update Meeting, July 21, 2014, GS–0018861, at GS–0018908.

for the largest health insurers, UnitedHealth, WellPoint, Aetna and Humana, which "could drive payers to push back on cost or change coverage going forward."[355] The slide below summarizes Sovaldi's financial impacts to private payers during 2014:[356]

Major payers have been actively adjusting forecasts and working with their state partners to prepare for expected increased HCV spend

GILEAD

PAYER	COMMENTARY
Express Scripts	• Specialty spend is forecasted to increase +63% over the next three years • HCV is expected to be a key driver of this increased spend
Humana	• EPS was lower than the second quarter of last year due to HCV drug costs • Working with states (e.g., Florida, Illinois, Virginia) to fund HCV exposures
Aetna	• Medical cost trends continue to be moderate and consistent with previous range of projections despite HCV cost pressures
WellPoint	• More than doubled HCV costs in pricing for 2014 compared to 2013 and added $100M to that outlook in Q1 2014 • Working with states to incorporate full expected HCV costs into reimbursement rates
Centene	• Net cost impact of HCV in Q2 2014 was $13.7M (compared to $4.2M in Q2 2013 and $7.3M in Q1 2014) • Working with states to include full expected HCV costs into reimbursement rates
United Health Group	• Q2 spend for HCV was 'in line with' revised expectations after Q1
WellCare	• HCV drugs have had a meaningful short term budget impact ($0.30 per share in expenses) • Florida is the first state to provide a specific reimbursement agreement for the managed Medicaid lives

Source: Payers' Q2 Earnings Calls, via RBC

-32-

Gilead prioritized outreach to certain health care providers based on the number of HCV patients they were seeing and treating. For providers who were already prescribing Sovaldi, the company's "[b]ehavioral [o]bjective" was to continue and expand use of the drug.[357] For providers who were not using Sovaldi, the company planned to initiate sales calls and urge them to begin prescribing.[358]

The company also broke down consumer and patient groups into high, medium and low priorities. Within the high priority category were diagnosed patients whose average age was 50 and were employed, insured, "more educated" and with an annual income of $60,000.[359] Gilead's "behavioral objective" with these patients was to "[e]ngage patients to re-think their Hep C, [a]ctivate urgency to treat, [d]rive linkage to treating specialists, [a]sk provider for treatment by name."[360] Community service providers and allied health care providers in clinical settings were designated a "low-medium" priority.[361] Gilead estimated that there were 9,000 community health clinics that would need to be engaged to ensure the com-

[355] *Id.* at GS–0018908—GS–0018909.
[356] *Id.* at GS–0018891.
[357] Appendix E, Ex. 48, Gilead Sciences, Inc., 2014–2015 U.S. HCV Franchise BPOA (Draft), GS–0014143, at GS–0014151—GS–0014153.
[358] *Id.*
[359] *Id.* at GS–0014154.
[360] *Id.*
[361] *Id.* at GS–0014155.

pany's treatments were used.[362] It expected that "[t]o activate [community health workers, Gilead would] need to educate about evolving treatment paradigm, cure, importance of linkage to HCV care."[363]

Finally, Gilead ranked payers, with commercial, Medicare, and VA rated as "high" priorities, and Medicaid as a "medium" priority. Corrections were rated as a "low-med" priority, as were integrated delivery networks like Kaiser Permanente "depending on risk."[364] Payers participating in exchanges were "low" priority, with the company noting that "[o]nly 6% of treated patients will come from exchange plans by 2016," and that while coverage was similar to commercial and managed care Medicaid plans, exchanges are "generally more restrictive, and with higher cost-sharing."[365] Two months later, the company would observe that payers would be reluctant to block access to new HCV drugs, "instead, payers may pick two 'winners' and generate rebates off the volume."[366]

In regards to determining the price point for Harvoni, Gilead studied $84,000, $115,000 and $145,000. Notably, Gilead labeled the $145,000 price point as "unacceptably expensive."[367] In a survey of payers, $84,000 was viewed as "reasonable," while $115,000 was viewed as "at the top end of value alignment" and "pushing the upper limit."[368] However, like when it priced Sovaldi, Gilead was aware that market competition, particularly for genotype 1 patients, would restrict the company's ability to capture higher prices with its second wave drug, Harvoni.

Gilead was concerned that since Bristol-Myers Squibb was exploring a combination of its own drug with sofosbuvir that it would create competition over price and possibly undercut Harvoni if priced it too high: "As a consequence, if LDV/SOF is priced at a significant premium to the alternative, physicians will allocate a substantial share of prescriptions to the DCV+SOF combination."[369] Likewise, the company spent a significant amount of effort comparing its price to different price points for AbbVie's Viekira Pak, and the trade-offs between market access and revenue maximization.[370]

It also studied what Wall Street analysts expected in terms of a price for Harvoni, and the "potential impact on estimate earnings," which would affect equity investment.[371] Documents show that the company had had an interest in analysts' opinions on Harvoni's price during the lead-up to Sovaldi's release. On October 31, 2013, Robin Washington received a lengthy "buy-side survey" from health care analyst Mark Schoenebaum that contained financial and pric-

---

[362] *Id.*
[363] *Id.*
[364] Appendix E, Ex. 45, Gilead Sciences, Inc., 2015–2016 HCV Commercial Plan, April 22, 2014, GS–0014083, at GS–0014157.
[365] Appendix E, Ex. 48, Gilead Sciences, Inc., 2014–2015 U.S. HCV Franchise BPOA (Draft), GS–0014143, at GS–0014156—GS–0014157.
[366] Appendix E, Ex. 47, Gilead Sciences, Inc., U.S. HCV Pricing Update, SVP Update Meeting, July 21, 2014, GS–0018861, at GS–0018865.
[367] *Id.* at GS–0018866.
[368] *Id.*
[369] *Id.* at GS–0018863.
[370] *Id.* at GS–0018869.
[371] Appendix E, Ex. 46, Gilead Sciences, Inc., Topics for Discussion—LDV/SOF U.S. Pricing, August 4, 2014, GS–0019000, at GS–0019009—GS–0019010.

ing predictions that had been collected from 203 respondents.[372] These analysts expected that the gross price for a 12-week regimen of Sovaldi would be $85,400; the price of Harvoni was expected to be $94,000.[373]

On September 9, 2014, the company discussed its contracting strategy with a price of $94,500, specifying specific discounts for various payer groups and payers:[374]

Segment	Discount	Approach	Commentary
Kaiser Permanente	20%	Proactive	
Integrated Delivery Networks (Geisinger, University of Pittsburgh Medical Center, Selective, Henry Ford)	8%–10%	Proactive	Henry Ford is reactive only
Departments of Corrections (CA, FL, NY, OH, MI, AZ & University of Texas Medical Branch)	10%–20%	Proactive	Contract with listed State DOC's at a discount of 10–20%. UTMB will receive 340B pricing and a 15% supplemental discount on eligible utilization (10% on Commercial utilization)
FFS Medicaid Medicaid Pools Magellan and SSDC Independent States: Magellan Independent States: FL, MO, TN, TX, VA All other independent states: CA, CO, GA, IL, IN, MA, OH	4–10%	Proactive	Independent states will be negotiated if they are listed as "select payers" or reactive, as needed Discounts will be tiered based on the coverage levels (fibrosis level) – Listed on preferred drug list (4%) – F2–F4 (8%) – Prior Authorization to Label (10%)
Managed Medicaid	See Commentary	PROACTIVE for PerformRx and Envision Rx REACTIVE FOR ALL OTHER MMCO ACCOUNTS ACCORDING TO GUIDELINE CRITERIA	– At launch, for Type A accounts, proactively extend rebates for SOF/LDV at 4%–5% – At formulary review/competitor launch, rebates for the Type A accounts in 5%–7% range – For Type B accounts, either half of rebate available to account capped at 7% or rebate range of 5%–7% – For Type C accounts, discounts will be considered based on guideline criteria
VA/DOD	10% (plus 26% statutory discount)	Proactive	VA discounts will be proactively submitted via TPR

[372] Appendix E, Ex. 51, Email from Mark Schoenebaum to Robin Washington, FINAL data from gild/bmy (and sort of MRK/ROG) buy-side survey, (Oct. 31, 2013), GS–0020496, at GS–0020496—GS–0020497.

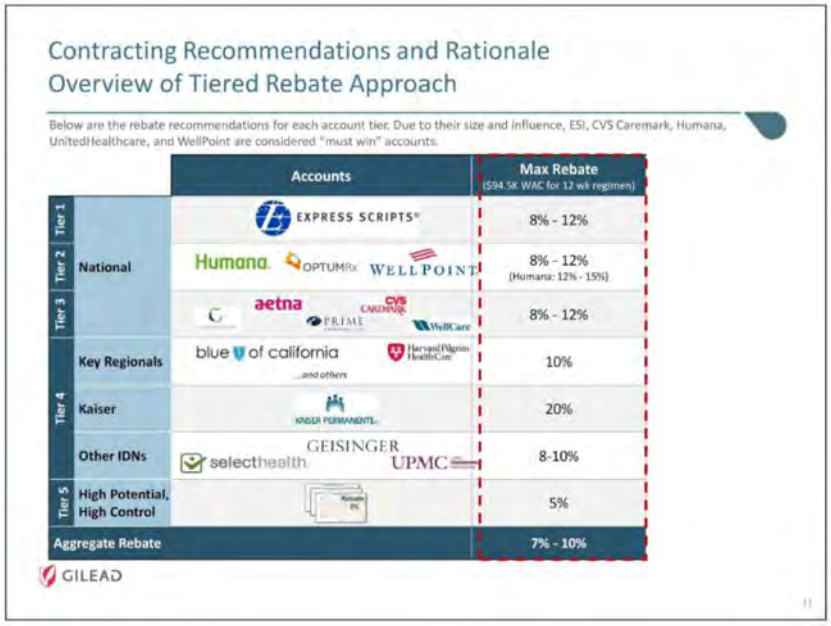
[373] *Id.*

[374] Appendix E, Ex. 52, Gilead Sciences, Inc., HCV Wave 2 Contracting Recommendations, September 9, 2014, GS–0019058, at GS–0019060—GS–0019063.

Segment	Discount	Approach	Commentary
340B	Statutory Discounts	Proactive	All 340B accounts will receive statutory discounts with the exception of UTMB and Puerto Rico DOH
Healthcare exchanges	Equal to commercial discounts	Proactive	Exchange utilization will be included in commercial account contracts at the commercial discount rate

Source: Appendix E, Ex. 52, Gilead Sciences, Inc., HCV Wave 2 Contracting Recommendations, September 9, 2014, GS–0019058, at GS–0019060—GS–0019063

Gilead further broke down its priority accounts by tier. Standing alone at the top tier was Express Scripts, which Gilead estimated had 233,900 HCV patients.[375] The second tier included Humana (43,700 HCV patients), Optum Rx (78,900 HCV patients), WellPoint (76,520 HCV patients), and CVS Caremark (22,035 HCV patients).[376] With most of the largest national accounts, Gilead planned to begin contracting negotiations at a 5% rebate, generally maxing out at between 8% and 12%.[377] These highest priority accounts were followed by eight pages of tables with dozens more accounts that, because of size or other reasons, were deemed a lower priority by Gilead.[378] Rebate strategies varied widely, ranging from no rebate to 12% (see slide below).[379]



[375] *Id.* at GS–0019069.
[376] *Id.*
[377] *Id.*
[378] *Id.* at GS–0019068—GS–0019078.
[379] *Id.*

The company appears to have been strict in its limits for rebate negotiations. For example, while the company was willing to provide Kaiser Permanente with a higher discount than other payers (20%), Kaiser had "articulated expectations of a rebate as high as 30% to 49%."[380] In notes on the contracting approach for Kaiser, the company states "the rebate may be extended by BU and Executive Leadership above 20%."[381] It is not clear who or what "BU" is in this instance. Similar notations can be found for other accounts, as well.

Gilead estimated that about 360,000 of the 1.2 million-person state prisoner population were infected with HCV, but the company planned to limit its contracting approach to the most populous state systems. The company had already secured contracts with California and Texas and would seek to contract with only the five largest Departments of Corrections that remained, because the company saw diminishing benefits in smaller prison systems. The five states—Florida, New York, Ohio, Michigan, and Arizona—represented "~42% of non-contracted inmate lives."[382] In focusing on the prison population, Gilead saw an "[a]bility to treat inmates before they are released and potentially treated through Medicaid."[383] Risks included "[s]pillover to other non-contracted state DoCs," and potentially "miss[ing] out on treatment opportunities arising from public policy changes."[384] The company noted it would "[s]upport HCV treatment in DoC segment by providing reduced price which will stretch the existing DoC budgets."[385]

Gilead also studied what factors payers and physicians would focus on when making a conclusion as to what price point was palatable. Payers appeared to provide the company with some conflicting views with respect to the price of Harvoni. For example, the company expected that for "scenarios with the same net price, access is more favorable for a high WAC/high discount approach," than lower WAC and lower rebates.[386] However, a key finding with its payer advisory board indicated that SVR rates were a focal point; "[a]lthough advisors initially responded negatively to the cost of the regimen, most advisors responded positively to data presented as cost per SVR."[387] As an example, when members of Gilead's payer advisory board were asked during a May 2014 meeting to "price each regimen based on the clinical profile as if they were the manufacturer," the average was $102,855, with a range of $84,000 to $126,000.[388] William Cardarelli, director of pharmacy at Atrius Health, believed the controversy over the drugs' prices would be short-lived: "The best thing you can do is help us figure out who gets treated and not position yourselves as treating everyone at diagnosis. This too will pass, the hysteria will die down;

---

[380] *Id.* at GS–0019082.
[381] *Id.*
[382] *Id.* at GS–0019094.
[383] *Id.* at GS–0019098.
[384] *Id.* at GS–0019096.
[385] *Id.* at GS–0019098.
[386] Appendix E, Ex. 47, Gilead Sciences, Inc., U.S. HCV Pricing Update, SVP Update Meeting, July 21, 2014, GS–0018861, at GS–0018910.
[387] Appendix E, Ex. 50, Gilead Sciences, Inc., Managed Markets Hepatitis C Virus (HCV) Payer Advisory Board Final Report, October 3, 2014, GS–0018760, at GS–0018772.
[388] *Id.* at GS–0018797.

there's something new every year. The government has the attention of a 2-year-old." [389]

Notably, physicians did not assign great importance to the price of the drug, which Gilead was keenly aware of throughout its process of pricing Sovaldi and Harvoni. A survey of payers ranked net cost as the second most important issue for management of therapies.[390] Physicians, meanwhile, ranked five clinical attributes ahead of cost: SVR, tolerability, adverse events, treatment duration, and ease of administration ahead of a patient's out-of-pocket expenses.[391] Such divergence was one of the reasons that Gilead was focused on keeping decisions in the hands of providers.

Gilead's Marketing to Doctors and Patients

Part of Gilead's strategy was to seed demand by having patients approach their health care providers (HCPs) for treatment, and to convince providers of the drug's merits so they would "expand their definition of 'treatment candidates' so that they reengage untreated patients for SOF." [392] At the same time, the company needed "access and advocacy" to eliminate "barriers" to treatment and medical society treatment guidelines, as well as KOLs (key opinion leaders) to advocate on behalf of the products.[393] To that end, the company's top goal was to quickly establish sofosbuvir as the standard of care for all genotype 1, genotype 2, and genotype 3 patients, and to "sustain launch trajectory by growing treated patient pool," specifically, increasing treated patients 73% beginning in November 2013.[394]

As Gilead began to consider how to price its soon-to-be-approved drug, the company refined its commercial pitch to ensure that it would be financially successful. A 44-page presentation on April 4, 2013 titled "2013–2015 HCV Launch Commercial Plan," shows that Gilead wanted to maximize the opportunities, and minimize the threats through a combination of advertising, brand placement, lobbying, public relations and marketing, developing supporters in the medical and patient advocacy communities, targeted speeches at medical conferences, published articles in medical journals, and extensive salesforce training on a country-by-country basis taking into account national requirements. These initiatives would be led by the company's Commercial Planning and Operations department, whose job it would be to marshal the resources of employees in departments ranging from public affairs to research and development, medical affairs and sales.[395]

In order to prepare the market for sofosbuvir's launch, Gilead planned to court providers using a branded campaign to sell "HCV Treaters, Past Treaters and high potential Non-Treaters" on the clinical efficacy of Sovaldi through in-office visits, journals, and on-

---

[389] *Id.* at GS–0018773.
[390] Appendix E, Ex. 47, Gilead Sciences, Inc., U.S. HCV Pricing Update, SVP Update Meeting, July 21, 2014, GS–0018861, at GS–0018926.
[391] *Id.* at GS–0018926, GS–0018943.
[392] Appendix E, Ex. 29, Gilead Sciences, Inc., Gilead HCV U.S. BPOA, October 2012, GS–0013489, at GS–0013493.
[393] *Id.* at GS–0013493.
[394] *Id.* at GS–0013490.
[395] Appendix E, Ex. 32, Gilead Sciences, Inc., 2013–2015 HCV Launch Commercial Plan, April 4, 2013, GS–0013503, at GS–0013527—GS–0013534.

line material.[396] Each category of "treater" was prioritized based on the potential for providers to take up "target behaviors" to "quickly adopt sofosbuvir as SOC, re-engage untreated patients in their practice and discuss sofosbuvir with them, [and] become advocates for sofosbuvir and increasing treatment rates."[397] The company further analyzed the groups in terms of the number of patients, prescriptions for interferon, and speed with which they began using previous protease inhibitors. The most valuable "customer group" for the company's sales force were 660 "high value current PI (protease inhibitor) treaters." Based on prescription data for other HCV drugs, the company estimated that these providers had an average of 26 patients per provider—more than five times as many as the next category of 4,452 "Community PI Rxers."[398] One goal was to ensure that Gilead's sales resources were being used to convince providers to prescribe sofosbuvir.

In addition, a cornerstone of Gilead's strategy to court the medical community was its "[s]peaker [f]aculty and [t]raining."[399] Gilead recruits, trains and retains third-party health care professionals that are part of a "Speakers Bureau" to communicate on behalf of the company's products and the diseases they treat. In order to incentivize experts to speak on behalf of their products, Gilead will pay speaking fees and reimburse travel expenses for the speakers.[400] Gilead reported paying speaking fees of $2.1 million for Harvoni and $2.9 million for Sovaldi in 2014.[401] An analysis by investigative staff shows that Gilead made 2,630 payments to 293 providers in 46 states for "compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program," related to Sovaldi or Harvoni.[402] The average payment was $1,379, and the median payment was $2,500.[403]

These speakers use materials, slides and handouts that have been approved and are tightly controlled by Gilead:

> Speakers may not edit, reorder, or hide any slides or otherwise modify the content emphasis, balance or context of the material in the slides. Speakers must move through the on-label deck, displaying every slide. They need not verbalize all content on every slide but should address points of interest or relevance for the particular audience or setting. A substantial portion of the presentation must be devoted to the presentation and discussion of this slide deck. Speakers may only use their own slides in excep-

---

[396] *Id.* at GS–0013494.
[397] *Id.* at GS–0013497.
[398] *Id.* at GS–0013498.
[399] Appendix E, Ex. 48, Gilead Sciences, Inc., 2014–2015 U.S. HCV Franchise BPOA (Draft), GS–0014143, at GS–0014163.
[400] Gilead Sciences, Inc., *2009 Pocket Guide to Gilead's Business Conduct Manual,* at 17–19, *available at* http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9MjE0Mjl8Q2hpbGRJRD0tMXxUeXBlPTM=&t=1 [hereinafter Gilead, 2009 Pocket Guide].
[401] Gilead Sciences, Inc., *Sunshine Act/Open Payments Compliance: Reporting Period: January 1 to December 31, 2014, available at* http://www.gilead.com/responsibility/sunshinepercent20act percent20open percent20payments percent20compliance (last visited Sept. 10, 2015).
[402] Data available from Gilead Sciences, Inc., 2014 Non-Research Speaker Payments (spreadsheet), *available at* http://goo.gl/iTu3Ld (accessed July 14, 2015).
[403] *Id.*

tional circumstances and if they are pre-approved by Gilead.[404]

Gilead aimed to conduct 2,500 to 2,750 speaker programs related to its HCV treatments with as many as 400 speakers onboard by the third quarter of 2014.[405] Presentations promoting Harvoni were approved by the company within two days of the FDA's approval of the drug, and speeches began within two weeks after approval.[406]

Convincing providers was only part of the equation for Gilead as the company wanted patients who had long been told to wait for development of more effective cures to go to their providers seeking help. These combined efforts would "need to drive more patients into care and increase referral rates," and "overcome inertia towards non-treatment."[407]

Gilead recognized that years of warehousing had shrunk the annual number of people receiving HCV treatment to 56,000 annually.[408] To combat the low number of patients, Gilead calculated that Sovaldi, and its would-be competitor, Olysio, needed to increase the number of annual treatments to be viable: "Sofosbuvir and simeprivir launch must increase treated pool by 41K patients to be consistent with forecast."[409] The document does not indicate that Gilead ever expected the two drugs to be used in an off-label combination as AASLD ultimately recommended for patients who could not tolerate interferon.

To foster demand, the company planned to use a non-branded disease awareness advertising campaign to target baby boomers to ask providers about new HCV treatments.[410] The working document had many components ranging from geography ("20 states capture 75% of Baby Boomer population") to effective types of media ("TV, Internet, and radio have the highest reach to Boomers") to potential advantages to using a spokesperson ("Credible individual that baby boomers can relate to (e.g. Sally Field for Boniva)").[411] The company would measure the campaign's success based on rating points and other tracking metrics, response to the campaign demonstrated by seeking out more information, and, finally, action as demonstrated by provider visits and drug prescriptions.[412]

While not explicitly discussed in this presentation, one example of the awareness campaign includes the website *www.hepchope.com,* which Gilead set up in addition to a toll-free phone number 1–844–4HepcHope. The toll-free number is staffed from 9 a.m. to 9 p.m. by health educators employed by Gilead in Foster City, California, where the company is based. When calling, the caller is asked to provide an email or physical mailing address with which Gilead and its partner companies can send educational

---

[404] Gilead, *2009 Pocket Guide,* at 17–19.
[405] Appendix E, Ex. 48, Gilead Sciences, Inc., 2014–2015 U.S. HCV Franchise BPOA (Draft), GS–0014143, at GS–0014163.
[406] *Id.* at GS–0014163—GS–0014165.
[407] Appendix E, Ex. 29, Gilead Sciences, Inc., Gilead HCV U.S. BPOA (Oct. 2012), at GS–0013492, GS–0013493.
[408] *Id.* at GS–0013490.
[409] *Id.*
[410] *Id.* at GS–0013499.
[411] *Id.* at GS–0013500.
[412] *Id.* at GS–0013499—GS–0013502.

information about HCV (see below), strategies for finding a provider and discussing the disease, and information about Gilead's HCV treatments.

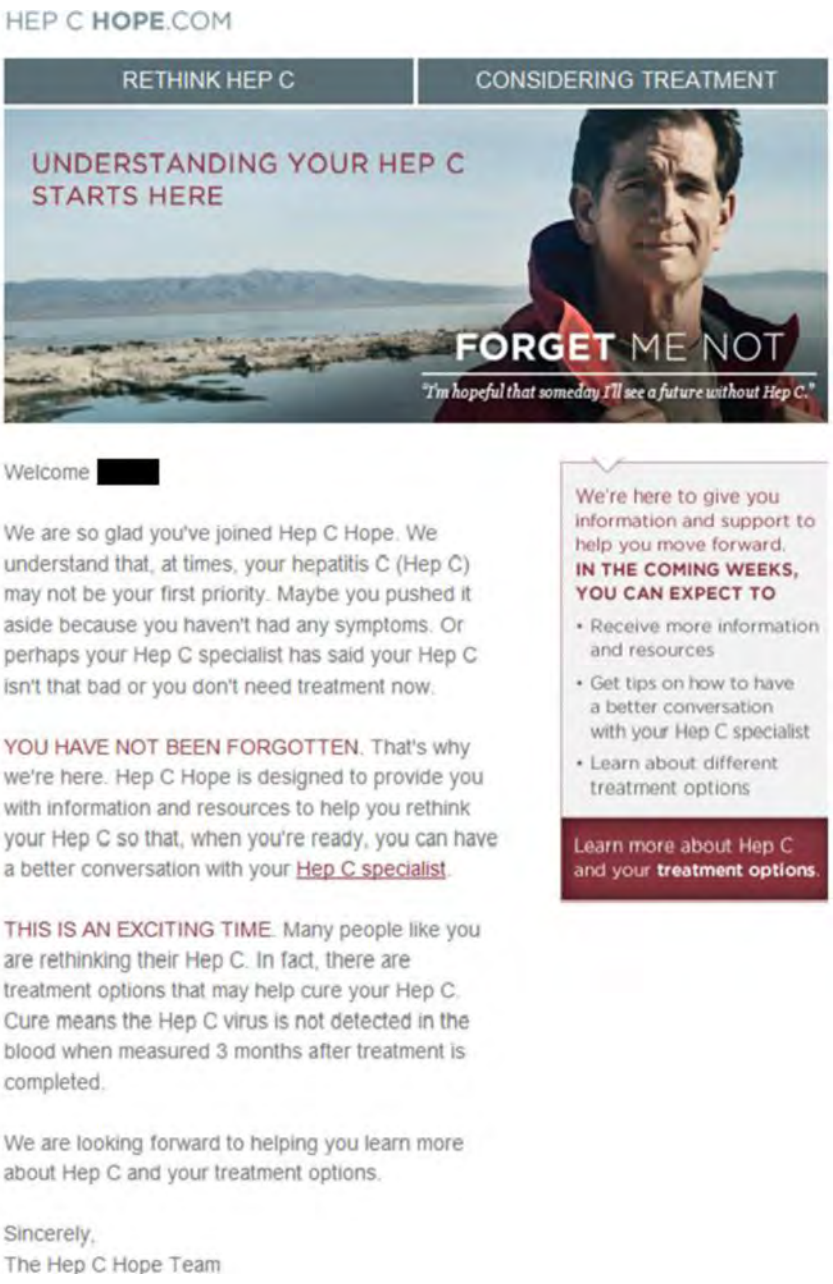
The caller is further asked how they heard about the hotline/website, and are advised that, while their privacy will be protected, Gilead may use their information for market research. Callers can be transferred to Gilead's "Support Path" program, which is designed to help "patients get started on therapy and move toward treatment completion," through on-call nurses, financial assistance for drug purchases, and prepared forms such as "letters of medical necessity" that providers send to insurers.[413] Like HepCHope, the program provides valuable and detailed market intelligence for Gilead. For example, a presentation in September 2014 analyzing Medicaid fee-for-service programs says a "majority of states are managing HCV with strict criteria," pointing to "953 unique patients on Support Path."[414]

On the website, clicking "learn more about a treatment option for Hepatitis C" links to a website advertising Harvoni. According to an advertising industry website, a Gilead commercial that advertises the HepCHope phone number and website had aired at least 9,816 times as of November 18, 2015.[415]

[413] Gilead Sciences, Inc., Support Path, *available at* http://www.mysupportpath.com/ (accessed Nov. 10, 2015).

[414] Appendix E, Ex. 52, Gilead Sciences, Inc., HCV Wave 2 Contracting Recommendations, September 9, 2014, GS–0019058, at GS–0019104.

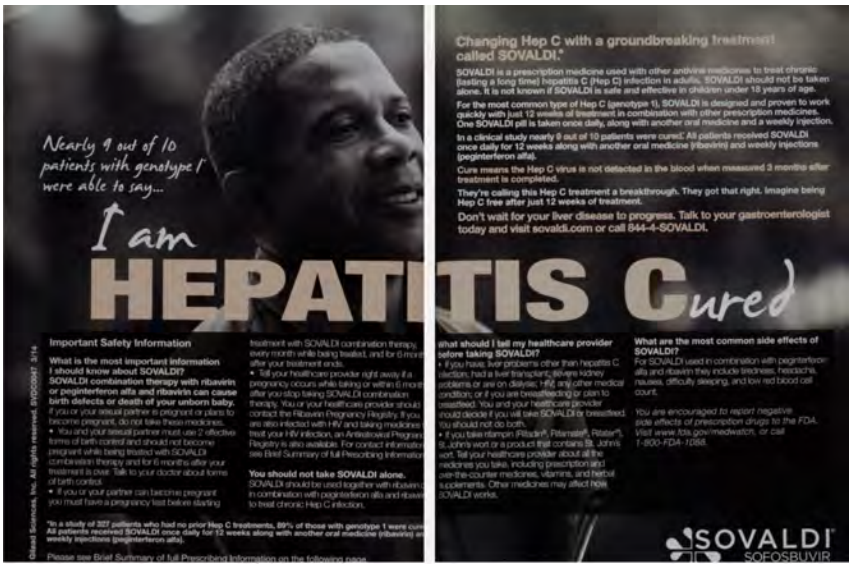
[415] Gilead Sciences, Inc., *HepCHope.com TV Commercial, "Forget Me Not," available at* http://www.ispot.tv/ad/7Ba0/hepchope-com-get-me-not (accessed Nov. 18, 2015).



Meyers told investigative staff that the company never launched a branded campaign for Sovaldi on television. Instead, the company provided visual materials to physicians and advertised in medical journals. Meyers said the print campaign started in February 2014 and lasted roughly a month-and-a-half, at which point the company

noted an unexpected volume surge.[416] Examples of print advertisements for Sovaldi can be found in the July 2014 and September 2014 issue of Esquire magazine.[417] The purpose of the ads was to build disease awareness, Meyers said, but Gilead was experiencing such large volume that it was not deemed necessary.[418]

Gilead has advertised a great deal for Harvoni—ads for the drug have aired 8,224 times as of November 18, 2015.[419]



In addition, the company needed to ensure that policymakers were aware of HCV as a public health issue, so it would be a higher priority for government outlays. The company planned to boost government awareness by "creating tools necessary to engage policymakers in advocating and elevating HCV as a major public health issue and increase budgets accordingly."[420] To that end, before launching the drug, Gilead planned to "articulate the unmet needs and disease burden of HCV to multiple stakeholders including physicians, health policy makers, payers, and advocates," and "develop evidence of HCV disease burden and a plan for raising HCV as a national health priority."[421]

Gilead believed sofosbuvir's shortening and simplification of treatment for genotype 1 patients would be appealing to providers, who in turn would be more likely to prescribe the drug than they had been with predecessor therapies. However, because relatively few physicians routinely prescribed drugs for HCV, the company

---

[416] Interview with Jim Meyers, Senior Vice President, North America Commercial Organization, Gilead Sciences, Inc., in Washington, D.C. (October 30, 2014).

[417] Gilead Sciences, Inc., *Sovaldi* (advertisement), Esquire Magazine, at 44–45 (July 2014 Esquire Magazine (Sept. 2014), at 128–129.

[418] Interview with Jim Meyers, Senior Vice President, North America Commercial Organization, Gilead Sciences, Inc., in Washington, D.C. (October 30, 2014).

[419] Gilead Sciences, Inc., *Harvoni TV Commercial,* "I am Ready," *available at* http://www.ispot.tv/ad/786d/harvoni-i-am-ready#moreData (accessed Nov. 18, 2015).

[420] Appendix E, Ex. 32, Gilead Sciences, Inc., 2013–2015 HCV Launch Commercial Plan, April 4, 2013, GS–0013503, at GS–0013533.

[421] *Id.* at GS–0013519.

would need to convince more providers to pursue treatment for their patients. By increasing the number of prescribing providers, more patients would become potential consumers. To that end, the company would "strive for rapid inclusion in guidelines" from medical organizations that would raise its profile in the medical community.[422] The company planned to target the Conference on Retroviruses and Opportunistic Infections (CROI), the European Association on the Study of the Liver (EASL), the International Society for the Pharmacoeconomics and Outcomes Research (ISPOR), the Asian Pacific Association for the Study of the Liver (APASL), and the American Association for the Study of Liver Disease (AASLD).[423]

As the drug was launched, Gilead wanted to "ensure payers and national health authorities are supportive of the value offered by SOF-based regimens," and its goal was "from the outset, SOF-based regimens should be considered first for all GT2/3 and GT1 TN patients."[424]

The goal following launch would be to "maintain SOF value and eliminate access barriers with payers," by working to "protect price erosion in advance of SOF/LDV launch, and maintain value in GT2/3," and "work to ensure restrictions are not imposed in key markets."[425] At the same time, the push for patients would be sharpened with efforts to "increase the numbers of patients accessing treatment," and "encourage treating physicians to initiate SOF-based regimens in the majority of patients for whom previously no treatment was offered."[426] Over the course of three years, the company wanted to "increase referral of diagnosed patients to treating physicians," and "support efforts to increase delivery of HCV care beyond specialists who treat today."[427]

At the same time that Gilead was laying out plans to maximize sales of sofosbuvir, it also recognized potential commercial threats, including:

- HCPs (health care providers) may wait for IFN-free regimens in GT1
- Apathy for Tx (treatment/treating) early disease due to limited data on benefits of treating earlier
- Payers may limit access and force declining value
- Potential for market fragmentation with launches of competitive regimens
- Low government prioritization of HCV in many countries[428]

The company planned to prioritize targeting sofosbuvir for genotype 1 patients in Europe and the U.S. as that genotype was predominant in both regions. In the U.S., as well as in France, Germany, and Italy, secondary emphasis would be given to genotype 2 patients, reflecting the second largest bloc in the countries' re-

[422] *Id.* at GS–0013510.
[423] *Id.* at GS–0013528.
[424] *Id.* at GS–0013519.
[425] *Id.* at GS–0013522.
[426] *Id.*
[427] *Id.*
[428] Appendix E, Ex. 32, Gilead Sciences, Inc., 2013–2015 HCV Launch Commercial Plan, April 4, 2013, GS–0013503, at GS–0013510.

spective patient populations. Similarly, for Spain and the United Kingdom, the company would focus on genotype 3 patients, based on the number of prospective prescriptions.[429] Gilead also singled out two "special populations" to target: pre-transplant patients (of which the company estimated to be 6,400 in the U.S., and 4,800 in the EU) who would receive up to 48 weeks of sofosbuvir, and patients with both HIV and HCV, of which there were an estimated 55,000. As the company noted, most of these patients were already under the care of specialists, and had "fewer barriers to initiating treatment vs mono-infected" patients with only HCV.[430]

In its April 4th commercial plan, Gilead had defined its commercial opportunity, strategy, and initiatives. Its success in the U.S. ultimately would be measured post-launch by "key metrics" on a monthly and quarterly basis.[431] These metrics included "ex-factory units," i.e., sales directly from the factory to distributors, total prescriptions of Sovaldi, revenue, and "forecast attainment."[432] No other documentation of this meeting has been provided, despite repeated requests that Gilead provide supporting documents.

Once the drug was launched, a series of metrics would be used to measure success in the United States and across the world. The company planned to "establish and communicate unified launch success metrics," and "track success metrics" that would be communicated monthly.[433] Among those metrics were physician surveys to determine brand awareness; profile constructs of patients being prescribed the drug; message testing; tracking various prescription data, including new-to-brand prescriptions, new proscriptions, total prescriptions, and longitudinal (i.e., geographic) prescriptions;[434] revenues, respectively; factory-to-distributor sales; monitoring the prescriber base; and attaining forecast goals.[435] Many of these same metrics would be repeated in the "EAME" market comprising Europe, Asia, and the Middle East.[436]

Impact of AASLD/IDSA HCV Treatment Recommendations

In late January 2014, on the heels of Sovaldi's 2013 launch, an advisory committee under the auspices of the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) issued guidance on the treatment of HCV.[437] The panel declared sofosbuvir as the "recommended" regimen for treatment-naive genotype 1 patients who were eligible to receive interferon regardless of subtype.[438] Simeprevir, a drug manufactured by Gilead's competitor Johnson & Johnson as Olysio, was declared "acceptable" for subtype 1b and some subtype 1a patients.[439] The endorsement effectively rendered Sovaldi the new

---

[429] *Id.* at GS–0013511—GS–0013513.
[430] *Id.* at GS–0013511—GS–0013514.
[431] *Id.* at GS–0013537.
[432] *Id.*
[433] *Id.* at GS–0013532.
[434] These were referred to in the presentation as NBRx, NRx, TRx, LRx, respectively.
[435] Appendix E, Ex. 32, Gilead Sciences, Inc., 2013–2015 HCV Launch Commercial Plan, April 4, 2013, GS–0013503, at GS–0013536—GS–0013537.
[436] *Id.* at GS–0013538.
[437] American Association for the Study of Liver Disease & Infectious Diseases Society of America, *HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C* (2014), *available at* http://www.hcvguidelines.org.
[438] *Id.* at 18.
[439] *Id.* at 19.

standard of care for HCV. It should be noted that the FDA labels required interferon to be administered with both Sovaldi and Olysio for genotype 1 patients, though for shorter periods than previous therapy regimens.

In addition, the panel made a recommendation that sofosbuvir (Sovaldi) and simeprevir (Olysio) could be administered together for genotype 1 patients who could not tolerate interferon.[440] This recommendation was based largely on a single phase 2 clinical trial of 167 patients known as COSMOS. This combination was not officially approved by the FDA until October 2014 and did not conform to the FDA label for either drug until then.[441] Nonetheless, an increasing number of physicians prescribed this off-label regimen in order to address the continuing treatment obstacles to interferon. By some estimates, the combination represented upwards of 1/3 of all Sovaldi prescriptions by the end of the 2nd quarter of 2014.[442] When faced with the expert panel's recommendation, many payers accepted the off-label regimen, but then faced the double cost of two expensive HCV drugs being co-prescribed. The wholesale price of the two together was roughly $150,000.[443]

Gilead pointed to this off-label use as a major factor in payers' growing complaints about the cost of Sovaldi during 2014. In its written response to the senators' letter, Gilead stated that it opposed the recommendation of using the two drugs together.[444] While it is true that a significant number of patients were given the Sovaldi/Olysio combined regimen, it appears that this was done by physicians to address one of the drawbacks inherent in Sovaldi, which was its continued reliance on interferon for the largest cohort of HCV patients, i.e., those with genotype 1. With the advent of the all-oral Harvoni and Viekira Pak products, use of the combination decreased dramatically.[445]

Finally, it is important to note that without the AASLD/IDSA expert panel recommendation, the combination off-label use would not likely have occurred at the levels of use seen in 2014.

Potential conflicts of interest could have played a role in the AASLD/IDSA's recommendations for Sovaldi and the Sovaldi/Olysio combination, and a number of panel members reported that they received compensation and/or research funding from the two manufacturers.[446] However, we located no direct evidence of influence on

---

[440] *Id.* at 18.

[441] Johnson & Johnson's Janssen division applied to the FDA for approval to use the two in combination on May 7, 2014, citing the COSMOS study. Press Release, Johnson & Johnson, Janssen Submits Supplemental New Drug Application to U.S. FDA for Olysio TM (Simeprevir) for Once-Daily Use in Combination with Sofosbuvir for 12 Weeks for the Treatment of Adult Patients With Genotype 1 Chronic Hepatitis C (May 7, 2014), *available at* http://www.investor.jnj.com/releasedetail.cfm?releaseid=846096. FDA approved the combined use on November 5, 2014. Anna Edney, *J&J Wins U.S. Approval for Hepatitis C Combo With Gilead,* Bloomberg (Nov. 5, 2014), *available at* http://www.bloomberg.com/news/articles/2014-11-05/j-j-wins-u-s-approval-for-hepatitis-c-combo-with-gilead.

[442] Hepatitis C Online, Medications to Treat HCV, Simeprevir (Olysio), http://www.hepatitisc.uw.edu/page/treatment/drugs/simeprevir-drug (last visited Nov. 11, 2015).

[443] *Id.*

[444] Appendix F, Gilead Sciences, Inc., Response to Chairman Wyden/Senator Grassley letter dated July 11, 2014, narrative answer to questions 17, 18d (Sept. 9, 2014).

[445] *Id.*

[446] Appendix F, Gilead Sciences, Inc., Response to Chairman Wyden/Senator Grassley letter dated July 11, 2014, narrative answer to questions 18a, 18b (Sept. 9, 2014); American Association for the Study of Liver Diseases & Infectious Diseases Society of America, *Recommendations*

Continued

panel members and, as noted above, the recommendation on the Sovaldi/Olysio combination was contrary to Gilead's longer-term interests and its corporate position as explained in its written response. Members of the panel interviewed indicated that their primary concern in making the recommendation was addressing the need for improved treatment regimens that did not rely upon interferon and providing better outcomes compared to the prior regimens.

for Testing, Managing, and Treating Hepatitis C, Disclosure Information (2014), *available at* https://web.archive.org/web/20140428013944/http:/www.hcvguidelines.org/disclosure_information.

Section 4: The Financial Burden of Treating HCV and Resulting Access Restrictions

Investigative staff closely examined how Sovaldi, Harvoni, and other recent therapies for HCV affected three different federal public payer programs—Medicaid, Medicare, and the Bureau of Prisons. These programs have a disproportionate population of the nation's HCV patients and are an important part of the nation's health care system. As noted at various points in this report, Gilead's two drugs have dramatically increased the amount spent on HCV care. These programs combined to spend at least $5.2 billion for Gilead's HCV therapies in calendar year 2014 before rebates—$4.4 billion attributable to Sovaldi and more than $800 million to Harvoni, which only gained FDA approval in mid-October of that year.[447] Through the first six months of the year, Medicare reports having paid $4.4 billion, before rebates, for Gilead's HCV therapies, compared to just $200 million for all other drugs approved to treat the disease. As a result, these public payers, as well as traditional insurance plans, adopted access restrictions to limit the number of patients who could benefit from this new class of HCV therapies. The nature and extent of these restrictions appear to go well beyond what Gilead anticipated in its pricing process.

Medicaid and Prescription Drug Purchasing

Medicaid is a jointly funded state-federal program that provides health insurance to over 72.4 million low-income Americans.[448] In order to receive federal financial participation, states must establish and administer their Medicaid programs within broad federal guidelines under which states have flexibility to determine the type, amount, duration, and scope of services they provide.

States generally provide a comprehensive set of benefits consisting of mandatory benefits such as inpatient and outpatient hospital care and physician services as well as optional services including prescription drugs.[449] While prescription drug coverage, including coverage for HCV treatments, is considered an optional benefit, every state has chosen to cover outpatient prescription drugs for nearly all of their Medicaid enrollees.[450] As a result, due to the unique structure of the Medicaid drug program, state Medicaid programs can be particularly sensitive to the cost of drugs.

The Medicaid Drug Rebate Program was created by the Omnibus Budget Reconciliation Act of 1990 to help offset the cost of certain

---

[447] The pharmaceutical spending data collected from Medicare Part D and state Medicaid programs represent outlays before mandatory (Medicaid) or voluntary/supplemental (Medicaid and Part D) rebates were applied. Federal law limits the disclosure of pricing information in a form that discloses the identity of a specific manufacturer or wholesaler, subject to limited exceptions. See 42 U.S.C. §§ 1395w–102, 1395w–104, 1396r–8.

[448] Department of Health and Human Services, Centers for Medicare & Medicaid Services, *Medicaid & CHIP: August 2015 Monthly Applications, Eligibility Determinations and Enrollment Report* at 2 (2015) [hereinafter HHS, *Medicaid & CHIP Report*], *available at* http://medicaid.gov/medicaid-chip-program-information/program-information/downloads/august-2015-enrollment-report.pdf.

[449] *Benefits,* Medicaid.gov, *available at* http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/medicaid-benefits.html.

[450] *Prescription Drugs,* Medicaid.gov, *available at* http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/prescription-drugs.html.

outpatient dugs.[451] Under the program, drug manufacturers are allowed to enter into a national rebate agreement with the Secretary of the Department of Health and Human Services to offer certain rebates to states' Medicaid programs in exchange for guaranteed state Medicaid coverage of FDA-approved drugs sold by the drug manufactures. The basic Medicaid rebate for brand name drugs is the greater of: (1) the difference between the drug's average manufacturer price (AMP) during the drug's rebate period—typically the previous calendar quarter—and the drug's best price *or* (2) 23.1% of the drug's AMP.[452] Under the Medicaid Drug Rebate Program, drug manufactures would owe an additional rebate on brand name drugs when they raise prices faster than the inflation rate.[453] According to the Centers for Medicare & Medicaid Services (CMS), approximately 600 drug manufactures are currently participating in the Medicaid Drug Rebate Program, including Gilead.[454] In addition to the basic and additional Medicaid drug rebate, state Medicaid programs collaborate through purchasing pools to negotiate supplemental drug rebates with drug manufactures.[455]

Medicaid has faced significant costs for treating individuals infected with HCV. Historically, Medicaid eligibility was limited to certain low-income children, pregnant women, parents of dependent children, the elderly, and individuals with disabilities.[456] However, under the Affordable Care Act of 2010, states were provided with enhanced federal funding to extend coverage to low-income adults—many of whom were previously uninsured.[457] As a result of this policy, enrollment in Medicaid has ballooned by more than 12 million since October 2013 to a total of more than 71 million enrollees today.[458] Medicaid is now the single largest health insurer in the country, covering more individuals than Medicare or any other private insurer.

As a result of the sheer size and complex health needs of the Medicaid population and the program's unique drug rebate program, the impact of Sovaldi and Harvoni on state Medicaid programs has been particularly deep. The impact can be best seen when examining state Medicaid budgets and program coverage policies.

State Medicaid programs typically pay for outpatient drugs in one of two ways—either through a fee-for-service (FFS) payment made directly to the pharmacist, or through a capitated payment made directly to a managed care organization (MCO), which then manages payment to the pharmacist.[459] In both cases, upon enter-

---

[451] Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101–508, § 4401, 104 Stat. 1388.

[452] *Medicaid Drug Rebate Program,* Medicaid.gov, *available at* http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program.html.

[453] *Id.*

[454] *Id.* (see link to Drug Manufacturer Contact Information file).

[455] *See, e.g., NMPI—National Medicaid Polling Initiative,* Provider Synergies, *available at*http://www.providersynergies.com/services/medicaid/default.asp?content=NMPI.

[456] Julia Paradise, Kaiser Family Foundation, The Kaiser Commission on Medicaid and the Uninsured, *Medicaid Moving Forward 2* (2015), *available at* http://kff.org/health-reform/issue-brief/medicaid-moving-forward.

[457] Patient Protection and Affordable Care Act, Pub. L. No. 111–148, 124 Stat. 119 (2010).

[458] HHS, *Medicaid & CHIP Report,* at 2.

[459] Brian Bruen & Katherine Young, Kaiser Family Foundation, The Kaiser Commission on Medicaid and the Uninsured, *Paying for Prescribed Drugs in Medicaid: Current Policy and Upcoming Changes* 1, 3 (2014), *available at* https://kaiserfamilyfoundation.files.wordpress.com/2014/05/8593-paying-for-prescribed-drugs-in-medicaid-current-policy-and-upcoming-changes.pdf.

ing the market, Sovaldi had a demonstrable financial impact described with greater detail in the following pages.

The Outsized Impact of Gilead's HCV Drugs on State Medicaid Drug Spending

The financial impact of Gilead's line of HCV drugs on state Medicaid programs has been dramatic. Shortly after Harvoni was approved by the FDA, the National Association of Medicaid Directors (NAMD) wrote to Congress on October 28, 2014 that "the challenge Sovaldi and other new hepatitis C medications pose for the Medicaid program is the intersection of a high-cost therapy and a potentially large population eligible for therapy."[460]

According to NAMD, during its first year on the market, states were largely unsuccessful in securing supplemental rebates for Sovaldi. In its letter to Congress, NAMD wrote, "states are not well positioned to secure meaningful supplemental rebates for Sovaldi. . . . To date, supplemental rebates states have secured for Sovaldi are minimal, with any further concessions predicted on unrestricted access to the drug."[461] In fact, just five state Medicaid programs reported that they reached supplemental rebate agreements with Gilead for Sovaldi in 2014.[462]

Thus, in order to manage the costs of Sovaldi and Harvoni, which made up the majority of pharmaceutical spending to treat HCV, state Medicaid programs developed access restrictions to control costs in a constrained budget environment,[463] pitting patients seeking therapy against those agencies "weighing complex ethical questions, scientific evidence and public health needs to maximize appropriate access to new treatments."[464] A recent study of HCV patients in four Mid-Atlantic states showed that Medicaid recipients were more likely than those with Medicare or commercial insurance to have their prescriptions for DAAs rejected, or have their treatment delayed.[465]

To better quantify and qualify the financial impacts of these drugs on individual state programs, investigative staff requested quantitative and qualitative data from Medicaid programs in all 50 states and the District of Columbia regarding a series of issues related to HCV infections, pharmaceutical spending, interactions with Gilead, and the financial impact of Sovaldi and Harvoni on state Medicaid spending. State Medicaid programs were asked to provide:

- Total spending (pre-rebate) on Sovaldi and Harvoni in CY2014
- The number of prescriptions filled for Sovaldi and Harvoni during CY2014

---

[460] Appendix D, Ex. 2, Letter from Darin J. Gordon and Thomas J. Betlach, National Association of Medicaid Directors, to Congress (Oct. 28, 2014) at 3.

[461] *Id.*

[462] *See* Appendix A.

[463] *See* Appendix B for a compilation of access restrictions supplied by the Oregon Health & Sciences University.

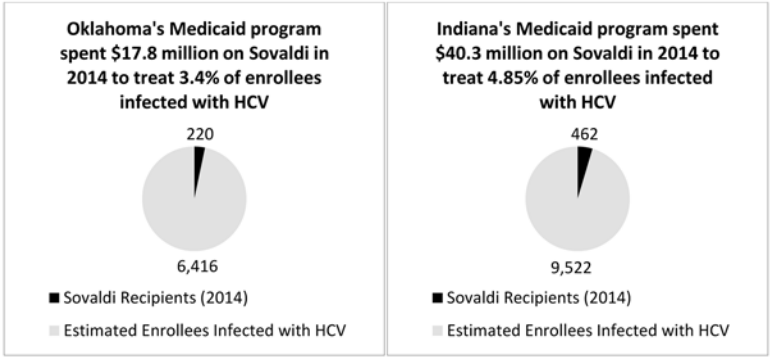
[464] Appendix D, Ex. 2, Letter from Darin J. Gordon and Thomas J. Betlach, National Association of Medicaid Directors, to Congress (Oct. 28, 2014) at 4.

[465] Vincent Lo Re, et al., American Association for the Study of Liver Diseases (AASLD) Abstract, *Incidence and Determinants of Denial of DAA Treatment for Chronic HCV Infection by Insurance Type During the First 6 Months of the Modern HCV Treatment Era,* 62 Hepatology 1382A (2015) *available at* http://www.aasld.org/sites/default/files/TLM-2015-LakeBreaking Abstracts.pdf.

- The number of unique recipients who were dispensed Sovaldi and Harvoni during CY2014
- The top 25 drugs, in terms of aggregate spending, in CY2014
- The rank of Sovaldi and Harvoni in the state's pharmaceutical spending
- The estimated number of enrollees infected with HCV
- The estimated number of enrollees in each state's Medicaid program
- Whether the state signed a supplemental rebate agreement with Gilead in CY2014

All 51 programs responded to the information request, providing valuable data showing how state Medicaid programs were affected by the price of Sovaldi and Harvoni (see Appendix A). State Medicaid programs reported that $1.3 billion was spent on Sovaldi during CY2014, prior to any statutory or supplemental rebates. For this cumulative outlay for Sovaldi in 2014, state agencies reported that just 16,281 enrollees received the drug, constituting less than 2.4% of at least 698,000 Medicaid recipients nationwide believed to carry the disease (map 1 shows the percentage of enrollees who were treated with Sovaldi during CY2014 on a state-by-state basis).[466] Oklahoma and Indiana are examples of states that spent heavily on HCV drugs in 2014 to treat small portions of Medicaid enrollees infected with the disease (see graph).

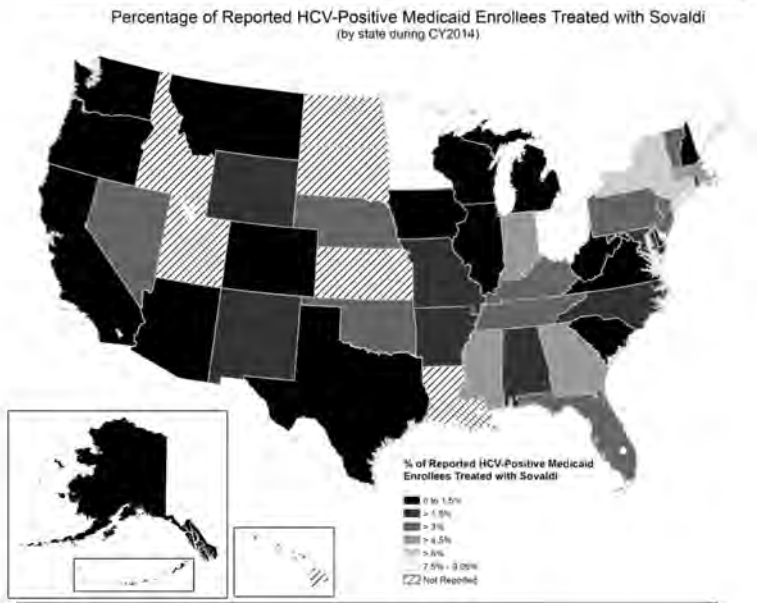
Graph 1 – HCV Spending and Percentage of Medicaid Enrollees treated in Oklahoma and Indiana (CY 2014)



Source: State of Oklahoma, State of Indiana. (Appendix A)

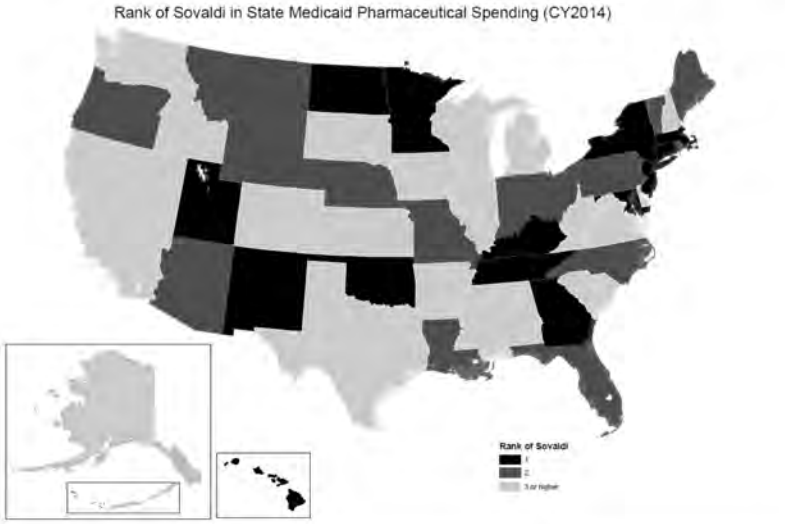
[466] The estimate of 698,000 enrollees was derived from data reported by states to staff. The actual number of Medicaid enrollees infected with HCV is likely significantly higher, because seven states did not provide estimates—Hawaii, Idaho, Louisiana, North Dakota, Ohio, South Dakota, Utah. *See* Appendix A.

Map 1



Source: State Medicaid program data; Appendix A, tables 1 and 2

Map 2



Source: State Medicaid program data; Appendix A, table 2

The data collected by investigative staff show that outlays for Sovaldi ranked it among the top five pharmaceutical spending items for 33 different state Medicaid agencies (see map 2).[467] Fourteen states reported that Sovaldi was the top pharmaceutical cost for their FFS, MCO or combined programs.[468] Fifteen more reported that Sovaldi was the second highest cost.[469] Four more states reported that Sovaldi ranked third, fourth or fifth in their pharmaceutical spending for CY2014.[470]

Researchers at the Brigham and Women's Hospital found that spending on Sovaldi accounted for more than 6.6% of the pharmaceutical program budgets for state Medicaid programs in Connecticut, New York and Massachusetts.[471] Oregon's Medicaid program, which spent $591.2 million in 2014, expected that HCV treatment would make up a significant portion of its future drug spending:

> Based on historical utilization and assumptions regarding provider capacity, we concluded approximately 500 patients would be treated annually at a projected cost of $51 million per year for the first six years.[472]

Investigative staff received responses from 48 state programs to the question regarding supplemental rebates, and only five reported reaching a supplemental rebate agreement with Gilead during 2014.[473] This illustrates that Gilead's supplemental rebate terms for Sovaldi were not accepted by the vast majority of state Medicaid programs. The states that reached agreement with Gilead estimated having roughly 15,000 enrollees infected with HCV, less than 2.2% of Medicaid enrollees believed to be infected with the disease.[474] As referenced above and discussed in more detail below, in the absence of acceptable rebate offers, many states reacted to the high cost of Sovaldi and Harvoni by restricting access to the sickest patients and requiring that patients be under the care of hepatologists or other specialists prior to receiving the drugs.

The high cost of Sovaldi and Harvoni has exerted a strain on state Medicaid budgets, and is predicted to continue to do so. For example:

- Washington's Medicaid director wrote that "if [the Health Care Authority] were to pay for hepatitis C treatment for all Med-

---

[467] *See* Appendix A. Gilead valued this type of spending rank data. In April 2014, the company requested state-by-state ranks for Sovaldi from Magellan Medicaid Administration, a contractor that negotiated rebates on behalf of 25 state agencies. When a Magellan official questioned the relevance of such data to the company, William Dozier, a senior manager for national accounts, wrote that the data were "relevant to the Gilead.pricing committee [sic] because it shows the impact current pricing has on Medicaid." Appendix D, Ex. 3, Email from Eric Kimelblatt to Christopher J. Andrews and William Dozier, "Re: Sovaldi Data" (Apr. 15, 2014).

[468] Connecticut, Georgia, Hawaii, Kentucky, Maryland, Massachusetts, Minnesota, New Jersey, New Mexico, New York, North Dakota, Oklahoma, Tennessee, Utah. *See* Appendix A.

[469] Arizona, Florida, Indiana, Louisiana, Maine, Missouri, Montana, Nevada, North Carolina, Ohio, Oregon, Pennsylvania, Rhode Island, Vermont, Wyoming. *See* Appendix A.

[470] Colorado, Illinois, Kansas, South Dakota. *See* Appendix A.

[471] Joshua M. Liao and Michael A. Fischer, New England Journal of Medicine, Early Patterns of Sofosbuvir Utilization by State Medicaid Programs, September 24, 2015, (figure 1) *available at* http://www.nejm.org/doi/full/10.1056/NEJMc1506108.

[472] Appendix D, Ex. 4, Letter from Lynne Saxton to the Honorable Ron Wyden and the Honorable Chuck Grassley, (Oct. 19, 2015), at p. 2.

[473] Louisiana, South Dakota, and Wisconsin did not provide a response to this question. Georgia, Maine, Minnesota, Vermont, and Wyoming agreed to supplemental rebate terms. *See* Appendix A.

[474] *See* Appendix A.

icaid clients infected with hepatitis C, the cost would be three times the current total pharmacy budget [of roughly $1 billion].” Taking into account rebates with Gilead, the state anticipates spending more than $242 million in FY2016 alone to treat eligible Medicaid patients.[475]

- Georgia reported to investigative staff that $30.4 million was spent to treat 329 patients with Sovaldi during 2014.[476] The patients treated with Sovaldi represented less than 6% of the estimated 6,000 enrollees who have been diagnosed with HCV.[477] In an August presentation to the state legislation, the Georgia Department of Community Health reported that $40.8 million had been spent on Harvoni through the first six months of 2015 and projected that $80 million would be spent on hepatitis C drugs during FY2016 with an expectation that the budget impact would continue through FY2017.[478]
- Pennsylvania estimated that “the cost could range from $2.87 billion to $3.05 billion paid to the dispensing providers, or $1.58 billion to $1.73 billion after the federal drug rebates are collected.” [479] There are an estimated 31,000 enrollees in Pennsylvania’s Medicaid program diagnosed with HCV.[480]
- New York’s MCOs and FFS alone spent more than $363 million on Sovaldi.[481]

In addition, several states wrote to Senators Grassley and Wyden, or otherwise communicated to investigative staff, that they were compelled to undertake unusual financial arrangements with MCOs, seek targeted budgetary authority for the management of costs related to managing HCV treatment, and, in at least one case, enact new legislation. For example:

- The Iowa Department of Human Services “has incorporated the cost of specialty drugs (including HCV medications) in its current and future Medicaid budget requests.” [482]
- Arizona “added an additional $30 million in funding to the capitation rates [for managed care organizations] to address the additional costs of Sovaldi and Harvoni, for total funding of $45 million.” [483]
- Florida established “kick payments” for HCV drugs in mid-2014 after managed care plans expressed concern that costs for treating the disease would exceed what had been expected at the time capitation rates were set for the year.[484]

---

[475] Appendix D, Ex. 5, Letter from MaryAnne Lindeblad to the Honorable Ron Wyden and the Honorable Chuck Grassley (Sept. 23, 2015), at 2.

[476] Georgia reported spending $7.5 million on Harvoni and $6.2 million on Olysio in 2014. *See* Appendix A.

[477] *See* Appendix A.

[478] Georgia Department of Community Health, *Hepatitis C Overview, Medicaid and SHBP* (Aug. 11, 2015), p. 7–9, *available at* http://dch.georgia.gov/sites/dch.georgia.gov/files/Hepatitis%20C%20presentation.pdf.

[479] Appendix D, Ex. 6, Letter from Theodore Dallas to the Honorable Ronald L. Wyden and the Honorable Charles E. Grassley, (Oct. 2, 2015) at 2.

[480] *See* Appendix A.

[481] *See* Appendix A.

[482] Appendix D, Ex. 7, Letter from Charles M. Palmer to Peter Gartrell, (Feb. 9, 2015), at 1.

[483] Appendix D, Ex. 8, Letter from Thomas J. Betlach to Peter Gartrell (July 17, 2015), at 2.

[484] Appendix D, Ex. 9, Letter from Justin M. Senior to the Honorable Orrin G. Hatch and the Honorable Ron Wyden (Oct. 19, 2015), at 2. “A kick payment is a rate mechanism to manage the uncertainty of the number of people who will need high cost Hepatitis C treatment. A kick

Continued

- Kentucky reported in a letter to the senators that the state's "spending related to HCV has increased to about 7 percent of its total Medicaid budget, providing new hepatitis C drugs to a relatively small number of patients."[485]

Texas sent a letter to the Senators expressing its concern with respect to HCV drug prices:

> The state's experience with second generation HCV drugs prompted the 84th Texas Legislature to pass a rider on the state's appropriations act in June 2015. The rider requires [The Health and Human Services Commission] to estimate the potential cost of all new outpatient drug products prior to covering the products. All products with an estimated annual cost of greater than $500,000 must be submitted to the Legislative Budget Board for review. This requirement may increase the amount of time between approval of a new treatment by the FDA and provision of that treatment to Medicaid clients.[486]

The letter went on to say:

> The rebate revenue from manufacturers lessens the impact of second generation HCV drugs on the state's Medicaid budget. However, given the exorbitant price of these medications, the rebates are insufficient and these drugs jeopardize the solvency of the state's Medicaid and public health programs. Manufacturers lowering the price at which these drugs are sold to providers would be more beneficial than rebates to the Texas Medicaid program and would also benefit its state-funded health program.[487]

In a letter to Senators Wyden and Grassley, Oregon's Medicaid director stated:

> What we face is not a drug cost problem; it is a drug price problem. State Medicaid programs are limited in our ability to control pharmacy benefit expenditure, particularly as federal law requires us to provide a pathway to coverage for all FDA-approved drugs, no matter how minimal the likely benefit per dollar spent. While federally mandated rebates help, they provide limited relief.[488]

Kentucky is preparing to begin HCV screening tests at county health departments, partly due to the rising use of injectable drugs in the state, which has contributed to the spread of the disease:

> Given the current cost of the newer treatment options and to remain fiscally responsible we will be forced to make

---

payment allows the Medicaid program to pay the health plans based on expected costs for each enrollee who is prescribed the drugs for treatment." *Id.*

[485] Appendix D, Ex. 10, Letter from Samantha McKinley to the Honorable Charles E. Grassley and the Honorable Ron Wyden (Oct. 21, 2015).

[486] Appendix D, Ex. 11, Letter from Andy Vasquez to the Honorable Ron Wyden and the Honorable Charles E. Grassley (Aug. 14, 2015), at 3.

[487] *Id.* at 4.

[488] Appendix D, Ex. 4, Letter from Lynne Saxton to the Honorable Ron Wyden and the Honorable Chuck Grassley, (Oct. 19, 2015), at 2.

difficult decisions regarding who does and does not get access to treatment medications upon diagnosis.[489]

One of the tools that Kentucky, and many other states, has used to prioritize treatment and manage costs is establishing prior authorization criteria.[490]

Adoption of Prior Authorizations in Response to HCV Drug Pricing by State Medicaid Programs

In light of Sovaldi's high price and an inability to negotiate suitable supplemental rebate terms that would moderate program costs, more than half the nation's state Medicaid programs implemented prior authorization (PA) criteria, which restrict access in order to the drug to control costs.

With the assistance of the Oregon Health & Sciences University's Center for Evidenced-based Policy ("OHSU"), investigative staff examined how the PAs were structured for Sovaldi, and later, Harvoni and Viekira Pak.[491] OHSU conducted an initial survey of publicly available data on state Medicaid programs' approval of Sovaldi between May 30, 2014 and September 24, 2014.[492] Within this period—roughly six and nine months after introduction of Sovaldi, respectively—OHSU found:

- 27 state Medicaid programs had adopted PA criteria for the drug;
- 24 state Medicaid programs of those that adopted PA criteria adopted PAs based on disease severity as measured by Metavir fibrosis scores;
- 19 of the programs that managed the disease on the basis of fibrosis scores allowed use of the drug for only the most advanced stages of disease with fibrosis scores of F3 or F4; and
- Other PA criteria included prescription by or consultation with a specialist in liver disease, alcohol and drug use screening, interferon-free eligibility, achievement of early viral response to initial treatment, no prior treatment with sofosbuvir, and once-in-a-lifetime access.[493]

After OHSU's review, some states' programs that researchers listed as not having PAs for Sovaldi or Harvoni subsequently implemented restrictions. For example, Nebraska adopted PA criteria for Sovaldi that limited prescriptions of the drug to patients with a Metavir score of F3 or F4.[494] Likewise, following FDA approval of Harvoni and Viekira Pak, Texas set PA criteria requiring patients have a F3 or F4 fibrosis score, in addition to other restrictions such as treatment by a specialist and demonstrating sobriety.[495]

---

[489] Appendix D, Ex. 10, Letter from Samantha McKinley to the Honorable Charles E. Grassley and the Honorable Ron Wyden, (Oct. 21, 2015), at 2.
[490] *Id.*
[491] *See* Appendix B.
[492] *See* Appendix B, tables 1(a) and 1(b).
[493] *See* Appendix B.
[494] *Nucleotide Analog NS5B Polymerase Inhibitor (Sovaldi© -sofosbuvir) Prior Authorization Criteria, available at* https://nebraska.fhsc.com/Downloads/NEcriteria_Sovaldi-201409.pdf.
[495] Texas Medicaid/CHIP Vendor Drug Program, *Medicaid Fee-For-Service Prior Authorization Criteria and Policy (Antiviral Agents for Hepatitis C Virus)* (Mar. 2015), *available at* https://paxpress.txpa.hidinc.com/hepc_initial_request.pdf.

OHSU also performed a survey of publicly available state Medicaid program restrictions on the use of Harvoni, which was introduced on October 10, 2014, shortly after the Sovaldi survey was completed.[496] This second survey also included the use of Viekira Pak, the most direct, all-oral, competing regimen for genotype 1. The OHSU survey of Harvoni/Viekira Pak restrictions was conducted between April 30, 2015 and May 5, 2015, roughly six-to-nine months after introduction. The OHSU survey found:

- 33 state Medicaid programs had adopted criteria governing the use of these two drugs;
- 25 of those that adopted PA criteria also adopted PAs based on disease severity;
- 19 had requirements that patients have fibrosis scores of F3 or F4; and
- Other criteria included alcohol sobriety and drug use screening, prescription or consultation by a specialist, once-in-a-lifetime access, viral response to initial treatment, and informed consent.[497]

Texas was one of 13 state Medicaid programs reported in the survey to have placed Viekira Pak on its preferred drug list (PDL), meaning that it was essentially the default medication unless patients could not tolerate the drug or it was not indicated for use with the patient's HCV genotype. The state's pharmaceutical and therapeutics committee chose Viekira Pak for the PDL "based on the understanding that both Harvoni and Viekira Pak were effective treatments, but because AbbVie submitted more aggressive rebates to HHSC's [Health and Human Services Commission] PDL vendor, Viekira Pak was more cost effective."[498] Even with the discounts, the state expects spending on HCV therapies will total $194 million through FY2018.[499] The program estimates that 17,325 Medicaid enrollees are infected with the virus.[500]

The Medicare Prescription Drug ("Part D") Benefit: An Overview

Prior to the 2003 enactment of the Medicare Modernization Act, the Medicare program lacked a prescription drug benefit. As a result, one-third of all Medicare enrollees lacked prescription drug coverage with many of these beneficiaries deciding to forgo some of their prescribed medications due to high cost.[501] In the year the law was passed, a quarter of Medicare seniors did not fill at least one prescription due to high costs, and a third spent $100 or more per month on drugs.

The three groups of Medicare enrollees most vulnerable to out-of-pocket drug costs were those without prescription coverage, low-income seniors, and the complex chronically ill (those with three or

[496] Appendix B, tables 2(a) and 2(b).
[497] Appendix B, tables 2(a) and 2(b).
[498] Appendix D, Ex. 11, Letter from Andy Vasquez to the Honorable Ron Wyden & the Honorable Charles E. Grassley (Aug. 14, 2015), at 2.
[499] *See id.* at 3.
[500] Appendix A, table 1.
[501] Sebastian Schneeweiss et al., *The Effect of Medicare Part D Coverage on Drug Use and Cost Sharing Among Seniors Without Prior Drug Benefits,* 28 Health Affairs w305, w305–w316 (2009), *available at* http://content.healthaffairs.org/content/28/2/w305.full.

more complex conditions). Seniors with access to prescription coverage typically received it from employers, through private, individual purchase of Medigap, Medicare Part C (then Medicare+ Choice) plans, or through Medicaid, with the former method prevalent among higher-income seniors, and the latter two more common among the low-income.[502] Since the creation of Part D, the program has only grown. As of 2014, 37 million Medicare beneficiaries received drug coverage through Part D, roughly 69% of the Medicare program's beneficiaries.[503]

Part D relies on private insurers, known as Prescription Drug Plans (PDPs), to deliver the prescription drug benefit to beneficiaries.[504] Medicare Advantage plans can also offer a prescription drug benefit. Medicare beneficiaries choose from a range of PDPs offering benefits in their geographic region, and pay a premium subsidized by Medicare. Medicare covers about 75% of the cost of the drug benefit and the remainder is paid by the beneficiary. However, low-income beneficiaries receive a more substantial subsidy. In each of the 34 regions, PDPs compete based on premiums, the availability of prescription drugs, pharmacy networks, and quality.[505]

The amount Medicare pays a PDP is directly related to bids submitted by each plan to the CMS. A plan's bid is an estimate of its costs to provide the drug benefit to enrollees in the next year.[506] To determine payment to plans, CMS calculates a national average bid, and each plan then receives a payment equal to that national average. If an individual plan's bid is higher than the national average, the difference is made up by an increase in the size of that plan's premium paid by enrollees. As a result of this payment structure, large increases in projected drug costs not only affects a plan's ability to offer affordable drug coverage, but also affects all Part D enrollees and the overall spending by Medicare.

The plans themselves are also unique. Medicare sets a standard drug benefit design but allows for individual plans to vary the structure so long as the plan meets certain actuarial equivalence tests. Low-income beneficiaries also receive even greater cost-sharing protection than provided by the standard benefit. In 2015, the standard benefit includes a $320 deductible; coverage for 75% of drug expenses up to a benefit level of $2,960; and a catastrophic coverage for costs above a total drug spending threshold of $7,061.76.[507] Above the latter level, a beneficiary is required to pay 5% of the costs of drugs, with 95% borne by the Medicare program.[508] As a result, the higher an enrollee's annual drug spend, the greater the proportion of their costs will be paid for by Medi-

---

[502] Dana Gelb Safran, *Prescription Drug Coverage and Seniors: Findings From a 2003 National Survey,* Health Affairs W5–152, W5–160 (Apr. 2005), *available at* http://content.healthaffairs.org/content/early/2005/04/19/hlthaff.w5.152.short.

[503] Medpac, *Status Report on Part D,* Report to the Congress: Medicare Payment Policy, at 347 (Mar. 2015), *available at* http://www.medpac.gov/documents/reports/chapter-14-status-report-on-part-d-%28march-2015-report%29.pdf?sfvrsn=0.

[504] Some Medicare Advantage plans also provide drug coverage in addition medical benefits.

[505] Medpac, *Part D Payment System* (2014), at 2, *available at* http://www.medpac.gov/documents/payment-basics/part-d-payment-system-14.pdf?sfvrsn=0 [hereinafter Medpac, Part D Payment System].

[506] The bid is subsequently adjusted by a number of factors including the enrollees' health statuses.

[507] Medpac, *Part D Payment System,* at 1–2.

[508] *Id.*

care. This arrangement is of particular importance in the context of increased utilization of high-cost drugs and their impact on Medicare spending.

The coverage between the $2,960 and $7,061.76 thresholds is known as the Part D coverage gap or "donut hole." Prior to the enactment of the ACA, Part D offered no drug coverage between these two thresholds; the ACA phases out the coverage gap over time. In 2015, 55% of the cost of brand name drugs purchased in the coverage gap will be paid for on behalf of beneficiaries (50% through discounts provided by manufacturers and 5% through a subsidy provided by Medicare).[509]

Unlike FFS Medicare for hospitals and physicians, Part D prices for health services are not set administratively, but rather are set through negotiations between PDPs (or often PBMs on behalf of PDPs) and drug manufacturers. The government is prohibited by law to interfere in these negotiations.[510] The outcome of these negotiations and the size of price discounts PDPs receive from manufacturers are the result of multiple factors including the bargaining power of the PDPs (or PBMs), the level of competition among drug manufacturers, and alternative therapies available to patients.

Part D relies on private negotiations between Part D prescription drug plans and drug manufacturers to establish the price of drugs offered to Medicare beneficiaries. Many factors influence the outcome of these negotiations and the ultimate price of drugs that is borne by both Medicare and Part D enrollees. Two particularly important factors affecting the size of a rebate are: (1) the presence of similar drugs in the market, and (2) the Part D plan's ability to steer enrollees toward one manufacturer's drug over another.

In the instance where only one drug is on the market, manufacturers have little incentive to offer price discounts or rebates if the manufacturer is confident the plan will include the drug on its formulary and physicians will prescribe the drug to their patients. This dynamic changes significantly if a competitor enters the market with a drug in the same therapeutic class. In that case, both manufacturers have an incentive to offer price discounts or rebates in the hope that a plan places the manufacturer's drug on the plan's formulary. The Congressional Budget Office (CBO) has found, "rebates tend to be higher in therapeutic classes containing more drugs that are close substitutes." [511]

Manufacturers also provide price discounts or rebates if a plan adjusts its benefit design to increase the likelihood patients will be prescribed its drug over a competitor's drugs. The CBO found that "[t]he ability to steer beneficiaries toward preferred drugs gives Part D plan sponsors leverage when negotiating drug prices." [512] Manufacturers "tend to offer the largest rebates to plan sponsors that actively steer a large share of beneficiaries to their drugs." [513] Without multiple, similar drugs on the market, the needed leverage to extract price discounts or rebates from drug manufacturers does

---

[509] *Id.*

[510] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108–173, 117 Stat. 2066 (42 U.S.C. § 1395w–111(i)).

[511] Congressional Budget Office, *Competition and the Cost of Medicare's Prescription Drug Problem* (2014), at 28, *available at* https://www.cbo.gov/sites/default/files/45552-PartD.pdf.

[512] *Id.* at 27.

[513] *Id.*

not exist and as a result, Medicare and Part D enrollees will typically pay for higher drug costs.

Sovaldi, Harvoni, and the Impact on Medicare

Medicare Part D has been lauded as a successful addition to the Medicare benefit. However, recent spending growth and future projections of Part D spending show costs increasing considerably. The 2015 Medicare Trustees report states that Part D spending growth from 2013 to 2014 was 12.1%, compared to 6.5% over the previous eight years.[514] According to the CBO, Part D spending growth will far outpace traditional Medicare fee-for-service spending growth over the next ten years. CBO notes that Parts A and B spending will increase by 89% between 2014 and 2025. Part D will see spending growth over the same time period of 168%.[515]

Increased spending growth leads to higher premiums for Part D enrollees and additional fiscal pressure on the federal budget. Because each plan's bid contains the plan's cost of providing drug therapies to expected enrollees and these bids are proprietary, it is difficult to assess an individual drug's impact on plans' bids. However, the Medicare Trustees report specifically notes a projected acceleration in per capita benefits for 2015 because "additional plan spending for several high-cost drugs to treat hepatitis C was not factored into plan bids for the 2014 plan year, resulting in significant reconciliation payments from Part D to plans in 2015."[516]

Data analyzed by investigative staff shows that in the 18 months since Gilead's HCV drugs gained FDA approval, Medicare spent nearly $8.2 billion on pre-rebate spending on Sovaldi and Harvoni. (See Graph 2 below, and Appendix C for corresponding tables). Part D's spending before rebates on Sovaldi in 2014 was greater than any individual drug paid for by Medicare's Part D or Part B programs during 2013 and the same can be said for pre-rebate spending Harvoni through the first six months of 2015.[517]

---

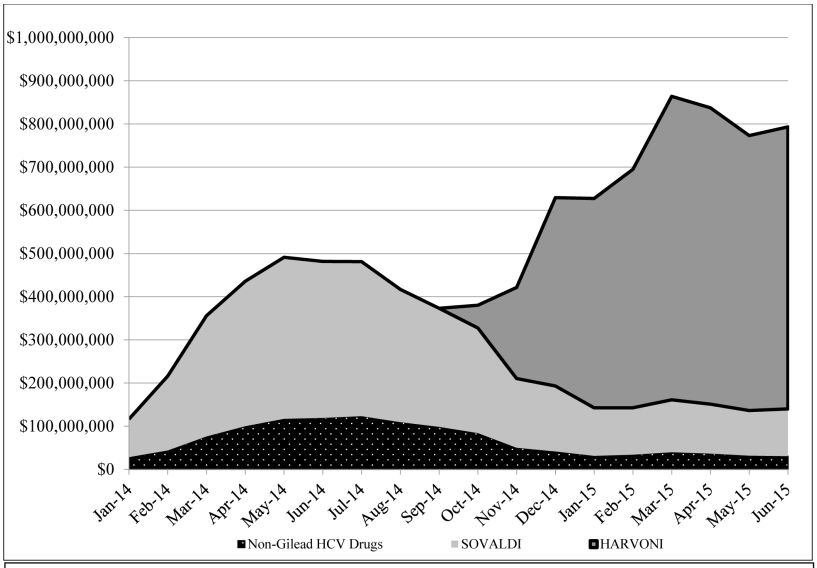
[514] The Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, *2015 Annual Report,* at 106, *available at* http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2015.pdf.

[515] Congressional Budget Office, *March 2015 Medicare Baseline, by Fiscal Year,* (Mar. 9, 2015), *available at* https://www.cbo.gov/sites/default/files/cbofiles/attachments/44205-2015-03-Medicare.pdf.

[516] *Id.*

[517] Nexium, which is prescribed for treatment of heartburn, was the top drug by total expenditures (before rebates) for Part D at $2.5 billion; Rituximab, which is used to treat cancer and rheumatoid arthritis, was the top drug by total expenditures for Part B at $1.5 billion. CMS, *Medicare Provider Utilization and Payment Data: Part D Prescriber,* Part D Prescriber National Summary table, CY 2013, *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Part-D-Prescriber.html; MedPac, *Report to Congress: Medicare and the Healthcare Delivery System* (June 2015), at 66 (Table 3–1), *available at* http://www.medpac.gov/documents/reports/chapter-3-part-b-drug-payment-policy-issues-%28june-2015-report%29.pdf?sfvrsn=0.

Graph 2—Monthly Part D Spending on Hepatitis C Drugs (Jan. 2014–June 2015)



Source: CMS
Notes: Harvoni was approved by the FDA on October 10, 2014; "Other" includes Olysio, Viekira Pak, Copegus, Pegasys, Pegasys Proclick, Moderiba, Intron-A w Diluent, Victrelis, Intron-A, Rebetol, Rebetron, Peg-Intron, Sylatron, Peg-Intron Redipen, Ribavirin, Virazole, Infergen, Ribatab, Ribapak, Ribasphere, Incivek, Ribasphere, and Ribapak

In 2014, Medicare spent $4.8 billion on HCV drugs prior to rebates, $3.1 billion of which was spent on Sovaldi, and nearly $700 million more on Harvoni, which was on the market for roughly 12 weeks after being approved in October by the FDA.[518] Medicare's spending on HCV drugs through the first six months of 2015 indicates that the aggregate cost of treating the disease is likely to grow. Medicare's pre-rebate spending for HCV drugs in 2015 had already reached $4.6 billion by the end of June, more than 95% of which was attributable to Gilead drugs ($3.7 billion for Harvoni; $669 million for Sovaldi).[519]

In the 18 months that Gilead's drugs have been on the market, Medicare's monthly spending on HCV treatments increased more than six-fold from $116.4 million in January 2014 (Sovaldi, 76%, Olysio, 9%, Other HCV drugs, 15%) to $793.2 million in June 2015 (Harvoni, 82%; Sovaldi, 14%; Other HCV drugs, 4%).[520] Medicare's average pre-rebate monthly spending on HCV drugs grew to $765 million during the first six months of 2015, more than double the average monthly spend of $349.5 million.[521]

By way of comparison, Medicare's pre-rebate spending on HCV drugs for calendar year 2013 was $396 million, of which $238 mil-

[518] *See* Appendix C.
[519] *See* Appendix C.
[520] *Id.*
[521] *Id.*

lion was spent on DAAs (Incivek, Olysio, Sovaldi, Victrelis) according to CMS data analyzed by investigative staff.[522]

Sovaldi and Harvoni's Effect on the Federal Prison System

The Bureau of Prisons (BOP) is responsible for delivering medically necessary health care to its inmates in accordance with proven standards of care.[523] As of November 5, 2015, the BOP reported that 9,216 of the system's 198,953 inmates have been diagnosed with HCV.[524] The prevalence of HCV infection in prison inmates is substantially higher than that of the general U.S. population, in part due to the prevalence of individuals who have used injectable drugs.[525]

In fiscal year 2014, the year Sovaldi became available to treat prisoners infected with HCV, the BOP's spending on HCV drugs increased 14%, even though the number of patients treated decreased 52%. By comparison, in fiscal year 2012, before the Gilead pharmaceuticals had been introduced as a viable treatment option, the BOP spent $4.4 million on treatment of 369 HCV cases (see table 4 below). In fiscal year 2014, after the introduction of Sovaldi, the BOP spent $5.9 million on the treatment of only 183 HCV inmates. Moreover, in fiscal year 2015 YTD with the use of both Sovaldi and Harvoni as HCV treatment, the BOP has spent nearly $13.7 million to treat just 222 HCV-diagnosed inmates. In fiscal year 2014, Gilead's drugs accounted for 46% of the BOP's HCV spending; by fiscal year 2015, Gilead's drugs accounted for 91% (see table 5 and graph 3 below).

Table 4—Bureau of Prisons Spending on HCV Medications

Fiscal Year	HCV Medication Purchases	Patients Treated
2012	$4,378,238	369
2013	$4,168,807	381
2014	$5,917,436	183
2015	$13,665,112	222

Source: *Federal Bureau of Prisons*

[522] *Id.*
[523] U.S. Department of Justice, Office of the Inspector General, *The Federal Bureau of Prison's Efforts to Manage Inmate Health Care, Audit Report 08–08* (Feb. 2008), *available at* https://oig.justice.gov/reports/BOP/a0808/final.pdf.
[524] Data provided by Federal Bureau of Prisons (Nov. 12, 2015).
[525] Eric Chak et al., *Hepatitis C Virus Infection in USA: An Estimate of True Prevalence,* 31 Liver Int'l 1090, 1090–1101 (Sept. 2011), *available at* http://www.ncbi.nlm.nih.gov/pubmed/21745274; Centers for Disease Control and Prevention, *Prevention and Control of Infections with Hepatitis Viruses in Correctional Settings* (Jan. 2003), *available at,* http://www.cdc.gov/mmwr/PDF/rr/rr5201.pdf.

Table 5—Annual Spending by Federal Bureau of Prisons on HCV Drugs (by brand name)

Drug	FY 2012	FY 2013	FY 2014	FY 2015
Harvoni	$0	$0	$0	$6,885,214
Sovaldi	$0	$0	$2,700,783	$5,556,731
Olysio	$0	$0	$166,802	$778,636
Pegylated Interferon	$1,803,072	$483,808	$990,854	$258,574
Viekira Pak	$0	$0	$0	$92,622
Ribavirin	$384,057	$310,715	$191,671	$71,049
Daklinza	$0	$0	$0	$14,399
Victrelis	$532,772	$2,115,613	$1,100,593	$7,888
Incivek	$1,658,337	$1,258,671	$766,733	$0
Total	**$4,378,238**	**$4,168,807**	**$5,917,436**	**$13,665,112**

Source: *Federal Bureau of Prisons*

Overall system medical costs have been increasing. According to data provided by the BOP, the BOP's total medical spending in fiscal year 2013 was $1.062 billion, of which $82.3 million was for pharmaceuticals; in 2014, total medical spending was $1.097 billion, of which pharmaceutical spending comprised $96.1 million; and in 2015, total medical spending was $1.147 billion, of which pharmaceutical spending was $108.4 million.

To most effectively deal with the rising cost of HCV treatment, the BOP's Health Services Division (HSD) issued Clinical Practice Guidelines (CPGs) on the Evaluation and Management of Chronic Hepatitis C Virus Infection.[526] Based on perceived risk for complications or progression of the disease, these guidelines prioritize inmates into four levels of treatment. According to a 2015 BOP memorandum, inmates with the highest priority (priority 1) have the most advanced HCV with rapidly progressing liver disease including:

- Cirrhosis (end-stage liver disease);
- Liver transplant candidates or recipients;
- Patients with liver cancer or comorbid conditions associated with HCV;
- Patients being cared for with immunosuppressant medications; and
- Prisoners who were receiving treatment when they entered the system.[527]

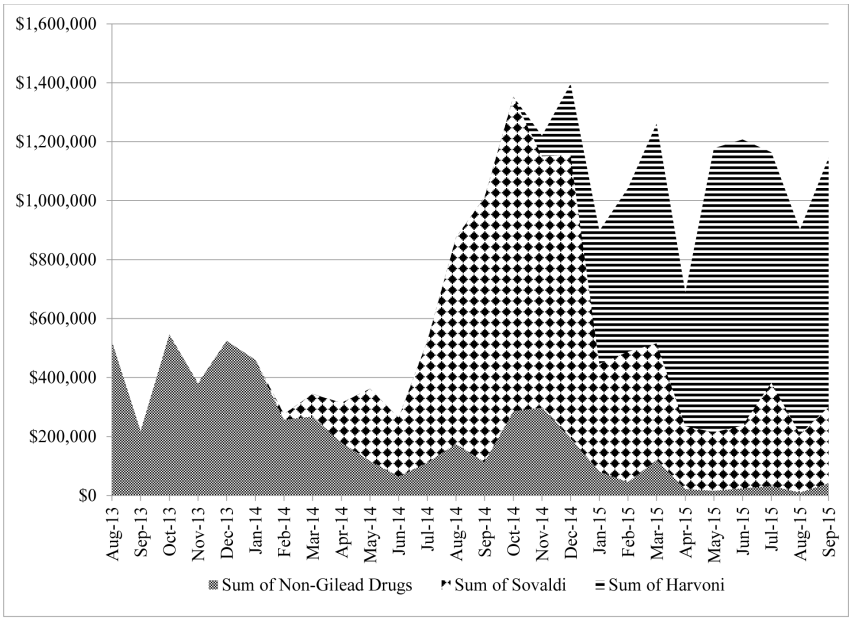
Several agencies, including the BOP, are required to maintain a Department of Veterans Affairs (VA) Schedule contract as a condition of receiving payment. The Veterans Health Care Act of 1992[528] authorizes the VA to negotiate drug prices on behalf of many government agencies, including the BOP. The VA's National

[526] Federal Bureau of Prisons, *Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection* (July 2015), *available at* https://www.bop.gov/resources/pdfs/hepatitis_c.pdf.
[527] *Id.* at 7.
[528] 38 U.S.C. § 8126.

Acquisition Center negotiates and establishes Federal Supply Schedule (FSS) prices for the Department of Defense, VA, the Public Health Service, and the U.S. Coast Guard (known as the "Big 4") receiving at least a 24% discount from the weighted average price of a single form and dosage unit paid by wholesalers to a manufacturer. This price is known as the Federal Ceiling Price (FCP).

Many of the FSS contracts are renegotiated on a five-year period, allowing for contractual modifications as new drugs or generics enter the market, with all covered drug pricing to be renegotiated at the end of every calendar year. If the BOP desires, it can enter into discussions with manufacturers for additional discounts, called Temporary Price Reductions (TPR), based on market share or access, but granting of a TPR to an agency like the BOP is completely discretionary by the manufacturer. The BOP is therefore rarely involved in one-on-one negotiations with individual companies, and has relatively little control over the prices it receives for pharmaceutical products.[529]

Graph 3—Monthly Hepatitis C Drug Spending by Federal Bureau of Prisons (Aug. 2013–Sept. 2015)



Source: Federal Bureau of Prisons
Note: "Non-Gilead HCV Drugs" include Daklinza, Olysio, Incivek, Victrelis, Pegylated-Interferon, and Ribavirin

[529] Telephone interview of BOP staff (Aug. 27, 2015).

Access Restrictions by Non-Public Payers

The OHSU survey conducted between May 30, 2014 and September 24, 2014 included several non-state payers to compare PA restrictions with state Medicaid programs.[530] OHSU found that non-state payers adopted similar PA restrictions. Publicly available criteria for Sovaldi used by Aetna, CIGNA, Regence BlueCross BlueShield, and Anthem BlueCross BlueShield were reported in the survey.[531] All PA restrictions for non-state payers included some level of disease severity, with the two BlueCross Blue Shield plans requiring F3 or F4 scores.[532] Aetna required early viral response to initial treatment. Several required alcohol sobriety and drug use screening and patient treatment support and management programs. All required determination of interferon ineligibility.[533] In communications with investigative staff separate from the OHSU survey, state program officials, as well as other payers, indicated that such restrictions were overwhelmingly based on concerns related to the cost impacts of sofosbuvir-based treatment on their programs.[534]

As described earlier, in order to help patients with private insurance offset the cost of co-pays and other coverage assistance, Gilead budgeted funds for its patient assistance programs. Through the first week of July 2014, Gilead reported providing co-pay coupons, worth an average of $919, to 18,618 unique patients.[535] The money was used to reduce co-payments, which means that patients had a lower cost burden, but does not offset the amount of money that insurers end up paying for the drug.[536] Gilead reported providing free product worth $225 million through the PAP to 3,568 unique patients (an average of $62,709 per patient), or roughly 5.4% of patients treated with Sovaldi up to that point.[537] The company said it did not have access to foundation assistance data, nor did the company disclose the names of the foundations or the amount they were provided. All of the costs related to operating the PAP, including manufacturing costs of the free product provided through it, copay coupons, and a patient support program called MySupportPath, are accounted for as operating expenses (sales and marketing operational expenses). The copay coupons offset Gilead's product revenue.[538] The company had already anticipated by late 2013 that the PAP program should be monitored; in the context of Gilead's approach to AIDS Drug Assistance Programs, Young wrote to Meyers, Stout, and Banks, "Let's monitor PAP very carefully. I do worry that people might attempt to stretch applications for PAP. We might see some strange behaviors we need to address early."[539]

---

[530] *See* Appendix B, Table 1b.
[531] *Id.*
[532] *Id.*
[533] *Id.* At the time of the survey, no publicly available criteria were found for United Health Care, another major payer.
[534] *See* Appendix D.
[535] Appendix F, Gilead Sciences, Inc., Response to Chairman Wyden/Senator Grassley letter dated July 11, 2014, narrative answer to question 20 (Sept. 9, 2014).
[536] *Id.*
[537] *Id.*
[538] *Id.*
[539] Appendix E, Ex. 40, Email from Kevin Young to Jim Meyers, Coy Stout, Re: ADAP and Sofosbuvir (Nov. 19, 2013), GS–0020802.

Gilead announced on July 1, 2015 that it would exclude some insured patients from the PAP program. Advocates, including the AIDS Healthcare Foundation, viewed Gilead's denial of patient access to HCV treatment through the PAP program as a "bargaining strategy" or "punitive measure against health insurers," and ultimately an attempt to force payers into further opening access to Gilead's HCV drugs.[540] In a letter addressed to "Community Partner" from Gilead's Coy Stout, vice president, managed markets, the company detailed its changes:

> [P]atients who are insured and who do not meet their payer's coverage criteria will no longer be eligible for support via Gilead's Patient Assistance Program. Patients who fall within the category of "Insured and Did Not Meet Payer Criteria" are patients whose insurance providers limit access to Sovaldi/Harvoni based on, but not limited to, the following:
>
> - Fibrosis score restrictions
> - Preferring or exclusively covering another product on formulary (i.e., Viekira Pak preferred)
> - Limiting coverage to a maximum treatment duration or denying subsequent treatment after a patient has failed therapy
> - Step-therapy requirements
> - Clinical criteria (e.g., psychiatric requirements, drug and alcohol testing)
>
> It is important to note that a very small number of patients fall into this category. Support Path experts will continue to treat each patient case individually and consider a number of variables when assessing patients for our free drug program.

The company justified the changes as followed:

> In the interest of facilitating patient access in the period immediately following the launch of Sovaldi and Harvoni, the Gilead Patient Assistance Program (PAP) made these medications available to virtually all patients who met financial and other program requirements. Gilead also implemented significant discounts for its HCV therapies across different payer groups. While many payers responded to these discounts by opening access broadly, some payers have continued to restrict access despite the discounts. As a result, our PAP criteria enabled continued restrictions by some payers by providing a generous route for them to deny access and refer patients they have chosen not to cover. While we have approved many of these patients in the past, we feel it is necessary to establish more specific guidelines for patient eligibility. Our PAP was designed to help uninsured patients with the most

---

[540] Senate Finance Committee Interview of Emalie Huriaux, Director of Federal and State affairs, Project Inform (July 10, 2015); *see also AHF Criticizes Gilead for Blacklisting Hepatitis C Patients from Drug Assistance Programs to Punish Insurers,* Aids Healthcare Foundation (July 23, 2015), *available at* http://cqrcengage.com/aidshealth/app/document/8671298;jsessionid=gAma-5LojCWfh42hyhRCL98y.undefined.

> need, and changes are necessary to remain true to that mission. We believe these changes also will help increase access among those payers who continue to restrict access.[541]

The price of Sovaldi constituted a large burden—notably among state Medicaid programs, Medicare, and the BOP—and triggered access restrictions across public and private payers, thus limiting the number of HCV-infected patients who could access the new treatment options. In response to these restrictions, Gilead stayed firm in its initial contracting strategy by offering only small discounts in return for opening patient access, and limiting its PAP program.

[541] Appendix D, Ex. 12, Letter from Coy Stout, Vice President, Managed Markets, Gilead Sciences, Inc., to Community Partner (July 1, 2015).

Section 5: Patients' and Payers' Reactions to the Price of Sovaldi

Gilead may not have anticipated the scope and depth of the resulting restrictions as it was attempting to price Sovaldi in a way that would not "hinder patient access to uncomfortable levels,"[542] but it should not have been surprised by negative reactions—particularly after the price was announced—as patient groups, public and private payers, and others began to provide direct feedback on the price, as detailed in this section.

By September 2014, as it considered a price for Harvoni, the company had done its own analysis of access restrictions that state Medicaid programs had put in place for Sovaldi:

- More than half of the states are limiting coverage to the sickest patients (i.e. F3–F4)
- Additional strict criteria including one per lifetime treatment, patient certifications, and drug/alcohol testing
- Budget concerns driving strict management through [prior authorization] requirements
- Staffing for [prior authorization] requirements has also impacted coverage decisions (i.e. IL Medi)
- Appeals require court hearings in WI, AR, IL[543]

"Extreme budget constraints drive strict criteria for treatment and an unstable formulary review process inhibiting access to Sovaldi," the presentation concluded.[544] Furthermore, the company expected that "[h]ighly restrictive criteria to control costs and F3-F4 restrictions will likely remain."[545]

The presentation shows that Gilead was clearly aware that the cost of providing Sovaldi to Medicaid patients had become—and would continue to be—problematic, even though executives believed $84,000 was a fair price that would be readily accepted by the marketplace, given their belief in the clinical efficacy of the product. Meyers said that Gilead had spoken to many major payers and received positive feedback, and that negative press about Sovaldi's price only took off after the spike in the off-label combination of Sovaldi and Olysio.[546] However, even before the product was introduced to market, Gilead officials were informed of significant concerns about the price.

For many payers, particularly in Medicaid, the combination of price and an influx of patients seeking treatment for HCV was a major part of the concerns—and the warnings—that Gilead received. The material that follows shows that Gilead officials were told, and in some cases repeatedly, about the potential negative consequences that a high price for Sovaldi and future HCV treatments could have on the American health system, public payers,

---

[542] Appendix E, Ex. 28, Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Assessment, Final Recommendations—July 31st, 2013, GS–0014018, at GS–0014020.

[543] Appendix E, Ex. 52, Gilead Sciences, Inc., HCV Wave 2 Contracting Recommendations, September 9, 2014, GS–0019058, at GS–0019107.

[544] *Id.*

[545] *Id.* at GS–0019108.

[546] Interview with Jim Meyers, Senior Vice President, North America Commercial Organization, Gilead Sciences, Inc., in Washington, D.C. (Oct. 30, 2014).

private payers, and ultimately, patients who would be denied treatment. The communications—in the form of meetings, phone calls, and written communications—began more than two months before Gilead received its approval for Sovaldi in December 2013, and continue into 2015.

Concerns Before and Shortly After FDA Approval

One of the first warnings about the potential impacts of high HCV drug prices came during a meeting of the FDA's Antiviral Drugs Advisory Committee.[547] The administrative hearing, which took place less than two months before the FDA's approval of Sovaldi, was one of the final steps in the agency's review process. Gilead was represented at the hearing by John McHutchison, William Symonds, and Diana Brainard, all of whom are either executives or senior managers in the company's liver disease unit.[548] The hearing allowed members of the committee to ask questions of the company with respect to its research, and in turn, receive input from the public.

Lynda Dee, a Baltimore attorney who for more than a decade has advocated on behalf of people infected with AIDS and HCV, was among those in attendance. For many years, she led a coalition of advocacy groups that has met with drug companies prior to drugs being released to the market. These advocacy group meetings were intended to provide companies with a "patient perspective" about the positive and negative impacts of drugs on consumers—clinically, financially, socially—and provide a forum to advocate for lower prices.[549]

"[O]h, happy day," Dee said of Sovaldi's pending approval, according to a transcript of the meeting.[550] Dee ticked off the positives of the drug and the company, one by one. The groups she was representing, AIDS Action Baltimore and the Fair Pricing Coalition (FPC), both received grant funding from Gilead. She was supportive of the company's study protocols. She also had a personal interest in her attendance:

"I'm actually cured of HCV using sofosbuvir, and I'm really elated to see this day come. And I think that most everybody in the HCV community feels that way."[551] However, she had concerns about price:

> I also hope that—you know, it's America. There are no rules about what you can charge. But it would be a shame that this drug would not be accessible to people because it cost too much. I would urge you. I would say I would beg you to consider pricing this drug reasonably. We all know

[547] U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Meeting Agenda, Antiviral Drugs Advisory Committee Meeting (Oct. 25, 2013), *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AntiviralDrugsAdvisoryCommittee/UCM375281.pdf.

[548] *Id.* At the time, McHutchinson was Senior Vice President for liver diseases; Symmonds was Vice President for liver diseases; and Brainard was Senior Director of liver diseases.

[549] Telephone interview with Lynda Dee (November 2014).

[550] U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Meeting Transcript, Antiviral Drugs Advisory Committee, at 212–216 (Oct. 25, 2013) [hereinafter FDA Meeting Transcript], *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AntiviralDrugsAdvisoryCommittee/UCM382913.pdf (statement by Lynda Dee).

[551] *Id.*

> that it's going to be cost-effective, but that scale of what's cost-effective is I think an unreasonable way to look at it.
>
> I mean, if the price of telaprevir[552] and boceprevir[553] I think is already exorbitant. I mean, if you could price it even close to what those drugs are, I think that would be reasonable under the circumstances, and you'd still make a fortune. The volume that you're going to get for this is I think it's outstanding. . . .
>
> [T]hank you for the good work and I hope we can get this drug out to people and as many people that need it as possible.[554]

An early call for lower pricing was also made during a day-long meeting between the FPC and Gilead at the company's Foster City, California, headquarters. Gilead was represented by McHutchison, David Johnson, vice president of marketing for the liver diseases business unit, Janice Tam, medical affairs, Coy Stout, vice president for managed markets; Bill Guyer, medical affairs; Cara Miller, medical affairs; and Michele Rest, medical affairs.[555] The coalition planned to urge Gilead to set the price for Sovaldi at or below the roughly $60,000 price of Victrelis and Incivek, protease inhibitors that were then the prevailing standard of care.[556]

Gilead's account of the meeting matches the FPC's agenda. Johnson sent a detailed summary of the FPC meeting to many of the company's most senior officials. Johnson described the meeting as a "collaborative" dialogue, noting "they also emphasized that they want both a reasonable price and a comprehensive patient support program," and specifying that "they hope Gilead will price sofosbuvir at or below current SOC ($60K)."[557] The email went on to foreshadow concerns that many state Medicaid programs would raise after the approval of Sovaldi and Harvoni:

> While they understand the clinical value of sofosbuvir (and believe it is a "very good drug"), they feel the cost-effectiveness argument will not matter in the current environment as states, insurers, physicians and patients are focused on the "right now" costs and not what the potential cost-savings may be down the road. This will be particularly true as more new compounds become available. They also are focused on the potential impact of a high price on VA/Correctional formularies—particularly as they expect Merck and Vertex to significantly lower the price for

---

[552] The cost of a 12-week treatment of telaprevir is $49,200, which does not include the cost of pegylated interferon and ribavirin, which are used in combination with telaprevir. Hepatitis C Online, Medications to Treat HCV, Telaprevir (Incivek), *available at* http://www.hepatitisc.uw.edu/page/treatment/drugs/telaprevir-drug (last visited Sept. 28, 2015).

[553] The cost of boceprevir is $26,400 for a 24 week course, $35,200 for a 32 week course, and $48,400 for a 44 week course. These prices do not include the cost of pegylated interferon and ribavirin, which must be used in combination with boceprevir. Hepatitis C Online, Medications to Treat HCV, Boceprevir (Victrelis), *available at* http://www.hepatitisc.uw.edu/page/treatment/drugs/boceprevir-drug (last visited Sept. 28, 2015).

[554] FDA Meeting Transcript at 215–16 (statement by Lynda Dee).

[555] Appendix D, Ex. 13, Meeting Agenda, HCV Fair Pricing Coalition Meeting (Oct. 3, 2013) (prepared by Cara Miller).

[556] Appendix D, Ex. 14, Meeting Agenda, "FPC Gilead 10–3–13 Meeting Agenda (FOR FPC ONLY)" (Oct. 3, 2013) (prepared by Lynda Dee).

[557] Appendix E, Ex. 53, Email from Cara Miller to Gregg Alton, FW: FPC Ad Board Feedback (Oct. 4, 2013), GS–0020133, at GS–0020133—GS–0020134.

> boceprevir/telaprevir in advance of our launch. It's possible that when a patient hears a high price, they may immediately assume they can't afford treatment and not pursue any further dialogue with their physicians regarding treatment. Similarly, a physician may make a value judgment as to whether it is worth putting a patient with high-risk behaviors on treatment. Education of both physicians and patients is critical. Patients have to advocate for themselves so educating them on how to/what to ask for will be key. Currently, patients are getting majority [sic] of their information from media, not from their doctors. Additional barriers to care include a lack of federal leadership and policy, and routine testing for HCV.[558]

The email's recipients included high-level Gilead executives.[559]

A month later, according to minutes Dee provided to investigative staff, the coalition held a teleconference on December 6, 2013, the day that FDA approved Sovaldi. The minutes show that coalition members expressed "disappointment" about the $84,000 list price of the drug. Gilead was represented on the call by Guyer, Johnson, Miller and Stout.[560]

On April 14, 2014, four months after Sovaldi had been approved by the FDA, the FPC sent a follow-up letter to Gilead. The letter was addressed to Stout and Rest, as well as Kristie Banks, senior director for business operations and contract compliance; Jim Drew, director, business operations and contract compliance and Flood.[561] The letter reiterated the coalition's call for the company to lower Sovaldi's price to improve access for HCV patients:

> We should remind you of our original warning that, even though new DAAs are a major improvement that may be cost-effective in the long run, our healthcare system lacks this particular downstream thinking. Both government and industry payer programs operate under short-term budget constraints that are incapable of absorbing the costs of Sovaldi for every patient they cover who needs access to this medication.
>
> We had hoped Gilead would be satisfied with cornering the larger volume market. By all accounts, Gilead will dominate the DAA market for years to come. This has made Sovaldi's price all the more unconscionable. Gilead is already close to recouping the Pharmasset purchase price of Sovaldi, even before the fixed-dose combination with ledipasvir is on the market. We still hope Gilead will consider a larger volume market strategy—one that will make

---

[558] *Id.* at GS–0020134.

[559] Coy Stout, Bill Guyer, Cara Miller, Jim Meyers, Kevin Young. *Id.* Other attendees of the meeting were Vice President for Public Affairs Amy Flood, Senior Vice President of Medical Affairs Hans Reiser, and Executive Vice President for Clinical Research and Development Operations Andrew Cheng. The email also was forwarded by Cara Miller to Executive Vice President, Corporate and Medical Affairs Gregg Alton. *Id.*

[560] Appendix D, Ex. 15, "Gilead 12–6–13 Call Notes" (prepared by Lynda Dee).

[561] Appendix D, Ex. 16, Letter from Murray Penner, Fair Pricing Coalition, to Coy Stout, Vice President, Managed Markets, Kristie Banks, Senior Director, Business Operations & Contract Compliance, Jim Drew, Director, Business Operations and Contract Compliance, Amy Flood, Vice President, Public Affairs, and Michele Rest, Director, Public Affairs, Gilead Sciences, Inc. (Apr. 14, 2014).

> a respectable profit for the company, while being priced so that it is accessible for the millions of patients for whom Sovaldi is indicated.[562]

In all, the FPC's message on pricing was directly communicated to at least a dozen Gilead employees in a private meeting, public forum, phone conference, and letter, in addition to multiple press releases and media interviews given by coalition members that received national press attention.

Early concern about Sovaldi pricing was not limited to patient advocates. On November 5, 2013, exactly a month before the FDA granted approval, Meyers sent an email to 16 people within the company with the "Synopsis of feedback from top HCV advisors at AASLD."[563] Meyers subsequently forwarded the email to John Martin, John Milligan, and Norbert Bischofberger.[564] Over the course of six pages, Meyers summarized discussions with doctors attending the annual meeting of liver experts, which had been held during the first five days of November in Washington, D.C. Portions of the email touched on potential pricing issues the company could face:

> Ira Jacobson was approached after the Gilead Symposium by a physician (GI) who works with Empire Blue Cross Blue Shield whom [sic] told him that Empire is "scared to death" by the pending launch of SOF. He indicated they put aside $500 million for the PI's and ended up spending $1.1 billion. When Ira asked the payer representative what they'd do with a decompensated cirrhotic who was prescribed 24–48 weeks of SOF + RBV, he replied "we'd cover it for 12 weeks, it's on the patient after that." Ira was very concerned with this response. He went on to say that he was happy to help us in our efforts with payers in any way that he could. Mark Sulkowski volunteered that the buzz at AASLD is that SOF will be the highest priced pill in the history of the pharmaceutical industry. "Everyone is speculating." [sic][565]

Controversy After the Price Was Set

Following the drug's approval on December 6, 2013, news outlets trumpeted the arrival of Sovaldi and the potential positive benefits for long-suffering hepatitis patients. Multiple outlets, ranging from national newspapers to regional outlets and trade press, noted the high price, the controversy it had created, and the potential barriers it would pose for patients seeking access to the drug. On December 7, the *New York Times* reported:

> [T]he greater convenience and effectiveness comes at a price. Gilead said the wholesale cost of Sovaldi, which is

---

[562] *Id.*

[563] Appendix E, Ex. 54, Email from Jim Meyers to David L. Johnson, et al., Synopsis of feedback from top HCV advisors at AASLD (Nov. 5, 2013), GS–0020776.

[564] *Id.; see also id.* (email from Jim Meyers to John Martin, Synopsis of feedback from top HCV advisors at AASLD (Nov. 14, 2013)); Appendix E, Ex. 55, Email from Jim Meyers to John Milligan, Synopsis of feedback from top HCV advisors at AASLD (Nov. 8, 2013), GS–0020765; Appendix E, Ex. 56, Email from Jim Meyers to Norbert Bischofberger, Synopsis of feedback from top HCV advisors at AASLD (Nov. 7, 2013), GS–0020753.

[565] *Id.* (included in all emails above).

> known generically as sofosbuvir, would be $28,000 for four week—or $1,000 per daily pill. That translates to $84,000 for the 12 weeks of treatment recommended for most patients, and $168,000 for the 24 weeks needed for a hard-to-treat strain of the virus. "This is unbearable to the health care system and it is completely unjustified," said Michael Weinstein, president of the AIDS Healthcare Foundation, which runs treatment clinics in the United States and abroad and has previously clashed with Gilead on the price of its drugs for H.I.V. The Initiative for Medicines, Access and Knowledge, a legal group based in New York, recently filed a motion to try to block patenting of the drug in India. If it succeeds, generic manufacturers in India will be able to manufacture cheap copies of the drug for distribution there and in some other developing countries. Gilead said the price was fair given the drug's higher cure rate and that the total cost for the 12-week regimen was "consistent with, and in some cases lower than" the cost of some other regimens for hepatitis C. It said it would offer financial assistance to some patients.[566]

Ten days later, the *Columbus Dispatch* (Ohio) reported:

> The advances come at a high cost. Sovaldi carries a wholesale-price tag of $1,000 a pill, or $84,000 for a full course. How much insurers will cover remains uncertain, as does when they'll pay for it. People can live normally with the virus and without serious liver damage. But once it starts to damage the liver—and especially after the onset of cirrhosis—treatment becomes more difficult. "People will want to get rid of hep C because it's there, but whether everybody is going to be offered treatment at this cost, we don't know," [said Dr. William M. Lee, a hepatitis C expert and clinical professor of internal medicine at Ohio State University's Wexner Medical Center.] [567]

On December 30, 2013, *National Public Radio* produced a story about Sovaldi titled *"$1,000 Pill For Hepatitis C Spurs Debate Over Drug Prices,"* in which reporter Richard Knox interviewed Alton and Camilla Graham, a former Vertex executive and hepatitis C specialist at Beth Israel Deaconess Hospital in Boston:

> RICHARD KNOX: Graham, who's at Beth Israel Deaconess Hospital in Boston, notes that Gilead paid $11 billion to acquire a smaller company that developed Sovaldi. She thinks Gilead should be allowed to recoup that investment. But . . .
>
> CAMILLA GRAHAM: You only need about 150,000 people to recover that cost. And so, you know, if you're treating two million people, once you've recovered your cost, then I think—I don't want to say it's unfair, but it does start feeling more exploitative.

---

[566] Andrew Pollack, *New Hope in Hepatitis As F.D.A. Allows Pill,* N.Y. Times, Dec. 7, 2013, at B1.

[567] Misti Crane, *New Drugs Close in on Hep C Cure,* Columbus Dispatch, Dec. 16, 2013, at 1A.

> RICHARD KNOX: She thinks once Gilead has recovered its investment cost, it ought to cut the price of Sovaldi.
>
> GREGG ALTON: That's very unlikely that we would do that. I appreciate that thought.
>
> RICHARD KNOX: Again, that's Gregg Alton of Gilead Sciences.
>
> GREGG ALTON: Really you need to look at the big picture. Those who are bold and go out and innovate like this and take that risk, there needs to be more of a reward on that. Otherwise it would be very difficult for people to make that investment.
>
> RICHARD KNOX: Alton says Gilead will help U.S. patients pay for Sovaldi if they can't afford it and will charge far less for a course of the drug in places such as India, Pakistan, Egypt, and China, where most people with hepatitis C live.
>
> GREGG ALTON: I don't think we'll be able to get it into the low hundreds. But I think we can get it into an affordable range for them. It'll be from the high hundreds to low thousands for these types of markets.
>
> RICHARD KNOX: It took more than 10 years before many people in developing countries got access to life-saving HIV drugs. Advocates hope it won't take anywhere near that long to start curing hepatitis C.[568]

On January 6, 2014, the pharmaceutical trade publication *FierceBiotech* wrote:

> Thomas Wei of Jefferies & Co. had initially figured that Gilead would have to hit a peak sales estimate of $4 billion to justify the cost of Sovaldi. Analysts have recently been settling in around $7 billion after calculating the returns on a pill that will cost $1,000 a day—or $84,000 for a 12-week course. But winning here has come at a cost that may be hard to calculate. Already whipped up by Gilead's steep prices on HIV drugs like the newly approved *Stribild,* some prominent nonprofits immediately took a swipe at Gilead's pricing strategy.[569]

On July 11, 2014, Gregg Alton, Gilead's Executive Vice President, Corporate and Medical Affairs, acknowledged, during an American Enterprise Institute forum, that the price of the drug had caused controversy and a "challenge" to the nation's medical system:

> A lot of what's happening here is we have a breakthrough, a quantum leap in the ability to treat Hepatitis C. We can do something today that we couldn't do last year and there's a cost associated with that. And I think that has

---

[568] Richard Knox, *$1,000 Pill For Hepatitis C Spurs Debate Over Drug Prices,* National Public Radio, Morning Edition (Dec. 30, 2013) (transcript available on LexisNexis).

[569] John Carroll, *Sovaldi: Gilead Hits Pay Dirt with a Breakthrough Hep C Drug,* FierceBiotech (Jan. 6, 2014), *available at* http://www.fiercebiotech.com/special-reports/sovaldi-gilead-hits-pay-dirt-breakthrough-hep-c-drug.

challenged our system. But what I really want to say in closing is that despite all the challenges and some of the criticism that you may be hearing, and the friction, and I guess the shrill tone of the conversation, there's a positive side to this, which is we're going to cure more people of hepatitis C this year than we ever have before.[570]

Responses From Medicaid Programs to Gilead

Following the launch of Sovaldi, Medicaid programs in states across the country were wrestling with the combination of Gilead's high cost and the flood of patients who wanted to take advantage of the shorter treatment regimen.

In recent years, a growing number of states have joined "pools," in which several Medicaid programs join forces to increase their market power. There are three primary pools—National Medicaid Pooling Initiative (NMPI), Top Dollar (TOP$), and Sovereign States Drug Consortium (SSDC).[571] Both NMPI and TOP$ are administered by Provider Synergies, LLC, a subsidiary of Magellan Health Services and the SSDC is administered by the member states.

On May 11, 2014, Gilead offered three tiers of supplemental rebates to the Medicaid pools—6%, 8%, and 10%—that had been approved by the company's legal department.[572] Each tier was tied to requirements that increased patient access, i.e., the higher the discount, the more access was to be provided:

- **6% discount—Unique Position 1.** Any PA [prior authorization] criteria imposed is consistent with and no more restrictive than the FDA approved label. Additional restriction for fibrosis score (Metavir) of F2–F4 [fibrosis levels two through four] is permissible. PA criteria may require prescriptions be written by Specialists (hepatologists or gastroenterologists, for example).
- **8% discount—Unique Position 2.** Any PA criteria imposed is consistent with and no more restrictive than the FDA approved label. PA criteria may require prescriptions be written by Specialists.
- **10% discount—Unique Position 3.** Any PA criteria imposed is consistent with and no more restrictive than the FDA approved label. Any PA criteria imposed shall not require prescriptions by Specialists. Of note, Gilead has stated that they are not detailing their hepatitis portfolio to non-Specialists.[573]

---

[570] American Enterprise Institute, Discussion transcript, *How Will We Pay for the Price of Cures?,* at 35 (July 11, 2014), *available at* http://www.aei.org/wp-content/uploads/2014/07/-cost-of-cures_154738513625.pdf.

[571] For more details, *see Pharmaceutical Bulk Purchasing: Multi-State and Inter-Agency Plans,* Nat'l Conf. of State Legis., http://www.ncsl.org/research/health/bulk-purchasing-of-prescription-drugs.aspx (last updated Jan. 2015).

[572] Appendix D, Ex. 17, Email from William Dozier, Senior Manager, National Accounts, Gilead Sciences, Inc., to Douglas M. Brown, Senior Director, Pharmacy Pricing & Value Based Solutions, Magellan Health Services (May 11, 2014).

[573] Appendix D, Ex. 18, Email from Douglas M. Brown, Senior Director, Pharmacy Pricing & Value Based Solutions, Magellan Health Services to Matthew D. Lennertz, Magellan Health Services (May 19, 2014). Brown told investigative staff that "not detailing their hepatitis portfolio to non-Specialists" meant that Gilead was not promoting Sovaldi to general practice doctors.

The relatively small discounts, coupled with requirements to reduce restrictions for treatment, made the rebates difficult for states to accept because of the potential budgetary impact. Magellan's Douglas Brown, who negotiated on behalf of NMPI and TOP$, made reference to the dynamic when he shared the offer with states on May 19th:

> I'm happy to have this offer in place for those states that cannot otherwise manage utilization in this category and are experiencing a sharp increase in total spend. However, I expect most states to forgo this offer and continue to actively manage this category. Our negotiations with Gilead continue, especially for those states that require fibrosis scores of F3 or greater as well as other PA criteria.[574]

Less than three weeks later on June 5, 2014, Brown gave an update to Gilead's William Dozier, a senior manager of national accounts, warning of the backlash from state Medicaid programs:

> I would say that 20 of 25 states have no interest in the offer. [Connecticut] looks to take the 10% offer. The other four are debating the offer (but not rushing their decision).[575]

Gilead officials also directly met with and received written correspondence from representatives of individual state Medicaid programs, who indicated that access restrictions would follow and that some were already occurring. The Ohio Medicaid program raised concerns about the price of Sovaldi in a teleconference with National Accounts Manager David Kaufman and National Accounts Director Justin Crum on June 26, 2014. Price concerns were again raised in an in-person meeting that included the state's Medicaid director, John McCarthy, on September 24, 2014. The second meeting included Associate Director for Government Affairs Rebecca O'Hara, Associate Director for Medical Sciences Paul Miner and outside counsel Joshua R. Sanders.[576]

In addition to his meeting with Ohio Medicaid officials, meeting minutes show that Miner was in attendance on July 8, 2014 when the Michigan Medicaid's pharmaceutical and therapeutics committee reviewed Sovaldi. Minutes show that Vanita Pindolia, the vice president, of ambulatory clinical pharmacy programs-pharmacy care management for Health Access Plan (HAP) of Michigan, spoke directly to the price of Sovaldi:

> Dr. Pindolia from HAP testified on behalf of the Michigan Association of Health Plans. She addressed the impact this medication will have on insurance premiums for both private and government programs and the review done by the Institute for Clinical and Economic Review (ICER) for California Technology Assessment Forum (CTAF). In the ICER report the cost effectiveness is addressed in terms of "cost per additional Sustained Viral Response (SVR)". Per

---

[574] *Id.*

[575] Appendix D, Ex. 19, Email from Douglas M. Brown, Senior Director, Pharmacy Pricing & Value Based Solutions, Magellan Health Services, to William Dozier, Senior Manager, National Accounts, Gilead Sciences, Inc. (June 5, 2014).

[576] Appendix D, Ex. 20, Letter from John B. McCarthy, Director, Ohio Department of Medicaid, to Peter Gartrell (Aug. 7, 2015).

> ICER, if Sovaldi is reserved to patients with advanced liver disease then the cost of the drug is recouped as total healthcare savings at the 20 year mark; however if Sovaldi was used to treat all patients with positive HCV, only 66% of drug cost is recouped with total healthcare savings at 20 year.[577]

The CTAF report Pindolia cited, was issued in March 2014, concluding:

> A majority of the CTAF Panel rated the new treatments as "low value" compared with older drugs due to the magnitude of the potential impact on health care budgets of treating large numbers of patients with these high-priced drug regimens. Because the financial impact of using these new drugs to treat all eligible patients with hepatitis C is untenable, policy makers should seek avenues to achieve reductions in the effective price of these medications. Panel members and outside experts nearly all agreed that for both clinical and cost reasons, not every patient with hepatitis C needs to be immediately treated with the new drugs. Informed, shared decision-making about the timing of treatment should be encouraged. Given the circumstances, it is reasonable to consider prioritizing treatment with the new drugs for patients who need urgent treatment and have some evidence of liver fibrosis but do not have advanced liver disease.[578]

Two days later, on September 9, 2014, Janet Zachary-Elkind, deputy director of the Division of Program Development and Management and a top official from New York State's Medicaid program, sent an email to Gilead's Vice President for Government Affairs Kacy Hutchinson that included a table that quantified the impact that Sovaldi was expected to have on the state's Medicaid program.[579] The email reads:

> As you can see, if all beneficiaries with CHC were to be treated with Sovaldi, our total spend (amount paid to pharmacies) would be greater than the total annual pharmacy spend in the NY Medicaid program (~$4.5B). The second chart identifies those beneficiaries that would meet the standardized criteria that we've developed. If all beneficiaries that meet our standardized criteria were to be treated, our total spend for Sovaldi would be equal to approximately 67% of our total annual pharmacy spend. While we can't predict the total number of people that will be treated with Sovaldi, we estimate that it will be somewhere between 10 and 20% of 35,010 (the number of members identified in the second chart) for this calendar year.[580]

---

[577] Meeting Minutes, Michigan Pharmacy and Therapeutics Committee (July 8, 2014), *available at* https://michigan.fhsc.com/Downloads/PTMinutes-20140708a.pdf.

[578] Institute for Clinical and Economic Review, California Technology Assessment Forum, *The Comparative Clinical Effectiveness and Value of Simeprevir and Sofosbuvir in the Treatment of Chronic Hepatitis C Infection,* at ES9 (Apr. 15, 2014), *available at* http://ctaf.org/sites/default/files/u119/CTAF_Hep_C_Apr14_final.pdf.

[579] Appendix D, Ex. 21, Email from Janet Zachary-Elkind to Kacy Hutchison (Sept. 9, 2014).

[580] *Id.*

On August 6, 2014 four company officials—Vice President for Government Affairs Kacy Hutchinson, Vice President of Managed Markets Coy Stout, National Account Director Justin Crum, and National Accounts Executive Manager Tyler Hunter—met with the Texas Health and Human Services Commission (HHSC):

> HHSC's former Executive Commissioner, Dr. Kyle Janek, expressed his displeasure with Gilead's pricing. He reminded the Gilead executives and representatives of the impact of their drug to the state budget. Given the size of the Texas Medicaid population, Dr. Janek also asked for a discounted rate. He referenced the Drug's availability at a fraction of the price in other countries and the likelihood that it would be cheaper for Texas to fly Medicaid recipients to those countries for treatment than to treat them in the U.S. Gilead executives and representatives explained that the company limited access to the drug in other countries to citizens of those countries and then defended their pricing model.[581]

The next month, Stephanie Tran, Gilead's Associate Manager for Medical Information, received a letter from the Texas Health and Human Services Commission requesting clinical data for Sovaldi and the drug that would eventually be marketed as Harvoni. The state was seeking more information as it considered clinical edits for HCV patients. "With such a significant impact on the state health care budget, there is very little room for error," Andy Vasquez, the state's director for vendor drug programs wrote.[582] ". . . [T]here is still data that would be crucial to providing the most accurate representation of cost-effective treatment, based on available clinical evidence."[583]

In addition to the August meeting and letter to Tran, company officials had seven more meetings with Texas officials between October 21, 2014 and January 16, 2015 to discuss Gilead's rebate offers for Harvoni and Sovaldi. In addition to Crum, Hunter and Stout, additional participants included Associate Director for Medical Science Michelle Puyear, Associate Director of Government Affairs Erin Smith, and Director for Government Contracts and Pricing Kimberly Hawkins.[584] In all, Texas raised concerns about pricing with at least eight different Gilead officials, yet, as cited above, the state's P&T Committee eventually designated Viekira Pak as the preferred therapy for HCV because "AbbVie submitted more aggressive rebates."[585]

During a forum in October 2014 at The Brookings Institution in Washington D.C., advocate Ryan Clary bookended criticism of access restrictions imposed by commercial insurers and state Medicaid programs with criticism about Sovaldi's price. He called for lower prices for future HCV therapies, noting that they were a contributing factor to Medicaid programs restricting access to patients.

---

[581] Appendix D, Ex. 11, Letter from Andy Vasquez, Deputy Director, Vendor Drug Program, Medicaid/CHIP, Texas Health and Human Services Commission, to Hon. Ron Wyden and Hon. Charles E. Grassley at 2 (Aug. 14, 2015).
[582] *Id.*, Attachment 1.
[583] *Id.*
[584] *Id.*, Attachment 2.
[585] *Id.* at 2.

Clary, the executive director of the National Viral Hepatitis Roundtable, an advocacy sponsored by several pharmaceutical companies, including Gilead,[586] delivered his remarks while sitting next to Gilead's Chief Operating Officer, John Milligan:

> The public programs, the state Medicaids, that's a different story. These are programs who are not in the business to make a profit off of health care; they are in the business to provide health care to low income people, many in vulnerable populations, who are in a safety net program and do the best they can with strapped budgets. And they are having a real hard time providing access to Hep C treatment. They don't pay $84,000, they get significant price relief, but they are still having issues. The problem with the state Medicaids is they reacted so quickly to the P.R. campaign and the misinformation and quickly implemented really harmful—not all Medicaids, many—harmful restrictions, that are blanket restrictions, that are discriminatory particularly toward people who either currently or have recently injected drugs—and those are folks who probably would like to be cured of Hepatitis C and not be transmitting to others—so that needs to be dealt with. And as far as the price, my organization and our colleagues have been on record, the price of Sovaldi is expensive, it is too high. The rationale makes sense, but when you look at the sheer number of people who have Hepatitis C, who we know have Hepatitis C, and you look at the cost of treating everybody and curing everybody, we are not going to do it in the next couple years, we know that—time to get through that misinformation—but that's a really high cost. And we've encouraged lower prices, we're hoping that the next wave of prices—and it's not just Gilead, we have other companies coming on board—really look at the access problems we're having, understand that price does play a factor treatment access and make decisions based on that. It's a fantastic drug. This all comes from the spirit and the hope that we can cure everyone with Hepatitis C who wants to be treated. I vote for the option of treating everyone with Hepatitis C.[587]

Congress Raises Concerns

In addition to the letter sent by Senators Wyden and Grassley that began this investigation, Gilead's CEO received a letter in March 2014 from three senior members of the House Energy and Commerce Committee, Henry A. Waxman, Frank Pallone, Jr., and Diana Degette. The letter raised concern about the cost of Sovaldi, and its use with Olysio, in an attempt by providers to avoid the use of interferon:

---

[586] National Viral Hepatitis Roundtable, *Sponsors, available at* http://nvhr.org/content/members/sponsors (last visited July 16, 2015).

[587] The Brookings Institution, Event, The Cost and Value of Biomedical Innovation: Implications for Health Policy (Oct. 1, 2014), *available at* http://www.brookings.edu/events/2014/10/01-cost-and-value-biomedical-innnovation-hep-c#/full-event/.

> These costs are likely to be too high for many patients, both those with public insurance and those with private insurance. Because Hepatitis C is "concentrated in low-income, minority patients," the affordability problems are likely to be particularly acute for state Medicaid programs and those patients served by these programs. Colorado and Pennsylvania have already announced that their Medicaid programs will be limiting use of the new drug to "only the sickest patients," such as those already suffering from liver disease. California's Medicaid program is still considering how and when to reimburse for the drug. The large pharmacy benefit manager Express Scripts has said it is "encouraging some doctors in its networks to delay prescribing Sovaldi." Even in cases where public or private insurers pay for the medication, it will impose substantial costs on taxpayers and could cause premium increases for those with employer or individual coverage.[588]

All told, officials from Gilead received communications from a number of policy makers, advocates, providers, and payers regarding concerns about the high price of Sovaldi and that because of the price, patients who could benefit would not receive the drug. In addition, many noted their concerns about the impact that its high price would have on public payers. While Gilead had predicted that a negative response from patients and advocacy groups was "very likely" at the price point it selected, it may have ultimately underestimated the extent of concerns. Investigative staff found that this negative response was directly communicated to Gilead from 2013 through the present.

[588] Appendix D, Ex. 22, Letter from Hon. Henry A. Waxman et al., to Dr. John C. Martin, Chief Executive Officer, Gilead Sciences, Inc. (Mar. 20, 2014).

Section 6: A Competitor Drug Enters the Market

The emergence of an effective competitor—AbbVie's Viekira Pak—altered the market for HCV drugs, as evidenced by Gilead entering into substantial discounts with some payers. However, even with Viekira Pak's entrance, some state Medicaid programs asserted that Gilead continued to draw a hard negotiating line and did not offer steep enough discounts. Thus, concerns regarding price and access restrictions remain, and regulatory agencies have taken various actions that may further affect the market for HCV drugs.

Gilead's products, Sovaldi and Harvoni, were the most widely used HCV treatments in the United States the year following FDA approval of Sovaldi in late 2013. The primary competitor to Sovaldi was Olysio, although the Johnson & Johnson drug was more frequently used as an off-label, interferon-free combination with Sovaldi than as a stand-alone treatment.[589] Following Harvoni's approval by the FDA in October 2014, use of Olysio sharply declined, most likely because Harvoni provided an interferon-free single-pill treatment for genotype 1 patients that was significantly less expensive than the Sovaldi-Olysio combination.[590] As the company prepared to release Harvoni, it was contemplating a similar contracting strategy to what it had employed for Sovaldi—a 4% supplemental discount for being listed on the preferred drug list, and generally 8% for allowing prescriptions for patients with F2–F4 fibrosis scores and 10% for allowing authorization to the FDA label (i.e., all patients).[591]

On December 19, 2014, the FDA approved Viekira Pak, manufactured by AbbVie.[592] As discussed in Section 3 of this report, Gilead had expected Viekira Pak to bring competition to genotype 1 patients, the largest segment of the U.S. HCV market. Like Harvoni, Viekira Pak can be used without interferon, and clinical trials demonstrated that Viekira Pak offered comparable cure rates to Harvoni.[593] However, unlike Harvoni, Viekira Pak is a multi-tablet regimen, rather than a single-pill treatment. CVS Pharmacy noted that a single-tablet regimen gave Gilead products the "best clinical profile," but that "there was not an appreciable clinical superiority of one product over another." [594]

Three days following Viekira Pak's approval, Express Scripts Holding Co., the nation's largest pharmacy benefit manager (PBM), announced that it would make Viekira Pak its preferred treatment

---

[589] Appendix D, Ex. 23, Troyen A. Brennan et al., CVS Health Corp., Analysis of "Real World" Sovaldi® (sofosbuvir) Use and Discontinuation Rates, September 2014, at Table 1.

[590] Michelle Fay Cortez & Cynthia Koons, *Johnson & Johnson Forecasts Profit Decline on Competition,* Bloomberg (Jan. 20, 2015), *available at* http://www.bloomberg.com/news/articles/2015-01-20/johnson-johnson-earnings-beat-estimates-on-prescription-sales.

[591] Appendix E, Ex. 52, Gilead Sciences, Inc., HCV Wave 2 Contracting Recommendations, September 9, 2014, GS–0019058, at GS–0019112.

[592] Press Release, U.S. Food and Drug Administration, FDA approves Viekira Pak to treat hepatitis C, *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm427530.htm.

[593] American Association for the Study of Liver Diseases and Infections Disease Society of America, HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C: Initial Treatment of HCV Infection, *available at* http://www.hcvguidelines.org/full-report/initial-treatment-hcv-infection (last updated Aug. 7, 2015).

[594] Appendix D, Ex. 1, Email from Ann Walker-Jenkins, Director, Federal Government Affairs, CVS Health Corp., to Peter Gartrell (Mar. 9, 2015), attaching written response to investigative staff.

for genotype 1 and would no longer cover Sovaldi and Harvoni for these patients.[595] The deal was the result of AbbVie offering discounted pricing for Viekira Pak that exceeded discounts Gilead had offered up to that point.[596] *Reuters* reported at the time that "AbbVie narrowed the price gap to resemble what Western European countries pay for Sovaldi, which runs from $51,373 in France to $66,000 in Germany."[597]

Gilead responded in January and February by entering into discounting agreements for Harvoni and Sovaldi with CVS,[598] Anthem,[599] Humana,[600] Aetna,[601] and UnitedHealth Group.[602] Cigna[603] struck agreements with Gilead for Harvoni only. Investigative staff could not verify the discount amounts because agreements between PBMs and drug manufacturers are confidential. However, in February 2015, Gilead announced that its "gross-to-net" deductions[604] for HCV products increased from 22% in 2014 to 46% in 2015, as a result of "the recent and ongoing round of negotiations with payers and PBMs."[605] Peter Wickersham, then-senior Vice president at Prime Therapeutics, LLC, a PBM representing 26 million people, described the sudden, steep discounting as unprecedented: "Wickersham said in his 20 years in the industry he had never seen prices for a brand-name drug cat-

---

[595] Caroline Humer, *Express Scripts drops Gilead hep C drugs for cheaper AbbVie rival,* Reuters (Dec. 22, 2014), *available at* http://www.reuters.com/article/2014/12/22/us-express-scripts-abbvie-hepatitisc-idUSKBN0K007620141222.

[596] *Id.*

[597] *Id.*

[598] Robert Langreth & Caroline Chen, *Gilead Makes Exclusive Deal With CVS For Hepatitis C Drugs,* Bloomberg Business (Jan. 5, 2015), *available at* http://www.bloomberg.com/news/articles/2015-01-05/gilead-makes-exclusive-deal-with-cvs-for-hepatitis-c-medicine.

[599] Robert Langreth, *Gilead Strikes Hepatitis C Deal With Anthem,* Bloomberg Business (Jan. 8, 2015), *available at* http://www.bloomberg.com/news/articles/2015-01-08/gilead-strikes-hepatitis-c-deal-with-anthem.

[600] Bob Herman, *Humana Opts For Gilead In Hepatitis C Drug Battle,* Modern Healthcare (Jan. 14, 2015), *available at* http://www.modernhealthcare.com/article/20150114/NEWS/301149943.

[601] Linda A. Johnson, *Aetna Chooses Gilead Sciences Hepatitis C Drugs Over AbbVie's,* San Jose Mercury News (Jan. 16, 2015), *available at* http://www.mercurynews.com/business/ci_27337565/aetna-chooses-gilead-sciences-hepatitis-c-drugs-over.

[602] Caroline Humer, *UnitedHealth Backs Gilead's Harvoni As Preferred Hepatitis C Treatment,* Reuters (Jan. 28, 2015), *available at* http://www.reuters.com/article/2015/01/28/us-unitedhealth-gilead-hepatitisc-idUSKBN0L12JP20150128.

[603] Press Release, Cigna Corporation, Cigna Signs Agreement With Gilead to Improve Affordability of Hepatitis C Treatment for Customers and Clients (Feb. 4, 2015), *available at* http://newsroom.cigna.com/NewsReleases/cigna-signs-agreement-with-gilead-to-improve-affordability-of-hepatitis-c-treatment-for-customers-and-clients.htm.

[604] Since filing its first Annual Report as a public company in 1996, Gilead has recognized and reported its net revenue by deducting from gross revenue three major items: "estimated product returns, cash discounts, and government programs and rebates." Gilead Sciences, Inc., Annual Report (Form 10–K) at 30 (Mar. 25, 1997), *available at* http://www.sec.gov/Archives/edgar/data/882095/0000912057-97-009728.txt. Gilead defined net product sales as sales "net of estimated mandatory and supplemental discounts to government payers, in addition to discounts to private payers, and other related costs," in its annual report for fiscal year 2014. Gilead Sciences, Inc., Annual Report (Form 10–K) at 58 (Feb. 25, 2015), *available at* http://www.sec.gov/Archives/edgar/data/882095/000088209515000008/a2014form10-k.htm. In 2013, Gilead forecast gross-to-net revenue deductions 17.9% for sofosbuvir during 2014, which included an 8.1% deduction for mandatory discounts (such as Medicaid discounts), a 4.8% deduction for supplemental discounts (such as discounts made per the terms of commercial contracts), and a 5% deduction for "Other" discounts, including IMA fees, prompt payment discounts, the Medicare "donut hole," and copay coupons. Appendix E, Ex. 36, Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Assessment, Response to Follow Up Questions (Aug. 26, 2013), GS–0013857, at GS–0013881, GS–0013883.

[605] Gilead Sciences, Inc., Fourth Quarter 2014 Gilead Sciences Earnings Conference Call, Webcast (Feb. 3, 2015), *available at* http://investors.gilead.com/phoenix.zhtml?p=irol-eventDetails&c=69964&eventID=5178585.

egory plummet so quickly after a competing drug was introduced."[606]

CVS told investigative staff that successfully negotiating with drug manufacturers typically depends on market competition, stating, "When single source drugs come to market, it is difficult to negotiate a lower cost because there is no market competition," but that "[t]he entrance of alternative drugs in a class generally increases manufacturers' willingness to negotiate with payors."[607] CVS, like Express Scripts, found that "as new drugs came on to the market like Viekira Pak, we were able to negotiate discounts."[608]

Some states also reached agreements with HCV drug manufacturers. In January 2015, Texas' Pharmaceutical and Therapeutics Committee selected Viekira Pak as the program's preferred drug, both because it viewed the drug as equally effective and "because AbbVie submitted more aggressive rebates . . . Viekira Pak was more cost effective."[609] Texas was one of 13 state Medicaid programs that OHSU researchers identified as having selected Viekira Pak as the preferred drug as of May 5, 2015. By comparison, 12 state Medicaid programs selected Harvoni as their preferred drug.[610]

Despite the benefits of competition, many state Medicaid programs remained concerned about the cost of new HCV therapies (and the resulting costs). "Through our multi-state rebate contract negotiating pool we have engaged HCV product manufacturers for various pricing level considerations. However, these efforts have been met with little to no success," Samantha McKinley, the pharmaceutical director for Kentucky's Medicaid program, wrote to Senators Wyden and Grassley on October 21, 2015.[611]

State Medicaid programs reported that obtaining suitable discounts from Gilead remained difficult even after Viekira Pak's entrance in the market. On October 2, 2015, Theodore Dallas, the Secretary of Human Services for Pennsylvania wrote that even with competition, Gilead's prices were not sufficiently reduced, and that the state has retained tight control over approving prescriptions:

> Initially, Gilead offered a very modest supplemental rebate for Sovaldi on the condition of a guarantee of unfettered access: no prior authorization, and no requirements for prescriptions to be written by, or in consultation with a medical specialist. When Gilead introduced Harvoni and AbbVie introduced Viekira Pak to the market, Gilead claimed willingness to negotiate supplemental rebates but negotiations were unproductive. Currently, Viekira Pak is designated as preferred on the [fee-for-service preferred

---

[606] Robert Langreth, *Hepatitis Drug Prices Fall So Low, No Exclusives Needed*, Bloomberg Business (Jan. 12, 2015), *available at* http://www.bloomberg.com/news/articles/2015-01-12/prime-covers-both-gilead-and-abbvie-liver-drugs-as-prices-plunge.

[607] Appendix D, Ex. 1, Email from Ann Walker-Jenkins, Director, Federal Government Affairs, CVS Health Corp., to Peter Gartrell (Mar. 9, 2015), attaching written response to investigative staff.

[608] *Id.*

[609] Appendix D, Ex. 11, Letter from Andy Vasquez to Hon. Ron Wyden and Hon. Charles E. Grassley at 2 (Aug. 14, 2015).

[610] Appendix B, Table 2a.

[611] Appendix D, Ex. 10, Letter from Samantha McKinley to Hon. Ron Wyden and Hon. Charles E. Grassley at 2 (Oct. 21, 2015).

> drug list]; Harvoni, Sovaldi, Daklinza and Technivie are designated as non-preferred. They are covered and available when determined to be medically necessary. All of the drugs, including Viekira Pak, require prior authorization.[612]

On November 5, 2015, Andrew M. Slavitt, Acting Administrator for CMS, published a blog post concerning access, affordability, and innovation for prescription drugs in which he singled out the high cost of new, highly effective HCV drugs as an ongoing challenge.[613] Slavitt wrote:

> A recent example of a much discussed, highly-effective drug is a therapy used by Hepatitis C patients. Hepatitis C, a debilitating and life threatening infection that leads to chronic conditions of the liver, has undergone a revolutionary improvement in cure rates with innovative new medicines. These medicines are changing the lives of many individuals, but they are also expensive, costing tens of thousands of dollars, sometimes even more than one hundred thousand dollars, per patient. These costs have strained personal as well as public budgets, particularly state health care budgets. Because state budgets generally need to be balanced every year, new drug treatments can surprise states with tens or hundreds of millions of dollars in new spending. As these costs often necessarily compete with other state programs like K–12 education, transportation, law enforcement, and public health programs, some states have made tough choices, including limiting access to these therapies.[614]

However, as Slavitt also noted, states have an obligation to provide treatment. CMS simultaneously issued a notice to all state Medicaid directors specifically related to HCV drug access to reinforce the point.[615] As Slavitt explained in his post:

> Our notice to state Medicaid directors reminds states of their obligation to provide access to these promising therapies (consistent with section 1927 of the Social Security Act) based on the medical evidence, and that they have tools available to manage their costs.[616]

The Agency also sent letters to HCV drug companies, Gilead, Johnson & Johnson, Merck & Company, Inc., and AbbVie, in which Slavitt wrote:

---

[612] Appendix D, Ex. 6, Letter from Theodore Dallas, Secretary, Department of Human Services, Commonwealth of Pennsylvania, to Hon. Ron Wyden and Hon. Charles E. Grassley at 3 (Oct. 2, 2015).

[613] Andrew M. Slavitt, "Prescription Drugs: Advancing Ideas to Improve Access, Affordability, and Innovation," *The CMS Blog* (Nov. 5, 2015), *available at* http://blog.cms.gov/2015/11/05/prescription-drugs-advancing-ideas-to-improve-access-affordability-and-innovation.

[614] *Id.*

[615] Department of Health and Human Services, CMS, Release No. 172, Medicaid Drug Rebate Program Notice, Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs (Nov. 5, 2015), *available at* http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf.

[616] Andrew M. Slavitt, "Prescription Drugs: Advancing Ideas to Improve Access, Affordability, and Innovation," *The CMS Blog* (Nov. 5, 2015), *available at* http://blog.cms.gov/2015/11/05/prescription-drugs-advancing-ideas-to-improve-access-affordability-and-innovation.

> Manufacturers also have a role to play in ensuring access and affordability. The agency believes it is important that state Medicaid agencies have access to the lowest available manufacturer prices in the market. Additionally, they should be given the opportunity to participate in discount or value-based purchasing arrangements offered by manufacturers.[617]

Additional factors may affect the U.S. market for HCV therapies. For example, as demonstrated this year by FDA safety warnings that were issued for Sovaldi and Viekira Pak. On March 24, 2015, the FDA warned "that serious slowing of the heart rate can occur when the antiarrhythmic drug amiodarone is taken together" with Harvoni or Sovaldi in combination with other direct-acting antiviral HCV drugs such as Olysio or daclatasvir.[618] The warning advised to avoid such co-prescriptions.[619] On October 22, 2015, the FDA issued a warning that Viekira Pak and Technivie (approved for treatment of genotype 4 patients) "can cause serious liver injury mostly in patients with underlying advanced liver disease."[620] The FDA required new safety warnings reflecting the risk to the drugs' labels.[621] While these warnings have not resulted in any of the drugs being pulled from the market at the time of this report, it is not known what impact they could have on practices and attitudes of patients, health care providers, and payers, which could affect competition in the market.

As such, the market for HCV therapies continues to evolve. Even as competition appears to have mitigated some of the pricing concerns discussed throughout this report, concerns about cost burden and access remain. In addition, future warnings or regulatory actions could further affect the HCV market.

---

[617] Department of Health and Human Services, CMS, HCV Communication, Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs (Nov. 5, 2015), *available at* http://medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/hcv-communication.html.

[618] FDA, FDA Drug Safety Communication: FDA warns of serious slowing of the heart rate when antiarrhythmic drug amiodarone is used with hepatitis C treatments containing sofosbuvir (Harvoni) or Sovaldi in combination with another Direct Acting Antiviral drug (Mar. 24, 2015), *available at* http://www.fda.gov/Drugs/DrugSafety/ucm439484.htm.

[619] *Id.*

[620] FDA, FDA Drug Safety Communication: FDA warns of serious liver injury risk with hepatitis C treatments Viekira Pak and Technivie (Oct. 22, 2015), *available at* http://www.fda.gov/Drugs/DrugSafety/ucm468634.htm.

[621] *Id.*

Section 7: Conclusions and Questions

This report is a case study of one company's experience in bringing a breakthrough therapy to market. Although it may have implications for other companies and other products, this report focuses only on the facts and circumstances of Gilead Sciences' introduction of sofosbuvir-based HCV drugs. Given that, despite the company's assurances of cooperation, Gilead failed to produce all relevant documents and supporting materials related to pricing, the staff's analysis of pricing decisions and strategies is necessarily based only on the documents and interviews that were provided by the company and from outside sources.

Gilead acquired access to its sofosbuvir-based drugs through a multi-billion dollar acquisition and spent hundreds of millions of dollars more completing clinical trials and FDA approvals. While there were extensive discussions regarding return on those investments while Gilead was considering the acquisition of Pharmasset, there is scant evidence that return on these investments played a significant role in determining the pricing of these drugs. Similarly, the cost of manufacturing Sovaldi, which was nominal, played no part in establishing the price. In an interview, Gilead executive Jim Meyers, who played a lead part in making the pricing recommendation did not know the cost of manufacturing the drug.

During the investigation, Gilead asserted that its primary concern in developing and marketing Sovaldi was to treat the largest number of HCV patients possible. For example, Gilead claimed that it shifted the emphasis of Sovaldi's Phase 3 trials to focus more heavily on treating genotype 1 patients, which Meyers told investigative staff was done to help as many patients as possible—as many as 5 million people are infected with HCV in the U.S., of which roughly 70% are carrying genotype 1. In reality, Gilead's marketing, pricing, and contracting strategies were focused on maximizing revenue—even as the company's analysis showed a lower price would allow more people to be treated—not only for Sovaldi, but more importantly for its follow-on sofosbuvir-based product pipeline. Significantly, when confronted with the widespread initiation of access restrictions, Gilead refused to offer substantial discounts and did not significantly modify its contracting strategy to improve patient access.

A key consideration in Gilead's decision-making process to determine the ultimate price of Sovaldi was setting the price such that it would not only maximize revenue, but also prepare the market for Harvoni and its even higher price. To that end, Gilead's goal throughout its pricing decision process appears to have been to identify the price just below the level where payers would place significant restrictions on patient access. Although it knew there would be some patient loss in the $80,000 to $85,000 per standard dosage range, Gilead's internal analysis indicated that it was a viable level for the majority of payers, and would also help secure what the company later referred to as "market share leader-

ship"[622] for Harvoni as a preferred future therapy and baseline price for the next wave of HCV drugs. The response to the launch price by payers appears to have been more severe than Gilead's expectations.

While Gilead claimed in interviews with investigative staff that payers readily accepted the proposed $80,000 to $85,000 price range during its pre-marketing surveys and focus groups, not a single one of the states, payers, or pharmacy benefits managers interviewed by staff investigators told us that it communicated assent in such surveys, nor did its organization. To the contrary, several experts and entities privately and publicly warned Gilead about the consequences of excessive pricing before introduction.

Even though Gilead assumed that the final price recommendation of $84,000 would not result in significant patient access restrictions, it quickly became apparent that this assumption was incorrect as many public and private payers quickly reacted and adopted restrictions. Ultimately, these restrictions reduced the number of patients who could have received treatment.

When presented with these access restrictions and pleas by both public and private payers for supplemental rebates or discounts to reduce the cost of HCV treatment for their respective patient populations, Gilead offered supplemental rebates and discounts of minimal value (on the order of 10% if all restrictions were lifted for Medicaid, for example). Only a handful of payers accepted these additional reductions. When payers proposed additional discounts, Gilead rejected them.

When launching Harvoni, Gilead essentially executed the same revenue maximizing methodology that it used for Sovaldi, even though it was aware that such an approach could cause similar access challenges. Gilead always intended to extract a premium for this follow-on, all oral drug. Its acquisition advisor, during the run-up to Gilead's purchase of Pharmasset, called it a "convenience bump." By elevating the price for the new standard of care set by Sovaldi, Gilead intended to raise the price floor for all future HCV treatments, including its follow-on drugs and those of its competitors. Its expectations were confirmed when AbbVie entered the market with its multi-drug, all oral Viekira Pak for genotype 1 at a base treatment price of $83,319, marginally below Gilead's prices. Gilead was able to maintain pricing power until Express Scripts, a major pharmacy benefits manager, entered into an agreement with AbbVie to make Viekira Pak its preferred genotype 1 HCV drug. Gilead quickly entered into its own agreements with other major benefits managers and payers including CVS Caremark and Anthem with what appear to have been substantial discounts. Industry sources have estimated these discounts to be on the order of 40% from the list price, although due to their confidential nature, those discounts have not been confirmed.

[622] Appendix E, Ex. 45, Gilead Sciences, Inc., 2015–2016 HCV Commercial Plan (Apr. 22, 2014), GS–0014083, at GS–0014085.

Potential Areas for Committee Consideration

The evidence collected for this report presents the Senate Finance Committee with a warning for critical policy areas under its jurisdiction. The federal government has responsibility for billions of dollars in payments for pharmaceuticals through the Medicare and Medicaid programs. However the federal government is not the direct payer for either. In Medicare, payments for pharmaceuticals are made through prescription drug plans sponsors. In Medicaid, each state program is responsible for payments, with the federal government reimbursing a state-specific percentage, or "match." The Finance Committee is responsible for policies that govern these programs and the intermediaries making payments on behalf of the federal government.

The narrative in the case of Sovaldi is fairly straightforward: Pharmasset developed the drug that ultimately became known as Sovaldi. Gilead purchased Pharmasset and shepherded Sovaldi through the completion of the FDA approval process. Gilead engaged in a complex process in determining the price of Sovaldi, ultimately settling on a price that underestimated the reaction from both private and public payers. When the payer community reacted negatively to the price of Sovaldi during its initial period of monopoly pricing power, Gilead provided only limited price flexibility, which led to implementation of widespread treatment restrictions that limited access to the sickest patients. Roughly a year later, AbbVie received approval for its drug, Viekira Pak, and competition through third parties—Express Scripts and CVS Caremark—immediately extracted rebates and discounts from the previously set list prices of both products.

One could argue that the system "worked," in that a new entrant into the market impacted the negotiated cost of the "first to market," or breakthrough, drug. In other words, competition worked to lower the cost of pharmaceuticals. Gilead's ability to set and hold the price for Sovaldi at a point that clearly caused stress to the payer community lessened with the entrance of a competitor. However, even as competition lowered prices for therapies, this report documents that concerns remain, particularly in the public payer community, about high costs for treating millions of people in the U.S. infected with HCV.

There is no question that Viekira Pak's entrance into the market changed the status quo. It is true that aspects of the system worked, in this case, because AbbVie came to the market with a competitor drug roughly a year after Sovaldi's release. However, only looking at that one event in a vacuum ignores the impact of the efforts that Gilead had undertaken to change the HCV market as a whole.

Sovaldi was a significant breakthrough for those diagnosed with HCV. However, comparing the drug with the previous standard of care is like comparing apples to oranges. At the most basic level, patients' ability to tolerate it meant that more patients could take it. This dramatic increase in market size and resulting revenue to Gilead was anticipated by the company. However, when payers attempted to extract rebates or discounts to ease cost concerns given the higher numbers of patients being treated, Gilead rebuffed those

efforts. The result was that patients who could benefit from these drugs did not receive them due to the high cost. Those patient populations remain at risk and will, for the most part, still require treatment in the future.

Accordingly, the public and private payer community continue to face a higher cost for the prevailing (new) standard of care, and higher overall costs because the new generation of HCV drugs is better tolerated and will most likely be far more widely prescribed.

Understanding the significance of AbbVie's entrance into the market is critical. If no other company had developed a breakthrough competitor with similar clinical results, Gilead's de facto control of the market could have lasted much longer. The average time between a single source innovator entering the market and a generic manufacturer producing its equivalent product and bringing it to market is 12.6 years.[623] Without successful competition, the costs to the public and private payers could have caused much more significant disruptions and access restrictions for years.

While it is premature to make specific legislative recommendations, several specific questions warrant public discussion:

1) What are the effects of a breakthrough, single source innovator drug on the marketplace?

Among other things, this report reflects the reality that federal health care programs—notably Medicare and Medicaid—have little to no policy levers at their disposal to significantly impact the price of a single source innovator drug. This report found that not until reasonable competition entered the marketplace did Gilead's pricing incentives and behavior change. Not all expensive innovator drugs face competition so soon after launch, and thus the next expensive innovator drug could potentially create significant budgetary pressures for federal payers and lead to access restrictions for an extended timeframe. In light of Gilead's abrupt change in behavior when faced with competition, what policy levers are available to increase competition with a single source innovator or otherwise ensure single source breakthrough drugs are available to those who would benefit clinically?

2) Do the payers in the programs have adequate information to know the cost, patient volume, and increases in efficacy of a new treatment regimen?

With respect to Sovaldi, cost drove much of the negative reaction to the introduction of the drug. Gilead argued that the price point for Sovaldi was less than that of the total cost associated with the previous treatment regime. The payers argued that the cost of Sovaldi was greater than any single treatment previously considered for HCV. What is clear is that payers were caught off guard by the price of the treatment regimen, especially when Sovaldi was used in combination with Olysio, driving the cost of treatment to approximately $150,000.

With respect to volume, HCV impacts millions of Americans, the full count of which is unknown. In the case of Sovaldi, payers were

[623] Henry Grabowski et al., *Recent Trends in Brand-Name and Generic Drug Competition,* 17 J. Med. Econ. 207, 207–14 (Dec. 10, 2013), *available at* http://informahealthcare.com/doi/abs/10.3111/13696998.2013.873723.

overwhelmed by the cost of the drug in conjunction with the volume of patients now eligible for treatment. The volume was further driven by patients being warehoused in anticipation of new drugs, as well as aggressive marketing by Gilead and other manufacturers. Again, payers clearly did not anticipate the demand for Sovaldi, and it is possible Gilead itself was caught off-guard. However, if the latter is true, the company decidedly did not take action to self-correct, and instead remained committed to securing its original price from public and private payers alike, regardless of volume.

While the Committee does not have jurisdiction over the approval process of drugs, the Committee's role as a significant payer cannot be ignored. If the payers do not have the opportunity to know what is coming and react accordingly with their plans and pricing, that is a problem. The Committee should explore ways to provide greater transparency in this area.

3) What role does the concept of "value" play in this debate, and how should an innovative therapy's value be represented in its price?

The Committee should consider that cost, patient volume, and increases in efficacy ultimately speak to the concept of value. The Committee has worked exhaustively to inject the concept of value into the reimbursement regimes in Medicare. While the Committee has worked with value-based purchasing largely in Medicare Parts A and B, the Committee should turn its attention to ensuring that the program is getting value for the spending in Part D. The Congressional Budget Office has already shown that spending increases for Part D can lead to decreases in Parts A and B spending. But in the future, the Committee will also have to consider whether the payers in Medicare and Medicaid are doing enough to ensure that innovative drugs produce additional value that supports their additional expense.

4) What measures might improve price transparency for new higher-cost therapies while maintaining incentives for manufacturers to invest in new drug development?

The Committee should explore the degree to which transparency could put downward pressure on pricing without exposing confidential, proprietary information about a new drug's scientific development. When confronted by dramatically higher costs, many payers restricted access. The Committee should examine ways to support manufacturers that direct their efforts toward expanding access to their cures.

The process which a payer of health care services, whether it be an employer or the federal government, must go through to determine the exact price it will pay for pharmaceuticals is long, complicated, and often opaque. While most drug manufacturers publicly announce the "price" of their drugs, the actual amount paid by individual payers is kept secret for a variety of potentially legitimate reasons. However, there are reasons to believe that increased transparency in actual prices paid would better inform the public as well as help policy makers make more informed decisions. On the latter point, the public may be surprised to learn that members

of Congress are forbidden by law[624] to have access to information regarding price discounts and rebates agreed to by drug manufacturers as part of the Medicare and Medicaid programs. Congress and payers alike need more complete information on the ultimate prices paid.

5) What tools exist, or should exist, to address the impact of high cost drugs and corresponding access restrictions, particularly on low-income populations and state Medicaid programs?

The data contained in this report provides estimates of the number of Medicaid enrollees infected with HCV, the number of enrollees who received treatment, and the cost of that treatment to taxpayers. More often than not, states responded to the high need for—and high cost of—HCV treatments by imposing access restrictions leading to a fraction of the infected population actually receiving treatment. In addition, as shown in the report, this high cost, high need situation is expected to continue to strain state Medicaid budgets and affect decision-making around access. The Committee should explore the tools that states and the federal government can employ, or should be able to employ, to appropriately manage their patient populations, ensure timely access to medically necessary treatments, and address the financial constraints of new cures that enter the market.

[624] 42 U.S.C. § 1396r–8(b)(3)(D).

Timeline of Key Events

1987	Gilead Sciences, Inc. (Gilead) is founded in Foster City, California.
1992	Gilead becomes a publicly traded company.
1998	Pharmasset, Inc. (Pharmasset) is founded in Tucker, Georgia.
2006	Pharmasset becomes a publicly traded company.
2008	Pharmasset spends $770,000 researching PSI–7977, a molecule being developed for the treatment of the Hepatitis C virus (HCV). PSI–7977 would become Sovaldi.
2009	Pharmasset spends $6.9 million researching PSI–7977.
2010	Pharmasset announces initiation of Phase 2a and 2b studies for PSI–7977. This announcement is the first public acknowledgement that the compound is being developed. The company spends $16.4 million researching the compound.
May 13, 2011	The Food & Drug Administration (FDA) approves Vertex Pharmaceutical's Incivek (telaprevir) through priority review, for the treatment of Chronic Hepatitis C (CHC) genotype 1 in adult patients with compensated liver disease (including cirrhosis), in combination with pegylated interferon alfa and ribavirin. FDA approves Merck & Company's (Merck) Victrelis (boceprevir) through priority review, for the treatment of CHC genotype 1, in combination with pegylated interferon-alfa and ribavirin, in adult patients with compensated liver disease (including cirrhosis). These drugs are the first direct-acting antivirals (DAA) to receive FDA approval. DAAs work by targeting enzymes within the RNA of HCV.
September 2, 2011	Gilead begins negotiations to acquire Pharmasset. Gilead's initial offer is $100 per share.
November 1, 2011	Pharmasset initiates Phase 3 trials for PSI–7977.
November 6, 2011	Pharmasset announces results of a Phase 2 trial in which all Hepatitis C (HCV) patients who used PSI–7977 were cured of the disease.
November 21, 2011	Gilead announces agreement to purchase Pharmasset for $137 per share.
December 16, 2011	Pharmasset halts clinical trials for a second HCV drug, PSI–938. In response to the news, a Gilead spokesman tells the **Wall Street Journal,** ''[s]ince the announcement from Pharmasset regarding PSI–938 does not impact the development of PSI–7977, we do not believe the fundamental value of the deal has been impacted.''
January 17, 2012	Gilead completes its purchase of Pharmasset, Inc. for $11.2 billion. PSI–7977 becomes GS–7977.
March 25, 2013	Gilead begins its evaluation of pricing and access for GS–7977, which would be marketed as Sovaldi.
May 6, 2013	FDA grants Viekira Pak breakthrough therapy designation.
October 10, 2013	FDA grants Sovaldi breakthrough therapy designation. The designation would allow the company to include two additional Phase 3 studies, VALENCE and PHOTON–1, which provided data supporting treatment of genotype 3 patients, and genotype 1 patients co-infected with HIV, respectively.
November 22, 2013	FDA approves Olysio (simeprevir) through priority review, for the treatment of CHC genotype 1 as a component of a combination antiviral treatment regimen.
November 18–23, 2013	Gilead executives set the price of Sovaldi at $84,000.
December 6, 2013	FDA approves Gilead's Sovaldi (sofosbuvir) through priority review and with breakthrough therapy designation, for the treatment of CHC infection as a component of a combination antiviral treatment regimen.

Timeline of Key Events—Continued

January 29, 2014	The American Association for the Study of Liver Diseases (AASLD) and Infectious Disease Society of America (IDSA) issue recommendations that health care providers prescribe Sovaldi and Olysio in combination for genotype 1 patients who are not eligible to receive interferon.
July 11, 2014	Senators Wyden and Grassley send a letter to Gilead CEO John Martin seeking information about how the company priced Sovaldi.
August 11, 2014	Vertex Pharmaceuticals notifies providers it will discontinue sales of Incivek in October.
October 10, 2014	FDA approves Gilead's Harvoni (ledispasvir and sofosbuvir) through priority review and with breakthrough therapy designation, for the treatment of CHC genotype 1.
October 28, 2014	The National Association of Medicaid Directors sends letter to Congress raising concerns about the price of Sovaldi and Harvoni.
November 5, 2014	FDA approves Olysio-Sovaldi combination for treatment of patients with CHC genotype 1. The application for the combination was submitted by Johnson & Johnson.
December 19, 2014	FDA approves AbbVie Inc.'s Viekira Pack (ombitasvir, paritaprevir, and ritonavir, dasabuvir) through priority review and with breakthrough therapy designation, for use with or without ribavirin to treat patients with CHC genotype 1.
December 22, 2014	Express Scripts Holding Co., the nation's largest pharmaceutical benefits manager, announces that it has reached a deal to include Viekira Pak on its preferred drug list at a significant, but undisclosed discount. The deal sparks competition between AbbVie and Gilead.
January 20, 2015	Johnson & Johnson announces financial results for full year 2014. Sales of Olysio total $2.3 billion, largely attributable to co-prescriptions with Sovaldi. The company reports a sharp drop in Olysio sales during the fourth quarter of 2014, compared to the third quarter, which analysts attribute to competition from Harvoni. Merck notifies providers that it will discontinue sales of Victrelis by December 2015.
February 3, 2015	Gilead announces financial results for full year 2014. Net product sales for Sovaldi total $10.3 billion; net product sales for Harvoni total $2.1 billion. The company announces that it expects the ''gross-to-net'' discount for HCV drugs to average 46% in 2015, compared to 22% in 2014. The increase is attributed to recent agreements it has reached with payers. The company also announces a $15 billion stock buyback program, and initiates a 43-cent-per-share quarterly dividend.
March 24, 2015	FDA issues safety warning that Sovaldi and Harvoni, when used with other direct-acting antiviral drugs such as Olysio, can cause ''serious slowing of the heart rate'' when used with the arrhythmia drug amiodarone.
July 24, 2015	FDA approves Bristol-Meyer Squibb's Daklinza (daclatasvir) through priority review for the treatment of CHC genotype 3 in combination with Sovaldi. FDA approves AbbVie's Technivie (ombitasvir, paritaprevir, and ritonavir) through priority review and with breakthrough therapy designation, for use in combination with ribavirin for the treatment of CHC genotype 4 patients without cirrhosis.
October 22, 2015	FDA issues safety warning that Viekira Pak and Technivie can cause serious liver injury, ''mostly in patients with underlying advanced liver disease.''
October 27, 2015	Gilead announces third quarter financial results. For the first nine months of 2015, net product sales for Harvoni total $10.5 billion; net product sales for Sovaldi total $3.7 billion.

Timeline of Key Events—Continued

October 30, 2015	AbbVie announces third quarter financial results. For the first nine months of 2015, net revenue for Viekira Pak totals $1.1 billion.
November 5, 2015	The Centers for Medicare & Medicaid Services (CMS) sends a letter to state Medicaid programs expressing concerns about continuing access restrictions for HCV drugs, and encouraging states to negotiate with pharmaceutical companies. On the same day, CMS sends letters to Gilead, Johnson & Johnson, AbbVie, and Merck, seeking information about the companies' negotiating practices.

Glossary of Key Terms

AbbVie, Inc.	Markets and sells Viekira Pak™ and Technivie™.
American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA)	Medical societies that have issued clinical practice guidelines and best practices for treatment of hepatitis C.
Bristol Myers-Squibb Co.	Markets and sells Daklinza™.
Cirrhosis	Cirrhosis is a condition in which the liver slowly deteriorates and is unable to function normally due to chronic, or long lasting, injury. Scar tissue replaces healthy liver tissue and partially blocks the flow of blood through the liver. The buildup of scar tissue that causes cirrhosis is usually a slow and gradual process. In the early stages of cirrhosis, the liver continues to function. However, as cirrhosis gets worse and scar tissue replaces more healthy tissue, the liver will begin to fail. Chronic liver failure, which is also called end-stage liver disease, progresses over months, years, or even decades. With end-stage liver disease, the liver can no longer perform important functions or effectively replace damaged cells.
Daklinza™ (daclatasvir)	Developed by Bristol-Meyers Squibb. Approved in July 2015 for treatment of genotype 3 in combination with Sovaldi®.
Direct-acting antiviral drugs (DAA)	DAAs act against HCV by directly inhibiting viral activities including specific enzymes such as polymerase and protease. Among the DAAs are agents which specifically target the NS5A (replication complex), NS5B (polymerase) and NS3/4A (protease).
Early virologic response (EVR)	A significant or complete decline in hepatitis C RNA levels by week 12 of treatment. Failing to achieve an EVR typically means that treatment has failed and a patient will not clear the disease.
Fibrosis	The liver can regenerate most of its own cells when they become damaged. However, if injury to the liver is too severe or long lasting, regeneration is incomplete, and the liver creates scar tissue. Scarring of the liver, also called fibrosis, may lead to cirrhosis.
Genotype	Hepatitis C is divided into distinct strains known as genotypes, which vary in geographic distribution and respond differently to treatment. Also referred to as ''GT.''
Genotype 1	The most common strain of hepatitis C in the United States, accounting for roughly 70%–75% of infections.
Genotype 2	The second most common strain of hepatitis C in the United States, accounting for roughly 15%–16% of infections.
Genotype 3	The third most common strain of hepatitis C in the United States, accounting for roughly 10%–12% of infections.
Gilead Sciences, Inc.	Markets and sells Sovaldi® and Harvoni®.
Gross-to-net price	The difference between the gross—wholesale—price of a drug and the net price after deducting mandatory and supplemental discounts to government payers, in addition to discounts to private payers, and other related costs.
Harvoni® (ledispasvir/sofosbuvir)	Developed by Gilead as a fixed-dose, once daily, single tablet regimen of two agents. Approved in October 2014 for treatment of genotype 1 without interferon or ribavirin. First interferon-free therapy. Also referred to as Wave 2 and ''SOF/LDV''
Incivek® (telaprevir)	Developed by Vertex. Approved in May 2011 for treatment of genotype 1 in combination with pegylated interferon-alfa and ribavirin. Was among the first two direct-acting antivirals approved to treat hepatitis C, along with Victrelis®.

Glossary of Key Terms—Continued

Interferon-alfa	The first approved therapy for hepatitis C, this injectable drug works by boosting the immune system to effectively block new cell sites to which a virus can attach. It had major drawbacks for patients because it required frequent visits to a health care provider and was often accompanied by difficult side effects. Also referred to as IFN.
Johnson & Johnson	Markets and sells Olysio™.
Merck & Co.	Marketed and sells Victrelis®.
NS5A Inhibitors	Class of drugs including ledipasvir (part of Harvoni®), ombitasvir (part of Viekira Pak™), and daclatasvir (Daklinza™), that inhibit the NS5A part of the virus that is required to create the replication complex. A unique class of antivirals that first allowed for all-oral regimens for hepatitis C.
Olysio™ (simeprevir)	Developed by Johnson & Johnson. Approved in November 2013 to treat genotype 1. The AASLD/IDSA recommended in January 2014 that it be used in combination with Sovaldi for treatment of patients not eligible for treatment with interferon. The FDA approved its use in combination with Sovaldi in November 2014.
Pegylated interferon-alfa	Interferon-alfa linked with polyethylene glycol, which prolongs its effect allowing once weekly injections. Pegylated interferon in combination with ribavirin was the standard of care for the treatment of hepatitis C for over a decade until 2014. Also referred to as PEG IFN or PEG.
Pharmasset, Inc.	Bought by Gilead in 2011, this company was the original developer of PSI–7977, the molecule that would become Sovaldi® and be component of Harvoni®.
Polymerase inhibitors	Class of drugs, including Sovaldi®, Harvoni® and Viekira Pak™ that work by disrupting the polymerase enzyme that mediates hepatitis C RNA replication.
Protease inhibitors	Class of drugs including Olysio™, Victrelis®, and Incivek®, that work by blocking the protease, which cleaves and processes viral polyproteins, an important part of hepatitis C's life cycle.
Rapid virologic response (RVR)	When hepatitis C virus is undetectable at week 4 of treatment. Reaching RVR typically signifies high likelihood that a patient has been successfully cured of the disease.
Ribavirin	An antiviral drug discovered in 1972 used for treatment of RNA viruses including hepatitis C. It was part of the standard of care until 2014 and may be a component of current DAA-based regimens. Also referred to as RBV.
Sovaldi® (sofosbuvir)	Developed clinically by Gilead. Approved in December 2013 to treat genotypes 1, 2, 3 and 4. Also referred to as PSI–7977, GS–7977, SOF, and Wave 1.
Standard of care	Treatment accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals. Also called best practice, standard medical care, and standard therapy.
Sustained virologic response (SVR)	Hepatitis C virus RNA is undetectable a set time after treatment—typically 12 or 24 weeks. Signifies that a patient has likely been cured of the disease.
Technivie™ (obmitasvir/paritaprevir/ritonavir)	Developed by AbbVie. Approved in July 2015 for treatment of genotype 4.
Treatment experienced (TE)	Patient who has received treatment for a disease.
Treatment naive (TN)	Patient who has not yet received treatment for a disease.

Glossary of Key Terms—Continued

Vertex Pharmaceuticals, Inc.	Marketed and sold Incivek®.
Victrelis™ (boceprevir)	Developed by Merck. Approved in May 2011 for treatment of genotype 1 in combination with pegylated interferon-alfa and ribavirin. Was among the first two direct-acting antivirals approved to treat hepatitis C, along with Incivek®.
Viekira Pak™ (obmitasvir/ paritaprevir/ritonavir/dasabuvir)	Developed by AbbVie as a fixed-dose regimen of three agents active against HCV. Ritonavir is included as a dose-boosting agent. Approved in December 2014 for treatment of genotype 1 without interferon or ribavirin.
Warehousing	The common, though informal, practice of doctors encouraging their patients to delay treatment close to the release date of a new therapy that is expected to be more effective or less burdensome (in terms of side effects). Typically results in a surge of patients using the new therapy.
Wholesale Acquisition Cost (WAC)	The price of a drug before any discounts, deductions, or other costs.

Letter from Senators Wyden and Grassley to John Martin, CEO, Gilead Sciences (July 11, 2014)

ORRIN G. HATCH, UTAH, CHAIRMAN
CHUCK GRASSLEY, IOWA
MIKE CRAPO, IDAHO
PAT ROBERTS, KANSAS
MICHAEL B. ENZI, WYOMING
JOHN CORNYN, TEXAS
JOHN THUNE, SOUTH DAKOTA
RICHARD BURR, NORTH CAROLINA
JOHNNY ISAKSON, GEORGIA
ROB PORTMAN, OHIO
PATRICK J. TOOMEY, PENNSYLVANIA
DANIEL COATS, INDIANA
DEAN HELLER, NEVADA
TIM SCOTT, SOUTH CAROLINA
RON WYDEN, OREGON
CHARLES E. SCHUMER, NEW YORK
DEBBIE STABENOW, MICHIGAN
MARIA CANTWELL, WASHINGTON
BILL NELSON, FLORIDA
ROBERT MENENDEZ, NEW JERSEY
THOMAS R. CARPER, DELAWARE
BENJAMIN L. CARDIN, MARYLAND
SHERROD BROWN, OHIO
MICHAEL F. BENNET, COLORADO
ROBERT P. CASEY, JR., PENNSYLVANIA
MARK R. WARNER, VIRGINIA
CHRIS CAMPBELL, STAFF DIRECTOR
JOSHUA SHEINKMAN, DEMOCRATIC STAFF DIRECTOR

United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

July 11, 2014

Dr. John C. Martin,
Chairman and Chief Executive Officer
Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404

Dear Dr. Martin:

The Committee on Finance has jurisdiction of matters related to "health programs under the Social Security Act and health programs financed by a specific tax or trust fund," as provided by Rule XXV of the Standing Rules of the Senate. These federal health care programs include Medicare and Medicaid, which together provide health care to over 100 million Americans and represent nearly $900 billion in annual federal spending.

The Federal government is the health care industry's largest customer, and Congress has a responsibility to conduct oversight and ensure that taxpayer dollars are used wisely in a transparent market. Gilead received federal regulatory approval last year for Sovaldi, a drug developed to treat and cure the Hepatitis C virus (HCV). The drug has been hailed as a breakthrough treatment, and its commercial release is a welcome advance in medical research for the 3.2 million Americans infected with HCV and their families.[1]

Although Sovaldi has the potential to help people with HCV, at $ 1,000 per pill, its pricing has raised serious questions about the extent to which the market for this drug is operating efficiently and rationally. While a standard course of treatment for Sovaldi has been widely reported to cost $84,000 in the United States, Gilead will offer the drug in other countries for a fraction of the price. In Egypt, for example, Sovaldi could be offered for as low as $900 per course of treatment—a 99 percent discount of the price in the U.S.[2]

The total cost of a course of this therapy also remains in question. The U.S. Food and Drug Administration dosage approval shows the price could be higher than the $84,000 for a standard treatment. Some patients with HCV genotypes 1 and 3 will require 24 weeks of treatment.[3] The longer treatment regimen roughly doubles the cost-per-patient-per-treatment to $168,000 for Sovaldi, not including the additional cost of peg-interferon alfa and ribavirin used in combination treatments.[4] HCV patients with liver cancer could require 48 weeks of treatment.[5]

---

[1] Centers for Disease Control and Prevention, *Hepatatis C FAQs for the Public,* http://www.cdc.gov/Hepatitis/C/cFAQ.htm#statistics, accessed July 10, 2014.

[2] Maggie Fick and Ben Hirschler, Gilead offers Egypt new hepatitis C drug at 99 percent discount, *Reuters,* March 21 ,2014, http://www.reuters.com/article/2014/03/21/us-hepatitis-egypt-gilead-sciences-idUSBREA2K1VF20140321, accessed July 10, 2014.

[3] U.S. Food & Drug Administration, *Label for Sovaldi (NDA no. 204671),* December 6, 2013, http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204671s000lbl.pdf, accessed July 10, 2014.

[4] Leof, A., et al., (2014). *Sofosbuvir for the treatment of hepatitis C and evaluation of the 2014 American Association for the Study of Liver Diseases treatment guidelines.* Portland, OR: Center for Evidence-Based Policy, Oregon Health & Science University, p. 7–8, http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/med/upload/Sofosbuvir_for_HepatitisC_Final_5_19_2014.pdf, accessed July 10, 2014.

[5] *Supra* at note 3.

The large patient population combined with the high price of each individual treatment creates a question as to whether payors of health care, including Medicare and Medicaid, can carry such a load. Health care experts recently estimated that Sovaldi alone could increase Medicare's spending on prescription drugs by $2 billion between 2014 and 2015 if just 25,000 patients enrolled in the program's prescription drug benefit, known as Part D, receive prescriptions.[6] That represents "roughly 10 percent of Part D enrollees with the hepatitis C virus and about one-fourth of enrollees who have been diagnosed." If 75,000 Part D enrollees took the drug during the same period, program costs would increase by $6.5 billion and premiums for all Part D enrollees could jump 8 percent, "a bigger increase than in any year since 2008."[7]

Sovaldi's cost also could dramatically increase the government's spending in other programs, including health care for prisoners with HCV. According to a recent survey, over 1.8 million people with hepatitis C are currently incarcerated.[8] This represents up to 32.8 percent of the total cases of HCV in the U.S.[9] The Federal Bureau of Prisons within the Department of Justice has already approved Sovaldi for use in treating prison populations, and it is reported that it receives a 44 percent discount.[10] Even with this discount, American taxpayers could end up paying billions of dollars buying Sovaldi to treat inmates infected with HCV.

Given the impact Sovaldi's cost will have on Medicare, Medicaid and other federal spending, we need a better understanding of how your company arrived at the price for this drug. In order for a marketplace to function properly, it must be competitive, fair, and transparent. It is unclear how Gilead set the price for Sovaldi. That price appears to be higher than expected given the costs of development, and production and the steep discounts offered in other countries. An efficient market needs informed consumers to keep costs down. Consequently, we have directed our staff to investigate issues related to Sovaldi and Gilead's pricing of the drug. As part of this investigation, we are seeking information and documents related to the merger of Gilead Sciences, Inc. and Pharmasset, Inc., the original developer of Sovaldi, that was announced November 21, 2011, and the subsequent pricing of Sovaldi.

The following document requests, questions and statements use "Gilead" to refer to Gilead Sciences, Inc., its board of directors, any subsidiaries and contracted third parties; "Pharmasset" is used to refer to Pharmasset, Inc., its board of directors, any subsidiaries and contracted third parties; "Morgan Stanley" refers to Morgan Stanley & Co., LLC, and all its subsidiaries. "Barclays" refers to Barclays Bank PLC, and all its subsidiaries, including but not limited to Barclays Capital. "Bank of America Merrill Lynch" refers to Bank of America Corporation, and all its subsidiaries, including, but not limited to Merrill Lynch. Any reference to "Sovaldi", "PSI–7977" or "GS–7977" refers to sofosbuvir, a drug used in the treatment of hepatitis C virus, and any other names or codenames used to refer to said drug, its predecessor, and related formulas, compounds, research or development projects. "Supporting documents" refers to, but is not limited to, emails, faxes, notes, minutes, memoranda, reports, forecasts, transcripts, charts, spreadsheets and government forms.

Please answer the following questions and provide the following documents:

1. Please provide copies of all presentations, financial analyses, and supporting documents given to Pharmasset and/or to Gilead from 2010 to present from Morgan Stanley in its role as Pharmasset's financial advisor.[11]
2. Please provide a copy of the fairness opinion prepared by Morgan Stanley in conjunction with Gilead's final offering price,[12] and all supporting documents

---

[6] Tricia Neuman, et al., The Cost Of A Cure: Medicare's Role In Treating Hepatitis C, *Health Affairs,* June 5, 2014, http://healthaffairs.org/blog/2014/06/05/the-cost-of-a-cure-medicares-role-in-treating-hepatitis-c/, accessed July 10, 2014.

[7] *Ibid.*

[8] Varan, A.K., et al. "Hepatitis C Seroprevalence among Prison Inmates Since 2001: Still High But Declining." *Public Health Reports,* 129, no. 2 (March/April, 2014): 187–195. (http://www.ncbi.nlm.nih.gov/pubmed/24587554), accessed July 10, 2014.

[9] *Ibid.*

[10] Peter Loftus, New Hepatitis Drugs Vex Prisons, *Wall Street Journal,* April 24, 2014, http://online.wsj.com/news/articles/SB10001424052702304311204579510054146055222, accessed July 10, 2014.

[11] Pharmasset Schedule 14D–9, December 6, 2011, p. 8.

[12] *Ibid.,* p. 12–13.

related to or referencing the fairness opinion, including but not limited to assumptions about the pricing and market for PSI–7977.

3. Please provide copies of the three prospective commercialization forecasts prepared by Pharmasset's management "in and prior to September 2011"[13] and all supporting documents.
4. Please provide copies of Pharmasset' s revised forecasts (prepared before the American Association for the Study of Liver Diseases conference in November 2011)[14] and all supporting documents, including but not limited to assumptions about the pricing and market for PSI–7977.
5. Please provide copies of all communications between Pharmasset's board and its senior management regarding PSI–7977 and all supporting documents, including assumptions about the pricing and market for the drug.
6. In its final annual financial filing with the Securities and Exchange Commission (SEC), Pharmasset reported that its research and development costs totaled $176.7 million for the fiscal years ending 2009, 2010 and 2011, the period during which PSI–7977 was being developed.[15] Of that total, Pharmasset attributed $62.4 million directly to the development of PSI–7977.
   a. Please provide an itemized accounting of Pharmasset's total research and development costs prior to the completion of the merger with Gilead on January 17, 2012.
   b. Please provide an itemized accounting of Pharmasset's research and development costs directly attributable to the development of PSI–7977 prior to the completion of the merger with Gilead on January 17, 2012.
7. Gilead retained Barclays and Bank of America Merrill Lynch as its financial advisors for the acquisition of Pharmasset.[16]
   a. Please provide copies of all communication between Barclays and Gilead relating to the valuation and acquisition of Pharmasset, including assumptions, projections, analyses, recommendations, and any related supporting documents about the pricing and market for PSI–7977.
   b. Please provide copies of all communication between Bank of America Merrill Lynch and Gilead, relating to the valuation and acquisition of Pharmassett, including assumptions, projections, analyses, recommendations, and any related supporting documents about the pricing and market for PSI–7977.
8. Please provide all analyses, recommendations, and supporting documents related to the proposed valuation and acquisition of Pharmasset, including assumptions and projections about the price and market for PSI–7977. Please include all documents related to the following:
   a. The September 2, 2011 meeting between Pharmasset and Gilead to discuss acquisition;
   b. The October 7, 2011 proposal from Gilead to purchase Pharmasset for $125 per share;
   c. The November 17, 2011 proposal from Gilead to purchase Pharmasset for $135 per share;
   d. The November 20, 2011 proposal from Gilead to purchase Pharmasset for $137 per share.
9. Please provide copies of all communications between Gilead and Pharmasset concerning the proposed valuation and acquisition of Pharmasset, including assumptions and projections about the price and market for PSI–7977. Please include all supporting documents related to the following:
   a. The September 2, 2011 meeting between Pharmasset and Gilead to discuss acquisition;
   b. The October 7, 2011 proposal from Gilead to purchase Pharmasset for $125 per share;

---

[13] *Ibid.,* p. 29–30.

[14] *Ibid.,* p. 31–32. Referred to as the "Updated Forecast", management assumed PSI–7977 would be launched in the United States no earlier than the third quarter of 2014; that a course of treatment using PSI–7977 would be priced at $36,000 in the United States, and that European Union pricing would be 60% to 70% of the U.S. price.

[15] Pharmasset, Inc., 10–K for the fiscal year ended September 30, 2011, November, 14, 2011, p. 60.

[16] Gilead Sciences, Inc., and Pharmaset, Inc., *Gilead Sciences to Acquire Pharmasset, Inc., for $11 Billion,* November 21, 2011, http://gilead.com/news/press-releases/2011/11/gilead-sciences-to-acquire-pharmasset-inc-for-11-billion, accessed July 10, 2014.

c. The November 17, 2011 proposal from Gilead to purchase Pharmasset for $135 per share;
d. The November 20, 2011 proposal from Gilead to purchase Pharmasset for $137 per share.

10. Please provide copies of the analysis of the fair value of the In-Process Research and Development (IPR&D) related to GS–7977 cited in Gilead's 10–Q filed with the U.S. Securities and Exchange Commission (SEC) for the quarter ending March 31, 2012,[17] and all supporting documents related to the preparation of this valuation. Identify and describe the key assumptions in the IPR&D valuation.

11. Please provide copies of the analysis of the fair value of IPR&D related to sofosbuvir cited in Gilead's 10–K filed with the SEC for the fiscal year ending December 31, 2012,[18] and all supporting documents related to the preparation of this valuation. Identify and describe the key assumptions in the IPR&D valuation.

12. Please provide an itemized accounting of research and development costs[19] related directly to the development of sofosbuvir that was incurred by Gilead after the completion of the Pharmasset merger on January 17, 2012. This accounting should include separate line items for personnel costs, clinical studies, materials and supplies, licenses and fees, milestone payments under collaboration arrangements, overhead allocations, facilities costs and the value contracts with contract research organizations (CROs) related directly to the development of sofosbuvir.

13. Before Gilead could complete its acquisition of Pharmasset, both companies were required to file pre-merger notifications with the U.S. Federal Trade Commission (FTC).
    a. Please provide copies of Gilead's filing with the FTC, all documents provided to the FTC pursuant to 16 C.F.R. §803.1 and 16 C.F.R. §803.2, all communications with the FTC related to the filing, and all supporting documents related to the filing.
    b. Please provide copies of Pharmasset's filing with the FTC, all documents provided to the FTC pursuant to 16 C.F.R. §803.1 and 16 C.F.R. §803.2, all communications with the FTC related to the filing, and all supporting documents related to the filing.

14. Please provide copies of the marketing and pricing plans prepared for, and being used in, the launch of Sovaldi in the U.S. and internationally,[20] including all communications and supporting documents related to the preparation of these plans, materials, and prices.
    a. Looking forward, please describe how the commercial success of Sovaldi, as evidenced by first quarter sales, will affect marketing and pricing plans, including the cost of production, and future prices in the U.S. and internationally. If there will not be any effect, explain why.

15. Sovaldi is currently prescribed in combination with other medications, which increases the total cost per patient per course of treatment.[21] Gilead has applied for approval to sell single-dose combinations of Sovaldi with other drugs.
    a. If approval is granted for a single-dose combination drug, how will it affect the future price of Sovaldi?
    b. Please provide copies of any pricing plans, marketing plans, or price estimates related to these pending combination drugs, and all supporting documents related to the plans and related forecasts.

---

[17] Gilead Sciences, Inc. Form 10–Q for the quarterly period ended March 31, 2012, May 4, 2012, p. 16.
[18] Gilead Sciences, Inc., Form 10–K for the fiscal year ended December 31, 2012, February, 27, 2013, p. 105.
[19] Gilead Sciences, Inc., Form 10–K for the fiscal year ended December 31, 2013, February 25, 2014, p. 60.
[20] Gilead Sciences., Inc., Form 10–Q for the quarterly period ended March 31, 2014, May 5, 2014, p. 29. Gilead's Selling, General, and Administrative expenses (SG&A) for the quarter ending March 31, 2014, "increased by $173.8 million or 46%, compared to the same period in 2013, due primarily to a $113.6 million increase in headcount and other expenses to support the ongoing growth and expansion of our business, which includes ongoing launches of Sovaldi in the United States and internationally as well as the anticipated launch of idelalisib."
[21] *Supra* at note 3.

16. Please provide copies of Gilead's estimates of the U.S. treatment cost-per-patient and U.S. cost-per-cure for each of the FDA's approved genotype-based treatment regimens for Sovaldi, including itemization of the cost of Sovaldi, the cost of combination drugs, and all supporting documents used in developing such estimates.

17. Looking forward, what are Gilead's expected changes in the treatment cost-per-patient and the cost-per-cure of Sovaldi-based treatment over the next five years for each of the FDA approval regimens for the U.S. HCV populations?

18. Oregon Health & Science University researchers reviewed treatment guidelines for Sovaldi jointly issued by several professional societies, concluding there is a "substantial risk of conflict of interest influencing the recommendations from both individual panel members and funding sources."[22] The organizations' website shows 18 of the 27 panel members involved in developing the guidance for the American Association for the Study of Liver Disease (AASLD) and the Infectious Diseases Society of America (IDSA) disclosed either a direct financial relationship with Gilead or received institutional funding from the company.[23] Both groups, and a third collaborating partner, the International Antiviral Society–USA (IAS–USA), have all received funding from Gilead.[24]
    a. Please provide an itemized accounting of all payments from 2009 to present between Gilead and/or Pharmasset and the following organizations:
        i. AASLD
        ii. IDSA
        iii. IAS–USA
    b. Please provide an itemized accounting of all payments from 2009 to present between Gilead and/or Pharrnasset and the expert panel members that developed the AASLD/IDSA treatment guidelines for HCV.[25]
    c. For each organization or individual identified in (a) or (b), provide:
        i. Date of payment
        ii. Payment description
        iii. Amount of payment
        iv. Year-end or year-to-date payment total and cumulative total payments for each organization or individual
    d. Describe any communications between employees of Gilead and the organizations and individuals identified in (a) and (b) regarding the AASLD/IDSA treatment guidelines for HCV. Please provide all supporting documents related to those communications.

19. Gilead's advertising and promotional expenses have increased from $116.6 million in 2011 to $216.2 million in 2013.[26]
    a. How much money does Gilead plan to spend on advertising and promotional expenses in 2014?
    b. How much money does the company plan to spend on advertising and promotion of SovaIdi in 2014?
    c. How much money did the company spend on advertising and promotion of Sovaldi prior to January 1, 2014?

20. Gilead has included Sovaldi in its patient assistance program , which includes coupons for reducing the cost of patient co-pays.[27] Gilead estimated that 30,000 patients were treated with Sovaldi during the first quarter of 2014:[28]
    a. How many patients have been treated in the United States with Sovaldi to date?

---

[22] *Supra* at note 4, p. 21.

[23] AASLD/IDSA, Recommendations for Testing, Managing, and Treating Hepatitis C, Disclosure Information, http://hcvguidelines.org/disclosure_information, accessed July 10, 2014.

[24] See AASLD 2012 Annual Report p. 29, http://www.aasld.org/aboutus/Documents/2012AnnualReport.pdf, accessed July 10, 2014; IDSA Industry relations, Grants and Contributions 2010–2014, http://www.idsociety.org/IDSA_Industry_Relations, accessed on July 10, 2014; IAS–USA Cases on the Web Grant Support, https://www.iasusa.org/cow-grant-support, accessed on July 10, 2014.

[25] AASLD/IDSA, Recommendations for Testing, Managing, and Treating Hepatitis C, Disclosure Information, http://hcvguidelines.org/disclosure_information, accessed on July 10, 2014.

[26] *Supra* at note 19, p. 96.

[27] Gilead, *Support Path for Sovaldi,* http://www.gilead.com/responsibility/us-patient-access/support%20path%20for%20sovaldi, accessed on July 10, 2014.

[28] *Supra* note at note 20. p. 27.

b. How many patients in the United States have been assisted by Gilead's patient assistance program to date?
c. What percentage of patients does Gilead expect to be covered under this program?
d. What is the average outlay-per-patient in the patient assistance program?
e. What percentage of the patient's cost for Sovaldi will the payment assistance program cover for each of the FDA-approved treatment regimens?
f. What patients are eligible for this assistance? What patients are ineligible for this assistance?
g. There are a number of HCV-infected populations, such as those exposed through intravenous drug use, contaminated blood and those born to someone infected with the virus. Describe the patient populations expected to be covered by the Sovaldi patient assistance program.
h. How are the costs of this assistance accounted for within Gilead's financials, e.g. are they deducted as part of the company's Selling, General, and Administrative (SG&A) expenses?

21. Sovaldi is and will be sold in multiple countries, many of which are expected to receive significant discounts compared to the price in the U.S.
    a. Please provide a list of all countries where Sovaldi is or will be sold, and the corresponding price or planned price for each country. Describe how the company reached the price for each country.
    b. How are the revenue, costs and any discounts associated with international sales, such as Egypt, accounted for within Gilead's financials, e.g. are they deducted as part of the company's Selling, General, and Administrative (SG&A) expenses?

Thank you in advance for your assistance in this matter. Please begin producing documents and information on a rolling basis no later than 14 days—and complete production no later than 60 days—after the receipt of this letter. Please contact our staff as soon as possible to discuss prioritizing the order in which responsive documents and information should be produced.

Please direct any questions about this letter to David Berick, Chief Investigator, or Elizabeth Jurinka, Chief Health Policy Advisor for Chairman Wyden, and to Jason Foster, Chief Investigative Counsel, or Rodney Whitlock, Health Policy Director for Senator Grassley.

Sincerely,

Ron Wyden,
Chairman

Charles E. Grassley,
Member

Appendix A

State Data and Methodology

To better quantify and qualify the financial impacts of Sovaldi and Harvoni on individual state Medicaid programs, investigative staff requested quantitative and qualitative data from all 50 states and the District of Columbia regarding a series of issues related to Hepatitis C virus (HCV) infections, pharmaceutical spending, interactions with Gilead Sciences, Inc., and the financial impact of Sovaldi and Harvoni on state Medicaid spending. State Medicaid programs were asked to provide:

- Total spending (pre-rebate) on Sovaldi and Harvoni in calendar year 2014 (CY 2014)
- The number of prescriptions filled for Sovaldi and Harvoni during CY 2014
- The number of unique recipients who were dispensed Sovaldi and Harvoni during CY 2014
- The top 25 drugs, in terms of aggregate spending, in CY 2014
- The rank of Sovaldi and Harvoni in the state's pharmaceutical spending
- The estimated number of enrollees infected with HCV
- The estimated number of enrollees in each state's Medicaid program
- Whether the state signed a supplemental rebate agreement with Gilead in CY 2014

What follows are descriptions of the data compiled by investigative staff.

Supplemental Rebate

State Medicaid programs were asked if the program agreed to a supplemental rebate with Gilead for Sovaldi during CY 2014. Federal law requires pharmaceutical manufacturers to return a rebate equal to either the difference between a drug's quarterly average manufacturer price (AMP) and the best price, or 23.1%, whichever is larger.[1] In addition to these statutory requirements, companies can provide supplemental rebates to Medicaid programs. The supplemental rebates are typically used by companies as leverage to secure placement on states' preferred drug lists and increase market share.

Forty-eight programs responded to this request, or were able to provide this information. The responses are noted in the column titled "Supplemental Rebate for Sovaldi in CY 2014" in Table 1.

HCV Enrollees in Medicaid

State Medicaid programs were asked to provide information about the number of enrollees infected with HCV. Investigative staff believe these data are the most accurate available representation of the HCV prevalence within each program. The methods of data collection were not uniform; reports to investigative staff used varying levels of detail to describe how the data were collected. Investigative staff outlined these methods (where applicable) in notes detailing state-by-state data variations (see "Data Variations by State" after Table 4). The data can be divided into three broad categories: diagnosed patients, population estimates, or hybrid figures based on a combination of diagnoses and estimates. In most cases, the figures were provided as a single number; in cases where there was a range, investigative staff used the lower bound, noting both the upper and lower estimates in the data variations.

Forty-four programs responded to this request. The data can be found in the column titled "HCV Enrollees in Medicaid" in Table 1.

Total Medicaid Population

State Medicaid programs were asked to provide the program's enrollment. The data reflect enrollment estimates, average monthly enrollment, or total enrollment figures for CY 2014, a specific month or date, or other specified time periods. In some cases, programs reported separate fee-for-service (FFS) and managed care organization (MCO) population figures; investigative staff listed a single number for consistency and noted full descriptions in the data variations (see "Data Variations by State") when multiple numbers were submitted.

[1] 42 U.S.C. § 1396r–8(c)(1) (setting the basic rebate for single source drugs and innovator multiple source drugs).

Fifty programs responded to this request. The data can be found in the column titled "Total Medicaid Enrollees" in Table 1.

Total Drug Spending Data

State Medicaid programs were asked to provide a list of the top 25 medications as ranked by total amount paid during CY 2014. The data do not reflect any required or supplemental rebates. For each medication, state programs were asked to provide (1) claim count, (2) wholesale acquisition cost (WAC), (3) drug quantity, (4) days of supply, and (5) the number of unique recipients. If Sovaldi did not fall within the top 25 medications by amount paid, state programs were asked to provide a separate line item with Sovaldi's rank and the above-requested information. Many state programs provided the same data for Harvoni and Olysio when they fell out of the list of top 25 medications.

All programs responded to this request. Data highlighting total spending, rank by total spending, and the number of unique Medicaid recipients for Sovaldi, Harvoni and Olysio can be found in Tables 2, 3 and 4, respectively. The first three data columns for each table show figures specific to FFS programs; the next three columns show stand-alone data for MCO programs; the final three columns show combined FFS and MCO data in cases where states did not report separate data for each program.

Individual state programs deliver Medicaid prescription drug benefits differently, which is reflected in the data. Twenty-eight states reported their total drug spending as all FFS; 13 states reported separate spending data for FFS and MCO programs; other states provided a single top 25 list with combined FFS and MCO data. These differences are specified in each column, as well as in the data variations detailed in "Data Variations by State."

Table 1—Supplemental Rebates and HCV/Total Medicaid Enrollees

State	Supplemental Rebate for Sovaldi in CY 2014	HCV Enrollees in Medicaid †	Total Medicaid Enrollees †
Alabama	No	6,200	1,031,000
Alaska	No	1,200	130,000
Arizona	No	18,000	1,746,175
Arkansas	No	1,381	902,378
California	No	237,000	12,342,888
Colorado	No	6,229	1,192,000
Connecticut	No	10,800	725,500
Delaware	No	1,444	202,064
District of Columbia	No	5,461	247,201
Florida	No	17,230	3,429,343
Georgia	Yes	6,000	1,913,957
Hawaii	No	*	328,000
Idaho	No	*	274,541
Illinois	No	15,520	3,000,000
Indiana	No	9,522	1,117,418
Iowa	No	5,406	560,000
Kansas	No	*	422,576
Kentucky	No	15,542	1,437,235
Louisiana	*	*	1,292,942
Maine	Yes	1,749	336,000
Maryland	No	15,019	1,300,000
Massachusetts	No	21,047	1,852,801
Michigan	No	17,605	2,000,000
Minnesota	Yes	5,600	939,902
Mississippi	No	1,711	703,015
Missouri	No	13,000	947,250
Montana	No	2,930	167,621
Nebraska	No	862	234,056
Nevada	No	3,513	556,015
New Hampshire	No	1,600	146,682
New Jersey	No	19,919	1,675,640
New Mexico	No	4,864	790,000
New York	No	57,897	6,221,396
North Carolina	No	19,246	1,840,215
North Dakota	No	*	81,000
Ohio	No	6,500	2,936,891
Oklahoma	No	6,416	1,025,312
Oregon	No	10,898	999,496
Pennsylvania	No	31,636	2,161,630
Rhode Island	No	2,200	265,000
South Carolina	No	4,000	1,200,000
South Dakota	*	*	117,346
Tennessee	No	9,772	1,360,000
Texas	No	17,325	3,884,958
Utah	No	*	*
Vermont	Yes	1,280	176,128
Virginia	No	10,312	1,136,180
Washington	No	23,310	1,535,509
West Virginia	No	16,342	494,460
Wisconsin	*	14,800	1,200,000
Wyoming	Yes	700	85,000

* Not available.
† State reported data vary by time period. For a full explanation, please see ''Data Variations by State'' following Table 4 in Appendix A.

Table 2—State Reported Medicaid Spending and Data for CY 2014—Sovaldi

State	Sovaldi Rank—FFS	Sovaldi Total Spending—FFS	Sovaldi HCV Recipients—FFS	Sovaldi Rank—MCO	Sovaldi Total Spending—MCO	Sovaldi HCV Recipients—MCO	Sovaldi Rank—Combined FFS/MCO	Sovaldi Total Spending—Combined FFS/MCO	Sovaldi HCV Recipients—Combined FFS/MCO
Alabama [A]	6	$11,903,250	151	*	*	*	*	*	*
Alaska [A]	50	$223,338	4	*	*	*	*	*	*
Arizona [B]	7	$313,031	4	2	$23,891,674	259	*	*	*
Arkansas [A]	15	$3,236,633	38	*	*	*	*	*	*
California [B]	31	$21,866,410	280	*	*	1,359	*	*	*
Colorado [A]	3	$8,537,340	93	*	*	*	*	*	*
Connecticut [A]	1	$66,127,237	744	*	*	*	*	*	*
Delaware [A]	20	$1,464,752	16	*	*	*	*	*	*
District of Columbia [A]	32	$605,735	9	*	*	*	*	*	*
Florida [D]	2	$26,826,502	336	2	$35,429,282	471	2	$62,255,785	712
Georgia [A]	1	$30,475,725	329	*	*	*	*	*	*
Hawaii [E]	*	*	*	1	$18,678,769	184	*	*	*
Idaho [A]	10	$1,739,667	18	*	*	*	*	*	*
Illinois [A]	4	$18,819,196	208	*	*	*	*	*	*
Indiana [C]	*	*	*	*	*	*	2	$40,304,301	462
Iowa [A]	53	$1,264,706	17	*	*	*	*	*	*
Kansas [C]	*	*	*	*	*	*	3	$11,316,299	137
Kentucky [D]	27	$515,424	6	1	$47,322,123	506	1	$47,837,547	511
Louisiana [B]	6	$5,645,304	67	2	$5,419,841	60	*	*	*
Maine [A]	2	$6,943,323	133	*	*	*	*	*	*
Maryland [B]	148	$472,145	9	1	$29,321,884	348	*	*	*
Massachusetts [B]	1	$41,471,082	492	1	$52,038,369	549	*	*	*
Michigan [A]	167	$800,482	16	*	*	*	*	*	*
Minnesota [A]	1	$9,181,119	114	*	*	393	*	*	*
Mississippi [D]	28	$1,951,548	23	3	$5,715,467	66	11	$7,667,015	87
Missouri [A]	2	$32,988,645	359	*	*	*	*	*	*
Montana [A]	2	$3,721,163	39	*	*	*	*	*	*
Nebraska [A]	6	$3,050,208	31	*	*	*	*	*	*
Nevada [A]	2	$11,882,983	126	*	*	*	*	*	*
New Hampshire [A]	36	$84,677	1	*	*	*	*	*	*
New Jersey [C]	*	*	*	*	*	*	1	$55,575,074	695
New Mexico [B]	6	$296,825	3	1	$8,433,631	105	*	*	*
New York [B]	1	$31,137,860	399	1	$332,459,598	3,509	*	*	*
North Carolina [A]	2	$38,952,473	473	*	*	*	*	*	*

Table 2—State Reported Medicaid Spending and Data for CY 2014—Sovaldi—Continued

State	Sovaldi Rank—FFS	Sovaldi Total Spending—FFS	Sovaldi HCV Recipients—FFS	Sovaldi Rank—MCO	Sovaldi Total Spending—MCO	Sovaldi HCV Recipients—MCO	Sovaldi Rank—Combined FFS/MCO	Sovaldi Total Spending—Combined FFS/MCO	Sovaldi HCV Recipients—Combined FFS/MCO
North Dakota [B]	5	$562,542	9	1	$2,081,450	*	*	*	*
Ohio [B]	2	$6,442,541	101	5	$30,294,252	387	*	*	*
Oklahoma [A]	1	$17,824,761	220	*	*	*	*	*	*
Oregon [B]	47	$558,280	9	2	$10,003,701	135	*	*	*
Pennsylvania [C]	*	*	*	*	*	*	2	$98,136,797	1,059
Rhode Island [B]	42	$84,010	2	2	$5,383,450	60	*	*	*
South Carolina [B]	250	$99,933	2	13	$4,267,112	48	*	*	*
South Dakota [A F]	5	$1,607,185	20	*	*	*	*	*	*
Tennessee [A]	1	$29,015,258	321	*	*	*	*	*	*
Texas [D]	*	*	*	317	$1,145,688	13	410	$1,145,688	13
Utah [C]	*	*	*	*	*	*	1	$5,583,957	66
Vermont [A]	2	$3,338,307	45	*	*	*	*	*	*
Virginia [B]	18	$1,254,445	21	7	$10,567,386	119	*	*	*
Washington [A]	9	$2,143,021	31	*	*	*	*	*	*
West Virginia [A]	32	$1,413,795	19	*	*	*	*	*	*
Wisconsin [A]	54	$3,073,300	38	*	*	*	*	*	*
Wyoming [A]	2	$1,147,913	13	*	*	*	*	*	*

[A] State reported total drug spending data through its FFS program.
[B] State reported separate total drug spending data for the FFS and MCO programs.
[C] State reported combined total drug spending data for the FFS and MCO programs.
[D] State reported combined total drug spending data for the FFS and MCO programs, as well as separate FFS and MCO total drug spending.
[E] Hawaii reported combined total drug spending data for the FFS and MCO programs, but given Hawaii's Medicaid program is less than 1% FFS, the data is noted as MCO for our purposes (there was one unique recipient for Sovaldi in the FFS program).
[F] South Dakota reported a duplicated patient count for Sovaldi recipients.
* Not available or not applicable.

Table 3—State Reported Medicaid Spending and Data for CY 2014—Harvoni

State	Harvoni Rank—FFS	Harvoni Total Spending—FFS	Harvoni HCV Recipients—FFS	Harvoni Rank—MCO	Harvoni Total Spending—MCO	Harvoni HCV Recipients—MCO	Harvoni Rank—Combined FFS/MCO	Harvoni Total Spending—Combined FFS/MCO	Harvoni HCV Recipients—Combined FFS/MCO
Alabama [A]	*	$756,162	24	*	*	*	*	*	*
Alaska [A]	385	$31,812	1	*	*	*	*	*	*
Arizona [B]	*	$46,566	1	*	$63,507	2	*	*	*
Arkansas [A]	*	*	*	*	*	*	*	*	*
California [B]	164	$2,882,089	57	*	*	101	*	*	*
Colorado [A]	*	*	*	*	*	*	*	*	*
Connecticut [A]	4	$16,724,290	319	*	*	*	*	*	*
Delaware [A]	494	$61,250	2	*	*	*	*	*	*
District of Columbia [A]	*	*	*	*	*	*	*	*	*
Florida [D]	888	$127,905	3	142	$1,439,135	36	236	$1,567,040	39
Georgia [A]	15	$7,575,827	125	*	*	*	*	*	*
Hawaii [E]	*	*	*	30	$1,118,087	22	*	*	*
Idaho [A]	239	$118,169	3	*	*	*	*	*	*
Illinois [A]	549	$188,987	8	*	*	*	*	*	*
Indiana [C]	*	*	*	*	*	*	23	$4,412,692	74
Iowa [A]	440	$162,876	3	*	*	*	*	*	*
Kansas [C]	*	*	*	*	*	*	26	$2,128,971	49
Kentucky [D]	*	*	*	27	$5,871,678	92	29	$5,871,678	92
Louisiana [B]	38	$2,047,978	44	1,070	$32,128	1	*	*	*
Maine [A]	*	$158,796	15	*	*	*	*	*	*
Maryland [B]	155	$445,055	10	8	$7,209,942	144	*	*	*
Massachusetts [B]	4	$12,252,727	243	*	*	*	*	*	*
Michigan [A]	*	*	*	*	*	*	*	*	*
Minnesota [A]	*	*	*	*	*	*	*	*	*
Mississippi [D]	250	$99,795	2	131	$299,384	6	185	$399,179	8
Missouri [A]	*	*	*	*	*	*	*	*	*
Montana [A]	59	$321,285	280	*	*	*	*	*	*
Nebraska [A]	144	$403,704	7	*	*	*	*	*	*
Nevada [A]	11	$2,763,618	55	*	*	*	*	*	*
New Hampshire [A]	*	*	*	*	*	*	*	*	*
New Jersey [C]	*	*	*	*	*	*	24	$6,983,022	159
New Mexico [B]	111	$33,393	1	40	$974,977	22	*	*	*
New York [B]	*	*	*	22	$32,362,005	581	*	*	*
North Carolina [A]	*	*	*	*	*	*	*	*	*

Table 3—State Reported Medicaid Spending and Data for CY 2014—Harvoni—Continued

State	Harvoni Rank—FFS	Harvoni Total Spending—FFS	Harvoni HCV Recipients—FFS	Harvoni Rank—MCO	Harvoni Total Spending—MCO	Harvoni HCV Recipients—MCO	Harvoni Rank—Combined FFS/MCO	Harvoni Total Spending—Combined FFS/MCO	Harvoni HCV Recipients—Combined FFS/MCO
North Dakota [B]	*	*	*	2	$901,124	*	*	*	*
Ohio [B]	*	*	*	627	$457,585	11	*	*	*
Oklahoma [A]	*	*	*	*	*	*	*	*	*
Oregon [B]	131	$126,039	1	55	$1,103,510	23	*	*	*
Pennsylvania [C]	*	*	*	*	*	*	112	$2,962,739	66
Rhode Island [B]	*	*	*	*	*	*	*	*	*
South Carolina [B]	220	$124,509	4	352	$159,131	4	*	*	*
South Dakota [A F]	*	$65,774	1	*	*	*	*	*	*
Tennessee [A]	172	$1,046,544	21	*	*	*	*	*	*
Texas [D]	*	*	*	*	*	*	*	*	*
Utah [C]	*	*	*	*	*	*	*	$1,073,705	20
Vermont [A]	204	$126,240	2	*	*	*	*	*	*
Virginia [B]	180	$133,606	3	268	$458,679	8	*	*	*
Washington [A]	*	*	*	*	*	*	*	*	*
West Virginia [A]	270	$224,919	5	*	*	*	*	*	*
Wisconsin [A]	*	*	*	*	*	*	*	*	*
Wyoming [A]	*	*	*	*	*	*	*	*	*

[A] State reported total drug spending data through its FFS program.
[B] State reported separate total drug spending data for the FFS and MCO programs.
[C] State reported combined total drug spending data for the FFS and MCO programs.
[D] State reported combined total drug spending data for the FFS and MCO programs, as well as separate FFS and MCO total drug spending.
[E] Hawaii reported combined total drug spending data for the FFS and MCO programs, but given Hawaii's Medicaid program is less than 1% FFS, the data is noted as MCO for our purposes (there was one unique recipient for Sovaldi in the FFS program).
[F] South Dakota reported a duplicated patient count for Sovaldi recipients.
* Not available or not applicable.

Table 4—State Reported Medicaid Spending and Data for CY 2014—Olysio

State	Olysio Rank—FFS	Olysio Total Spending—FFS	Olysio HCV Recipients—FFS	Olysio Rank—MCO	Olysio Total Spending—MCO	Olysio HCV Recipients—MCO	Olysio Rank—Combined FFS/MCO	Olysio Total Spending—Combined FFS/MCO	Olysio HCV Recipients—Combined FFS/MCO
Alabama [A]	*	*	*	*	*	*	*	*	*
Alaska [A]	*	*	*	*	*	*	*	*	*
Arizona [B]	*	*	*	*	*	*	*	*	*
Arkansas [A]	225	$342,455	5	*	*	*	*	*	*
California [B]	*	*	*	*	*	*	*	*	*
Colorado [A]	*	*	*	*	*	*	*	*	*
Connecticut [A]	6	$14,407,876	221	*	*	*	*	*	*
Delaware [A]	*	*	*	*	*	*	*	*	*
District of Columbia [A]	*	*	*	*	*	*	*	*	*
Florida [D]	35	$5,166,141	91	32	$5,988,711	109	32	$11,154,852	185
Georgia [A]	18	$6,175,803	97	*	*	*	*	*	*
Hawaii [E]	*	*	*	4	$4,615,489	69	*	*	*
Idaho [A]	*	*	*	*	*	*	*	*	*
Illinois [A]	*	*	*	*	*	*	*	*	*
Indiana [C]	*	*	*	*	*	*	16	$9,299,691	155
Iowa [A]	*	*	*	*	*	*	*	*	*
Kansas [C]	*	*	*	*	*	*	*	*	*
Kentucky [D]	*	*	*	34	$4,990,572	79	41	$4,990,572	79
Louisiana [B]	*	*	*	*	*	*	*	*	*
Maine [A]	*	*	*	*	*	*	*	*	*
Maryland [B]	*	*	*	17	$3,911,975	61	*	*	*
Massachusetts [B]	8	$7,079,983	122	9	$7,491,262	117	*	*	*
Michigan [A]	*	*	*	*	*	*	*	*	*
Minnesota [A]	*	*	*	*	*	*	*	*	*
Mississippi [D]	*	*	*	*	*	*	*	*	*
Missouri [A]	*	*	*	*	*	*	*	*	*
Montana [A]	641	$22,561	28	*	*	*	*	*	*
Nebraska [A]	*	*	*	*	*	*	*	*	*
Nevada [A]	*	*	*	*	*	*	*	*	*
New Hampshire [A]	*	*	*	*	*	*	*	*	*
New Jersey [C]	*	*	*	*	*	*	22	$7,304,069	138
New Mexico [B]	*	*	*	*	*	*	*	*	*
New York [B]	*	*	*	15	$42,514,707	669	*	*	*
North Carolina [A]	*	*	*	*	*	*	*	*	*

Table 4—State Reported Medicaid Spending and Data for CY 2014—Olysio—Continued

State	Olysio Rank—FFS	Olysio Total Spending—FFS	Olysio HCV Recipients—FFS	Olysio Rank—MCO	Olysio Total Spending—MCO	Olysio HCV Recipients—MCO	Olysio Rank—Combined FFS/MCO	Olysio Total Spending—Combined FFS/MCO	Olysio HCV Recipients—Combined FFS/MCO
North Dakota [B]	*	*	*	13	$138,173	*	*	*	*
Ohio [B]	*	*	*	*	*	*	*	*	*
Oklahoma [A]	*	*	*	*	*	*	*	*	*
Oregon [B]	2,349	$30	1	48	$1,302,597	23	*	*	*
Pennsylvania [C]	*	*	*	*	*	*	24	$15,555,728	248
Rhode Island [B]	*	*	*	*	*	*	*	*	*
South Carolina [B]	*	*	*	146	$520,477	8	*	*	*
South Dakota [A F]	*	*	*	*	*	*	*	*	*
Tennessee [A]	*	*	*	*	*	*	*	*	*
Texas [D]	*	*	*	1,548	$136,186	2	1,853	$136,186	2
Utah [C]	*	*	*	*	*	*	25	$1,121,245	18
Vermont [A]	32	$819,966	12	*	*	*	*	*	*
Virginia [B]	156	$155,985	4	118	$1,204,435	19	*	*	*
Washington [A]	*	*	*	*	*	*	*	*	*
West Virginia [A]	*	*	*	*	*	*	*	*	*
Wisconsin [A]	*	*	*	*	*	*	*	*	*
Wyoming [A]	*	*	*	*	*	*	*	*	*

[A] State reported total drug spending data through its FFS program.
[B] State reported separate total drug spending data for the FFS and MCO programs.
[C] State reported combined total drug spending data for the FFS and MCO programs.
[D] State reported combined total drug spending data for the FFS and MCO programs, as well as separate FFS and MCO total drug spending.
[E] Hawaii reported combined total drug spending data for the FFS and MCO programs, but given Hawaii's Medicaid program is less than 1% FFS, the data is noted as MCO for our purposes (there was one unique recipient for Sovaldi in the FFS program).
[F] South Dakota reported a duplicated patient count for Sovaldi recipients.
* Not available or not applicable.

Data Variations by State

Acronyms

FFS: fee-for-service

MCO: managed care organization

CY: calendar year (Calendar Year 2014 = January 1, 2014–December 31, 2014)

FFY: federal fiscal year (Fiscal Year 2014 = October 1, 2013–September 30, 2014)

SFY: state fiscal year (State Fiscal Year 2014 = July 1, 2013–June 30, 2014, unless otherwise noted)

HCV: Hepatitis C virus

ICD–9: International Classification of Diseases (ICD), maintained by the World Health Organization. ICD–9 refers to the ninth revision of these codes.

Alabama

Spending: Reported total drug spending data are FFS for CY 2014;
Medicaid Population: Average monthly enrollment during CY 2014;
HCV Enrollees in Medicaid: Enrollees with a claim indicating HCV diagnosis codes during the period July 2013–December 2014.

Alaska

Spending: Reported total drug spending data are FFS for CY 2014;
Medicaid Population: Total enrollees during CY 2014 (none enrolled in managed care);
HCV Enrollees in Medicaid: Estimate of enrollees infected with Hepatitis C based on available claims data.

Arizona

Spending: Reported total drug spending data are separate FFS and MCO data for CY 2014 (Harvoni rank not available because Harvoni was not released until the fourth quarter of 2014);
Medicaid Population: Enrollment during July 2015 (excluding the Medicare Savings Program and emergency services populations, 92.7% of the Arizona Health Care Cost Containment System (AHCCCS) population is enrolled in MCO's and 7.3% is in FFS);
HCV Enrollees in Medicaid: Enrollees identified in the AHCCCS who have a claim or encounter with an HCV diagnosis attached to that claim or encounter.

Arkansas

Spending: Reported total drug spending data are FFS for CY 2014;
Medicaid Population: Number of Medicaid beneficiaries during SFY 2014 (July 1, 2013–June 30, 2014);
HCV Enrollees in Medicaid: Estimated enrollees with a diagnosis code (Acute HCV, Chronic HCV, and Unspecified HCV) in medical claims history during January 1, 2013–January 23, 2015.

California

Spending: Reported total drug spending data are separate FFS and MCO data for CY 2014 (unable to provide total spending and rank data for MCO population);
Medicaid Population: Enrollment during March 2015;
HCV Enrollees in Medicaid: Estimate of enrollees based on a 3% HCV prevalence of Medi-Cal adults.

Colorado

Spending: Reported total drug spending data are FFS for CY 2014;
Medicaid Population: Estimates for both FFS and MCO populations combined;

HCV Enrollees in Medicaid: Enrollees identified from claims and diagnosis codes during April 2014.

Connecticut

Spending: Reported total drug spending data are FFS for CY 2014;
Medicaid Population: Total enrollment for June 2014;
HCV Enrollees in Medicaid: Enrollees with HCV as primary diagnosis during July 2015.

Delaware

Spending: Reported total drug spending data are FFS for CY 2014;
Medicaid Population: Total enrollment for June 2014;
HCV Enrollees in Medicaid: Enrollees with an HCV diagnosis in their active profile between May 1, 2014 and April 30, 2015.

District of Columbia

Spending: Reported total drug spending data are FFS for CY 2014;
Medicaid Population: Enrollment estimates for both FFS and MCO populations combined (Time period: January 1, 2014–April 30, 2015);
HCV Enrollees in Medicaid: Estimate of enrollees with an HCV diagnosis during July 2015 (Additional estimate: 11,000 enrollees may be amenable to treatment).

Florida

Spending: Reported total drug spending data are combined FFS and MCO data, as well as separate FFS and MCO data, for CY 2014;
Medicaid Population: Total enrollment on January 31, 2014;
HCV Enrollees in Medicaid: Enrollees with at least one HCV diagnosis record between January 1, 2014 and December 31, 2014.

Georgia

Spending: Reported total drug spending data are FFS for CY 2014;
Medicaid Population: Enrollment for December 2014 reflects total enrollee count eligible for Medicaid and PeachCare;
HCV Enrollees in Medicaid: Estimated enrollees in the FFS population with HCV.

Hawaii

Spending: Hawaii reported combined FFS and MCO data, but given Hawaii's Medicaid program is less than 1% FFS, the data are noted as MCO for our purposes (in CY 2014, there was one unique recipient for Sovaldi in the FFS program);
Medicaid Population: Estimate based on December 2014 enrollment statistics;
HCV Enrollees in Medicaid: No data provided.

Idaho

Spending: Reported total drug spending data are FFS for CY 2014;
Medicaid Population: Enrollees during CY 2014;
HCV Enrollees in Medicaid: Estimate not provided.

Illinois

Spending: Reported total drug spending data are FFS for CY 2014;
Medicaid Population: Projected Medicaid enrollment for SFY 2015 (July 1, 2014–June 30, 2015), with approximately 1.2 million enrolled in an MCO and 1.8 million in FFS;
HCV Enrollees in Medicaid: Estimated number of enrollees with HCV based on diagnoses submitted on medical claims during SFY 2014 (July 1, 2013–June 30, 2014).

Indiana

Spending: Reported total drug spending data are combined FFS and MCO data for CY 2014 (All Indiana Medicaid enrollees received pharmacy benefits through FFS program);
Medicaid Population: Total enrollment for December 2014 (68.9% Managed Care/ 31.1% FFS);
HCV Enrollees in Medicaid: Enrollees with an HCV diagnosis in 2014.

Iowa

Spending: Reported total drug spending data are FFS for CY 2014;
Medicaid Population: Estimate for February 2015;
HCV Enrollees in Medicaid: Estimate of enrollees.

Kansas

Spending: Reported total drug spending data are combined FFS and MCO data for CY 2014;
Medicaid Population: Total enrollment during December 2014 (399,968 enrolled in an MCO);
HCV Enrollees in Medicaid: No data provided.

Kentucky

Spending: Reported total drug spending data are combined FFS and MCO data, as well as separate FFS and MCO data, for CY 2014;
Medicaid Population: Total combined enrollment for CY 2014 (FFS: 179,031, MCO: 1,301,166);
HCV Enrollees in Medicaid: Enrollees identified with HCV from medical claims with an adjudication date of August 17, 2015 (Dates of service: January 1, 2014–December 31, 2014).

Louisiana

Spending: Reported total drug spending data are separate FFS and MCO data for CY 2014;
Medicaid Population: Total enrollment on January 6, 2015;
HCV Enrollees in Medicaid: No data provided.

Maine

Spending: Reported total drug spending data are FFS for CY 2014;
Medicaid Population: Enrollees during CY 2014 based on a January 29, 2015 analysis;
HCV Enrollees in Medicaid: Enrollees identified in Medicaid following an analysis of medical claims with an HCV diagnosis during CY 2014.

Maryland

Spending: Reported total drug spending data are separate FFS and MCO data for CY 2014;
Medicaid Population: Estimate for SFY 2015 (July 1, 2014–June 30, 2015);
HCV Enrollees in Medicaid: Estimated enrollees with an HCV diagnosis.

Massachusetts

Spending: Reported total drug spending data are separate FFS/Primary Care Clinician (PCC) Plan and MCO data for CY 2014 (Not all MCO's reported complete data for December 2014);
Medicaid Population: Total enrollment for CY 2014 (1,037,108 unduplicated FFS/ PCC members; 815,693 unduplicated MCO members);
HCV Enrollees in Medicaid: Estimated enrollees (MCO and FFS) with relevant diagnosis codes in their claims data; the 21,047 figure is based on the low end range estimates for the MCO (9,161–9,319) and FFS (11,886–12,471) populations.

Michigan:

Spending: Reported total drug spending data are FFS for CY 2014;
Medicaid Population: Estimate of enrollees during CY 2014 (75% are typically enrolled in an MCO and approximately 600,000 are in the FFS program during CY 2014);
HCV Enrollees in Medicaid: Enrollees having at least one Medicaid claim or encounter in Michigan's data warehouse with one of the following ICD–9 codes in FY 2014 (070.44 Chronic hepatitis C with hepatic coma, 070.54 Chronic hepatitis C without mention of hepatic coma, 070.70 Unspecified viral hepatitis C without coma, 070.71 Unspecified viral hepatitis C with coma).

Minnesota

Spending: Reported total drug spending data are FFS for CY 2014 (MCO reported data include MinnesotaCare enrollees);
Medicaid Population: Combined average monthly enrollment during CY 2014 for Medicaid enrollees (838,256) and MinnesotaCare (101,646);
HCV Enrollees in Medicaid: Estimate of enrollees with HCV during September 2014 (approximately 1,300 in FFS).

Mississippi

Spending: Reported total drug spending data are combined FFS and MCO data, as well as separate FFS and MCO data, for CY 2014;
Medicaid Population: Average monthly total enrollment for CY 2014;
HCV Enrollees in Medicaid: Total enrollees having HCV during December 2014 based on paid medical claims containing any ICD–9 code for HCV (Time period: January 1, 2013–December 31, 2014).

Missouri

Spending: Reported total drug spending data are FFS for CY 2014 (Pharmacy benefit carved out, meaning all MCO and FFS enrollees are covered through the FFS program);
Medicaid Population: Average monthly enrollment for October 2015;
HCV Enrollees in Medicaid: Estimated enrollees with a diagnosis of HCV in their claims history on October 2, 2014.

Montana

Spending: Reported total drug spending data are FFS for CY 2014;
Medicaid Population: Total enrollees during CY 2014;
HCV Enrollees in Medicaid: Total enrollees with claims containing HCV diagnosis codes (070.41–070.49) with eligibility in June and July 2015.

Nebraska

Spending: Reported total drug spending data are FFS for CY 2014 (all outpatient prescription medications covered by FFS);
Medicaid Population: Total average monthly enrollment during 2014;
HCV Enrollees in Medicaid: Enrollees as of July 6, 2014, based on diagnoses submitted on medical claims for the following ICD–9 diagnosis codes (070.41, 070.44, 070.51, 070.54, 070.70, 070.71) during FFY 2013 among FFS clients.

Nevada

Spending: Reported total drug spending data are FFS for CY 2014 (70% of Medicaid recipients are in MCOs);
Medicaid Population: Total enrollment for December 2014;
HCV Enrollees in Medicaid: Enrollees diagnosed with HCV during CY 2014.

New Hampshire

Spending: Reported total drug spending data are FFS for CY 2014 (Sovaldi carved out of MCO and paid on FFS basis for CY 2014);

Medicaid Population: Average enrollment for those with full Medicaid benefits in CY 2014;
HCV Enrollees in Medicaid: Estimate of enrollees with an ICD–9 diagnosis in CY 2013.

New Jersey

Spending: Reported total drug spending data are combined FFS and MCO data for CY 2014;
Medicaid Population: Total enrollment on December 31, 2014;
HCV Enrollees in Medicaid: Enrollees diagnosed between July 1, 2012–December 31, 2014.

New Mexico

Spending: Reported total drug spending data are separate FFS and MCO data for CY 2014;
Medicaid Population: Estimate of total enrollees during CY 2014;
HCV Enrollees in Medicaid: Estimate of enrollees with HCV.

New York

Spending: Reported total drug spending data are separate FFS and MCO data for CY 2014;
Medicaid Population: Total enrollment for March 2015;
HCV Enrollees in Medicaid: Estimated enrollees with a diagnosis of chronic HCV as identified by ICD–9 codes (data extracted by SUNY Buffalo on June 3, 2014 with service dates December 13, 2013–April 30, 2014).

North Carolina

Spending: Reported total drug spending data are FFS for CY 2014;
Medicaid Population: Enrollment during March 2015;
HCV Enrollees in Medicaid: Enrollees diagnosed with HCV according to medical claims from July 1, 2013–July 28, 2015 (7,350 or 38.2% are dually eligible for both Medicaid and Medicare; 11,896 patients are eligible for Medicaid only).

North Dakota

Spending: Reported total drug spending data are separate FFS and MCO data for CY 2014;
Medicaid Population: CY 2014 enrollment estimate including the FFS (65,000) and MCO (16,000) populations;
HCV Enrollees in Medicaid: No data provided.

Ohio

Spending: Reported total drug spending data are separate FFS and MCO data for CY 2014;
Medicaid Population: Total enrollment for December 2014;
HCV Enrollees in Medicaid: Estimate of Medicaid patients infected with HCV.

Oklahoma

Spending: Reported total drug spending data are FFS for CY 2014;
Medicaid Population: Total enrollment during CY 2014;
HCV Enrollees in Medicaid: Estimated enrollees with a diagnosis of HCV during SFY 2014 (July 1, 2013–June 30, 2014).

Oregon

Spending: Reported total drug spending data are separate FFS and MCO data for CY 2014;
Medicaid Population: Total enrollment on December 15, 2014;
HCV Enrollees in Medicaid: Current enrollees (as of September 2014) with a chronic HCV-related diagnosis code (January 2010–September 2014).

Pennsylvania

Spending: Reported total drug spending data are combined FFS and MCO data for CY 2014 (FFS: 29%, MCO: 72% during CY 2014);
Medicaid Population: Current enrollees on July 2015, including those dually eligible for Medicare and Medicaid;
HCV Enrollees in Medicaid: Estimate based on a 2014 University of Pittsburgh study estimating 46,397 non-dual eligible enrollees in Pennsylvania infected with HCV. Based on this model, 31,636, or 68%, have not been successfully treated.

Rhode Island

Spending: Reported total drug spending data are separate FFS and MCO data for CY 2014 (approximately 6% of enrollees in FFS);
Medicaid Population: Average monthly enrollment during CY 2014;
HCV Enrollees in Medicaid: Estimate based on an average of total enrollees served in CY 2014, multiplied by a mid-range of incidence/prevalence information for HCV, and adjusted for adult population range (adjusted further if based on policy of treating Stage 3 and 4 disease only).

South Carolina

Spending: Reported total drug spending data are separate FFS and MCO data for CY 2014;
Medicaid Population: Total enrollment on July 1, 2015 (63% in one of six MCO plans);
HCV Enrollees in Medicaid: Number of enrollees with an ICD–9 diagnosis of HCV in their medical claims history.

South Dakota

Spending: Reported total drug spending data are FFS for CY 2014;
Medicaid Population: Average monthly enrollment during SFY 2015 (July 1, 2014–June 30, 2015);
HCV Enrollees in Medicaid: No data provided.

Tennessee

Spending: Reported total drug spending data are FFS for CY 2014 (Tennessee is a 100% managed care state, though pharmacy services are delivered through an administrative services only contract with a Pharmacy Benefit Manager, generally considered FFS);
Medicaid Population: Estimate of total CY 2014 enrollment (including dual-eligibles);
HCV Enrollees in Medicaid: Estimate for CY 2014.

Texas

Spending: Reported total drug spending data are combined FFS and MCO data, as well as separate FFS and MCO data, for CY 2014 (rank by total spending is the only difference between MCO and combined FFS and MCO data; Sovaldi, Harvoni and Olysio not in FFS);
Medicaid Population: Average monthly enrollees during CY 2014 (includes all full-benefit Medicaid clients);
HCV Enrollees in Medicaid: Enrollees with an HCV diagnosis code in the first 10 diagnosis code fields during SFY 2013 (September 1, 2012–August 31, 2013) claims/encounters data.

Utah

Spending: Reported total drug spending data are combined FFS and MCO data for CY 2014;
Medicaid Population: No data provided;
HCV Enrollees in Medicaid: No data provided.

Vermont

Spending: Reported total drug spending data are FFS for CY 2014;
Medicaid Population: Enrollment during December 2014;
HCV Enrollees in Medicaid: Estimate of treatable enrollees with Chronic Hepatitis C (CHC), according to a model based on a 1.6% prevalence among the adult Medicaid population.

Virginia

Spending: Reported total drug spending data are separate FFS and MCO data for CY 2014;
Medicaid Population: Total enrollment on December 31, 2014;
HCV Enrollees in Medicaid: Enrollees during December 2014 with any diagnosis for HCV based on all available claims (January 2005–December 2014).

Washington

Spending: Reported total drug spending data are FFS for CY 2014;
Medicaid Population: Enrollment during December 2014, of which 234,518 enrolled in FFS and 1,300,992 enrolled in an MCO (approximately 15% FFS and 85% MCO);
HCV Enrollees in Medicaid: CY 2014 estimate based on enrollee demographics and CDC published estimates of HCV prevalence data.

West Virginia

Spending: Reported total drug spending data are FFS for CY 2014;
Medicaid Population: January 31, 2015 total enrollment figures for both FFS (291,846) and MCO (202,614) populations;
HCV Enrollees in Medicaid: Enrollees diagnosed with HCV in the FFS program based on a January 31, 2015 analysis.

Wisconsin

Spending: Reported total drug spending data are FFS in CY 2014 (Wisconsin carves out the pharmacy benefit from managed care; 69% enrolled in a managed care plan);
Medicaid Population: Estimated enrollment during December 2014;
HCV Enrollees in Medicaid: Estimate for Wisconsin enrollees with HCV.

Wyoming

Spending: Reported total drug spending data are FFS for CY 2014 (Wyoming is 100% FFS);
Medicaid Population: Estimate of annual enrollment during SFY 2014 (July 1, 2013–June 30, 2014);
HCV Enrollees in Medicaid: Enrollees with a diagnosis of HCV from a January 2014 query.

Appendix B

Table 1a.

State Medicaid Coverage Policies for Sofosbuvir (Solvaldi™) – Summary Findings

Methods

To identify states with policies for sofosbuvir (Solvaldi™), Center for Evidence-based Policy (Center) staff searched all 50 Medicaid agency websites, including provider manuals (pharmacy and medical), preferred drug lists, committee meeting minutes and agendas, and state statute or administrative rule websites. Center staff analyzed policies that were publically-available and accessible online at the time of our search (May 30, 2014, September 24, 2014). Information from state policies is summarized below and described in detail in the partner report (Center for Evidence-based Policy, 2014b). The excerpted state policies have been assessed by two Center staff members for accuracy. New or revised sofosbuvir (Solvaldi™) policies that became publically-available after our search dates were excluded from our analysis.

Sofosbuvir Policy Review Findings		
States with Identified Prior Authorization Criteria for Sofosbuvir	**States where Sofosbuvir Coverage Appears to be Unrestricted[1]**	**States without an Identified Coverage Policy**
27	**7**	**16**
AL, AK, AZ, AR, CA, CO, DE, FL, ID, IL, IN, IA, LA, ME, MD, OH, OK, OR, PA, RI, SD, TN, VT, VA, WV, WI, WY	CT, GA, MA, MN, NV, NY, UT	HI, KS, KY, MI, MS, MO, MT, NE, NH, NJ, NM, NC, ND, SC, TX, WA

[1]Publicly available policies include no clear restrictions on coverage.

Summary of State Medicaid Coverage Policies for Sofosbuvir Treatment of Hepatitis C

This analysis includes the 27 publicly available coverage policies which contain restrictive criteria for coverage.

Policy Criteria	Number of States	States

Policy Criteria		Number of States	States
Disease Severity Requirement?[1]		24	
	≥ F4	3	DE, IL, OR
	≥ F3	16	AK, AZ, AR, CA, CO, FL, ID, IA, LA , OH, PA, RI, TN, VA, WV, WI
	≥ F2	3	MD, OK, SD
	Level unclear	2	AL, IN
SUD Criteria		22	
	≥ 3 months sober	3	AK, DE, IA
	≥ 6 months sober[2]	13	AZ, CA, CO, ID, MD, OK, OR, PA, RI, SD, WV, WI, WY
	≥ 12 months sober	2	IL, LA
	Requires sobriety during tx or for no specific time period	4	FL, OH, TN, VA
Specialist physician requirements		20	
	Prescribe	11	FL, IN, IA, LA, MD, OH, PA, RI, SD, TN, WI
	Prescribe or consult	9	AZ, CO, ID, IL, ME, OK, OR, VA, WV

Policy Criteria	Number of States	States
Detailed Interferon-free Eligibility Requirements	16	AK, AZ, CA, DE, FL, ID, IA, LA, ME, MD, MN, OR, PA, RI, WV, WI
Response driven therapy (e.g. continuation dependent upon achieving early viral response)	10	AZ, CA, CO, FL, ID, LA, MD, VA, WV, WI
Pt must be sofosbuvir treatment-naïve	7	AK, AZ, CO, IA, MD, PA, WV
Once in a lifetime benefit	6	AL, AZ, , CO, IL, WV, WY
Require providers to collect efficacy data (SVR12, SVR24 and/or SVR52)	5	AL, ID, IL, RI, WV,

[1]Disease severity is most often described through Metavir fibrosis scores. The scale runs from F0 to F4: F0 = no fibrosis ; F1 = portal fibrosis without septa; F2 = portal fibrosis with few septa; F3 = numerous septa without cirrhosis; F4 = cirrhosis. Policies generally include other disease severity criteria in addition to Metavir fibrosis scores. See Chart for details.

[2]Alabama's policy requests information on substance use in past 6 months but does not spell out sobriety criteria.

Reference

Center for Evidence-based Policy. (2014b). *State Medicaid Coverage Policies for Sofosbuvir (Sovaldi™) Treatment of Hepatitis C.* Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

Suggested citation: Center for Evidence-based Policy. (2014a*). State Medicaid Coverage Policies for Sofosbuvir – Summary Findings.* Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University

Table 1b.

State Medicaid Coverage Policies for Sofosbuvir (Sovaldi™) Treatment of Hepatitis C

Methods

To identify states with policies for sofosbuvir (Sovaldi™), Center for Evidence-based Policy (Center) staff searched all 50 Medicaid agency websites, including provider manuals (pharmacy and medical), preferred drug lists, committee meeting minutes and agendas, and state statute or administrative rule websites. Center staff analyzed policies that were publically-available and accessible online at the time of our search (May 30, 2014, September 24, 2014). Information from state policies is described in detail below and summarized in the partner report (Center for Evidence-based Policy, 2014a). The excerpted state policies have been assessed by two Center staff members for accuracy. New or revised sofosbuvir (Sovaldi™) policies that became publically-available after our search dates were excluded from our analysis.

Suggested citation: Center for Evidence-based Policy. (2014b). *State Medicaid Coverage Policies for Sofosbuvir (Sovaldi™) Treatment of Hepatitis C.* Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
Alabama 6/17/2014 PA Instructions PA Form	Yes	Yes	Unclear	**Treatment Regimens:** Clinician must select from a list of treatment regimens by genotype on PA form. List includes all FDA approved regimens. SOF + SIM is not listed as an option. **Treatment Criteria:** • Once in a lifetime benefit • State requires submission of SVR12 and SVR24 for approved requests PA form requests the following information but does not indicate approval

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes

				criteria:
				• SUD:
				  ○ Alcohol or drug use in past 6 months
				• Glomerular filtration rate
				• If HIV co-infection, viral load, CD4 count and whether patient is on stable HIV Rx regimen for ≥ 8 weeks
				• Disease Severity: "Applicable" liver disease diagnostic criteria including:
				  ○ Metavir fibrosis score
				  ○ Child-Turcotte-Pugh classification
				  ○ Acoustic radiation force impulse image m/sec
				  ○ Abdominal imaging and evidence of surface abnormalities, features of portal hypertension, ascites
				  ○ AST to platelet ratio index
				  ○ Fibroscan value
				  ○ Fibrosis-4 (FIB-4) score

Alaska
4/18/2014
PA Criteria
	Yes	Yes	No	**Treatment Regimens:**
				All FDA approved regimens listed on PA form; SOF + SIM explicitly excluded.
				
				Treatment Criteria:
				• Age 18+ years
				• SOF tx naïve
				• Disease severity:
				  ○ ≥ stage F3 or HCC on transplant list
				  ○ Cirrhosis documented by biopsy OR two of the following:

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				▪ Cirrhotic features on imaging ▪ Ascites ▪ Esophageal varices ▪ Reversed AST:ALT ratio (> 1), thrombocytopenia (< 130,000 platelets/μL), and coagulopathy (INR > 2) ○ Bridging fibrosis documented via biopsy • <u>SUD:</u> ○ Abstention from illicit drugs and alcohol for minimum of 3 months as evidenced by negative urine confirmation tests in each of the two months immediately prior to therapy • If HIV co-infection: ○ CD4 count > 500 cells/mm^3 w/o antiretroviral therapy OR ○ CD4 count > 200 cells/mm^3 with virological suppression (e.g., HIV RNA < 200 copies/mL) • Exclusions: ○ Pregnant or lactating ○ SUD w/I 3 months of tx ○ Decompensated cirrhosis (CTP ≥ 6, class B or C) ○ Severe renal impairment, ESRD ○ Post liver transplant **Interferon Ineligibility Criteria:** • Baseline platelet count < 90,000/μL • Baseline neutrophil count < 1,500/μL • Baseline hemoglobin < 10 g/dL

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Decompensated hepatic disease • Clinical features consistent with depression • Autoimmune hepatitis or other autoimmune diseases • Intolerance of hypersensitivity to IFN • Preexisting cardiac disease
Arizona 7/17/2014 Medical Policy for Sovaldi (Sec 320-36)	Yes	Yes	Yes	**Treatment Regimens:** Arizona includes in "recommended tx regimens" all FDA approved SOF regimens. However, standard tx for genotype 3 pts in Arizona policy is SOF+RBV+PEG for 12 wks. Only IFN ineligible genotype 3 pts allowed SOF + RBV for 24 wks. Also includes non-FDA approved or studied regimens for genotype 1 null or partial responders (SOF for 12 wks + RBV and PEG for 12 to 24 wks). SOF + SIM ± RBV allowed for genotype 1 IFN ineligible, null or partial responders, *and* genotype 4 IFN ineligible. **Treatment Criteria:** • Age ≥ 18 years • Once in a lifetime benefit • Prescribed by or in consultation with gastroenterologist, hepatologist, or infectious disease specialist • Disease Severity: Evidence of serious liver disease as demonstrated

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				by: o Ultrasound, CT or MRI evidence of "cirrhosis or severe fibrosis" of "nodular-appearing liver in combination with evidence of splenomegaly and portal hypertension" OR o Elastrography score ≥ 11kPa OR o Metavir score ≥F 3 OR o FibroSure (e.g. FibroTest) ≥ 0.58 OR o Extrahepatic manifestations including leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia despite mild liver disease • Immunity to or vaccinations for Hep A and Hep B • SUD: o If hx of SUD, remission for six months prior to tx o If hx of SUD w/I past 12 months, random drug/alcohol screens during tx • If HIV co-infection: o CD4 count > 500 cells/mm^3 w/o antiretroviral therapy OR o CD4 count > 200 cells/mm^3 with virological suppression (e.g., HIV RNA < 200 copies/mL) • Pts must participate in a "treatment adherence program" • Exclusions: o Previous SOF or SIM tx o "documented non-adherence to prior HCV medications, HCV medical tx, or failure to complete HCV disease evaluation appointments and procedures" o Decompensated liver disease (CTP score > 9)

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				○ Elastography score < 11 kPa ○ Metavir score < F3 ○ FibroSure score < 0.58 ○ Any substance abuse w/l 6 months ○ Severe renal impairment or ESRD ○ Post-liver transplant **Interferon Ineligibility Criteria:** • Autoimmune hepatitis or other autoimmune diseases • Previous intolerance to IF leading to tx discontinuation: ○ Pre-existing hematological disease as evidence by: ▪ Baseline neutrophil count < 1500/µL OR ▪ Baseline platelet count < 90,000/µL OR ▪ Baseline hemoglobin < 10g/dL ○ History of psychiatric disorders: ▪ Schizophrenia ▪ Bipolar disorder ▪ Previous inpatient psychiatric admission ▪ History of suicide attempt w/i two years ▪ Unstable major depressive disorder ○ Ischemic heart disease **Response Determinant Therapy:** • Must test patient viral loads and if HCV viral load is detectable (> 100 IUs) at 4 wks for a 12 wk regimen, or at 4 or 12 wks for a 24 wk regimen, tx will be discontinued.

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
Arkansas 4/16/2014 PA Form PA Criteria Links	Yes	No	No	**Treatment Regimens:** Standard of Care (SOC) remains PEG+RBV+PI for genotype 1, PEG+RBV for genotypes 2,3 & 4. **Treatment Criteria:** SOF will be considered on a case-by-case basis under the following circumstances: • All genotypes pre-transplant due to shorter duration of SOF tx regimens • Genotype 1 tx naïve patients with stage 4 cirrhosis, biopsy required • Genotype 2 & 3 relapsed patients and non-responders "Any requests for 'intolerance' or 'allergy' to PEG will be reviewed on a case-by-case basis."
California 6/30/2014 Policy Web Page Tx Policy Tx Regimen Chart Tx Algorithm	Unclear	No	Yes (but requires PA and meet criteria for "investigational treatment")	**Treatment Regimens:** All FDA approved regimens allowed *except* for genotype 4. California does not include treatment of genotype 4 pts in its policy recommendations due to "insufficient evidence." CA includes the following tx regimens that are not FDA approved as tx options if pt gets approval for "coverage of investigational services": (see requirements below) • Genotype 1: SOF + SIM ± RBV • Genotype 2: SOF + PEG+ RBV • Gentoype 3: SOF + PEG + RBV

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Post liver tx patients **Treatment Criteria:** • Age ≥ 18 years • Patients with genotype 1, 2 and 3 with mild liver disease and no extra-hepatic manifestations "are not eligible for SOF or SIM-based regimens;" algorithm says to "wait" • Disease Severity: SOF or SIM requires significant liver disease as defined by: o Metavir score ≥ F3 OR o Clinical findings: "physical exam findings (palpable left lobe, splenomegaly, palmar erythema) AND low platelet count (<100,000/mm$^{3)}$ AND abdominal imaging findings" (surface abnormalities, features of portal hypertension, ascites) OR o Serum markers of advanced fibrosis/cirrhosis: ▪ APRI score > 1.5 ▪ FIB-4 > 3.25 ▪ FibroSure/FibroTest > 0.58 OR o Non-invasive assessment of liver fibrosis: ▪ Fibroscan > 9.5 kilopascals ▪ ARFI > 1.75 m/sec ▪ MRE > 6.47 kilopascals o Pts with mild liver disease (Metavir F0-F2) AND extra hepatic manifestations (leukocytoclastic vasculitis, clinical evidence of symptomatic cryoglobulinemia and membranoproliferative glomerulonephritis) "should be

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				considered for treatment" o Pts with HCC "should be considered for tx" • <u>SUD:</u> o All pts screened for SUD AND urine toxicology screen at baseline o Heavy alcohol use, binge alcohol use, active injection drug or illicit drug use requires referral to SUD tx before HCV tx o "Pts with SUD must be actively participating in tx...or be abstinent 6 months prior to tx" • Screened and/or vaccinated for Hep A and Hep B, screened for HIV • If HIV co-infection: o "optional candidates for HCV tx are pts who have been on a stable regimen for HIV with a suppressed HIV viral load for at least 8 wks and have a CD4 count > 200 cells/mm" • "Caution must be exercised with pts who have a hx of tx failure with prior Hep C tx due to non-adherence." • Insufficient evidence for genotypes 4, 5 or 6 so they will be "considered on a case-by-case basis" **Interferon Ineligibility Criteria:** • Platelet count < 100,000/mm^3 OR • Decompensated liver cirrhosis (CTP class B or C score ≥ 7, albumin < 3.5) • Severe mental health conditions ("including but not limited to psychotic disorders, bipolar disorder, major depression,

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				posttraumatic stress disorder) • Autoimmune diseases • Prior interferon-related adverse effect • Preexisting cardiac disease **Response Guided Treatment Criteria:** • SOF based tx: Pts have HCV RNA assessed at 4 wks tx; if detectable, reassess HCV RNA in 2 wks. "If HCV RNA increases (e.g., >1 log_{10}IU/mL from nadir) at any time point or if the 8-2k HCV RNA is detectable, discontinuation of all treatment must be strongly considered." • SIM based tx: Pts have HCV RNA assessed at 4, 12 and 24 wks. If HCV RNA detectable at any of these time points, "all treatment should be discontinued." **Coverage of Investigational Services Criteria (e.g., non-FDA approved regimens):** All of the following must apply: • "Conventional therapy will not adequately treat the intended patient's condition" • "Conventional therapy will not prevent progressive disability or premature death" • "The provider of the proposed service has a record of safety and success with it equivalent or superior to that of other providers of the investigational service"

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• "The investigational service is the lowest cost item or service...and is less costly than all conventional alternatives" • "There is a reasonable expectation that the investigational service will significantly prolong the intended patient's life or will maintain or restore a range of physical and social function suited to activities of daily living." • Investigational services require prior authorization.
Colorado 7/1/2014 PA Form PA Criteria	Yes	No	No	**Treatment Regimens:** Treatment regimens not specified; SOF + SIM explicitly excluded. **Treatment Criteria:** Approval for pts with genotypes 1, 2 or 4 on a "case-by-case" basis with the following criteria; patients with genotype 4 only on transplant list: • Age ≥ 18 years • Prescribed by "on in conjunction with" an infectious disease specialist, hepatologist, or gastroenterologist • SOF limited to once-in-a-lifetime benefit • Disease severity: (as determined by liver biopsy or "other accepted test"): o Extra-hepatic manifestations of HCV: leukocytoclasic vasculitis, HCC meeting Milan criteria, membranoproliferative glomerulonephritis, symptomatic cryoglobulinemia o Compensated or decompensated cirrhosis as defined by Child-Turcotte Pugh class A or B (Score 5-9 ascites), hepatic

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				encephalopathy, or variceal bleeding; o Transplant pts with fibrosing cholestatic HCV or recurrent HCV approved for re-transplantation o On transplant list with wait time < 1 year o Metavir fibrosis score ≥F3 • For genotype 1, must be tx naïve • All pts SOF naive • No severe renal impairment • SUD: o Free from substance abuse/alcohol dependence for 6 months as "documented by appropriate alcohol/drug screens." o Pts w/ SUD hx w/I 2 years must have monthly alcohol/drug screens **Response Guided Therapy:** • Pts must have HCV RNA levels assessed at 4 and 12 wks and tx discontinued if HCV RNA > LLOQ at these times • Tx discontinued if pt not medication adherent as determined by Rx fills
Connecticut 04/2014 PDL	No	Unclear	Unclear	Connecticut Medicaid has both SOF and SIM as preferred medications on its PDL. No prior authorization is required and no policy was identified.
Delaware 06/2014	Yes	Yes	No	**Treatment Regimens:** "Medication can only be approved as part of a regimen that is FDA

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes

PA Criteria and Form				approved for the client's genotype. This includes indication, dosing regimen and duration"
				
				Treatment Criteria:
				Approval of SOF or SIM requires:
				• Documented failure of or contraindication to preferred drug (Note: failure due to noncompliance "may be considered a contraindication to retreatment.")
				• Disease Severity: Documentation of "an imminent need to initiate therapy such as cirrhosis or a pending liver transplant." Cirrhosis documented by:
				  ○ Metavir score = F4
				  ○ "combination of an ultrasound or CT scan along with extrahepatic manifestations or clinical findings such as the presence of ascites"
				• SUD:
				  ○ No use of illegal substances for 90 days prior to therapy. Drug screens required.
				  ○ Abstinence from alcohol for 90 days prior to therapy
				• If HIV co-infection:
				  ○ Undetectable HIV viral load or CD4 count ≥ 350 cells/μL
				• Client signs informed consent addressing need for tx adherence, side effects of RBV, risk of birth defects and commitment to contraception, commitment to avoid alcohol and illegal substances.
				
				Interferon Ineligibility Criteria:

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Previous intolerance or known hypersensitivity to IFN • Autoimmune hepatitis or other autoimmune disorders • Documentation of depression with a psychiatric consult • Platelet count < 70,000/mm^3 • Preexisting cardiac disease

Florida
5/12/2014
SOF Criteria
SOF+SIM Criteria
	Yes	Yes	Yes	**Treatment Regimens:**
				All FDA-approved SOF regimens allowed (including HIV co-infection and pts awaiting transplant) for one month under following conditions:
				
				Treatment Criteria:
				• Prescribed by a hepatologist, gastroenterologist, infectious disease specialist, or transplant physician.
				• SUD:
				  ○ Documented abstention from drugs/alcohol or in treatment
				• Explicit patient agreement to adhere to tx including Rx regimen, Dr visits and blood tests and pt must be 100% compliant as noted by Rx fills and lab tests to continue treatment beyond 1 month
				• Negative pregnancy and test and agreement to use contraception
				• Disease Severity: Stage 3 or 4 hepatic fibrosis documented by:
				  ○ Biopsy METAVIR score ≥ F3, OR
				  ○ Fibroscan score ≥ 9.5 kPa, OR
				  ○ FibroTest score ≥ 0.58, OR
				  ○ APRI score > 1.5, OR
				  ○ Radiological imaging consistent with cirrhosis, OR

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				○ Evidence "as attested by the prescribing physician." • No early refills allowed due to lost, stolen medication, or vacation override • SOF+SIM allowed for: ○ Genotype 1, interferon ineligible ○ No prior tx with PI ○ Prescribed by specialist ○ Documentation of cirrhosis • Exclusions: ○ SOF tx for genotypes 5 or 6, ○ SOF tx for pts with decompensated cirrhosis (Child-Pugh score > 6) ○ SOF tx for post liver transplant pts. **Interferon Ineligibility Criteria:** • Prior intolerance to interferon therapy (urticarial, angioedema, bronchoconstriction, anaphylaxis or Stevens-Johnson syndrome) • Autoimmune hepatitis or other autoimmune disorders • Hypersensitivity to IFN • Decompensated hepatic disease (CPT > 6, class B or C – these cases require individual case review) • Major uncontrolled depressive illness • Hx of psychosis, schizophrenia, bipolar disorder, schizoaffective disorder or suicidal ideation • Baseline neutrophil < 1500/µL

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Baseline platelet < 90,000/µL • Baseline hemoglobin < 10 g/dL • Hx of cardiac disease • Refractory diabetes mellitus • Untreated thyroid disease **Response to Therapy Criteria:** • Continuation of therapy dependent on documented response to therapy as ≥ log reduction in HCV RNA or HCV RNA < 25 IU/mL at 4 and 12 wks after initiation of therapy • Pt 100% compliant to regimen as verified by prescriber and Rx fill history • No sign of high risk behavior (recurring alcoholism, IV drug use, etc.)
Georgia 4/22/2014 PA Criteria	Yes	Yes	Yes	All FDA approved regimens allowed with no added criteria. Georgia allows SOF + SIM for pts with fibrosis stage 3 or 4, pts who have failed PEG + RBV therapy w/o a PI, and pts who are interferon ineligible
Hawaii No information available	n/a	n/a	n/a	n/a
Idaho 6/13/2014 PA Criteria PA Form	Yes	Yes	No	**Treatment Regimens:** Only FDA approved treatment regimens are allowed. **Treatment Criteria:** • Age 18+ years

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes

				• Prescribed by on in consultation with gastroenterologist, hepatologist, infectious disease physician or liver transplant specialist
				• Provider must submit SVR12 and SVR24 post tx
				• Disease Severity: Advanced liver disease
				  ○ Metavir ≥ F3 OR
				  ○ Batts-Ludwig scale 3-4 OR
				  ○ Fibroscan measurement ? 12.5 kPa OR
				  ○ ARFI value > 1.75 m/sec OR
				  ○ CT/MRI with features of portal hypertension, ascites, and hepatosplenomegaly OR
				  ○ APRI score > 1.5 OR
				  ○ FIB-4 > 3.25
				• SUD:
				  ○ If hx of SUD, documentation of 6 months abstinence for injection drug use/alcohol dependency;
				  ○ Urine/blood toxicology tests monthly for pts with hx of SUD
				• Due to limited evidence on tx-experienced pts, those cases will be reviewed on case-by-case basis.
				
				Response to Treatment Criteria:
				All initial approvals for 4 wks of tx with continuation determined by following:
				• Provider must test HCV RNA at 2 wks of tx to determine compliance and efficacy

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes

				• Provider must obtain HCV RNA at 4 and 8 wks for 12 wk therapy and 4, 8, and 12 wks for 24 wk therapy
				• Tx will be discontinued/renewals declined if:
				  ○ Pt does not achieve HCV RNA below the limit of detection after 4 wks or has not demonstrated a decrease in HCV RNA from baseline after 4 wks
				  ○ If HCV RNA > 25 IU/mL at wk 4 or any other time after
				  ○ Positive urine or blood toxicology test
				
				Interferon Ineligibility Criteria:
				• Autoimmune hepatitis or autoimmune disorders
				• Major uncontrolled depressive illness
				• Hx of psychosis, schizophrenia, bipolar disorder, schizoaffective disorder, or suicidal ideation
				• Uncontrolled seizures
				• Moderate or severe retinopathy
				• Poorly controlled diabetes
				• Baseline neutrophil count < 750 cells/mm^3
				• Baseline platelet count < 75,000 cells/mm^3
				• Baseline hemoglobin < 10 g/dL
				• Significant ischemic cardiac disease
				• Prior intolerance or hypersensitivity to IFN
				• Symptomatic hepatitis C induced cryoglobulinemia

Illinois 8/12/2014	Yes	No	No	**Treatment Regimens:** Must be FDA approved regimen, but the alternative regimen for genotype

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes

PA Criteria
PA Forms
				1, IFN ineligible is not allowed (e.g., SOF+RBV for 24 wks).
				
				Treatment Criteria:
				• Age 18+ years
				• Once in a lifetime SOF benefit
				• Prescribed by or in consultation with gastroenterologist, transplant hepatologist, or infectious disease specialist
				• Disease severity: Metavir score ≥ 4 or equivalent
				• SUD:
				  ○ Documented negative standard urine drug screen w/I 15 days of PA submission
				  ○ Pts excluded if "evidence of SUD or treatment in past 12 months based on department claims records, prescribers knowledge, medical record entry, state's narcotic prescription registry database, reports from a hospital, an ED visit, an urgent care clinic, a physician's office or practice or another setting"
				• Exclusions:
				  ○ Cancer, except HCC cleared for transplant
				  ○ Terminal disease with life expectancy < 12 months or in hospice
				• Dispensed for 2 wks at a time with refills available for additional 2 wks (see forms); Non-compliance or failure to fill Rx will cause termination of tx
				• Prescriber must report HCV RNA within first 8 weeks of tx, upon

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				completion of therapy, and at 12 months post tx
Indiana 5/1/2014 PA Form PA Criteria	Yes	Yes	Yes	**Treatment Regimens:** SOF regiment must include concurrent PEG and RBV, RBV or SIM therapy. **Treatment Criteria:** • Disease severity: Requires compensated liver disease "including cirrhosis or hepatocellular carcinoma that meets criteria for liver transplant." Dx tests not defined. • Prescribed by infectious disease or gastrointestinal specialist • Refills beyond 12 wks require documented compliance with therapy • Allows SOF + SIM therapy except in pts who have failed prior triple therapy (PEG + RBV + PI)
Iowa 10/1/2014 PA Criteria PA Form	Yes	Yes	No	**Treatment Regimens:** Only FDA approved or "compendia indicated" therapy regimens. **Treatment Criteria:** • Age 18+ years • Requires documentation of monthly pregnancy tests • SUD: o Abstention from alcohol and illicit drugs for a minimum of three months prior to tx confirmed by urine test • Prescribed by gastroenterologist, hepatologist, infectious disease specialist or "other hepatitis specialist" • If pt has hx of "failed tx due to non-compliance, documentation

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes

				that steps have been take to correct or address the causes of non-compliance"
				• Disease Severity: Metavir score ≥ F3 as documented by liver biopsy or HCC meeting Milan criteria awaiting liver transplant
				• Exclusions:
				  ○ Previous tx with or failed tx with protease inhibitor
				  ○ Decompensated cirrhosis
				  ○ CrCl < 30 mL/min or receiving dialysis
				
				Interferon Ineligibility Criteria:
				Requests for IFN-free regimens for genotype 1 or 4 decided on case-by – case basis.
				• Documented life-threatening side-effects
				• Decompensated hepatic disease
				• Autoimmune hepatitis and other autoimmune disorders
				• Baseline neutrophil < 1500/µL
				• Baseline platelets < 90,000/µL
				• Baseline hemoglobin < 10 g/dL
				• Preexisting unstable cardiac disease

Kansas *No results returned in search; Discussed at July*	n/a	n/a	n/a	n/a

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
9, 2014 DUR meeting but minutes not available				
Kentucky PDL Drug Look Up	Yes	n/a	n/a	According to Magellan Medicaid Administration, Kentucky Medicaid's pharmacy benefit manager, SOF requires PA and has clinical criteria. Details were not available on-line.
Louisiana 7/1/2014 PA Criteria and form	Yes	No	No	**Treatment Regimens:** Not specified **Treatment Criteria:** • Age 18+ years • Genotype 2 or 3 OR HCC meeting Milan criteria and awaiting transplant. *(Note: Genotypes 1 and 4 do not appear to eligible unless they are on transplant list)* • Documented history of relapse or nonresponse to standard therapy • Prescribed by gastroenterologist, hepatologist, or infectious disease specialist • Disease Severity: o Liver biopsy showing advanced fibrosis or cirrhosis: Metavir score ≥ F3 or Ishak stage ≥4 o CTP score ≤ 6, class A (compensated liver disease) • SUD: o No active SUD w/I one year as "attested by prescriber and substantiated by negative urine drug screen and blood

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				alcohol level" w/I 30 days of tx ○ For pts w/hx of SUD, monthly random urine drug screen and blood alcohol level. Positive test = discontinuation of tx • Signed patient treatment agreement • Exclusions: ○ Severe renal impairment or ESRD ○ Solid organ transplant except liver **Response to Treatment Criteria:** • Initial PA for 8 weeks, additional PAs required for each additional 8 wks of tx; maximum 48 wks for pre-transplant pts • PA renewals dependent upon pt HCV RNA < 25 IU/mL at tx weeks 4, 12, 20, 28 and 36 **Interferon Ineligibility Criteria:** • Platelet count < 75,000/mm^3 • Decompensated liver cirrhosis (CTP score ≥ 7 HCV mono-infection; HCV-HIV co-infection) • Severe mental health condition • Autoimmune diseases • Documented interferon-related adverse effects and/or hypersensitivities
Maine 5/5/2014 PA Form	Yes	Yes+ *Maine includes	Yes	**Treatment Regimens:** Maine defines 7 tx regimens for different pt groups. Treatment regimens or identified patient groups underlined when they differ from FDA approved

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes

		regimens not specified in FDA approval		protocols.
				• SOF + RBV + PEG 12 wks
				  ○ Genotype 1 tx naïve/relapsed (w/ or w/o HIV co-infection)
				  ○ Genotype 2 tx experienced w/ prior null response or partial response with cirrhosis*
				  ○ Genotype 3 regardless of prior tx status*
				  ○ Genotype 4 regardless of prior tx status
				  ○ Genotype 5 or 6 regardless of prior tx status*
				• SOF + RBV + PEG 12 wks followed by additional 12 wks PEG*
				  ○ Genotype 1 prior null or partial response w/ or w/o a PI
				  ○ Genotype 1 HIV+ prior null or partial response to PEG + RBV + PI
				• SOF + RBV 12 wks
				  ○ Genotype 2 tx naïve, relapsed or null responder w/out Cirrhosis
				• SOF + RBV 16 wks*
				  ○ Genotype 2 pts, tx naïve, relapsed or null responders with cirrhosis and IFN intolerant*
				Regimens 5 and 6 below "will only be approved in those patients who require immediate treatment because it is anticipated that safer and more effective IFN-free treatments will be available in 2015."
				• SOF + SIM w/ or w/o RBV 12 wks*
				  ○ Genotype 1 pts with stage 3 or 4 fibrosis confirmed by biopsy, Child-Pugh < 6 and IFN intolerant
				  ○ Genotype 1 pts with HIV and prior PEG + RBV non response*[1]

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes

				• SOF + RBV 24 wks
				  ○ Genotypes 1,2 and 3 with re-infection of allograft liver after transplant*
				  ○ Genotype 1 IFN-intolerant and Child-Pugh > 6
				  ○ Genotype 3 IFN-intolerant and stage ≥ 3 fibrosis confirmed by biopsy
				• SOF + RBV for up to 48 wks or until transplant
				  ○ Any genotype w/ dx of HCC awaiting transplant
				
				Form also allows providers to submit their own regimen or apply one of the above to a different population with a rationale.
				
				Treatment Criteria:
				• Prescribed by or in consultation with gastroenterologist, hepatologist, infectious disease specialist or other "hepatitis specialist"
				• "Documentation of counseling regarding abstinence from alcohol, IV drug use and education o how to prevent HCV transmission."
				• Exclusion: severe renal disease
				• Approval is for two 14 day fills and a subsequent 28 day fill.
				
				Interferon Ineligibility Criteria:
				• Documented life-threatening side effects or potential side effects
				• Decompensated cirrhosis (CTP > 6) or CPT ≥ 6 if HIV co-infected
				• Baseline neutrophil < 1500/μL

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Baseline platelets < 90,000/µL • Baseline hemoglobin < 10 g/dL • Hx of unstable or significant cardiac disease

Maryland
7/23/2014
PA Criteria
PA Form
	Yes	Yes	No	**Treatment Regimens:**
				All FDA approved regimens included.
				
				Treatment Criteria:
				• Prescribed by gastroenterologist, hepatologist, or infectious disease specialist
				• Patient must be SOF tx naive
				• Disease Severity: Liver fibrosis equivalent to Metavir score ≥ 2
				• SUD:
				  o "patient must be 6 months free of substance/alcohol/opioid dependence, unless a patient has significant progression of disease state"
				• If HIV co-infection:
				  o CD4 count > 500 cells/mm^3 w/o antiretroviral therapy
				  o CD4 count > 200 cells/mm^3 if pt virologically suppressed (HIV RNA < 200 copies/mL)
				• Exclusions:
				  o Decompensated cirrhosis (CTP score > 6, class B or C)
				  o Severe renal impairment or ESRD

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes

				Response to Treatment Criteria:
				• Initial approval for 8 weeks
				• Refuse renewal and discontinue tx if:
				  ○ Tx wk 4: < 2 log reduction in HCV RNA
				  ○ Tx wk 12: HCV RNA ≥ 25 IU/mL
				  ○ Tx wk 24: HCV RNA ≥ 25 IU/mL
				
				Interferon Ineligibility Criteria:
				• Intolerance to IFN alfa
				• Autoimmune hepatitis or other autoimmune disorders
				• Hypersensitivity to IFN
				• Decompensated hepatic disease
				• Unstable depression or mood disorder
				• Platelet count < 75,000/mm^3
				• Hx of cardiac disease

Massachusetts 2/2014 PA Form Mass Health Drug List	Yes	Yes	No	All FDA regimens appear to be approved without additional criteria. SOF + SIM does not appear to be allowed as approval criteria for both drugs requires treatment with PEG and RBV.
Michigan Drug Info Page	n/a	n/a	n/a	As of search September 24, 2014 on Magellan's Michigan Medicaid page, SOF is not covered.
Minnesota 3/12/14 PA Criteria	Yes	Yes	No	**Treatment Regimens:** All FDA approved regimens. Concurrent SIM therapy excluded.

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				Treatment Criteria: • Age 18+ years • No other criteria specified **Interferon Ineligibility Criteria:** • "Tried and failed interferon therapy" • Decompensated hepatic disease • Major depressive disorder • Baseline neutrophil < 1500/µL • Baseline platelet < 90,000/µL • Baseline hemoglobin < 10 g/dL • Preexisting heart disease (stroke, MI, heart failure, arrhythmia, valvular heart disease)
Mississippi PDL	Yes	Unclear	Unclear	Pharmacy PDL list states SOF is a preferred drug but it requires manual PA. No PA criteria identified.
Missouri 9/5/2014	n/a	n/a	n/a	No policy identified. Drug Prior Authorization Policy for MO HealthNet dated 9/5/2014 included no information on hepatitis drugs, SOF or Sovaldi. The Hepatitis C Therapy PDL was last updated 10/3/2013 and does not include SOF.
Montana PDL	Yes	Unclear	Unclear	Montana's PDL notes that SOF PA approval subject to clinical criteria. Criteria not available.
Nebraska 7/17/2014 PDL PA Form	Yes	Unclear	Unclear	Nebraska has SOF as a non-preferred drug on its PDL and requires PA for all Hep C agents. PA form requests information on prior tx, hx of SUD, and cirrhosis but hasn't been updated since 9/2013. The Hep C clinical criteria is dated 9/2013 and does not include SOF.

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
Nevada 9/1/2014 PDL	No	Yes	Unclear	Both SOF and SIM are preferred on PDL and do not appear to require PA. Only PA form for HCV drugs dated 11/2013 and for boceprevir or telaprevir.
New Hampshire 9/2/2014 PA Form	Yes	Unclear	Unclear	State requires PA, but PA criteria not available.
New Jersey	n/a	n/a	n/a	New Jersey has managed care for pharmaceutical benefits. No information available.
New Mexico	n/a	n/a	n/a	New Mexico is a managed care state. No information available.
New York 2/20/2014 PA Form	Yes	Yes	Yes	All FDA regimens appear to be approved without additional criteria.
North Carolina 5/17/2014 PDL	n/a	n/a	n/a	No results returned. PDL as of 5/17 did not list either SOF or SIM.
North Dakota	n/a	n/a	n/a	No policy returned. Hepatitis C agents discussed at September 3, 2014 DUR meeting.
Ohio 10/1/2014 PA Criteria in PDL	Yes	Yes Ohio includes regimens not specified in FDA approval	Yes	**Treatment Regimens:** • All FDA approved regimens • SOF + SIM for IFN ineligible genotype 1 pts • Includes SOF + RBV 12 wks for genotypes 5 and 6 **Treatment Criteria:** • Age 18+ years • Prescribed by hepatologist, gastroenterologist, or infectious disease

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes

				specialist
				• Patient readiness must be assessed and providers discuss deferred therapy to wait for more effective/less toxic treatments
				• Vaccinate against Hep A and Hep B
				• SUD:
				  ○ "Screening for and maintenance of sobriety (alcohol/controlled drugs/IV drug use) before and during treatment"
				• Requires evaluation of fibrosis using biopsy, imaging, or "non-invasive markers"
				• Disease Severity:
				  ○ Advanced liver fibrosis of Metavir score ≥ F3 or Ishak score ≥ F4 OR
				  ○ Extra-hepatic manifestations: lymphoma, symptomatic cryoblobulinemia, membranoproliferative glomerulonephritis
				• Exclusions:
				  ○ Severe renal impairment or ESRD

Oklahoma No date PA Criteria PA Form Initial Tx Pt Contract Pharmacist	Yes	Yes	No	**Treatment Regimens:** • All SOF regimens must include RBV • All FDA approved SOF regimens approved • "New regimens will apply as approved by the FDA" **Treatment Criteria:** • Age 18+ years

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes

Contract
PA Renewal Form
				• Prescribed by gastroenterologist, infectious disease specialist, or transplant specialist or pt must have been evaluated by one of these specialists w/I three months
				• Disease Severity: Metavir fibrosis score ≥ 2
				• Pt must sign intent to treat contract
				• SUD:
				  o Must have no illicit IV drug use or alcohol abuse in past 6 months, and agree to no usage during tx and post tx
				• Documented immunization against Hep A and Hep B
				• "All other clinically significant issues must be addressed prior to tx including but not limited to following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease or autoimmune thyroid disease"
				• Monthly pregnancy test
				• Exclusions:
				  o Decompensated liver disease (CTP > 6 class B or C)
				  o Pregnancy
				• Adherence: discontinuation of tx if tx gap > 3 days/month

Oregon 8/13/2014 PA Criteria	Yes	Yes	Yes	**Treatment Regimens:** All FDA approved regimens; SOF + SIM for interferon ineligible genotype 1 pts. **Treatment Criteria:**

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes

				• Prescribed by or in consultation with a gastroenterologist or hepatologist
				• Disease Severity: Significant liver disease defined by:
				  ○ Severe fibrosis (≥ F4) defined by biopsy, Fibroscan, Fibrosure, or Fibrotest OR
				  ○ Radiologic, laboratory, or clinical evidence of cirrhosis w/o decompensation (MELD score between 8 and 11, MELD score > 11 may be eligible with medical director review) OR
				  ○ Extra hepatic manifestations (e.g., vasculitis, glomerulonephritis, cryoglobulinemia, lymphoma) OR
				  ○ Transplant patients after medical director review
				• Expected survival > 5 years
				• SUD:
				  ○ Abstinent from IV drug and marijuana use and alcohol abuse ≥ 6 months
				• HIV+ patients must meet other criteria and be under care of HIV specialist
				• Approved for 12 wks, extension of tx dependent adherence and tolerated
				• Exclusion:
				  ○ Severe renal impairment of ESRD
				
				Interferon Ineligibility Criteria:
				• Previous adverse reaction / hypersensitivity to interferon
				• Decompensated liver disease

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Severe or uncontrolled psychiatric disorder • Autoimmune hepatitis or other autoimmune disorders • Unstable cardiac disease • Severe cytopenias • Other comorbidities that would be exacerbated by interferon use

Pennsylvania
6/2/2014
PA Criteria
PA Form
PA Renewal Form
	Yes	Yes	Yes	**Treatment Regimens:**
				All FDA approved regimens and SOF + SIM for genotype 1 interferon ineligible.
				
				Treatment Criteria:
				• Age 18+ years
				• Prescribed by gastroenterologist, hepatologist, infectious disease specialist or transplant specialist
				• Disease Severity: Metavir score ≥ F3 through biopsy, blood test or fibroscan
				• Negative pregnancy test and monthly tests during tx
				• SUD: Documented abstinence from alcohol and drugs for 6 months prior to tx:
				  ○ Hx of SUD requires blood alcohol level and urine drug screen that supports abstinence
				  ○ If currently in treatment, evidence of tx compliance
				• Ribavirin requires following:
				  ○ Platelet count ≥ 90,000 cells/mm^3
				  ○ Neutrophil count ≥ 1500 cells/mm^3
				  ○ Hemoglobin ≥ 10 g/dL

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes

				• Exclusions:
				  ○ Prior tx (failure or incomplete) with SOF
				  ○ Severe renal disease or ESRD
				
				Interferon Ineligibility Criteria:
				• Autoimmune hepatitis or other autoimmune disorders
				• Hypersensitivity to interferon
				• Decompensated hepatic disease
				• Hx of depression with suicidality or resulting in hospital admission and the recipient is currently receiving antidepressant therapy
				• Baseline neutrophil count < 1500/µL
				• Baseline platelet count < 90,000/µL
				• Baseline hemoglobin < 10 g/dL
				• Hx cardiac disease

Rhode Island 9/9/2014 PDL PA Criteria	Yes	Yes	Unclear	**Treatment Regimens:** "All requests for non-FDA approved regimens will be reviewed on a case by case basis." **Treatment Criteria:** • Prescribed by gastroenterologist, hepatologist or infectious disease specialist. Other physicians may apply to state to be recognized as eligible to prescribe DAAs for hepatitis • Disease Severity: Serious liver disease defined as stage 3 or 4 fibrosis or cirrhosis demonstrated by: ○ APRI ≥ 1.0

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				○ Metavir score ≥ 3 ○ Fibroscan ≥ 9.5kPa ○ Fibrotest ≥ 0.58 ○ Imaging study consistent with cirrhosis • <u>SUD:</u> ○ If hx of SUD, pt must be "abuse free" for 6 months prior to tx or actively participating in a SUD tx program • Pt must sign contract • Follow-up: "If requested, provider agrees to cooperate with EOHHS data collection efforts related to SVR, compliance and relapse data. Information will be used for research purpose only and in a de-identified manner." • Program transitions: "When transitioning between publicly funded delivery systems (e.g., between fee-for-service Medicaid and managed care Medicaid or between Department of Corrections and Medicaid), any authorization granted by the prior delivery system should be honored for the portion of the treatment that remains after the transition." **Interferon Ineligibility Criteria:** • Severe psychiatric disease, particularly depression with or without suicidal risk • Hx of solid organ transplant • Autoimmune hepatitis or similar disorders • Uncontrolled endocrine disorders

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Platelet count < 75,000 • Neutrophil count < 1,500 • Hemoglobin < 10 g/dL • Hypersensitivity to interferon • Presence of inflammatory bowel disease, rheumatoid arthritis, sarcoidosis or systemic lupus • Uncontrolled seizures • Hepatitis c induced cryoglobulemia
South Carolina	Yes	Unclear	Unclear	South Carolina's PDL indicates SOF requires PA; PA criteria not identified.

South Dakota
No date
PA Algorithm
PA Form
	Yes	Yes	No	**Treatment Regimens:**
				SOF must be given in combination with RBV or RBV + PEG
				
				Treatment Criteria:
				• Age 18+ years
				• Disease Severity: Pt must have "compensated liver disease"
				  ○ Biopsy showing Metavir ≥ F2 or Ishak score ≥ F3 OR
				  ○ "other accepted test demonstrating liver fibrosis"
				• Prescribed by gastroenterologist, hepatologist, or infectious disease specialist
				• SUD:
				  ○ Documentation that pt alcohol and drug free for past 6 months
				• SOF must be given in combination with RBV or RBV + PEG
				• Exclusion:
				  ○ Serious renal impairment or ESRD

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
Tennessee 9/15/2014 Interim PA Criteria (prior to PAC committee review)	Yes	Yes	No	**Treatment Criteria:** Prescribed by "physician specialist with experience in the treatment of hepatitis C infection." • Disease Severity: Fibrosis equivalent to Metavir score ≥ F3 demonstrated by biopsy or FibroScan • SUD: o No active illicit substance use or alcohol abuse during therapy as confirmed by: ▪ Validated screening instrument such as Alcohol Use Disorders identification Test (AUDIT C) or CAGE alcohol screen or NIDA's drug screening tool ▪ Alcohol consumption tests such as: serum gamma-glutamyl transpeptidase, mean corpuscular volume, carbohydrate-deficient transferrin, urine ethylglucuronide ▪ Urine toxicology screen results o With hx of SUD, confirmation the patient has completed or is participating in tx • Exclusions: o Severe renal impairment or ESRD o Decompensated cirrhosis (CTP score ≥ 6, class B or C)
Texas	n/a	n/a	n/a	No policy identified.
Utah 9/9/2014 PA Form and Criteria	Yes	Yes	Unclear	**Treatment Criteria:** Utah has no restrictive criteria.

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
Vermont 7/1/2014 PDL PA Form and Criteria	Yes	Unclear	Unclear	Vermont requires all hepatitis C medications to be obtained through the state's specialty pharmacy vendor. **Treatment Criteria:** "DVHA Medical Director will review case details to determine eligibility for requested medication."
Virginia 7/1/2014 PDL and Criteria	Yes	Yes	No	**Treatment Criteria:** • Age 18+ years • Prescribed by or in consultation with hepatologist, gastroenterologist, or infectious disease specialist • Disease severity: Fibrosis Metavir score ≥ F3 with evidence of diagnostic/disease severity submitted • SUD: o Patient must be evaluated for current history of substance abuse and alcohol abuse with validated screening instrument • Tx naïve to SOF **Response Guided Treatment Criteria:** Authorized for 8 wks of tx; renewal requires: • Documented regimen compliance through pharmacy claims history • Maintenance of alcohol/substance abstinence ("Prescriber can submit clinical rational for tx continuation for positive tests that are false positive and not thought to be due to relapse in alcohol or substance abuse.")

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Submission of lab results showing response to therapy from a CLIA-certified laboratory
Washington	Unclear	Unclear	Unclear	Discussed at June 18, 2014 P&T Committee Meeting; no criteria published.
West Virginia 9/17/2014 PA Criteria Pt Consent Form	Yes	No	Yes	**Treatment Regimens:** • Genotypes 1, 3 & 4: SOF + PEG + RBV 12 wks • Genotype 2: SOF + RBV 12 wks • Genotype 1 IFN ineligible: SOF + SIM 12 wks, SOF + RBV 24 wks • Genotypes 1-4 pre-transplant: SOF+RBV up to 48 wks *(Note: this does not include the FDA approved regimen of SOF + RBV for 24 wks for genotype 3)* **Treatment Criteria:** • Age 18+ years • Prescribed by or in consultation with gastroenterologist, hepatologist, or infectious disease specialist • No prior SOF tx • Once in a lifetime SOF benefit • SUD: o Abstention from illicit drugs and alcohol for 6 months "as indicated by patient's signature on the patient consent form" • Vaccinated against Hep A and Hep B • Disease severity: o Stage F3 or greater cirrhosis as defined by biopsy or two of following:

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				▪ Cirrhotic features on imaging ▪ Ascites ▪ Esophageal varices ▪ Reversed AST:ALT ratio (>1), thrombocytopenia (< 130,000 platelets/μL), and coagulopathy (INR>2) o Fibrosis level of F3 or greater identified by biopsy or "other accepted method (e.g., FibroSure Assay)" o NO decompensated cirrhosis (Child-Puch score > 6), severe renal impairment, or post-liver transplant • For HIV+ pts, either: o CD4 count > 500 cells/mm3 w/o antiretroviral therapy o CD4 count > 200 cells/mm3 if pt is virological suppressed (e.g., HIV RNA < 200 copies/mL) • Exclusions: o Current SUD o Decompensated cirrhosis (CTP score ≥ 6, class B or C) o Severe renal impairment or ESRD o Post-liver transplant **Response Guided Treatment Criteria:** • Initial approval for 6 wks (except transplant pts who receive 12 wks) • Renewal depends on: o Treatment adherence o Continued abstinence o HCV RNA < 25 IU/mL at 4 wks of tx

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Transplant pts must show HCV RNA < 25 IU/mL at wks 12, 24 and 36 of tx **Interferon Ineligibility Criteria:** • Intolerance to interferon from previous tx • Autoimmune hepatitis and other autoimmune disorders • Hypersensitivity to IFN • Decompensated hepatic disease • Baseline neutrophil count < 1,500/µL • Baseline platelet count < 90,000/µL • Baseline hemoglobin < 10 g/dL Provider must collect HCV RNA levels at 12 wks and 24 wks post tx and submit to WV Medicaid (SVR12 and SVR24)

Wisconsin
10/1/2014
PA Form
PA Form Instructions
PA Criteria
	Yes	Unclear	Unclear	**Treatment Regimens:**
				Approved tx regimens not specified.
				
				Treatment Criteria:
				• Age 18+ years
				• Prescribed by gastroenterologist of infectious disease provider
				• Disease severity: Advanced liver disease characterized by:
				  ○ Compensated cirrhosis
				  ○ Metavir score ≥ F3 or evidence of bridging fibrosis
				  ○ HCC if pt is on liver transplant list
				  ○ Serious extra-hepatic manifestations of HCV
				• Negative pregnancy test

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes

				• SUD:
				  ○ Documentation of 6 months abstinence from alcohol abuse or illicit drug use
				• Exclusions:
				  ○ Significant or uncontrolled concurrent disease (e.g., depression, thyroid disease, diabetes, cardiovascular disease, pulmonary disease)
				  ○ Decompensated cirrhosis
				  ○ Acute HCV
				  ○ Post liver transplant
				  ○ Currently abusing drugs or alcohol
				  ○ Non-compliance with treatment 9renewals only)
				
				Response Guided Therapy Criteria:
				• Initial approval for 8 wks
				• Additional wks if HCV RNA < 25 IU/mL
				
				Interferon Ineligibility Criteria:
				• Platelet count < 75,000/mm^3
				• Severe mental health condition
				• Autoimmune disease
				• Documented IFN-related adverse events

Wyoming 9/3/2014 PA Form	Yes	Unclear	Unclear	**Treatment Regimens:** No information on approved treatment regimens available.

State Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				Treatment Criteria: • SUD: ○ No substance abuse w/I past 6 months as documented by a drug screening w/I one month • Client completion of psychosocial readiness evaluation and preparation for hepatitis C treatment survey (https://prepc.org) • Once per lifetime benefit

ALT= alanine aminotransferase; APRI= AST to platelet ratio index; ARFI= acoustic radiation force impulse imaging; AST= aspartate aminotransferase; CD4= cluster of differentiation 4; CLIA= Clinical Laboratory Improvement Act; COPD= chronic obstructive pulmonary disease; CrCl= Creatinine Clearance; CTP= Child-Turcotte-Pugh score; DAA= direct acting antiviral; DUR= drug utilization review; DVHA= Department of Vermont Health Access; dx= diagnosis; ESRD= end stage renal disease; FDA= U.S. Food and Drug Administration; FIB-4= fibrosis-4 clinical calculator; HBV= hepatitis B virus; HCC= hepato cellular carcinoma; HCV= hepatitis C virus; HIV= Human Immunodeficiency Virus; hx= history; IASL= International Association for Study of the Liver; IFN= interferon; INR= international normalized ratio; IU= international units; LLOQ= lower limit of quantification; MELD= Model End Stage Liver Disease; MRE= magnetic resonance elastography; MRI= magnetic resonance imaging; PA= prior authorization; PDL= preferred drug list; PEG= pegylated interferon; PI= protease inhibitor; pt= patient; RBV= ribavirin; RNA= ribonucleic acid; rx= prescription; SIM= simeprevir (Olysio™); SOF= sofosbuvir (Sovaldi™); SUD= substance use disorder; SVR= sustained virological response; tx= treatment; wk= week

*Treatment regimen not included in FDA approval or not for this population

[1]The SOF + SIM is an off-label combination that is currently under FDA review for approval. There are no studies on this combination treatment in HIV+ populations.

Private Payer Sovaldi Policies

Payer Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes

Payer Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes

Aetna
2/2014
PA Form
 	
PA Criteria
	Yes	Yes	Yes	**Treatment Regimens:**
				• All FDA approved regimens on list.
				• Also includes post liver transplant pts
				• SOF + SIM option for genotype 1 interferon ineligible patients and post liver transplant
				
				Treatment Criteria:
				• Disease Severity: "For initial authorization (6 week maximum) provider must submit medical records…documenting any one of the following related to staging of liver disease:" (no levels provided)
				  ○ Metavir scores
				  ○ Fibroscan scores
				  ○ FibroSURE score
				  ○ APRI score
				  ○ Radiological imaging consistent with cirrhosis (i.e., evidence of portal hypertension)
				  ○ Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician
				• Exclusion:
				  ○ HBV co-infection
				
				Response Guided Therapy Criteria:
				• Continuation of therapy contingent on HCV RNA levels decline > $\log_{10}$ IU/mL at 4 wks of therapy

Payer Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				Interferon Ineligibility Criteria: • Uncontrolled seizures • Suicidal attempt within past year • Moderate to severe retinopathy • Neutrophils < 750 cells/mm^3 w/I past month • Hemoglobin < 10 g/dL w/I past month • Platelets < 50,000 cells/mm^3 w/I past month • Major uncontrolled depressive illness with supporting treatment/counseling documents • Solid organ transplant (renal, heart or lung) • Autoimmune hepatitis or other autoimmune condition • Untreated thyroid disease • Pregnant or unwilling to comply with adequate contraception • Severe concurrent medical disease such as severe hypertension, heart failure, significant coronary heart disease, poorly controlled diabetes, COPD • Age < 2 years • Known hypersensitivity to drugs used to treat HCV • Known hypersensitivity reactions such as uticaria, angioedema, bronchoconstriction, anaphylaxis, or Stevens-Johnson syndrome • Hepatic decompensation CPT > 6, class B and C or CPT ≥ 6 with HIV co-infection
Cigna 10/1/2014	Yes	Yes	Yes	**Treatment Regimens:** • All FDA approved regimens listed

Payer Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
Coverage Criteria				• Also includes PEG + SOF + RBV for genotypes 5 or 6 • SOF + SIM approved for tx naïve or prior relapse and interferon ineligible OR partial or null responder to PEG + RBV **Treatment Criteria:** • Disease severity: o "documentation of the degree of hepatic fibrosis (i.e. Metavir score or alternative" (no levels defined o "compensated liver disease (i.e., CTP score ≤ 6, class A) • SUD: o "Absence of active use of illicit intravenous drugs" o "Absence of active alcohol abuse" • Participation in a hepatitis C disease state management program • SOF tx naive **Interferon Ineligibility Criteria:** • Hx of intolerance to interferon • Autoimmune hepatitis or other autoimmune disorder • Hypersensitivity to PEG • Decompensated hepatic disease • History of depression or clinical features consistent with depression • Baseline neutrophil court < 1500/µL • Baseline platelet count < 90,000/µL • Baseline hemoglobin < 10 g/dL • Hx of cardiac disease
Regence BCBS	Yes	Yes	No	**Treatment Regimens:**

Payer Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes

3/14/2014
Coverage Policy
				All FDA approved regimens
				
				Treatment Criteria:
				• No prior tx with PI
				• Disease Severity: Metavir ≥ F3 as documented by biopsy or non-invasive markers of fibrosis (ultrasound, CT scan, liver elastography, FibroScan, FIB-4 score, or other serum fibrosis marker panels)
				• SUD:
				  o Documentation of no marijuana or IV drug use or alcohol abuse in past six months
				• Pt receives drug from pharmacy providing clinical support services
				  o Patient intake to identify drug-drug interactions and patient specific needs or barriers to completion of HCV therapy
				  o Issue refill reminders
				  o Provide minimum necessary quantities while ensuring therapy is no interrupted
				  o Demonstrate ability to dispense partial month fills
				  o Medications must be supplied w/I 48 hours of receiving Rx order
				  o Provide assistance to members in scheduling laboratory blood draws to measure viral response that can guide therapy and determine the need for continuing treatment
				  o Monitor adverse effects through telephone consultation
				  o Provide dedicated team of clinical pharmacists for 24 hr/7 day support

Payer Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				○ Provide documentation to Rx of pt program enrollment and contacts. • SOF considered "investigational" for: ○ Monotherapy ○ Retreatment following tx failure with PI ○ Retreatment following liver transplantation **Interferon Ineligibility Criteria:** • Intolerance to IFN • Autoimmune hepatitis and other autoimmune disorders • Hypersensitivity to IFN • Decompensated hepatic disease • History of depression, or clinical features consistent with depression • Baseline neutrophil court < 1500/µL • Baseline platelet count < 90,000/µL • Baseline hemoglobin < 10 g/dL • Hx of cardiac disease
Anthem BCBS 4/15/2014 Clinical Criteria PA Form	Yes	Yes	Yes	**Treatment Regimens:** • All FDA regimens listed • Also includes SOF + PEG + RBV for genotypes 5 & 6 • SOF + SIM for genotype 1 interferon ineligible or prior tx failure with PEG + RBV **Treatment Criteria:**

Payer Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes

				• Age ≥ 18 years
				• <u>Disease Severity:</u>
				  ○ Pt must have compensated liver disease (CTP score ≤ 6, class A)
				  ○ Biopsy proven fibrosis score ≥ F3 on Metavir, Batts-Ludwig, or IASL fibrosis staging scales
				  ○ Biopsy proven fibrosis score ≥ F4 on Ishak staging scale
				  ○ In absence of biopsy, fibrosis ≥ F3 on IASL, Batts-Ludwig or Metavir scales or ≥ F4 on Ishak scale based on medical imaging-proven fibrosis staging
				• <u>SUD:</u>
				  ○ "Individual not actively abusing illicit drugs and/or alcohol," OR
				  ○ "Individual receiving concurrent tx to facilitate cessation of drug and/or alcohol abuse"
				• Exclusions:
				  ○ Severe renal impairment
				  ○ Previous tx with any PI or other polymerase inhibitor (e.g., SOF)
				
				Interferon Ineligibility Criteria:
				• Intolerance to IFN
				• Autoimmune hepatitis and other autoimmune disorders
				• CTP score > 6
				• Hypersensitivity to IFN

Payer Date of Policy Documentation Links	Prior Authorization	Approved for all FDA Indications	SOF + SIM Allowed	Notes
				• Decompensated hepatic disease • History of uncontrolled major depression, clinical features consistent with depression or suicidal ideation • Uncontrolled epilepsy • Retinal disease • Baseline neutrophil court < 1500/µL • Baseline platelet count < 90,000/µL • Baseline hemoglobin < 10 g/dL • Hx of cardiac disease
United Health Care	n/a	n/a	n/a	None identified

ALT= alanine aminotransferase; APRI= AST to platelet ratio index; ARFI= acoustic radiation force impulse imaging; AST= aspartate aminotransferase; CD4= cluster of differentiation 4; CLIA= Clinical Laboratory Improvement Act; COPD= chronic obstructive pulmonary disease; CrCl= Creatinine Clearance; CTP= Child-Turcotte-Pugh score; DAA= direct acting antiviral; DUR= drug utilization review; DVHA= Department of Vermont Health Access; dx= diagnosis; ESRD= end stage renal disease; FDA= U.S. Food and Drug Administration; FIB-4= fibrosis-4 clinical calculator; HBV= hepatitis B virus; HCC= hepato cellular carcinoma; HCV= hepatitis C virus; HIV= Human Immunodeficiency Virus; hx= history; IASL= International Association for Study of the Liver; IFN= interferon; INR= international normalized ratio; IU= international units; LLOQ= lower limit of quantification; MELD= Model End Stage Liver Disease; MRE= magnetic resonance elastography; MRI= magnetic resonance imaging; PA= prior authorization; PDL= preferred drug list; PEG= pegylated interferon; PI= protease inhibitor; pt= patient; RBV= ribavirin; RNA= ribonucleic acid; rx= prescription; SIM= simeprevir (Olysio™); SOF= sofosbuvir (Sovaldi™); SUD= substance use disorder; SVR= sustained virological response; tx= treatment; wk= week

*Treatment regimen not included in FDA approval or not for this population

[1]The SOF + SIM is an off-label combination that is currently under FDA review for approval. There are no studies on this combination treatment in HIV+ populations.

Table 2a.

State Medicaid Coverage Policies for Harvoni® and Viekira Pak™ – Summary Findings

Methods

To identify states with policies for Harvoni® and Viekira Pak™, Center for Evidence-based Policy (Center) staff searched all 50 Medicaid agency websites, including provider manuals (pharmacy and medical), preferred drug lists, committee meeting minutes and agendas, and state statute or administrative rule websites. Center staff analyzed policies that were publically available and accessible online at the time of our search (April 30-May 5, 2015). Information from state policies is summarized below and described in detail in the partner report (Center for Evidence-based Policy, 2015b). The state policies have been assessed by two Center staff members for accuracy. New or revised Harvoni® and Viekira Pak™ policies that became publically available after our search dates were excluded from our analysis.

Harvoni® and Viekira Pak™ and State Preferred Drug Lists

Preferred Drug List		
States where Harvoni® is the preferred agent	**States where Viekira Pak™ is the preferred agent**	**No stated preference between Harvoni® and Viekira Pak™**
12	**13**	**18**
AZ, CA, GA, IL, IA, NH, SD, UT, VT, VA, WA, WV	AK, AR, FL, KY, MN, MO, MT, NY, NC, SC, TN, TX, WI	AL, CO, CT, DE, ID IN, KS, ME, MD, MA, MS, NE, ND, OK, OR, PA, RI, WY

Summary of State Medicaid Medical Coverage Policies for Harvoni® and/or Viekira Pak™ Treatment of Hepatitis C

This analysis includes the 33 publicly available policies that contain detailed clinical coverage criteria for Harvoni® or Viekira Pak™ treatment for chronic hepatitis C virus (HCV) infection.

Policy Criteria		Number of States	States
Disease severity requirement			
	≥ F4	2	DE, IL
	≥ F3	17	AZ, AR, CO, FL, ID, IA, MO, NY, PA, OR, SD, TN, VT, VA, WA, WV, WI
	≥ F2	6	AK, IN, MD, NC, ND, OK
Disease severity is most often described through Metavir fibrosis scores. The scale runs from F0 to F4: F0 = no fibrosis ; F1 = portal fibrosis without septa; F2 = portal fibrosis with few septa; F3 = numerous septa without cirrhosis; F4 = cirrhosis. Even policies which generally restrict coverage based on Metavir fibrosis scores often include other disease severity criteria which would make patients eligible for treatment even with a low fibrosis score. For example, patients with extrahepatic manifestations or patients on a transplant list may be treated even if they do not meet fibrosis score criteria. See companion report (Center 2015b) for details on state policies.			
SUD criteria			
	≥ 3 months abstinence	4	AK, DE, IA, MO
	≥ 6 months abstinence	12	AZ*, CO, ID*, ME, OK, OR, PA, SD, TN, VT, WV, WI
	≥ 12 months abstinence	2	IL, ND
	States that require abstinence *OR* current enrollment in a treatment program	6	FL, GA, MN**, NC, WA**, WI
Some policies appear to require abstinence for all patients, some only for patients with a history of a SUD diagnosis, and some for patients who are currently assessed as misusing alcohol or drugs. Policies that request information on substance use but do not make clear coverage criteria are excluded from this table. *Criteria applies only to patients with a history of SUD **Patients in SUD treatment must be abstinent for at least 3 months before receiving HCV treatment			

Specialist physician requirement			
	Prescribe	8	IN, IA, MD, MS, PA, SD, TN, UT
	Prescribe or consult	16	AZ, CO, FL, ID, IL, ME, MN, NY, ND, OK, OR, VT, VA, WA , WV,WI
Once in a lifetime benefit/pt allowed only 1 treatment with DAA therapy *Once in a lifetime benefit applies to Viekira Pak only.		17	AL*, AZ, CO, FL, IL, IA, NY, NC, OK*, OR*, PA, TN, VT, VA, WV, WI, WY
Response-driven therapy (e.g., continuation dependent upon achieving early viral response)		15	AK, AZ, CO, FL, ID, MD, MA, MO, NY, NC, ND, TN, VA, WV, WI
Informed consent			
	Requires physician to certify patient has been educated on HCV treatment/other related issues	9	AL, FL, ID, ME, MN, NY, PA, VT, WA,
	Requires patient to sign formal informed consent form	7	DE, IL, NC, ND, OK, WV, WY
Require providers to collect efficacy data (SVR12, SVR24, and/or SVR52)		6	ID, IL, MN, OK, WA, WV
Requires that patient is vaccinated against Hepatitis A and B		4	AZ, CO, OK, WV

Reference

Center for Evidence-based Policy. (2015b). *State Medicaid Coverage Policies for Harvoni® and Viekira Pak™ Treatment of Hepatitis C.* Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

Suggested citation: Center for Evidence-based Policy. (2015a). *State Medicaid Coverage Policies for Harvoni and Viekira Pak Treatment of Hepatitis C.* Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

Table 2b.

State Medicaid Coverage Policies for Harvoni® and Viekira Pak™ Treatment of Hepatitis C

Methods

To identify states with policies for Harvoni® and Viekira Pak™, Center for Evidence-based Policy (Center) staff searched all 50 Medicaid agency websites, including provider manuals (pharmacy and medical), preferred drug lists, committee meeting minutes and agendas, and state statute or administrative rule websites. Center staff analyzed policies that were publically available and accessible online at the time of our search (April 30-May 5, 2015). Information from state policies is described in detail below and summarized in the partner report (Center for Evidence-based Policy, 2015a). The excerpted state policies have been assessed by two Center staff members for accuracy. New or revised Harvoni® and Viekira Pak™ policies that became publically available after our search dates were excluded from our analysis.

Suggested citation: Center for Evidence-based Policy. (2015b). *State Medicaid Coverage Policies for Harvoni and Viekira Pak Treatment of Hepatitis C.* Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

State Date of Policy Documentation Links	Notes
Alabama 2/18/2015 Harvoni PA Form Harvoni PA Instructions 2/18/2015 Viekira Pak PA Form Viekira Pak PA Instructions	**Treatment Regimens: Alabama has separate prior authorization forms and criteria for Harvoni and Viekira Pak.** General criteria for the2 drugs is the same (listed below) with only slight differences (see notes below). Alabama does not list Harvoni or Viekira Pak on its PDL. **No stated preference between Harvoni and Viekira Pak.** **Treatment Criteria:** PA form requests the following information but does not indicate approval criteria: • Clinical criteria: o Patient's genotype

State Date of Policy Documentation Links	Notes
	○ Cirrhosis status ○ Requested dose/duration of tx ○ For Harvoni: ▪ Indicate treatment experience ▪ For tx-naïve, non-cirrhotic patients, indicated pre-treatment HCV RNA level (*presumably for consideration of 8-wk tx)* ▪ Indicate pt's GFR ○ For Viekira Pak: ▪ Indicate if pt has known sensitivity to ritonavir ▪ Indicate if pt has decompensated liver disease or moderate to severe hepatic impairment (CTP class B or C) ▪ Review of contraindicated medications with Viekira Pak ▪ Indicate if patient has received a liver transplant w/ Metavir score ≤ 2 • <u>Disease severity:</u> "Applicable diagnostic measures for liver disease" (but no required values): ○ Metavir fibrosis score ○ CTP classification ○ ARFI ○ Abdominal imaging (ultrasound, CT, MRI) and evidence of surface abnormalities, features of portal hypertension, ascites ○ APRI ○ FibroScan value ○ FIB-4 score • <u>SUD:</u> ○ Indicate alcohol or drug use in past 6 months ○ Requires drug and alcohol screening lab report submitted with PA form • <u>Once in a lifetime benefit:</u> ○ Pt must be informed that AL policy is to cover only 1 tx regimen w/Sovaldi or Viekira Pak per

State Date of Policy Documentation Links	Notes

	lifetime
	• Informed consent:
	  o Pt must be "counseled on the proposed regimen to include possible side effects that may occur"
	• HIV co-infection:
	  o If co-infected, indicate whether the pt has been on a stable HIV Rx regimen for at least 8 wks
	  o Report pt viral load & CD4 count

Alaska
 	
1/16/2015
PA Criteria
	Treatment Regimens: Viekira Pak "first line preferred treatment." Harvoni ("second line"), interferon-based regimens ("third line") and Olysio + Sovaldi ("fourth line") regimens allowed.
	
	Treatment Criteria:
	• Age:
	  o 18+ years
	• Clinical criteria required:
	  o Genotype and subtype
	  o HCV viral load documented
	  o Documentation of previous tx, whether it was completed, reasons for discontinuation, outcome of tx
	• Disease severity:
	  o Metavir score F2-F4
	• Specialists:
	  o Pts with CTP score > 6, class B or C must be managed by liver disease specialist
	• SUD:
	  o Abstention from illicit drugs and alcohol for minimum of 90 days as evidenced by negative urine confirmation test
	• HIV co-infection:
	  o Must include CD4 count, HIV viral load, tx regimen

State Date of Policy Documentation Links	Notes
	○ For Viekira Pak, must be on stable antiretroviral regimen • Exclusions: ○ Diagnostic disease severity evidence not submitted ○ Pt not abstaining from alcohol or drugs ○ For regimens with RBV, pregnant or lactating ○ For regimens with SIM, pt not SIM-naïve ○ For regimens with SOF, pt has severe renal impairment or ESRD ○ Contraindicated drug reactions • Retreatment: Not authorized within 2 years • Authorization duration: Initial authorization 8 wks, subsequent authorization for 4 or 8 wks depending on duration of regimen • Response driven therapy: ○ For regimens longer than 8 wks, HCV RNA must be submitted for tx weeks 4 and 8 ○ HCV RNA must be < 25 IU/mL at tx wk 4, **OR** if HCV RNA detectable at wk 4, HCV RNA at wk 6 must be lower than at wk 4 or undetectable
Arizona 3/15/2015 Hepatitis C Drug PA Criteria (Sec 320-N)	**Treatment Regimens:** Sovaldi and Harvoni are the preferred agents for Hepatitis C. **Treatment Criteria:** • Age: ○ 18+ years • Clinical criteria required: ○ HCV genotype ○ HCV RNA level ○ Cardiac clearance for members with ischemic heart disease ○ Psychiatric clearance for pts with serious mental illness

State Date of Policy Documentation Links	Notes
	○ HIV specialist clearance for HIV coinfection ○ Lab results: ▪ Total bilirubin, albumin, INR, CL_{cr} or GFR, LFTs, and CBC within past 90 days ○ Prior tx results including HCV RNA levels at baseline, at the time of tx, and at tx discontinuation (if available) • Disease severity: ○ "Imaging evidence of cirrhosis or severe fibrosis based upon ultrasound, CT, or MRI of the abdomen describing a nodular-appearing liver, generally in combination with evidence of splenomegaly and portal hypertension," **OR** ○ MRE ≥ 11 kPa, **OR** ○ Liver biopsy w/ Metavir score ≥ F3, **OR** ○ FibroSURE ≥ 0.58, **OR** ○ Extraheaptic manifestations including leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia despite mild liver disease • Specialists: ○ Prescribed by or in consultation with gastroenterologist, hepatologist, or infectious disease specialist • SUD: ○ Baseline alcohol/drug screen within 30 days ○ If member has a hx of SUD in past 12 months, must be in remission for at least 6 months prior to tx ○ Random drug/alcohol screens for pts with hx of SUD • Vaccinations: Pt must have hepatitis A and B vaccinations • Once in a lifetime benefit: ○ No prior tx with SOF or SIM ○ 1 course of therapy per lifetime • HIV co-infection:

State Date of Policy Documentation Links	Notes
	○ CD4 count > 500 cells/mm3 if member is not taking antiretroviral therapy, **OR** ○ CD4 count > 200 cells/mm3 if member is virologically suppressed (e.g., HIV RNA < 200 copies/mL) • Exclusions: ○ HCV-5 and -6 ○ Documented non-adherence to prior HCV tx ○ Member declines to participate in "treatment adherence program" ○ Decompensated liver disease (CTP > 9) ○ MRE score < 11 kPa ○ Metavir score < F3 ○ FibroSURE score < 0.58 ○ Current use of P-gp inducer drugs ○ Severe renal impairment or ESRD ○ Post-liver transplant tx • Adherence: ○ Members prescribed SOF or SIM "must participate in a treatment adherence program" • Response driven therapy: ○ HCV viral load testing at 4 wks for 12-wk regimen and 4 and 12 wks for 24-wk regimen ○ If viral load is undetectable, tx continues ○ If viral load is low but detectable, test again ○ If viral load is still detectable (>100 IUs), tx discontinued
Arkansas 3/12/15 PA Form PA Criteria	**Treatment Regimens:** Viekira Pak, Harvoni, or Sovaldi prescribed according to FDA criteria. **Harvoni is only an option for 8-week tx (when appropriate); otherwise, Viekira Pak is preferred for other HCV-1 pts. Sovaldi prescribed for HCV-2, -3, -4.** **Treatment Criteria:** • Clinical criteria

State Date of Policy Documentation Links	Notes
	○ Liver biopsy required for all requests ○ Patient's genotype and subgenotype ○ Prescribed medication dependent on: ▪ Cirrhosis status ▪ Prior treatment history • Disease severity: ○ Metavir ≥ F3 OR ○ Pre-liver transplant pt OR ○ Severe extrahepatic hepatitis C complications (case by case review) • HIV co-infection: ○ If co-infected, will receive Viekira Pak treatment ○ Should refer to drug interactions for dosage recommendations for concomitant HIV-1 antiviral drugs. • Exclusions: ○ Pts with HCV-5, -6
California 6/30/2014 Policy Web Page Tx Policy Tx Regimen Chart Tx Algorithm	**Treatment Regimen:** "Effective Jan 1, 2015 Sovaldi and Harvoni are on the Medi-Cal Contract Drugs List." *New policy issued July 1, 2015 and not described here. Link:* *http://www.dhcs.ca.gov/Documents/Hepatitis%20C%20Policy.pdf* **Clinical Criteria:** • Age: ○ 18+ years • Clinical criteria required (but no approval standards specified): ○ Tx history ○ RNA level and HCV genotype ○ Documentation of cirrhosis status

State Date of Policy Documentation Links	Notes

Colorado
 	
3/1/2015
Viekira Pak PA Form
 	
Sovaldi/Harvoni PA Form
 	
4/1/2015
PDL
	Treatment Regimen: All treatments will continue to be approved on a "case by case basis" during an interim period until final criteria and treatment rollout go into effect October 2015. **No tx preference stated.**
	
	Treatment Criteria:
	• Age:
	  ○ 18+ years
	• Clinical criteria required:
	  ○ HCV-1a or -1b
	  ○ Physician attest to pt readiness for adherence
	  ○ Physician attest to significant health impact if treatment is delayed
	  ○ Tx-naïve with DAA
	  ○ Baseline HCV RNA and ALT levels w/in 30 days of start date
	• Disease severity
	  ○ Extrahepatic manifestation of HCV (leukocytoclasic vasculitis, hepatocellular carcinoma meeting Milan criteria, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia despite mild liver disease), **OR**
	  ○ Compensated cirrhosis defined by CTP class A; or CTP class B AND on transplant list with projected time to transplant < 1 year, **OR**
	  ○ Transplant pt with fibrosing cholestatic HCV or a pt with cirrhosis from recurrent HCV who has been approved for re-transplantation, **OR**
	  ○ Pt on the transplant list with a projected time to transplant of < 1 year, **OR**
	  ○ Metavir ≥ F3
	• Specialists:
	  ○ Prescribed by or in conjunction with an infectious disease specialist, gastroenterologist, or hepatologist

State Date of Policy Documentation Links	Notes

	• SUD:
	  ○ 6 months free of alcohol, marijuana and other Schedule I controlled substances, cocaine, and opiate misuse
	  ○ Monthly screens for pts with a prior history (2 years) of drug/alcohol/opioid abuse
	• Vaccinations:
	  ○ Must have or plan to get hepatitis A and B vaccinations
	• Once in a lifetime benefit:
	  ○ One course of DAA therapy per lifetime
	• HIV co-infection
	  ○ Harvoni: Must be HIV-negative and hepatitis B-negative
	  ○ Viekira Pak: May be HIV-positive
	• Exclusions
	  ○ Pts not abstaining from alcohol or drugs
	  ○ Pts with severe renal impairment (eGFR < 30 ml/min/1.73m2), ESRD, or on hemodialysis
	  ○ Prior DAA treatment
	  ○ Pts currently taking contraindicated medications
	• Birth control/pregnancy:
	  ○ Women and their partners must use 2 forms of contraception
	  ○ Pregnancy test required prior to beginning therapy
	• Adherence:
	  ○ Adherence monitored based on prescription fills (must be filled w/in 7 days); treatment will be discontinued with non-adherence
	  ○ Pts must receive refills within 1 week of completing the prior fill
	• Response-driven therapy
	  ○ All approvals initially for an 8-week time period
	  ○ Further approval dependent on RNA level testing at wks 4, 12, and 24
	  ○ If viral load is detectable while on Viekira Pak or Harvoni, test again in 2 weeks

State Date of Policy Documentation Links	Notes
	○ If viral load has increased, all treatment discontinued unless documentation provided to support therapy continuation ○ For Sovaldi regimens, if HCV RNA is above the lower limit at wks 4, 6 (if applicable), and 12 (if applicable), all treatment will be discontinued
Connecticut 1/2015 PDL 1/2015 Sovaldi PA Form	**Treatment Regimen:** Effective 7/1/2015, Harvoni, Peg-Intron, and Viekira Pak are additions to the PDL. No additional criteria found for approval of Harvoni and Viekira Pak. Sovaldi PA identified.
Delaware 05/2015 PA Criteria and Form 4/9/2015 PDL (pg 21)	**Treatment Regimen:** Both Harvoni and Viekira Pak are preferred; only FDA-approved regimens allowed. **Treatment Criteria:** • Clinical criteria: ○ HCV RNA level ○ Documentation of prior tx • Disease severity: For all DAAs ○ Metavir ≥ F4 based on liver biopsy or "other objective laboratory test," **OR** ○ Documented cirrhosis through ultrasound or CT scan with extrahepatic manifestations, or clinical findings such as the presence of ascites • SUD: ○ Documented abstinence from illegal substance or alcohol use for 90 days prior to therapy ○ Drug screen required • Informed consent:

State Date of Policy Documentation Links	Notes
	○ Pts sign informed consent addressing need for tx adherence, RBV side effects, commitment to contraception and risk of birth defects, avoidance of drugs and alcohol. • HIV co-infection: ○ Submit medication regimen ○ Undetectable viral load or CD4 count ≥ 350 cell/uL • Birth control/pregnancy: ○ Informed consent includes commitment to birth control without regard to tx regimen
Florida Drug Criteria Page 11/12/2014 Harvoni PA Form 4/21/2015 Harvoni PA Criteria 4/30/2014 Viekira Pak PA Form 4/28/2015 Viekira Pak PA Criteria	**Treatment Regimens:** Viekira Pak preferred; Harvoni approved when Viekira Pak is contraindicated. **Treatment Criteria:** • Age: ○ 18+ years • Clinical criteria: ○ HCV genotype lab documentation ○ Quantitative viral load ○ Drug and alcohol test results, or medically documented addiction therapy or services. • Disease severity: ○ Treatment determined by the test results of : ▪ Metavir score (≥ F3) ▪ FibroScan score (≥ 9.5) ▪ FibroTest score (≥ .58) ▪ APRI score (≥ 1.5) • Specialists: ○ Prescribed by or in consultation with a hepatologist, gastroenterologist, infection disease specialist, or transplant physician • SUD:

State Date of Policy Documentation Links	Notes
	○ Drug test confirming no illicit drug or alcohol use in the previous month ○ Test results submitted with therapy request ○ Or, patient is receiving substance or alcohol abuse counseling services, or seeing an addiction specialist (medically documented) • Once in a lifetime benefit: ○ Harvoni: Tx-naïve to ledipasvir or Sovaldi ○ Viekira Pak: Tx-naïve to dasabuvir/ombitasvir/paritaprevir, Sovaldi with or without ledipasvir, and Olysio therapy. ○ Viekira Pak: Tx-experienced pts are those who tried and failed tx with PEG and RBV-based therapy. • Informed consent: ○ Patient must commit to course of treatment, blood test, and visits that will occur before and after treatment. • HIV co-infection: ○ Viekira Pak approved for HIV+ pts with HCV-1a or -1b • Exclusions: ○ Signs of risky behaviors ○ Decompensated cirrhosis (CTP score > 6) ○ HCV-2, -3, -4, -5, or -6 ○ For Harvoni: Post-liver transplant ○ For Viekira Pak: Positive pregnancy test • Birth control/pregnancy: ○ Viekira Pak (with RBV): Female pts required to have a negative pregnancy test w/in 30 days of starting therapy. • Authorization duration: ○ No early refills due to lost, stolen or vacation override • Adherence:

State Date of Policy Documentation Links	Notes
	○ Viekira patients have access to personalized adherence support system • Response-driven therapy: ○ Initial review: 1 month ○ For 8- and 12-week treatments, reauthorization occurs at 4 weeks to determine response to therapy For 24-week tx, reauthorization occurs at 4 and 12 wks ○ Lab results collected 2 or more weeks after the first prescription fill date must indicate a response to therapy (RNA < 25 IU/mL) for subsequent reauthorization ○ Continuation of treatment may be authorized for pts who are **100% compliant** as verified by the medication fill history
Georgia 2/25/2015 Hepatitis C Agents PA Criteria	**Treatment Regimens: Harvoni is preferred over Viekira Pak;** Viekira Pak or Sovaldi should only be prescribed when pts cannot take or tolerate Harvoni. **Treatment Criteria:** • Age: ○ 18+ years • Clinical criteria required: ○ Must be diagnosed with chronic HCV; HCV-1 only, subtype recorded ○ Viekira Pak: to qualify for tx, must also have compensated liver disease • SUD: ○ Pts who abuse alcohol or IV drugs must be enrolled in a substance abuse program • Transplant: ○ Pts who are transplant recipients must have normal liver function and can have up to mild fibrosis • Exclusions: ○ HCV-2 through HCV-6
Hawaii	n/a

State Date of Policy Documentation Links	Notes
No information available	
Idaho 4/24/15 PA Criteria	**Treatment Regimens: Harvoni, Olysio, Sovaldi, Viekira Pak.** **Treatment Criteria:** • Age: o 18+ years • Clinical criteria required: o HCV genotye 1,2,3 or 4 or hepatic carcinoma secondary to HCV awaiting liver transplantation o Documentation of recent laboratory values, within 6 months of request, including LFT's, CBC, genotype, HCV RNA viral count and negative pregnancy test (if applicable) o Previous history of HCV treatment (tx-naïve or treatment experienced) o Healthcare provider must submit a SVR at week 12 and week 24 after successful completion of treatment • Disease severity: o Liver biopsy with a Metavir stage F3-F4, **OR** o Batts-Ludwig scale 3-4, **OR** o FibroScan measurement > 12.5 kPa, **OR** o ARFI value > 1.75, **OR** o Radiographic imaging (CT/MRI) with features of portal hypertension, ascites, and hepatosplenomegaly, **OR** o APRI score > 1.5 OR FIB-4 > 3.25 and serious extrahepatic manifestations of hepatitis C o FibroSURE, FibroTest, and FIBROSpect are not recommended for routine use in the diagnosis of cirrhosis • Specialist: o Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease specialist, or a liver transplant physician

State Date of Policy Documentation Links	Notes

	• SUD:
	  ○ "Patient has no history of alcohol or substance abuse within the 6 months prior to treatment," **OR**
	  ○ Patients with a history of intravenous drug/substance abuse/alcohol dependence will require documentation of successful completion of 6 months of abstinence
	  ○ Negative urine toxicology and blood alcohol laboratory test within 1 month of request
	  ○ Patients with a history of substance/alcohol abuse will require monthly random urine toxicology and blood alcohol screening while on treatment
	• Informed consent:
	  ○ "Documentation that the provider has discussed with patient the potential risks and benefit of HCV therapy and progression of HCV disease and a shared decision has been made for antiviral treatment"
	• Exclusions:
	  ○ Non-FDA approved combinations/dosing regimens
	  ○ Patients with chronic HCV with minimal fibrosis (Metavir stage F0-F2)
	  ○ Pt will be excluded if there is "documented ongoing non-adherence to prior medical treatment or patient is unable to commit to scheduled follow-up/monitoring for the duration of treatment"
	  ○ History of intravenous drug abuse/alcohol dependency/substance abuse WITHOUT documented evidence of successful completion of 6 months of abstinence
	  ○ Co-administration with drugs that are contraindicated with hepatitis C agent requested
	  ○ Decompensated liver disease
	  ○ Viekira Pak: moderate to severe hepatic impairment (CTP class B or C) for Viekira Pak
	  ○ Sovaldi / Harvoni: Severe renal impairment or hemodialysis
	• Birth control:
	  ○ Prescriptions with RBV: Pregnant women or those who may plan to become pregnant during the course of treatment are excluded
	• Adherence:
	  ○ Adherence counseling performed; documented understanding by pt

State Date of Policy Documentation Links	Notes
	○ Pt will be excluded if there is documented ongoing non-adherence to prior medical treatment or patient is unable to commit to scheduled follow-up/monitoring for the duration of treatment ○ "Hepatitis C agents not recommended in patients with a history of relapse" ○ Failure to complete HCV disease evaluation appointments and procedures will result in discontinuation • Response-driven therapy: ○ Provider must submit viral count at 2, 4, and 8 weeks for 12- or 24-week tx regimens ○ Requests for renewal will be denied in pts who have not achieved RNA below the limit of detection after 4 weeks of therapy or who have not demonstrated a 1-log decrease in HCV RNA after 3 wks ○ All treatment must be discontinued if HCV RNA > 25 IU/ml at week 4 or any time after • Post-tx reporting: ○ Provider must submit SVR12 and SVR24 after completion of treatment
Illinois 1/2015 PA Criteria PA Form *Added Criteria: No Date* Harvoni PA Criteria Viekira Pak PA Criteria	**Treatment Regimens:** Harvoni and Sovaldi preferred. Viekira Pak is not preferred: "Patient must have documented clinical evidence supporting use of Viekira Pak over preferred agents." **Treatment Criteria:** • Age: ○ 18+ years • Clinical Criteria Required: ○ HCV-1, -2, -3, or -4 (including subtype for Viekira Pak) ○ Baseline HCV-RNA levels • Disease severity: ○ Stage 4 hepatic fibrosis documented by: ▪ Liver biopsy Metavir = F4, **OR** ▪ FibroScan score ≥ 12.5 kPa,**OR** ▪ FibroTest score ≥ 0.74, **OR**

State Date of Policy Documentation Links	Notes
	▪ APRI score > 2.0, **OR** ▪ Radiological imaging consistent w/cirrhosis (e.g., evidence of portal hypertension), **OR** ▪ Physical findings or clineical evidence consistent with cirrhosis • Specialists: o Prescribed by or in consultation within 3 months with a gastroenterologist, transplant hepatologist, infectious disease specialist • SUD: o Documented negative standard urine drug screen w/in 15 days of PA submission o No evidence of active SUD within 12 months; if existed, must submit 2 consecutive months of negative standard urine screen • Once in a lifetime benefit: o Once in a lifetime benefit for all newer DAAs • Informed consent: o Pt must sign tx plan showing commitment to dosing plan and schedule, schedule for refills, and information on how to reduce risk of exposure/transmission of disease • Exclusions: o Cancer, except HCC cleared for transplant o Pt with decompensated liver disease as defined by CTP class B or C. o Pts currently prescribed contraindicated medications o Terminal disease with life expectancy < 12 months or in hospice o Harvoni/Sovaldi: ▪ Pt with ESRD requiring dialysis ▪ Pt with GFR < 30 mL/min/1.73m2 • Birth control/pregnancy: o Viekira Pak: If taken with RBV, female pts must have a negative pregnancy test within the previous 30 days and monthly therefore during treatment, and male pts must not have a pregnant partner

State Date of Policy Documentation Links	Notes
	and must agree to use "adequate contraception" during treatment ○ Harvoni: In pregnant women, documentation is provided justifying potential benefits and risks to the fetus • Adherence: ○ Non-compliance or failure to fill Rx will result in termination of tx • Post-tx reporting: ○ Must submit HCV RNA levels w/l first 8 wks of tx, at completion, and SVR12 and SVR24
Indiana 4/1/2015 PDL PA Criteria PA Form	**Treatment Regimens:** Policy allows prescription of Harvoni, Viekira Pak, Sovaldi,, telaprevir, or boceprevir with criteria varying by medication. Criteria below applies to Harvoni and Viekira Pak. **Treatment Criteria:** • Age: ○ 18+ years • Clinical criteria: ○ HCV-1 • Disease severity: ○ > stage 2 fibrosis, **OR** ○ co-infection with HIV or AIDS, **OR** ○ post-liver transplant • Specialists: ○ Prescription must be written by an infectious disease specialist or gastroenterologist • HIV co-infection: ○ Either Harvoni or Viekira Pak approved for HIV co-infection • Birth control/pregnancy: ○ Women must confirm negative pregnancy test prior to therapy • Authorization duration:

State Date of Policy Documentation Links	Notes
	○ Up to 12 wks • Adherence: ○ Re-approval contingent on confirmed compliance
Iowa 6/1/2015 PA Criteria (p.18) PA Form	**Treatment Regimens: Sovaldi w/ RBV (and when appropriate, PEG)** is the primary treatment for pts with HCV-1 through -4 and pts with HCC (awaiting liver transplant). **Harvoni** is only used if PEG is contraindicated in pts with G1. Viekira Pak is not mentioned. **Treatment Criteria:** • Age: ○ 18+ • Clinical criteria: ○ Prior tx history (tx naïve, prior null responder, partial null responder, relapse) ○ If prior tx failure is due to non-compliance, documentation that steps to address and correct the causes of non-compliance is required ○ Viral load within 6 months of beginning therapy • Disease severity: ○ Documentation of ≥ stage 3 fibrosis confirmed by a liver biopsy • Specialist: ○ Prescriber is an infectious disease specialist, gastroenterologist, hepatologist, or other hepatitis specialist • SUD: ○ Abstinence from illicit drugs or alcohol in the 3 preceding months, indicated by a negative urine test • Once in a lifetime benefit: ○ Excluded if previously received protease inhibitor treatment • HIV co-infection:

State Date of Policy Documentation Links	Notes
	○ Sovaldi prescribed if HIV + - • Birth control/pregnancy: ○ Female pts must not be pregnant, and male pts must not have a pregnant partner ○ Both men and women pts must use 2 forms of effective contraception during tx and for at least 6 months after tx has concluded ○ Documentation of monthly pregnancy tests • Quantity limit: ○ Lost or stolen medication replacement requests will be denied ○ 72-hour emergency supply rule does not apply • Exclusions: ○ Previous non-compliance, without documentation indicating this behavior has been addressed and corrected ○ Pt has previously tried or failed therapy with a protease inhibitor ○ Pt receiving dialysis ○ Pt has decompensated cirrhosis ○ HCV-5 or 6
Kansas DUR Agenda	**Treatment Regimens:** As of June 1, 2015, Harvoni and Viekira Pak are preferred, and Sovaldi is non-preferred for HCV-1. No prior authorization criteria available.
Kentucky PDL	**Treatment Regimens: Viekira Pak is the preferred DAA**; Harvoni is not preferred. Clinical PA is required, and there is a quantity limit. No prior authorization criteria identified
Louisiana P&T Agenda	**Treatment Regimens:** HCV drugs considered at May 6, 2015 Pharmaceutical and Therapeutics Committee; no prior authorization criteria identified.
Maine 3/23/2015	**Treatment Regimens: Harvoni, Viekira Pak and Sovaldi regimens allowed.** **Treatment Criteria:**

State Date of Policy Documentation Links	Notes

PA Form	• Clinical criteria required:
	  ○ Active infection verified by viral load in the past year (must report genotype, Metavir score)
	• Disease severity:
	  ○ Metavir score and method used (doesn't specify score criteria)
	  ○ $CL_{cr} \geq 30mL/min$; creatinine levels taken within the past 6 mo
	• Specialist:
	  ○ Prescriber is consulting, or has consulted with, a gastroenterologist, hepatologist, infectious disease specialist, or other hepatitis specialist.
	• Informed consent:
	  ○ Counseling must be provided and documented regarding non-abuse of alcohol and drugs as well as education on how to prevent HCV transmission
	• SUD:
	  ○ Documentation that the pt has not abused drugs or alcohol in the past 6 months
	  ○ Must submit urine drug screen for members with history of drug abuse other than alcohol
	  ○ Counseling must be provided and documented regarding non-abuse of alcohol and drugs as well as education on how to prevent HCV transmission
	• Birth control/pregnancy:
	  ○ For any regimen that includes RBV:
	  ▪ Patient is not pregnant (or, if male, does not have a pregnant female partner) and is not planning to become pregnant during treatment or within 6 months of stopping
	  ▪ Agreement that partners will use 2 forms of effective contraception during treatment and for at least 6 months
	  ▪ Verification that monthly pregnancy tests will be performed throughout treatment
	• Exclusions:
	  ○ Pt not receiving dialysis
	  ○ Pt currently taking a contraindicated medication
	• Authorization duration:

State Date of Policy Documentation Links	Notes
	○ PA form covers up to 12 weeks of therapy; only a 14-day supply will be allowed for the first fill • Adherence: ○ Documentation of adherence (viral load changes or progress notes on compliance) are required for refill
Maryland 1/2015 PA Criteria Sample Treatment Plan PA Form	**Treatment Regimens:** Approved treatment includes Harvoni, Harvoni + RBV, Viekira Pak, and Viekira Pak + RBV, all for either 12 or 24 weeks; 8-week Harvoni may be permitted. Sovaldi-based regimens for HCV-2, -3, and -4. **Treatment Criteria:** • Age: ○ 18+ years • Clinical criteria required: ○ Baseline HCV RNA level w/in 60 days of anticipated start • Disease severity: ○ Metavir score of ≥ 2 demonstrated by a liver biopsy or other accepted test • Specialist: ○ Prescribed by gastroenterologist, hepatologist, or infectious disease specialist • SUD: ○ Form requires information on hx of drug/alcohol abuse, whether pt has been abstinent for 6 months or is currently in tx; coverage criteria not specified • Birth control/pregnancy: ○ If using RBV, pt or partner must use 2 forms of contraception ○ Viekira Pak w/ RBV for female pts who are pregnant or may become pregnant; male pts whose partners are pregnant are excluded • HIV co-infection: ○ Harvoni or Viekira Pak allowed ○ HIV+ pts treated with Viekira Pak should also be on suppressive ARV drugs to reduce risk of HIV

State Date of Policy Documentation Links	Notes
	protease inhibitor drug resistance • Exclusions: o Pt receiving concomitant therapy w/ a hepatitis protease inhibitor o ESRD requiring hemodialysis o Viekira Pak : pt receiving concomitant therapy w/ HCV polymerase inhibitor or NS5A inhibitor o Viekira Pak : pts with severe hepatic impairment / CTP class C secondary to risk of potential toxicity; not recommended for pts with moderate hepatic impairment/CTP class B o Harvoni: pts using P-gp inducers o Harvoni: Severe renal impairment • Authorization duration: o 8 wks • Adherence: o Initial therapy approved for 8 weeks o Authorized for additional 8-week period at a time o Must receive refill within 7 days of completing prior supply • Response Driven Therapy: o Virologic response is measured at 4, 12, and 24 (if applicable) weeks of therapy, and 12 weeks after therapy ends o Treatment should be discontinued when: ▪ Treatment 4 weeks: < 2 log reduction in RNA from baseline ▪ Treatment 12 weeks: any detectable HCV RNA level ▪ Treatment 24 weeks: any detectable HCV RNA level
Massachusetts 3/2015 PA Form	**Treatment Regimens:** Both Harvoni and Viekira Pak used; **12 wk RBV + Harvoni preferred** to 24-wk Harvoni or 24-wk Viekira Pak for tx-experienced pts with compensated liver; **8-wk Harvoni preferred** to 12-week Viekira Pak (tx-naïve, no cirrhosis).

State Date of Policy Documentation Links	Notes

Clinical Information
Drug List
	Treatment Criteria:
	• Age:
	  ○ + 18 years
	• Clinical criteria required:
	  ○ Diagnosis of chronic HCV-1
	  ○ Baseline viral load
	  ○ Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, FibroScan, FibroSURE, FIB-4)
	• Disease severity:
	  ○ Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, FibroScan, FibroSURE, FIB-4)
	  ○ No exclusion based on Metavir score; states guidelines based on if Metavir score is 0-2 or 2-4.
	• Exclusions:
	  ○ Excluded from Viekira Pak if pt previously treated with HCV protease inhibitor
	• Response-driven therapy:
	  ○ Tx naïve pts: Tx discontinued if viral load is detectable at wk 4 and has increased by > 10-fold (> 1 $\log_{10}$ IU/mL) on repeat testing at wk 6
	  ○ Tx experienced pts: For continuation of treatment beyond 12 weeks, lab values at 4 weeks and 6 weeks (if detected at 4 wks) must support continued use

Michigan Drug Info Page	**Treatment Regimens:** As of May 5, 2015 search on Magellan's Michigan Medicaid Drug LLookup, neither Harvoni or Viekira Pak are covered.
Minnesota 4/2015 PA Form	**Treatment Regimens: Viekira Pak is preferred ;** Harvoni, Olysio, and Sovaldi are listed as "non-preferred drugs." Treatment with SIM + SOF not allowed. **Treatment Criteria:**

State Date of Policy Documentation Links	Notes

PA Criteria	• Age:
	  ○ 18+ years
	• Clinical criteria for Viekira Pak:
	  ○ "At the time of treatment initiation, pt has evidence for FFS health insurance coverage for the duration of tx"
	  ○ Documentation of genotype and subtype
	  ○ Pre-treatment detectable RNA viral load measured w/in 1 year of tx start date.
	  ○ Notes of specialist consultation attached to authorization request
	  ○ Treating clinician attest patient has been evaluated for "readiness" of treatment, including potential impediments to effective treatment
	• Non-preferred drugs: Clinical criteria/severity required (Harvoni, Olysio, Sovaldi):
	  ○ Pt has met the preferred drug authorization criteria, **AND**
	  ○ Pt has HCV-1, -2, -3, -4 or HCV-1 with contraindication to Viekira Pak, **AND**
	  ○ Pt has at least 1 condition listed below:
	  1. Decompensated liver disease (CTP class B/C and MELD ≤ 20)
	  2. Abdominal imaging suggestive of cirrhosis
	  3. Evidence from at least 1 non-invasive test
	  a. APRI ≥ 1.5,
	  b. FibroSURE ≥ 0.49,
	  c. FibroScan ≥ 7.1,
	  d. FIB-4 > 3.25
	  e. MRE ≥ 6 kPa
	  f. FIBROSpect ≥ 42
	  4. Biopsy ≥ F3
	  5. HCV infection with post solid organ transplant, awaiting liver transplant, stage I-III HCC, post-liver transplant, severe complications from HCV of Type 2 or Type 3 essential mixed cryoglobulinemia with end organ manifestations, **OR** HCV-induced renal disease

State Date of Policy Documentation Links	Notes

	• Disease severity:
	  ○ None provided for preferred drug (Viekira Pak)
	• Specialist:
	  ○ Prescribed by, or in documented consult with, a gastroenterologist, hepatologist, infectious disease specialist, or a practitioner specializing in the treatment of hepatitis
	• SUD:
	  ○ If pt has a history of alcohol abuse, must be abstinent 6 mo prior. Exceptions include:
	  ▪ Pt is 3 mo abstinent, receiving treatment at an approved facility, and agrees to abstain during tx, **OR**
	  ▪ Pt is under the care of an addiction medicine/chemical dependency treatment provider and provider attests pt agrees to abstain during tx
	  ○ If pt has a history of IV drug use, must be abstinent 6 mo prior to starting tx. Exceptions include:
	  ▪ Pts who have abstained for 3 mo and are receiving chemical dependency tx (addiction medicine specialist/buprenorphine waived provider), **AND**
	  ▪ The chemical dependency provider can attest to 3 mo abstinence, **AND**
	  ▪ Pt must agree to a urine tox screen w/I 30 days of starting tx
	• Informed consent:
	  ○ Provider must attest pt is "ready" for tx "including identification of potential impediments to effective tx (e.g., difficulties with compliance, missing appointments, adequate social support, adequate control of mental health conditions, alcohol use disorder, IV drug use). Potential impediments to successful tx must be addressed in tx notes prior to initiating tx and submitted with authorization request."
	• Exclusions:
	  ○ Pts deemed by treating clinician unable to adhere to tx
	  ○ HCV-5 or -6
	  ○ Creatinine clearance (CL_{cr}) < 30 mL/min or on hemodialysis
	  ○ Severe end organ disease and not eligible for transplant (liver, heart, lung, kidney)

State Date of Policy Documentation Links	Notes
	○ Clinically significant illness or any other major medical disorder that may interfere with patient's ability to complete a course of tx ○ Pts determined by the primary clinician to "not achieve a long-term clinical benefit" (i.e. receiving palliative care, multisystem organ failure, etc.) ○ Viekira Pak: Decompensated liver disease CTP score > 12 or MELD > 20 ○ MELD <20 and either intrahepatic cholangiocarcinoma, HCC with metastatic spread, malignancy outside the liver not meeting oncologic criteria for cure, cardiopulmonary disease that cannot be corrected, hemangiosarcoma • Birth control/pregnancy: ○ Viekira Pak: Pregnant pts excluded • Adherence: ○ Treating clinician must assess pt ability to adhere (control of mental health illness, adequate social support, etc); impediments must be addressed in tx notes and submitted with authorization request • Post-treatment reporting: ○ Provider must submit SVR12 results to the Department
Mississippi 4/17/2015 PDL P&T Committee Minutes	**Treatment Regimen: Viekira Pak, Harvoni, and Sovaldi are all preferred agents.** Manual PA required; no detailed coverage criteria identified besides: • Specialist: ○ "Restricted to infectious disease and hepatologist specialsts."
Missouri 1/8/2015 PDL	**Treatment Regimen: Viekira Pak preferred** to Harvoni, Olysio, or Sovaldi. Viekira Pak prescribed for 12 or 24 weeks depending on prior tx history. Viekira Pak tx requires RBV for HCV-1a with or without cirrhosis and HCV-1b with cirrhosis

State Date of Policy Documentation Links	Notes

	Treatment Criteria:
	
	• Age:
	  ○ 18+ years
	• Clinical criteria required:
	  ○ Viekira Pak and Harvoni: HCV-1
	  ○ Baseline viral load
	  ○ For non-preferred medications: Trial and failure of Viekira Pak
	• Disease severity:
	  ○ Fibrosis score ≥ F3 (for HCV-3, fibrosis ≥ F2)
	• SUD:
	  ○ Negative urine alcohol and illicit drug screen results for 3 mo prior
	  ○ Any evidence of alcohol or drug use during tx will result in discontinuation
	• Once in a lifetime benefit:
	  ○ No: If pt fails Viekira Pak treatment, eligible for Harvoni tx
	• Birth control/pregnancy:
	  ○ Pregnant pts excluded
	• Quantity limit:
	  ○ 28-day supply, no more than a 7-day gap between prior and incoming claims
	• Exclusions:
	  ○ Lack of approval criteria
	  ○ Pregnant pts
	  ○ HCV-5 or -6
	  ○ Metavir score < F3
	  ○ Viral load > 25 IU/mL at tx wk 4 or beyond
	• Adherence:

State Date of Policy Documentation Links	Notes
	○ Tx withdrawn if there is a gap in therapy > 7 days from prior claim • Response-driven therapy: ○ Viral load submitted at wk 12 and 24; viral load at wk 12 must be < 25 IU/mL if tx duration is 24 weeks ○ Tx discontinued if viral load > 25 IU/mL at treatment week 4 or beyond
Montana 5/1/2015 PDL	**Treatment Regimen: Viekira Pak preferred** to Harvoni, Sovaldi, Olysio, and Victrelis. Prior authorization criteria not identified.
Nebraska Drug Lookup	**Treatment Regimen**: Nebraska Medicaid's Magellan Drug Lookup identifies both Harvoni and Viekira Pak as covered with required PA. Prior authorization criteria not identified.
Nevada 1/1/2015 PDL	**Treatment Regimen: Sovaldi, Olysio listed as preferred agents**. No mention of Viekira Pak or Harvoni.
New Hampshire 2/13/2015 PDL PA Form	**Treatment Regimen: Harvoni preferred to Sovaldi**; no mention of Viekira Pak on PDL. Prior authorization criteria not identified.
New Jersey	**Treatment Regimen:** New Jersey has managed care for pharmaceutical benefits. No information available.
New Mexico	**Treatment Regimen:** New Mexico is a managed care state. No information available.
New York	**Treatment Regimen: Viekira Pak preferred.**

State Date of Policy Documentation Links	Notes
Approved Prescriber List 4/9/2015 PDL 1/2015 PA Checklist Harvoni PA Worksheet 2/2015 Viekira Pak Worksheet	**Treatment Criteria:** • Clinical criteria required: o HCV genotype test results o Baseline RNA within 3 months of initiating therapy o Liver fibrosis evaluation o Tx history o Documentation of extra-hepatic manifestations o Documentation of concomitant conditions/comorbidities • Disease severity: o Evidence of stage 3 or 4 hepatic fibrosis confirmed by liver biopsy, FibroScan ≥ 9.5, FibroSURE ≥ .58, APRI > 1.5, or radiological imaging consistent with cirrhosis o Liver transplant o Other coexistent liver disease o Type 2 diabetes mellitus (insulin resistant) o Debilitating fatigue impacting quality of life • Specialist: o Therapy must be prescribed by a specialist, or a health care practitioner experienced and trained in the treatment of HCV, or a practitioner under the supervision of a specialist ▪ Non-specialists must fill out additional Medicaid authorization forms and must have 1) experience managing and treating at least 10 pts with HCV in the past year and 2) 10 HCV-related CME credits in the past year • Once in a lifetime benefit: o Maximum 12 wks (or 24 wks, if 24-wk regimen is prescribed) over beneficiary lifetime • Informed consent: o Provider must use "scales/assessment tools to evaluate the readiness of the patient," including SAMHSA/HRSA Drug & Alcohol Screening Tools or Psychosocial Readiness Evaluation and

State Date of Policy Documentation Links	Notes

	Preparation for Hepatitis C Treatment (http://prepc.org/)
	• Co-infection:
	  ○ Test for HBV co-infection
	• Birth control/pregnancy:
	  ○ Viekira Pak: a negative pregnancy test must be collected within 30 days of initiating tx
	• Response-driven therapy:
	  ○ Viral load confirms no detectable HCV RNA levels (or a ≥ 2 log reduction) before week 4 (for 12-wk tx) or before week 12 (for 24-wk tx) and submitted prior to additional approval

North Carolina
 	
3/23/2015
PA Criteria
 	
4/27/2015
PDL
	Treatment Regimen: Viekira Pak is the preferred treatment.
	
	Treatment Criteria:
	• Age:
	  ○ 18+ years
	• Clinical criteria required:
	  ○ Diagnosis chronic HCV with genotype and subtype
	  ○ Baseline HCV RNA tested within the past 6 mo
	  ○ Provider "must be reasonably certain tx will improve beneficiary's overall health status"
	• Disease severity:
	  ○ Any one of these can be submitted as documentation:
	  ▪ Metavir scores (≥F2)
	  ▪ Batts-Ludwig scores (≥F2)
	  ▪ IASL scores (≥F2)
	  ▪ Ishak scores (≥F3)
	  ▪ FibroScan score
	  ▪ FibroSURE score
	  ▪ APRI scores

State Date of Policy Documentation Links	Notes
	▪ Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension) ▪ Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician • SUD: o Pts with a history of alcohol or IV drug use must commit to abstinence o Pts with a recent history of alcohol or IV drug use (within1 year) requires enrollment in tx program **AND/OR** counseling **AND/OR** support group o Must agree to toxicology/alcohol screens (as needed) o Pts with signs of high-risk behavior (IV drug use, recurring alcoholism) will not be reauthorized • Informed consent: o Provider must complete a Beneficiary Readiness Evaluation with the pt ▪ The Beneficiary Readiness Evaluation includes directions for the provider to educate the pt about the risks of drug and alcohol abuse and includes 6 questions about drug use history, metal health, and social support ▪ In addition to SUD-related requirements, a mental health consult is required if mental health conditions are untreated ▪ Patient signs to indicate understanding of compliance expectations • Once in a lifetime benefit: o Pt will be denied coverage if the pt is requesting re-treatment and either failed to achieve a SVR (25 IU/mL) or relapsed after achieve a SVR during a previously completed Sovaldi regimen o Pt will be denied coverage if previously attempted a course of therapy with recommended drug • Transplant: o Viekira Pak approved for liver transplant recipients with fibrosis ≤ F2 • Exclusions: o Lab results indicate no response to therapy o Signs of high-risk behavior o Failure to complete HCV disease evaluation appointment and procedures

State Date of Policy Documentation Links	Notes
	○ Non-compliance to regimen ○ Previously attempted therapy course ○ Viekira Pak: Pt requires dialysis ○ Viekira Pak: Used in combination with other protease inhibitors or with Sovaldi, or with another NS5A or NS5B inhibitor ○ Viekira Pak: Decompensated liver disease (CTP class B or C) • Authorization duration: ○ 8 wks • Adherence: ○ Provider must complete a Beneficiary Readiness Evaluation with the pt meeting ALL of the criteria (see informed consent) ○ Pts who show signs of high-risk behavior, fail to complete disease evaluation appointments and procedures, and are not compliant to regimen will be denied reauthorization • Response-driven therapy: ○ Lab results collected 4 or more wks after the first prescription fill date must indicate a response to therapy of ≥ 2 log reduction in HCR RNA or HCV RNA < 25 IU/mL
North Dakota Harvoni PA Form Harvoni Authorization Algorithm Viekira PA Form Viekira Pak Authorization Algorithm	**Treatment Regimens: Viekira Pak, Harvoni.** **Treatment Criteria:** • Age: ○ 18+ years • Clinical criteria required: ○ Viekira Pak: Diagnosis of HCV-1 chronic HCV with compensated liver disease • Disease severity: ○ Must have compensated liver disease ○ Liver biopsy, must show Metavir score ≥ 2 or Ishak score ≥ 3 or other accepted test demonstrating

State Date of Policy Documentation Links	Notes
	liver fibrosis • Specialist: o Prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist • SUD: o Pt must be drug and alcohol free for past 12 mo • Informed consent: o State has hepatitis C patient consent form covering tx adherence, alcohol/drug use, education on reinfection, birth control requirements • Birth control: o Viekira Pak: Female pts must have a negative pregnancy test w/in 30 days prior to initiation of therapy and monthly tests during tx o Viekira Pak is contraindicated with oral contraceptives • Exclusions: o Severe renal impairment and ESRD o Any medications contraindicated with either Viekira Pak or Harvoni o Viekira Pak: Contraindicated in pts with severe hepatic impairment • Response-driven therapy: o Algorithm requires HCV RNA levels taken on week 4 and sent with renewal request
Ohio	**Treatment Regimens: Updated policy addressing Harvoni and Viekira Pak not identified.**
Oklahoma No date PA Criteria Harvoni Initiation Pt Intent to Treat Contract Pharmacist Contract	**Treatment Regimens: Both Viekira Pak and Harvoni are preferred.** "Use of Sovaldi (sofosbuvir) and Olysio (simeprevir) in combination or alone for treatment of HCV-1 will require patient-specific, clinically significant reasoning why Viekira Pak or Harvoni is not appropriate for the member." **Treatment Criteria:** • Age:

State Date of Policy Documentation Links	Notes
PA Renewal	○ 18+ years • Clinical criteria required: ○ Approved diagnosis of chronic HCV-1 ○ Pre-treatment viral load must be confirmed and indicated on the petition; viral load should be from the previous 3 months ○ "All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease or autoimmune thyroid disease" ○ For Viekira Pak, providers must monitor ALT levels during first 4 wks, then as needed • Disease severity: ○ Metavir fibrosis score ≥ 2 • Specialist ○ Prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist, **OR** ○ The pt must have been evaluated by a gastroenterologist, infectious disease specialist, or transplant specialist w/in the last 3 months • Informed consent: ○ Pt must sign the Intent To Treat contact ○ Pharmacy must submit the Therapy Pharmacy Agreement for each pt • SUD: ○ Pt must have no illicit IV drug use or alcohol abuse in last 6 mo ○ Pt must agree to no IV drug or alcohol use during tx and post-therapy • Once in a lifetime benefit: ○ For Viekira Pak: Pt must not have previously failed tx with protease inhibitor (non-responder or relapsed) • Vaccinations:

State Date of Policy Documentation Links	Notes
	○ Documentation of hepatitis A vaccines • Birth control/pregnancy: ○ Female pts must have a negative pregnancy test immediately before tx ○ Male and female pts must be willing to use 2 forms of non-hormonal birth control ○ For Viekira Pak, female partners of male pt should be "checked for pregnancy for informational purposes" • Exclusions: ○ Alcohol abuse or IV drug use in past 6 mo ○ Decompensated cirrhosis ○ Pregnancy ○ Current use of contraindicated medications ○ Failure to address clinically significant issues prior to starting therapy, including but not limited to: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease or autoimmune thyroid disease ○ Harvoni: Severe renal impairment ○ Viekira Pak: Pt must not have previously failed tx with protease inhibitor (non-responder or relapsed) • Authorization duration: ○ "Approval for 12 wks of tx will not be granted before the 10th of a month (for 24 wks, prior to the 15th of the month) to prevent prescription limit issues from affecting compliance" • Adherence: ○ Prescriber must verify they will work with the pt to ensure adherence ○ Tx gaps longer than 3 days/mo will result in denial of subsequent request for continued therapy • Post-treatment reporting: ○ "The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Viral Response (SVR-12)."

State Date of Policy Documentation Links	Notes
Oregon 4/2015 PA Criteria	**Treatment Regimens: Harvoni and Viekira Pak both preferred.** **Treatment Criteria:** • Clinical criteria required: o Expected survival from non-HCV associated morbidity > 5 years o A baseline HCV RNA level o Reported genotype • Disease severity: o Test (FibroSURE, FibroScan, FibroTest) indicates Metavir ≥ F3, **OR** o Cirrhosis w/o ongoing progressive decompensation (MELD score 8-11), **OR** o Extrahepatic manifestation due to HCV, **OR** o Pt listed for transplant, and tx is essential to prevent infection post-transplant, **OR** o Post-transplant pt with stage 4 fibrosis, **OR** o Post-transplant pt with fibrosing cholesteric hepatitis • Specialist: o 2014 PA criteria required prescription or consultation with a gastroenterologist or hepatologist • SUD: o Pt must be abstinent from IV drugs, illicit drugs, marijuana use, and alcohol abuse for > 6 mo o If pt has a history of alcohol abuse, has the pt been abstinent from alcohol > 6 mo • Once in a lifetime benefit: o Viekira Pak: Pt denied tx if previously failed DAA therapy • HIV co-infection: o HIV+ pts on Viekira Pak must not be on suppressive antiretroviral therapy or therapy with significant ARV drug interactions • Transplant:

State Date of Policy Documentation Links	Notes
	○ Approved if: ▪ Pt listed for transplant, and tx is essential to prevent post-transplant infection, **OR** ▪ Post-transplant pt with stage 4 fibrosis, **OR** ▪ Post-transplant pt with fibrosing cholesteric hepatitis • Birth control/pregnancy: ○ Viekira Pak: Pt must be off ethinyl estradiol birth control for at least 1 wk prior to starting tx • Exclusions: ○ Decompensated liver ○ Renal impairment or ESRD ○ Pts on medications contraindicated with tx ○ Viekira Pak: Pt previously failed DAA therapy
Pennsylvania 1/21/2015 PDL 12/9/2014 PA Bulletin PA Criteria PA Form	**Treatment Regimens: Olysio, Sovaldi are preferred;** Harvoni and Viekira Pak are not listed on PDL but discussed in prior authorization criteria **Treatment Criteria:** • Age: ○ 18 + years • Clinical criteria required: ○ Diagnosis with documented genotype ○ Disease severity/liver fibrosis documented by non-invasive test, FibroScan, or liver biopsy ○ Documented HCV RNA at baseline tested within past 3 months • Disease severity: ○ Metavir fibrosis ≥ F3 documented by recent noninvasive test, FibroScan, or liver biopsy • Specialist: ○ Prescribed by a physician specialist (infectious disease, gastroenterology, hepatology, transplant)

State Date of Policy Documentation Links	Notes

	• SUD:
	  o Documented pattern of abstinence from alcohol and drugs for 6 months prior to treatment
	  o Pts with a history of substance dependence: Lab testing (blood alcohol level and urine drug screen) that support abstinence
	  o Pt is compliant with substance dependence tx if currently being treated
	• Once in a lifetime benefit:
	  o Pt has not previously failed tx with requested DAA
	• Informed consent:
	  o Pt counseled on risks of medication interactions
	• Birth control/pregnancy:
	  o Tx w/ RBV: Negative pregnancy test prior to initiating therapy; agree to use 2 or more forms of contraception and take monthly pregnancy tests during therapy
	• Exclusions:
	  o Life expectancy < 12 months due to non-liver-related comorbid conditions
	  o Previously failed tx with requested DAA
	  o A history of an incomplete course of DAA therapy due to non-compliance with medications
	  o For combination therapy (ex: Harvoni, Sofobuvir), pt has renal impairment or ESRD
	• Re-treatment:
	  o Pt will be denied treatment if pt has a history of an incomplete course of DAA therapy due to non-compliance with medications
	  o Other requests for re-treatment will depend if the pt meets the medical necessity guidelines; has addressed issues of non-compliance (if previously a problem); or, in the judgement of the physician reviewer, the services are medically necessary

Rhode Island 1/2015	**Treatment Regimens: Viekira Pak, Harvoni, and Sovaldi** are included on a list of hepatitis C drugs to which "clinical criteria applies to this class / requires manual prior authorization." No prior authorization criteria identified.

State Date of Policy Documentation Links	Notes
PDL	
South Carolina 2014 PA Form	**Treatment Regimens: Viekira Pak is preferred; Harvoni, Sovaldi, and Olysio are not preferred.** Prior authorization form asks for patient information but does not describe criteria used to determine coverage.

South Dakota
No date
Harvoni PA Form
Algorithm
	Treatment Regimens: Harvoni, no mention of Viekira Pak.
	
	Treatment Criteria:
	• Age:
	  ○ 18+ years
	• Clinical criteria required:
	  ○ Diagnosis chronic hepatitis C, HCV-1
	• Disease severity:
	  ○ Liver biopsy confirming a Metavir score ≥ F3, unless medical contraindicated, or documentation of severe extrahepatic manifestations
	• Specialist:
	  ○ Prescribed by hepatologist, gastroenterologist, or infectious disease specialist
	• SUD:
	  ○ Drug and alcohol free for past 6 mo
	• Exclusions:
	  ○ Renal impairment or ESRD
	  ○ Concominent use of Harvoni and P-gp inducers, certain anticonvulsants, certain antiretrovirals, and rosuvastatin are not recommended.

Tennessee	**Treatment Regimens: Viekira Pak preferred; Harvoni, Sovaldi, and Olysio are non-preferred.** Non-preferred agents require pt have a contraindication or clinically significant drug-drug interaction with preferred agent.

State Date of Policy Documentation Links	Notes

5/1/2015
PDL
PA Criteria (p. 49)
Viekira Pak PA Form
Harvoni PA Form
	Treatment Criteria:
	• Clinical criteria required:
	  ○ Documentation of disease severity
	  ○ Documentation of risk for severe complications
	• Disease severity: must have evidence of 1 of the following:
	  ○ Medical documentation of Metavir score ≥ F3 through
	  ▪ Liver biopsy showing Metavir score ≥ F3, **OR**
	  ▪ FibroTest score ≥ .59, **OR**
	  ▪ FibroScan score ≥ 9.5, **OR**
	  ▪ FIB-4 index > 3.25, **OR**
	  ○ Documentation showing pt at the highest risk for severe complications:
	  ▪ "Evidence of essential mixed bryoglobulinemia with end organ manifestations (including arthralgias, palpable purpura, perifpheral neuropathy, central nervous system vasculitis), **OR**
	  ▪ Evidence of proteinuria, **OR**
	  ▪ Evidence of nephrotic syndrome, **OR**
	  ▪ Evidence of membranoproliferative glomerulonephritis
	• Specialist:
	  ○ Prescribed by a provider with a Tennessee Medicaid Provider ID
	  ○ PA requested by physician specialist with experience in the treatment of hepatitis C infection (e.g., hepatology, infectious disease, or gastroenterology)
	• SUD:
	  ○ Pt is not currently participating in illicit substance or alcohol abuse attested by the physician **AND**
	  ○ Confirmed by:
	  ▪ Validated screening tools (CAGE alcohol screen, NIDA's drug screening tool). **OR**
	  ▪ An acceptable alcohol consumption test (serum gamma-glutamyl transpeptidase, mean

State Date of Policy Documentation Links	Notes
	corpuscular volume, carbohydrate-deficient transferrin, and urine ethylglucuronide) and a urine toxicology screen in lieu of laboratory drug screen report ▪ Screens completed w/in 14 days of PA; results documented in medical file o Prescriber can submit a clinical rationale if a false-positive test is suspected o If pt has a prior history of substance or alcohol abuse, pt must be free of substance or alcohol use for 6 mo AND be participating in or have completed a recovery program, be receiving counseling, or be seeing an addiction specialist • Once in a lifetime benefit: o Pts previously treated with Harvoni or Viekira Pak are ineligible for re-treatment • Birth control/pregnancy: o Viekira Pak: Pts must not be pregnant or have concomitant therapy with ethyl estradiol-containing contraceptives • Exclusions: o Decompensated cirrhosis (CTP score > 6) o Pt receiving concomitant therapy with any contraindicated medications o Harvoni: Severe renal failure o Viekira Pak: Pt receiving concomitant therapy with a hepatitis C protease inhibitor o • Authorization duration: o 8 wks • Adherence: o Compliance must be confirmed based on pharmacy paid claims history for authorization renewal • Response-driven therapy: o RNA levels must be < 25 IU/mL at pre-defined treatment weeks o For 12-week therapy, reauthorization occurs at week 8 for the final 4 weeks of treatment, based on RNA levels tested at 4 weeks

State Date of Policy Documentation Links	Notes
	○ For 24-week therapy, reauthorization occurs at weeks 8 and 16, based on RNA levels tested at 4 and 12 weeks
Texas 1/22/2015 PDL/PA Criteria	**Treatment Regimen: Viekira Pak is preferred**; Harvoni, Olysio, Sovaldi are non-preferred. • Non-preferred treatments may be authorized if there is contraindication, allergic reaction, or treatment failure with preferred drugs • Other prior authorization criteria not identified
Utah 10/17/2014 Harvoni PA Form 1/6/2015 Viekira Pak PA Form 5/1/2015 PDL	**Treatment Regimen: Harvoni, Olysio, and Sovaldi all preferred drugs. Viekira Pak not on PDL, but there is a separate PA form for VP.** **Treatment Criteria:** • Clinical criteria required: ○ A copy of HCV genotype testing results (must be HCV-1) ○ A copy of pre-treatment viral load test results ○ Documentation of previous tx (although prior tx failure is not a requirement for approval) • Specialist: ○ Prescribed by gastroenterologist or hepatologist • Response-driven therapy: ○ None: Initial authorization period is for fill treatment course (12 weeks for Harvoni, 24 weeks for VP)
Vermont 1/2015 PA Form 2/2015	**Treatment Regimens: Harvoni is preferred for HCV1; Sovaldi is preferred for HCV-2 through HCV-6.** No mention of Viekira Pak. **PDL states** "these drugs must be obtained and billed through our specialty pharmacy vendor, Briova." **Treatment Criteria:** • Clinical criteria required:

State Date of Policy Documentation Links	Notes
PDL 1/2015 Pharmacy Benefit Manual	○ Documentation of active HCV infectious verified by viral load ○ Documentation of HCV genotype ○ $CL_{cr} \geq 30$ mL/min (verified by lab results w/ creatinine level in last 6 months) ○ "DVHA Medical Director will review case details to determine eligibility for requested medication" • Disease severity: ○ Metavir stage ≥ F3 • Specialist: ○ Prescriber is, or has consulted with, a gastroenterologist, hepatologist, infectious disease specialist, or other hepatitis specialist in the past year • Informed consent: ○ Counselling must be provided and documented regarding abstaining from alcohol and drugs and preventing HCV transmission • SUD: ○ Documentation showing pt has abstained from alcohol and drug abuse for 6 mo prior; pt must receive counselling on abstaining from alcohol and drug abuse ○ Pts with history of drug abuse (other than alcohol) must submit urine drug screenings • Once in a lifetime benefit: ○ "Treatment experienced" coverage applicable ONLY IF previously treated with PEG + IFN + RBV or PEG + IFN + RBV + (in some cases) a protease inhibitor or, in some cases, Sovaldi. • Birth control/pregnancy: ○ For tx with RBV: ▪ Female pt not pregnant, and won't be during tx or 6 mo after ▪ Male pt does not have a pregnant partner, and she won't become pregnant during tx or 6 mo after ▪ Pt agrees to use 2 forms of non-hormonal contraception during tx and for 6 months after ▪ Verification pregnancy tests will be performed throughout tx

State Date of Policy Documentation Links	Notes

	• Exclusions:
	  ○ Pt receiving dialysis
	  ○ Pt taking any contraindicated medications
	• Authorization duration:
	  ○ Initial Rx for 14 days
	  ○ Authorization for up to 12 wks of tx
	• Adherence:
	  ○ Initial prescription fill covers a 14-day supply
	  ○ Documentation of adherence (viral load changes, progress notes) required to continue therapy beyond 12 weeks

Virginia
 	
1/1/2015
PA Criteria
 	
8/2014
PA Form
	Treatment Regimens: Harvoni, Olysio, and Sovaldi are on preferred drug list. No mention of Viekira Pak.
	
	Treatment Criteria (for Harvoni):
	• Age:
	  ○ 18+ years
	• Clinical criteria required:
	  ○ Baseline HCV RNA
	• Disease severity:
	  ○ Metavir score ≥ F3, and/or
	  ○ Highest risk for disease progression (not defined)
	• Specialist:
	  ○ Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist
	• SUD:
	  ○ Pt must be evaluated for current history of substance and alcohol abuse

State Date of Policy Documentation Links	Notes

	• Once in a lifetime benefit:
	  o Tx-experienced pts eligible only if prior tx was PEG + RBV w/ or w/o protease inhibitor
	  o One course of ledipasvir and/or sofobuvir per lifetime
	• Exclusions:
	  o Pts receiving concomitant therapy with a HCV protease inhibitor
	  o Pts with decompensated cirrhosis (CTP score ≥ 6 [B or C class])
	  o Pts with severe renal impairment or ESRD
	  o HCV-2, -3, -4, -5, -6 (*HCV-2 and -3 have option for Sovaldi-based treatment)*
	  o At tx week 4 (and tx week 12, if applicable), tx will be discontinued if RNA levels ≥ 25 IU/mL
	• Adherence:
	  o Initial approval is 8 weeks, renewal is based on compliance with drug regimen (based on paid claims history)
	• Response-driven therapy:
	  o Initial approval is for 8 weeks
	  o 12-week treatment: Continue tx for 4 more weeks if RNA < 25 IU/mL (test at 4 wks)
	  o 24-week treatment: Continue tx for 8 more weeks if RNA < 25 IU/mL; re-authorize again at 16 weeks if RNA < 25 IU/mL (test at 4 wks; 12 wks)

Washington 1/15/2015 PA Criteria	**Treatment Regimens: Harvoni, Sovaldi-based regimens.** No record of Viekira Pak. Effective Jan. 1, 2015, HCV treatments carved out of Washington's Apple Health Managed Care Organization and covered by Apple Health Fee-For-Service program. **Treatment Criteria:** • Clinical criteria required: o Baseline detectable viral load

State Date of Policy Documentation Links	Notes
	○ Provider must agree to submit viral load after completion of full course of treatment upon request to track tx success. • Disease severity: ○ At least 1 of the 3 following conditions: ▪ Metavir ≥ F3 measured by • APRI ≥ 1.5 **AND** FibroSURE ≥ 0.49, **OR** • FibroScan ≥ 7.1 **AND** FibroSURE ≥ 0.49, **OR** • FibroScan ≥ 7.1 **AND** APRI ≥ 1.5, **OR** • Biopsy ≥ F3, **OR** • Abdominal imaging, in which radiologist determines findings are suggestive of cirrhosis (e.g., nodules; enlarged liver, especially the left lobe; tortuous hepatic arteries; ascites; or portal hypertension), **OR** ▪ HIV or HBV coinfection with Metavir ≥ F2 measured by • FibroScan ≥ 7.1, **OR** • APRI ≥ 1.5, **OR** • APRI = 0.5 – 1.5 **AND** FibroSURE ≥ 0.49, **OR** • Biopsy ≥ F2 **OR** ▪ Metavir = F0-F4 with 1 of the following: • Post solid organ transplant • Awaiting liver transplant • Stage I-III HCC meeting Milan Criteria • HCV infection post-liver transplant • Severe complications (cryoglobulinemia or HCV-induced renal disease) • Decompensated liver disease (CTP score 7-12 class B/C and MELD ≤ 20[6]) • Specialist: ○ Prescriber is a gastroenterologist, hepatologist, or infectious disease specialist, OR prescriber

State Date of Policy Documentation Links	Notes
	participates and consults with Project ECHO ○ Exceptions may be made for other non-specialist providers who work in coordination with an organized system of care, have received training in hepatitis C diagnosis, staging, and treatment protocols, and have ready access to specialists who treat HCV • Informed consent: ○ Pt must attend a medical care visit with the treating clinician to discuss the pros and cons of antiviral therapy, the importance of adherence to tx, and risk factors for fibrosis progression ○ Clinician must attest that the pt has been evaluated for "psychosocial readiness," including identifying potential impediments to adherence that must be addressed prior to initiating tx • SUD: ○ Pts satisfying inclusion criterion 1 and 2 (see disease severity) with a history of alcohol use disorder must be abstinent for 6 mo or longer ▪ Exceptions will be considered if, for at least 3 months, a pt is receiving treatment from an approved facility or under the care of an addiction medicine specialist and abstaining from alcohol during tx; documentation supporting an exception is required ○ Pts satisfying inclusion criterion 1 and 2 with a history of IV drug use must be abstinent from IV drugs for at least 3 months ▪ Exceptions will be considered for pts with IV drug use in the past 3 mo if receiving opiate substitution therapy or medication-assisted treatment from an approved facility or an addiction medicine specialist; documentation supporting an exception is required • Birth Control/Pregnancy ○ Excluded if pregnant or planning to become pregnant • Exclusions: ○ CL_{cr} < 30 mL/min or on hemodialysis ○ Pregnant or planning on becoming pregnant ○ Severe end organ disease and not eligible for transplant (e.g., liver, heart, lung, kidney) ○ Clinically significant illness or any other major medical disorder that may interfere with pt's ability

State Date of Policy Documentation Links	Notes
	to complete a course of treatment ○ Pts who, in the professional judgment of the primary clinician, would not achieve a long-term clinical benefit from HCV treatment (pt with multisystem organ failure, receiving palliative care, etc) ○ Decompensated liver disease with CTP score > 12 or MELD > 20[6] ○ MELD < 20[6] and one of the following: Cardiopulmonary disease that cannot be corrected; malignancy outside the liver; HCC with metastatic spread; intrahepatic cholangiocarcinoma; hemangiosarcoma; uncontrolled sepsis • Authorization duration: ○ Approved antiviral regimens may be limited to 7 days or a 14-day supply with exceptions for members with limited transportation to retail pharmacies; plans may limit dispensing to a single specialty pharmacy with exceptions for members without stable mailing addresses • Adherence: ○ Pt must participate in case management or adherence monitoring if required by the plan • Post-treatment reporting: ○ Providers must submit HCV RNA "after completion of full course of antiviral treatment"
West Virginia 3/2015 Prior Authorization Page Harvoni PA Criteria Pt Consent Form Viekira Pak PA Criteria Hep C Generic PA Form Hep C Continuation PA	**Treatment Regimen: Harvoni preferred.** Other regimens considered on a case-by-case basis."Viekira Pak criteria includes documented failure or contraindication to preferred HCV therapy." **Treatment Criteria:** • Age: ○ 18+ years • Clinical criteria required: ○ Patient must be diagnosed with HCV-1 for Harvoni or Viekira Pak • Disease sSeverity: ○ Patient must have a documented diagnosis of cirrhosis or a fibrosis level ≥ F3 ○ Cirrhosis may be substantiated either through biopsy or the presence of **at least 2** of the following

State Date of Policy Documentation Links	Notes
Form	clinical features: Cirrhotic features on imaging; ascites; esophageal varices; reversed AST:ALT ratio (> 1), thrombocytopenia (< 130,000 platelets/μL), and coagulopathy (INR > 2) o Fibrosis level must be substantiated via biopsy or other accepted method (e.g., FibroSURE) • Specialist: o Prescribed by, or in conjunction with, a gastroenterologist, hepatologist, or infectious disease physician • SUD: o Patient has abstained from the use of illicit drugs and alcohol for a minimum of 6 months, as indicated by the patient's signature on the Patient Consent form • Vaccinations: o Patient must be vaccinated against hepatitis A B • Once in a lifetime benefit: o Coverage is for 1 successful course of therapy in a lifetime; reinfection will not be covered Exceptions may be allowed on a case-by-case basis o For Harvoni, pt must be SOF tx-naïve • Informed consent: o Patient has abstained from the use of illicit drugs and alcohol for a minimum of 6 months, as indicated by the patient's signature on the Patient Consent form o Patient must consent to full 12- or 24-week treatment • HIV coinfection: o Harvoni: "Pt must not be co-infected with HIV" • Transplant: o Pt must not be awaiting liver transplant ("Harvoni is not indicated in this population") • Quantity Limit: o Lost/stolen medication replacement request will not be honored • Exclusions: o Harvoni: Pt is awaiting or post-liver transplant (Harvoni is not indicated in this population)

State Date of Policy Documentation Links	Notes
	○ Harvoni: Pt has severe renal impairment or ESRD ○ Viekira Pak: Pt is on dialysis ○ Viekira Pak: CTP class of B or C ○ Prescription for any other HCV anti-viral medication ○ Prescriber has determined that the pt has not abstained from illicit drugs and/or alcohol for 6 months prior to the start of treatment ○ Pt has a HIV co-infection ○ Pt takes a concomitant medication that may have a significant clinical interaction ○ Coverage will be discontinued if a pt's RNA level > 25 IU/ml OR if the prescriber has not submitted or has not obtained a viral load at wk 4 • Authorization duration: ○ Initial 6-wk authorization • Adherence: ○ Continued coverage after week 6 depends upon receipt of an HCV RNA level at treatment week 4, documentation of patient compliance, continued abstinence and an HCV RNA < 25 IU/ml. Failure to obtain and report RNA load will result in denial of further coverage • Response-driven therapy: ○ Initial approval is for 6 weeks; submission of RNA levels is required at the start of therapy and at week 4 ○ Continued coverage after week 6 depends upon receipt of a HCV RNA level at treatment week 4, documentation of patient compliance, continued abstinence and a HCV RNA < 25 IU/ml. Failure to obtain and report the pt's RNA viral load will result in denial of further coverage • Post-treatment reporting: ○ Pt and provider must agree to collect and submit SVR12 and SVR24
Wisconsin	**Treatment Regimens: Viekira Pak is preferred;** Harvoni, Olysio, and Sovaldi are not preferred. Only pts ineligible for Viekira Pak due to medical or medication contraindication will be considered for Harvoni.

State Date of Policy Documentation Links	Notes

12/2014
PA Form
PA Instructions
PA Form Renewal
 	
No date
Viekira Pak PA Criteria
Harvoni PA Criteria
 	
12/2014
PDL
	Prior authorization for HCV agents requires paper processing only.
	
	Treatment Criteria:
	• Age:
	  ○ 18+ years
	• Clinical criteria required:
	  ○ Chronic HCV-1 infection
	  ○ Lab data within last 6 months, including the following:
	  ▪ HCV-RNA level
	  ▪ LFTs
	  ▪ CBC
	  ▪ serum creatinine test
	  ▪ albumin test
	  ▪ INR
	  ○ Test results (if performed) from liver biopsy, scan, or ultrasound
	  ○ HCV clinical data, including:
	  ▪ Likely source of the HCV infection
	  ▪ Current medical records for HCV assessment and treatment
	  ▪ History of liver transplant, or documentation if the pt is on the liver transplant wait list
	  ○ Assessment of the presence or absence of cirrhosis. If cirrhotic, documentation of the following:
	  ▪ CTP score
	  ▪ HCC status based on liver CT, ultrasound, or MRI
	  ▪ Presence and treatment of ascites, esophageal varices, hepatic encephalopathy, jaundice, and portal hypertension
	  ▪ FibroScan results may be provided as 1 component of cirrhosis assessment
	  ○ Fibrosis stage or score

State Date of Policy Documentation Links	Notes
	▪ Staging calculators (APRI, FIB-4, NAFLD), blood assays (FibroSURE, FIBROSpect), and liver biopsies are not accepted as ways to differentiate between F2 and F3 Metavir scores. o Hepatitis C medication treatment history, including details of the following: ▪ When treatment occurred ▪ Medications taken and compliance ▪ Treatment results (e.g., null response, partial response, or relapse) o Relevant medical history not related to hepatitis C from the pt's primary care provider, including: ▪ Current medication list ▪ Current hx and physical ▪ Current and past psychosocial history, including alcohol and illicit drug use ▪ Other liver disease ▪ Transplant history ▪ Hepatitis A, hepatitis B, or HIV co-infection ▪ Autoimmune disease ▪ Other significant or uncontrolled diseases (e.g., depression, thyroid disease, diabetes, CVD, pulmonary disease) • Disease severity: o Compensated cirrhosis (i.e. CTP class A) o Metavir score ≥ F3 or evidence of bridging fibrosis ▪ "Note: ForwardHealth does not accept fibrosis staging as determined by calculators or blood assays to differentiate between F2 and F3 or greater Metavir scores. Some examples of fibrosis staging calculators may include APRI, FIB-4, and NAFLD. Some examples of blood assays may include FibroSUREand FIBROSpect. ForwardHealth does accept liver biopsy to determine a Metavir score or to determine fibrosis staging." o Serious extrahepatic manifestations of HCV o Liver transplant recipients w/ normal hepatic function and mile fibrosis (Metavir ≤ F2). • Specialist:

State Date of Policy Documentation Links	Notes
	○ Prescribed by board-certified gastroenterologist or infectious disease specialist or by "mid-level practitioner" who has a collaborative relationship with a board-certified specialist • SUD: ○ Past and current alcohol abuse or illicit drug use must be documented ○ Documentation of at least 6 months of abstinence from alcohol abuse or illicit drug use is required ○ Pts currently abusing drugs or alcohol will be denied tx ○ Active participation in a recovery program is required for members with a recent hx of alcohol or drug abuse • Once in a lifetime benefit: ○ Denied tx if past or current use of Viekira Pak, Sovaldi, Harvoni, Olysio, Incivek, or Victrelis • HIV co-infection: ○ Harvoni: pts co-infected with HIV will be denied tx • Transplant: ○ Harvoni not covered for post-liver transplant tx • Exclusions: ○ Pt has autoimmune hepatitis or another condition that is contraindicated for RBV ○ The pt has a significant or uncontrolled concurrent disease (e.g., depression, thyroid disease, diabetes, CVD, pulmonary disease) ○ Pt has cirrhosis with moderate or severe liver functional compromise (i.e. CTP class B or C). "If member is currently on a liver transplant wait list with an elevated MELD score, individual circumstances will be considered for review." ○ Harvoni: member has received a liver transplant ○ The pt has decompensated cirrhosis ○ The pt has acute hepatitis C ○ The pt is currently abusing drugs or alcohol ○ The pt has taken or is currently taking Sovaldi, Harvoni, Olysio, Incivek, or Victrelis ○ Non-compliance with approved hepatitis C treatment regimen (for renewals only)

State Date of Policy Documentation Links	Notes
	○ Use of contraindicated medications • Authorization duration: ○ 8 wks • Response-driven rherapy: ○ Treatment approved for 8 weeks; renewal if RNA < 25 IU/ml
Wyoming 05/2015 PA Form	**Treatment Regimens:** Viekira Pak, Harvoni both preferred agents subject to criteria. **Treatment Criteria:** • Clinical criteria required: ○ HCV genotype ○ Cirrhosis status ○ Any other medications given concurrently with HCV medication ○ Tx history • Disease severity: ○ Pt's cirrhosis status • Informed consent: ○ Pt must complete PREP-C (Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment) https://prepc.org ○ Pt and the prescriber must complete the Wyoming Medicaid Client Disclosure and Commitment to Take Hepatitis C Medications form (attached to PA form) • SUD: ○ A drug screen in the last month is required ○ If positive for illicit drugs, prior authorization will be denied • Once in a lifetime benefit: ○ Only 1 course of tx per pt will be covered

State Date of Policy Documentation Links	Notes

	• HIV co-infection:
	  ○ HIV and hepatitis B tests must be performed within 1 month of tx
	• Adherence:
	  ○ All approved pts will be preferred to WYHealth nurses for case management

Abbreviations: ALT = alanine aminotransferase; APRI = AST:platelet ratio index; ARFI = acoustic radiation force impulse imaging; ARV = antiretroviral; AST = aspartate aminotransferase; CBC = complete blood count; CD4 = cluster of differentiation 4; CL_{cr} = creatinine clearance; CLIA = Clinical Laboratory Improvement Act; COPD = chronic obstructive pulmonary disease; CT = computed tomography; CTP = Child-Turcotte-Pugh score; CVD = cardiovascular disease; DAA = direct-acting antiviral; DUR = drug utilization review; DVHA = Department of Vermont Health Access; dx = diagnosis; ESRD = end-stage renal disease; FDA = U.S. Food and Drug Administration; FFS = fee-for-service; FIB-4 = fibrosis-4 clinical calculator; GFR = glomerular filtration rate (and estimated GFR); HBV = hepatitis B virus; HCC = hepatocellular carcinoma; HCV = hepatitis C virus; HCV-1 = HCV genotype 1 (and equivalents for genotypes 2, 3, 4, 5, 6); HIV = human immunodeficiency virus; HRSA = Health Resources and Services Administration; hx = history; IASL = International Association for Study of the Liver; IFN = interferon; INR = international normalized ratio; IU = international units; IV = intravenous; LFT = liver function test; LLOQ = lower limit of quantification; MELD = model end-stage liver disease; mo = month(s); MRE = magnetic resonance elastography; MRI = magnetic resonance imaging; PA = prior authorization; pt = patient; P-gp = permeability glycoprotein; NALFD = non-alcoholic fatty liver disease; NIDA = National Institute on Drug Abuse; NS5A = nonstructural protein 5A (and equivalent for 5B); PDL = preferred drug list; PEG = pegylated interferon alpha; PI = protease inhibitor; pt = patient; RBV = ribavirin; RNA = ribonucleic acid; Rx = prescription; SAMHSA = Substance Abuse and Mental Health Services Administration; SIM = simeprevir (Olysio™); SOF = sofosbuvir (Sovaldi™); SUD = substance use disorder; SVR = sustained virological response; tx = treatment; wk = week

Appendix C

Monthly Part D Spending on Hepatitis C Drugs Since 2014

Month	Non-Gilead HCV Drugs	SOVALDI	HARVONI	Grand Total
Jan-14	$28,442,376	$87,971,156		**$116,413,532**
Feb-14	$43,853,177	$172,286,950		**$216,140,127**
Mar-14	$76,366,244	$279,584,516		**$355,950,760**
Apr-14	$100,038,835	$335,657,011		**$435,695,845**
May-14	$117,118,858	$374,015,256		**$491,134,114**
Jun-14	$119,223,080	$362,401,672		**$481,624,753**
Jul-14	$123,297,596	$357,824,949		**$481,122,544**
Aug-14	$109,346,905	$307,513,498		**$416,860,404**
Sep-14	$98,500,726	$274,536,702		**$373,037,428**
Oct-14	$84,139,502	$243,317,636	$52,627,766	**$380,084,904**
Nov-14	$50,040,416	$160,278,599	$211,035,968	**$421,354,984**
Dec-14	$41,520,872	$151,573,035	$436,228,838	**$629,322,745**
Jan-15	$31,306,240	$111,180,236	$484,972,311	**$627,458,787**
Feb-15	$33,999,630	$108,632,947	$552,282,193	**$694,914,770**
Mar-15	$39,714,722	$121,356,036	$702,916,231	**$863,986,988**
Apr-15	$36,506,518	$114,514,855	$686,400,733	**$837,422,106**
May-15	$31,753,078	$104,467,097	$636,896,854	**$773,117,030**
Jun-15	$30,554,998	$109,482,553	$653,142,640	**$793,180,191**
Grand Total	**$1,195,723,772**	**$3,776,594,704**	**$4,416,503,535**	**$9,388,822,010**

Source: *CMS Chronic Conditions Warehouse, http://ccwdata.org.*
Note: Spending data are prior to rebates.

CY2013 Part D Spending on HCV Drugs

Drug Name	Spending
INCIVEK	$177,000,000
INTERFERON	$138,000,000
VICTRELIS	$45,000,000
RIBAVIRIN	$18,000,000
SOVALDI	$14,000,000
OLYSIO	$2,000,000
Grand Total	**$394,000,000**

Source: *Centers for Medicare & Medicaid Services, Office of Enterprise Data and Analytics.*
Notes: Spending data are prior to rebates; Olysio was approved by the FDA on November 22, 2013; Sovaldi was approved by the FDA on December 6, 2013.

CY2014 Part D Spending on HCV Drugs

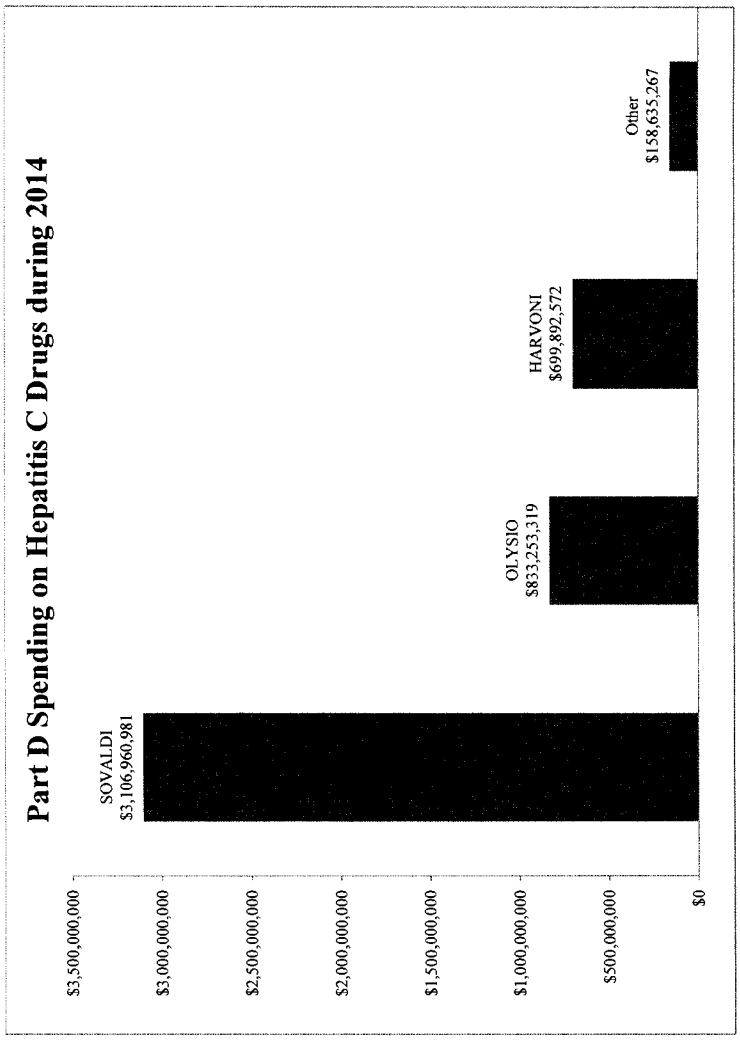
Drug Name	Spending
SOVALDI	$3,106,960,981
OLYSIO	$833,253,319
HARVONI	$699,892,572
Other	$158,635,267
Grand Total	**$4,798,742,139**

Source: *CMS Chronic Conditions Warehouse, http://ccwdata.org.*
Notes: Spending data are prior to rebates; Harvoni was approved by the FDA on October 10, 2014; "Other" includes Copegus, Pegasys, Pegasys Proclick, Moderiba, Intron-A w Diluent, Victrelis, Intron-A, Rebetol, Rebetron, Peg-Intron, Sylatron, Peg-Intron Redipen, Ribavirin, Virazole, Infergen, Ribatab, Ribapak, Ribasphere, Incivek, Ribasphere, and Ribapak.

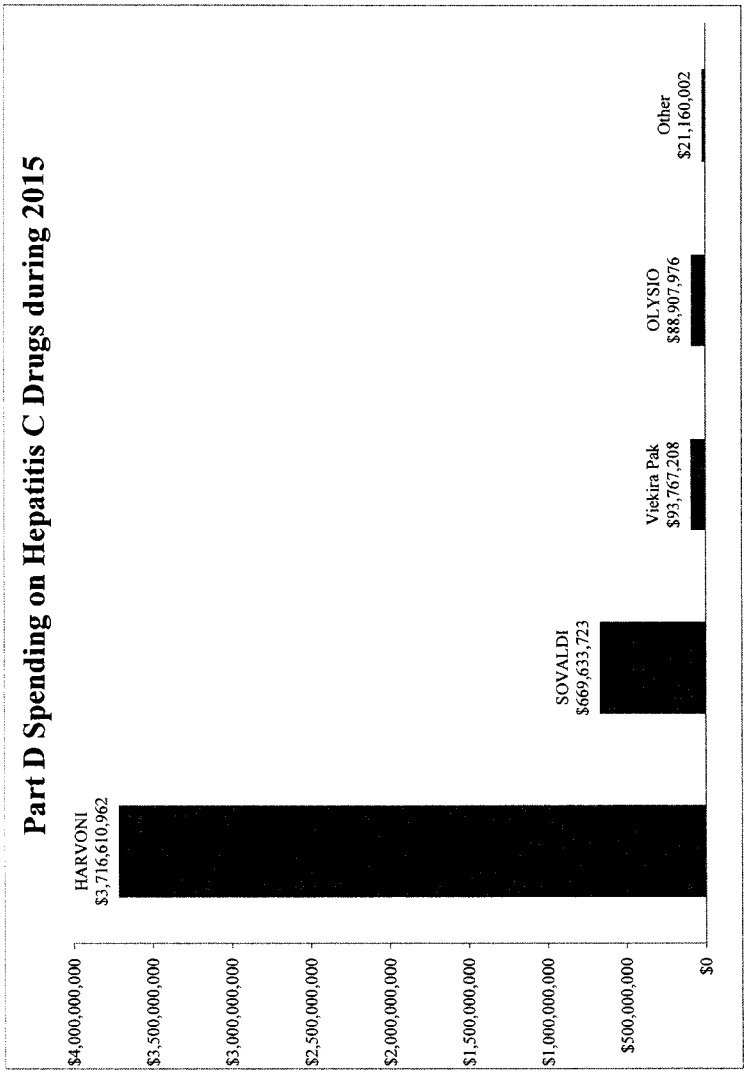
CY2015 Part D HCV Spending (Through June 30)

Drug Name	Spending
HARVONI	$3,716,610,962
SOVALDI	$669,633,723
VIEKIRA PAK	$93,767,208
OLYSIO	$88,907,976
Other	$21,160,002
Grand Total	**$4,590,079,872**

Source: *CMS Chronic Conditions Warehouse, http://ccwdata.org.*
Notes: Spending data are prior to rebates; "Other" includes Copegus, Pegasys, Pegasys Proclick, Moderiba, Intron-A w Diluent, Victrelis, Intron-A, Rebetol, Rebetron, Peg-Intron, Sylatron, Peg-Intron Redipen, Ribavirin, Virazole, Infergen, Ribatab, Ribapak, Ribasphere, Incivek, Ribasphere, and Ribapak.



Source: *CMS Chronic Conditions Warehouse, http://ccwdata.org/index.php.*
Notes: Spending data are prior to rebates; Harvoni was approved by the FDA on October 10, 2014; "Other" includes Copegus, Pegasys, Pegasys Proclick, Moderiba, Intron-A w Diluent, Victrelis, Intron-A, Rebetol, Rebetron, Peg-Intron, Sylatron, Peg-Intron Redipen, Ribavirin, Virazole, Infergen, Ribatab, Ribapak, Ribasphere, Incivek, Ribasphere, and Ribapak.



Source: *CMS Chronic Conditions Warehouse, http://ccwdata.org/index.php.*
Notes: Spending data are prior to rebates; "Other" includes Copegus, Pegasys, Pegasys Proclick, Moderiba, Intron-A w Diluent, Victrelis, Intron-A, Rebetol, Rebetron, Peg-Intron, Sylatron, Peg-Intron Redipen, Ribavirin, Virazole, infergen, Ribatab, Ribapak, Ribasphere, Incivek, Ribasphere, and Ribapak.

Appendix D

Exhibit 1

From: Jenkins, Ann **Redacted**
Sent: Monday, March 09, 2015 2:07 PM
To: Gartrell, Peter (Finance)
Subject: Q&A

Peter,

Attached is the Q&A. Please let me know that you received it. Thank you.

Ann Walker-Jenkins
Director, Federal Government Affairs

Redacted

CVS Health
Redacted

CVSHealth

CONFIDENTIALITY NOTICE: This communication and any attachments may contain confidential and/or privileged information for the use of the designated recipients named above. If you are not the intended recipient, you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or its contents is prohibited. If you have received this communication in error, please notify the sender immediately by email or telephone and destroy all copies of this communication and any attachments. Thank You.

We are pleased to answer your inquiries regarding some of the internal and external developments related to Gilead, AbbVie and Johnson & Johnson (the "Pharmaceutical Manufacturers") relative to their Hepatitis C (HCV) product offerings. Our desire is to be as open and transparent as possible. Having said that, as you would expect, we have stringent confidentiality obligations in our agreements with the Pharmaceutical Manufacturers to protect our respective proprietary information. As a result, some of the details you have requested we cannot provide.

Question 1: Please describe any negotiations or communications your company had regarding HCV drugs with Gilead, AbbVie, or Johnson & Johnson. When did these communications, meetings or negotiations take place? Any dates, emails or presentations that can substantiate those discussions would be helpful. How did the entrance of a competitor (or at least alternative drugs within the class) change the pharmaceutical makers' behavior?

Answer 1: Consistent with our standard approach to negotiating formulary rebates with manufacturers, we undertook an iterative RFP process which asked each manufacturer to submit competitive financial bids. Our evaluation of those bids was based on many factors including, among other things:

- Clinical considerations
- Acquisition cost of the product
- Net client cost for all Hepatitis C treatments
- Expected current and future distribution of patients between genotypes
- Market share of each product
- Expected average duration of therapy for the various agents
- Factors contributing to medication adherence
- Ability to further control cost through additional utilization management measures

The process began, and typically does begin, in anticipation of the introduction of the products as we seek to obtain additional value.

The entrance of alternative drugs in a class generally increases manufacturers' willingness to negotiate with payors, including PBMs. The degree of clinical differentiation of the products also typically impacts the manufacturers' willingness to negotiate. In this instance, based on the information available to us, our clinical evaluation of the products indicated that there was not material clinical superiority of one product over another. Prior to finalizing our selections, our recommendations were approved by both our internal clinical team and our external Pharmacy and Therapeutics Committee.

Question 2: What discount did Gilead initially offer CVS for Sovaldi and Harvoni? Have those discounts changes over the course of time?

Question 3: What discounts did Abbvie offer CVS for Viekira Pak?

Question 4: What discounts did Johnson & Johnson offer for Olysio?

Answers 2, 3, and 4: Discounts originally offered by each manufacturer were minimal. As the competitive landscape changed, the offered discounts increased. Our negotiations with and the terms offered to us by each manufacturer remain subject to non disclosure agreements and confidentiality obligations. That said, while a critically important component of our evaluation, discounts cannot be considered in isolation and a thorough evaluation must include those factors identified above in addition to the proposed discounts.

Question 5: What was the price point your company was seeking that allowed it to expand coverage of Sovaldi? What was the rationale behind the price point? Is this the same for other HCV drugs?

Answer 5: We negotiated the lowest price point for each product that we were able to achieve based upon the competitive process.

Question 6: Was the decision to grant Gilead's HCV drugs primarily financial? How did clinical information or differences influence choosing one drug over another?

Prior to negotiating on financial terms, we evaluated the clinical information and comparability for each product. Our clinical team, which includes experienced clinical pharmacists, prepared a therapeutic class review following a comprehensive review of available clinical literature. Numerous references and information resources were used to assist in evaluation and review of the medications under consideration for formulary addition. Although we believed that the Gilead products have the best clinical profile (in that it is administered once per day rather than twice, for example), our clinical evaluation indicated that there was not an appreciable clinical superiority of one product over another. As a result of these clinical considerations, cost was a significant factor in our formulary decisions. In addition, our recommendations were approved by an external Pharmacy and Therapeutics Committee after its review of the clinical information. This Committee is an external advisory body of experts from across the United States, composed of 19 independent health care professionals including 16 physicians and 3 pharmacists, all of whom have broad clinical backgrounds and/or academic expertise regarding prescription drugs. A majority of the CVS/caremark National P&T Committee members are actively practicing pharmacists and physicians.

Question 7: Is there a difference between the wholesale prices for Gilead's HCV drugs versus the pharmacy mark-up?

Answer 7: Yes, there is always a difference between wholesale prices and pharmacy mark up.

Question 8: What is the price of treating patients with Sovaldi compared with the cost of the prior treatment cocktail?

Answer 8: It is very difficult to compare the overall cost of the prior treatments to Sovaldi because of the longer course of treatment and relative effectiveness of the new products.

Question 9: There are several different lengths of treatment for Gilead's various HCV drugs, e.g. 8, 12, 24 and 48 weeks. Please provide data about the length (and corresponding cost) of treatment for different time periods of drug usage?

The American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) have recently provided updated Hepatitis C Virus (HCV) treatment guidelines with recommended durations for the various treatments. These durations of treatment range from 8 to 48 weeks based on the HCV genotype (1- 6), the patient's HCV viral load, the patient's level of liver fibrosis, and the patient's other co-morbid diseases. The AASLD/IDSA guidelines indicate that the most common treatment regimen would be the 12-week treatment regimen followed by the 24 week treatment regimen with much lower use of either the 8 week or 48 week treatment regimens. Although very early in the utilization of these very new drugs, CVS/caremark has seen utilization of consistent with the AASLD/IDSA guidelines.

Both Harvoni (ledipasvir/sofosbuvir) and Viekira Pak (paritaprevar/ritonavir/ombitasvir/dasbuvir) are indicated by the United States Food and Drug Administration (FDA) for the treatment of HCV genotype 1 patients or the most common HCV genotype.

<u>HCV genotype 1:</u>

1. Harvoni treatment durations range from an 8-week regimen (in treatment-naïve patients without fibrosis who have a very low viral load) to a 12-week regimen (in treatment-naïve and treatment-experienced patients without fibrosis) and a 24-week regimen for patients with fibrosis.
2. Viekira Pak treatment durations range from a 12-week regimen (in patients with genotype 1a and genotype 1b without cirrhosis) to a 24-week regimen (in patients with genotype 1b with cirrhosis).

HCV genotypes 2-6:

1. A 12-week regimen of Sovaldi (sofosbuvir) and ribavirin therapy is recommended in patients with genotypes 2 and 5.
3. A 24-week regimen of Sovaldi and ribavirin is recommended in patients with genotype 3.
4. A 12-week regimen of either Harvoni or Viekira Pak are recommended in patients with genotype 4 by the AASLD/IDSA guidelines.
5. A 12-week regimen of Harvoni is indicated for patients with genotype 6 by the AASLD/IDSA guidelines.

Lastly, a 48-week treatment regimen is recommended in rare circumstances (in patients who have a history of prior treatment with older HCV treatment regimens or patients with decompensated cirrhosis or hepatocellular carcinoma who are awaiting liver transplantation).

American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (ISDA). December 19, 2014. http://www.hcvguidelines.org/full-report

Question 10: Many payors have discussed the difference between clinical results and "real world" results of Sovaldi and other HCV drugs. Does CVS have any such data for Sovaldi, Harvoni and/or Viekira Pak?

Answer 10: Yes, following is a summary of an analysis we have done on this topic.

Analysis of "Real World" Sovaldi® (sofosbuvir) Use and Discontinuation Rates

Sovaldi was approved in December 2013 and was felt to be a clinical breakthrough as, in clinical trials, it provided a sustained viral response in 95% percent of patients with Hepatitis C, essentially a cure. This compared with the 40 - 50 percent cure rate observed with prior interferon-based therapies and up to a 70 percent cure rate with protease-inhibitor (Victrelis and Incivek) based regimens(1).

Beginning in December 2013, when Sovaldi first became available, there was rapid uptake in the use of the medication, with increasing numbers of patients beginning treatment each month (Fig 1). This was followed by a plateau and then a downward trend* in patients starting treatment with Sovaldi during May – August 2014 as evidenced in CVS Health data (Fig 1). In the nine months following release, 16,560 patients with pharmacy benefits through CVS/Caremark filled prescriptions for the medicine; 65% were for all-oral, interferon-free regimens.

Adherence with Sovaldi regimens treatment was noted to be greater than 90 percent, but was lower than that observed in clinical trials. As noted from an analysis of 1,965 patients who filled Sovaldi regimens in CVS/pharmacy retail locations or CVS/caremark specialty pharmacies, the average discontinuation rate was 8.1 percent compared with 2.0% - 3.6% noted in clinical trials. However, these discontinuation rates were lower than for patients who filled in non-CVS Health-related outlets; discontinuation rate at CVS/Caremark specialty pharmacy was 5.9% compared with 8.5% at non-CVS/Caremark specialty pharmacy**

[*Downward trend may have been due to warehousing of patients given the pending approval of Harvoni and Viekira pak (not due to a lack of coverage)

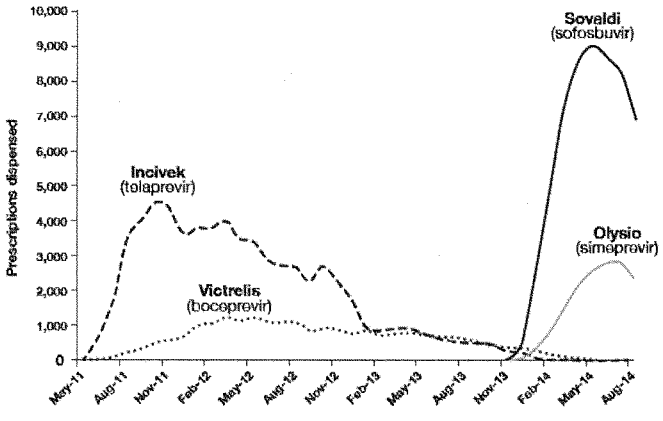
Harvoni Utilization in the Weeks after Launch

The uptake of Harvoni after its launch has been swift and approximately 2.5 times as rapid as that of Sovaldi prescribing after its launch. In the first eight weeks after launch, 7553 prescriptions for Harvoni had been dispensed to CVS/Caremark members compared with 3063 prescriptions of Sovaldi in the first eight weeks after the its launch the previous year (Fig 2).

Following the launch, within eight weeks, the contemporaneous use of Harvoni surpassed that of Sovaldi and weekly prescriptions for Sovaldi started to decrease (Fig 3).

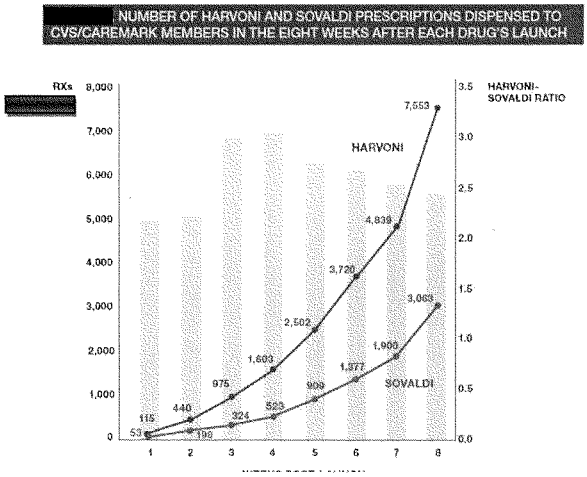
Harvoni use has been noted across all market segments - commercial clients (i.e., employers and health plans) as well as Medicare and Medicaid.

Figure 1: Utilization Trends of Hepatitis C Treatments (May 2011 – Aug 2014)



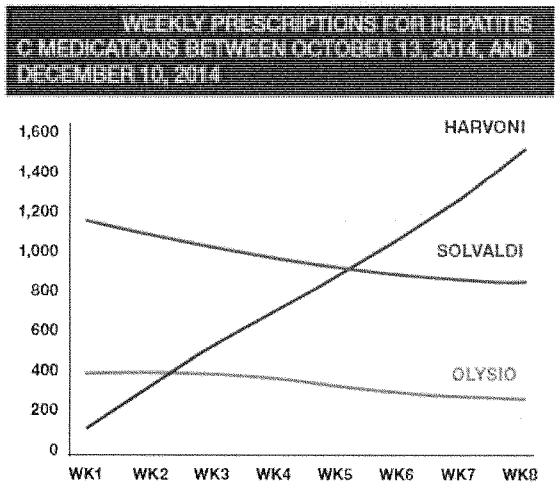
Source: Analysis of "Real World" Sovaldi® (sofosbuvir) Use and Discontinuation Rates
September 2014: Troyen A. Brennan, M.D., Chief Medical Officer, CVS Health; Alan Lotvin, M D., Executive Vice President, CVS/specialty, CVS Health; William Shrank, M.D., Chief Scientific Officer, CVS Health

Fig. 2



Source: Harvoni® Utilization in the Weeks after Launch: Patterns and Implications: Alan Lotvin M.D., Will Shrank M.D. M.S.H.S., Andrew Chang M.P.H, Lora Armstrong Pharm.D., Troyen Brennan M.D., J.D.

Fig. 3

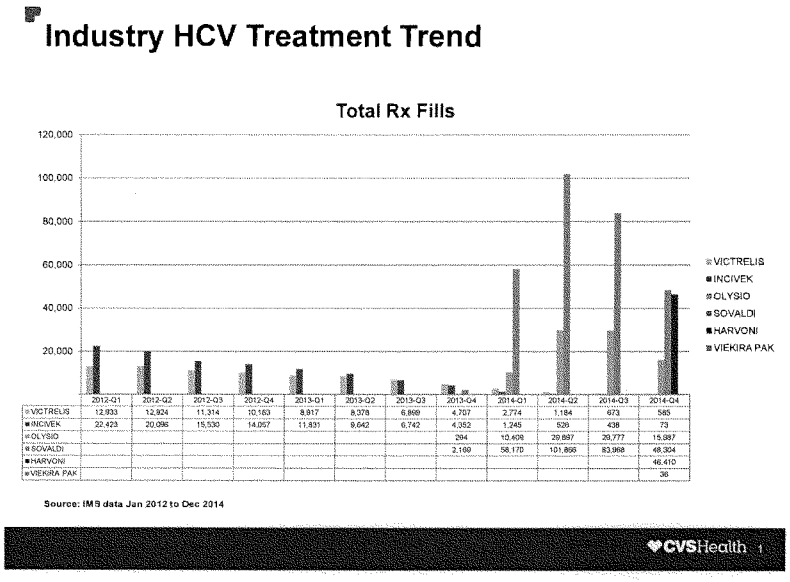


Source: Harvoni® Utilization in the Weeks after Launch: Patterns and Implications: Alan Lotvin M.D., Will Shrank M.D. M.S.H.S., Andrew Chang M.P.H, Lora Armstrong Pharm.D., Troyen Brennan M.D., J.D.

Ref 1: Ghany M, Nelson D, Strader D, et al. AASLD Practice Guideline. An update on treatment of genotype 1 chronic hepatitis C virus infection: 2011 practice guideline by the American Association for the Study of Liver Disease. Hepatology 2011; 54:1433–1444.

Question 11: How does the rate of prescriptions for the drugs that were the standard of care for HCV compare to the rates of prescriptions for the new SOCs starting with Sovaldi?

Answer 11: There has been a dramatic increase in the volume of prescriptions for the newer HCV standard of care medications as compared with prior treatments. The following graph illustrates the volume of prescriptions for earlier treatments, Victrelis and Incivek, as compared with newer treatments, Sovaldi, Olysio, Harvoni and Viekira Pak.



Question 12: Please describe CVS's plans for Part D coverage restrictions in 2015 for HCV drugs. How, if at all, will it differ from the coverage in 2014?

Answer 12: In 2014 we included Incivik and Victarlis on our Medicare Part D formulary and added Sovaldi in June during the 180 review period allowed by CMS for new products. In October 2014, Harvoni was approved by the FDA and in December, Viekira was approved. In early January 2015 we selected one of these new combination drugs to be added to our formulary, which allows us to provide coverage across all genotypes, and expanded the number of options available as compared to our 2014 formulary.

Question 13: To the extent that CVS has Medicaid managed care plans, please describe CVS's plans for state coverage criteria in 2015. How, if at all, will it differ from the coverage in 2014?

Answer 13: We provide support for each of our Medicaid clients to help our clients determine specific coverage criteria for their populations that are consistent with the requirements of the states in which they operate. Although the coverage criteria may impact the availability of formulary rebates, these decisions rest with the plans.

Question 14: Broadly speaking, what are/were the consequences of having a drug priced as high as Sovaldi when it was initially put on the market? How would you address the issues raised by the cost to the health system?

Answer 14: PBMs are skilled at helping its plan sponsors and health care providers manage patient care and lower overall drug costs. They provide services to support patients to help them stay adherent to their medication regimens, for example. The way to lower drug costs is to ensure the drugs are managed by a PBM who understands the clinical tools and competitive marketplace issues to drive to the solution—high quality care at a lower cost. When single source drugs come to market, it is difficult to negotiate a lower cost because there is no market competition. With Sovaldi, ultimately as new drugs came on the market like Viekira Pak, we were able to negotiate discounts and get people the drugs they need at a lower cost.

Question 15: How has Sovaldi been utilized in correlation with Olysio?

Answer 15: The use of Sovaldi with Olysio is an accepted treatment combination with supporting clinical trial results and recommendation in the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (ISDA) guidelines. This combination use received an FDA indication in 2014 as well. Prior to approval of Harvoni and Viekira Pak, the combination of Sovaldi and Olysio was the only available treatment for patients that could not tolerate interferon. Since the approval of Harvoni and Viekira Pak, the use of Sovaldi with Olysio has slowed and is expected to be used infrequently.

Exhibit 2

NAMD
National Association of Medicaid Directors

October 28, 2014

The Honorable Ron Wyden
Chairman
Senate Committee on Finance

The Honorable Orrin Hatch
Ranking Member
Senate Committee on Finance

The Honorable Tom Harkin
Chairman
Senate Committee on Health, Education, Labor and Pensions

The Honorable Lamar Alexander
Ranking Member
Senate Committee on Health, Education, Labor and Pensions

The Honorable Fred Upton
Chairman
House Committee on Energy and Commerce

The Honorable Henry Waxman
Ranking Member
House Committee on Energy and Commerce

The Honorable Dave Camp
Chairman
House Ways and Means Committee

The Honorable Sander Levin
Ranking Member
House Ways and Means Committee

Dear Senators and Congressmen:

We are writing on behalf of the nation's Medicaid Directors to provide insight on the challenges posed to Medicaid agencies by new and emerging treatments for one of our nation's most pressing public health problems – hepatitis C. We also wish to begin a dialogue with you on federal policies which strike a better balance between appropriate access to new pharmaceutical cures and treatments for consumers and the long-term fiscal health of the Medicaid program which currently covers nearly 70 million low-income, vulnerable individuals and families. Our letter identifies several ideas to ground these conversations.

NAMD is a bipartisan, non-profit organization which represents Medicaid Directors in the fifty states, the District of Columbia and the territories. The Association was created in large part to develop consensus among Directors on critical issues, specifically those that have national policy implications.

444 North Capitol Street, NW, Suite 524 • Washington, DC 20001 • Phone: 202.403.8620 • www.medicaiddirectors.org

NAMD
National Association of Medicaid Directors

The evolving situation with high-cost breakthrough drugs is an issue that has brought together the state Medicaid Directors. The current experience with hepatitis C has rightly commanded national attention, both for the promise that these new treatments hold, as well as their associated costs.

While the immediate focus and challenges present with hepatitis C treatments, we know this is a harbinger of the promises and challenges that will emerge in the years ahead. Publicly available information indicates that additional specialty drugs are currently moving through the drug pipeline. These are expected to enter the market by 2020 and will treat conditions including new immunotherapy treatments for cancer, cholesterol management, Alzheimer's disease, and multiple sclerosis reversing therapies.

This situation requires an immediate federal solution. We have noted the bipartisan engagement in efforts such as the "21st Century Cures" initiative, which seek to examine the steps federal policymakers can take to accelerate the pace of cures in America. However, we believe Congress has *not* sufficiently addressed the full continuum of issues associated with this process and related drug approval processes. Specifically, policymakers have failed to address the cost and reimbursement issues associated with faster or increased pathways for the development of high-cost therapies and treatments. This is particularly concerning when there is limited information about the evidence base for these products.

Policymakers must begin developing a new framework for conceptualizing the comprehensive costs and value associated with highly effective treatments in public health insurance programs, including Medicaid. In this process, policymakers and the public must also be realistic about the choices and trade-offs involved when taxpayer dollars are used to fund high-cost services and products. This conversation will be difficult, but it is one we believe federal policymakers must immediately begin with states and stakeholders.

The Hepatitis C Situation

In the short term, state Medicaid agencies are deeply concerned about the situation they face with new hepatitis C prescription drugs. As a primary payer for breakthrough treatments for hepatitis C, Medicaid agencies are using the limited tools they have to manage the very serious cost implications of emerging products. They are also weighing complex ethical questions, scientific evidence and public health needs to maximize appropriate access to new treatments.

This situation has several parallels to experiences with other products, namely those for the treatment of HIV/AIDS. As with HIV/AIDS prescription medications, there is sound, but still emerging, scientific evidence, a moral imperative to treat and a high cost based on investment and market dynamics.

However, as compared to HIV/AIDS, experts estimate that hepatitis C affects a much larger population. The Centers for Disease Control and Prevention (CDC) estimates that 3.2 million Americans are infected with hepatitis C. However, most people living with a chronic hepatitis C infection are unaware of their infection status. The CDC describes the disease's progression as "insidious, progressing slowly without any signs or symptoms for several decades." [1]

We anticipate the number of identified infected Americans will increase as more at-risk Americans are tested per CDC and 2012 United States Preventive Services Taskforce (USPSTF) recommendations and Medicare policy. With respect to Medicaid, precise estimates of the Medicaid-specific infected population are not widely available. We do know that experts believe the universe of infected individuals is disproportionately low income, and thus will likely be Medicaid-eligible in the majority of states.

The Challenges for Medicaid Agencies

Of significant concern to state Medicaid programs and other payers is the high cost of a Sovaldi treatment, which at a minimum is $84,000 wholesale acquisition cost per course of treatment, or $1,000 per pill. Still, Medicaid is no stranger to high-cost medications and therapies. Some of the most medically needy and expensive patients in the country are covered by the Medicaid program.

The challenge Sovaldi and other new hepatitis C medications pose for the Medicaid program is the intersection of a high-cost therapy and a potentially large population eligible for the therapy. To date, several states have reported that their first quarter 2014 prescription drug expenditures for hepatitis C treatments has doubled or tripled compared to their entire 2013 spending, which may reflect patients and providers waiting for these new treatments to enter the market. Another hepatitis C combination therapy targeted towards the most common types of hepatitis C infections, Harvoni, was released in mid-October 2014, with an even higher price point of $94,500 per 12 week course of treatment. Other drug manufacturers have signaled that they do not intend to compete on price when they introduce their own breakthrough therapies in 2015. These

[1] http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm#b1

facts suggest that the challenges posed by new hepatitis C therapies are likely to persist over many years.

States have one primary tool, the prior authorization (PA) process, to manage appropriate access to and act as competitive purchasers of prescription drugs. Unlike medical services, states are required to cover any drug which receives FDA approval and for which the manufacturer enters into the mandatory Medicaid drug rebate agreement. While states are employing their PA authority in a range of ways that fit the available evidence and their program structures, this tool is limited and should not be seen as a long term solution for new hepatitis C therapies and similarly-priced products for other diseases and chronic conditions.

For example, states are not well positioned to secure meaningful supplemental rebates for Sovaldi. As mentioned above, Medicaid is required to cover any outpatient drug which receives FDA approval, in return for receiving a mandatory 23 percent rebate from manufacturers. Typically, many states secure supplemental rebates on top of the required rebate by entering into negotiations with manufacturers. But just as Sovaldi is not a typical treatment, these typical approaches have not yielded results for the states.

To date, the supplemental rebates states have secured for Sovaldi are minimal, with any further concessions predicated on unrestricted access to the drug. States, neither individually nor collectively, are sufficiently equipped to secure the concessions required to make Sovaldi-like pricing a sustainable proposition. This is true for this product and for other comparatively priced products moving through the prescription drug pipeline. Though there is potential for more state negotiating power as new drugs enter the market, we cannot speculate as to how effective these negotiations will be in light of the possibility that these drugs will be priced similarly to Sovaldi.

Further, the pricing strategy introduced with Sovaldi is one which is modeled on trading high upfront costs for a believed accrual of savings to the overall healthcare system. This product is priced to reflect the value of its ability to cure, rather than manage, a debilitating infectious disease. As such, the upfront costs of providing Sovaldi are said to be offset by the money saved in not being required to manage the effects of untreated hepatitis C.

This may be true in the aggregate, though Sovaldi is different from prior therapies in that it can potentially benefit a broader range of patients than those who would have needed transplants or other treatments under the prior treatment paradigm. Regardless, this pricing strategy does not comport with the reality we face today. Individuals frequently transition on and off of public health insurance programs, between plans and programs,

or eventually transition from being Medicaid eligible to eligible solely for Medicare or dually eligible for both Medicaid and Medicare.

It is worth noting that Sovaldi's clinical trials were not conducted on patients with co-morbidities, such as HIV/AIDS, that may impact treatment efficacy and effectively lower its overall cure rate. Such populations are more common among Medicaid programs. As a result, there may be significant additional costs to states for patients who are not cured or, for whatever reason, fail to complete the initial full course of treatment and need to be retreated (potentially more than once). Additionally, data are lacking on the long-term "cure" potential of Sovaldi and similar hepatitis C medications. Thus, in the future, patients may potentially need to be maintained on these drugs for longer periods of time.

The long-term pricing strategy applied in this situation – which is also likely to be applied for future breakthrough products – does not align with the underlying Medicaid financing structure. At the state level, Medicaid is financed on an annual or biannual funding cycle, with funding appropriated in the context of balanced budget requirements in all but one state. It is not practical to expect Medicaid programs to finance the significant upfront costs of Sovaldi and other breakthrough hepatitis C treatments, at the expense of providing other needed services, on the promise of seeing savings 10, 20, or 30 years later. In this timeframe, the beneficiary will likely have transitioned to another source of coverage, as discussed above. The potential savings associated with the initial Medicaid purchase of Sovaldi would therefore not accrue to the state's Medicaid program, but rather to another payer. It is not reasonable to expect states to finance the full cost of an expensive treatment whose associated savings likely accrue to another entity decades in the future.

Some reports indicate that while Sovaldi may prove efficacious, its pricing presents a low value proposition to the health care system due to the potentially high costs of treating such a large number of patients with a very expensive medication.[2] We believe further research and analysis is needed to better understand the impact of this and emerging products for Medicaid and the broader health care system.

The Long Term Outlook Calls for Federal Solutions

Simply put, the federal Medicaid statute is not designed to allow states to respond to this new pricing approach for pharmaceuticals. Sovaldi is just the first of many such

[2] California Technology Assessment Forum, "The Comparative Clinical Effectiveness and Value of Simeprevir and Sofosbuvir in the Treatment of Chronic Hepatitis C Infection." http://ctaf.org/sites/default/files/assessments/CTAF_Hep_C_Apr14_final.pdf

exceptionally high-cost "curative" specialty drugs. As more of the specialty drugs that are brought to market adopt this same pricing rationale, new thinking and approaches are required to safeguard the financial integrity of state Medicaid programs and ensure low-income patients are able to access appropriate medical innovations.

We believe federal policymakers must begin to discuss the menu of policy solutions available to address the affordability issue for high-value products. We also urge caution and close inspection of proposed trade provisions to ensure that they do not undermine or limit the ability of states or the federal government to moderate escalating prescription drug, biologic drug and medical device costs in public programs, particularly new costlier drugs or treatments.

Here, we offer an initial list of policy strategies. We anticipate that a more comprehensive and transparent discussion of the issues will generate additional options to ensure this treatment and other high cost treatments are appropriately addressed.

At this time we are not endorsing any single solution on this list. We believe each solution carries advantages and disadvantages, but all merit further exploration by Congress and other federal policymakers and stakeholders.

As a start, we encourage you to solicit other recommendations and begin to evaluate the feasibility of the following:

- **Solutions for all public payers:** Congress can exert downward pricing on Sovaldi and similarly-priced specialty drugs targeting large patient populations. While we recognize that direct price controls would be a politically volatile topic which could be expected to encounter substantial pushback, a strong case can be made for the unique circumstances of hepatitis C in particular. Many of the potential patients for these drugs are covered by federal taxpayer dollars, whether they are covered by Medicare, the federal prison system, the Veterans Health Administration, or Medicaid. There is also a vested public health interest in the potential to eradicate this deadly disease, which is currently responsible for more annual deaths in the country than HIV/AIDS.

- **Mitigating the cost to Medicaid:** Congress could also choose from a menu of policy options that do not directly affect Sovaldi or other breakthrough drug pricing or coverage policies, but would still mitigate state Medicaid programs' exposure. These options include the following:

NAMD
National Association of Medicaid Directors

- Federal purchasing of the available supply and/or the supply chain, with subsequent discounted distribution of product to the states or a requirement that states pay only the administrative fee (modeled on federal purchasing of vaccines for children and other public health emergency situations);
- Enhanced federal match rates for this, or other such "curative" specialty drugs;
- Mandate additional rebates from a manufacturer, for example one that is triggered if a disease state or condition affects a certain percentage of the Medicaid population;
- Modify the "best price" policies for breakthrough drugs to include the selling price in other countries;
- Risk corridors or other reinsurance approaches, based on subsidizing any state spending in excess of clearly articulated federal projections of coverage and costs;
- A separate federal program created for the sole purpose of financing the provision of this drug to the affected population, similar to the Ryan White and state ADAP programs for HIV/AIDS drugs, with Medicaid serving as a payer of last resort; and
- Allow Medicaid programs to utilize cost-effectiveness research to identify whether or not a particular drug will be included in the program's formulary by granting Medicaid the flexibility to exclude products that are found to not be cost-effective; and
- Create waiver flexibility allowing states to contract with drug manufacturers outside of the Medicaid rebate program structure to allow innovative payment arrangements. For example, allow states to enter into outcomes-based contracts with manufacturers, where payment is made per successful course of treatment rather than per pill.

Sovaldi – both in its medical potential and its price – represents a new frontier for specialty drugs, which are anticipated to enter the market in the near future at increasingly high price points. Federal thinking on Medicaid financing must reflect these developments in order to maintain the fiscal strength of the program in the coming years.

NAMD
National Association of Medicaid Directors

Working through our association, we are prepared to work with you to address the complexities of this critical public health care issue. Please contact NAMD's Executive Director, Matt Salo, to discuss how we can further assist you in this matter.

Sincerely,

Darin J. Gordon
TennCare Director
Department of Finance and Administration
State of Tennessee
President, NAMD

Thomas J. Betlach
Arizona Health Care Cost
Containment System Director
State of Arizona
Vice-President, NAMD

Cc:
Members of the Senate Finance Committee
Members of the Senate Health, Education, Labor and Pensions Committee
Members of the House Energy and Commerce Committee
Members of the House Ways and Means Committee

Exhibit 3

From: Eric Kimelblatt **Redacted**
Sent: Tuesday, April 15, 2014 3:06 PM
To: Andrews, Christopher J.; William Dozier
Cc: Brown, Douglas M.
Subject: Re: Sovaldi Data

At least it would be directional. Other individual states have provided this either publicly or directly to us.
Thanks,
Eric

----- Original Message -----
From: Andrews, Chris **Redacted**
Sent: Tuesday, April 15, 2014 12:03 PM
To: William Dozier
Cc: Eric Kimelblatt; Brown, Douglas **Redacted**
Subject: RE: Sovaldi Data

That ranking would be inaccurate at this point based on how states have been handling Sovaldi dispensing.

Chris

Confidentiality Notice

This electronic message transmission contains information belonging to Magellan Health Services that is solely for the recipient named above and which may be confidential or privileged. MAGELLAN HEALTH SERVICES EXPRESSLY PRESERVES AND ASSERTS ALL PRIVILEGES AND IMMUNITIES APPLICABLE TO THIS TRANSMISSION. If you are no the intended recipient, be aware that any disclosure, copying, distribution, or use of this communication is STRICTLY PROHIBITED. If you have received this electronic transmission in error, please notify us by telephone at **Redacted** Thank you.

-----Original Message-----
From: William Dozier **Redacted**
Sent: Tuesday, April 15, 2014 2:36 PM
To: Andrews, Chris
Cc: Eric Kimelblatt
Subject: Re: Sovaldi Data

its relevant to the Gilead.pricing committee because it shows the impact current pricing has on Medicaid.

Best regards,

William

William E. Dozier, MBA
Senior Manager, National Accounts
Strategic Accounts East
Gilead Sciences

Redacted

----- Reply message -----
From: "Andrews, Chris" **Redacted**
To: "William Dozier" **Redacted**
Cc: "Brown, Douglas" **Redacted**
Subject: Sovaldi Data
Date: Tue, Apr 15, 2014 2:19 PM

I don't see how that is relevant to our discussion.

Chris

Confidentiality Notice

This electronic message transmission contains information belonging to Magellan Health Services that is solely for the recipient named above and which may be confidential or privileged. MAGELLAN HEALTH SERVICES EXPRESSLY PRESERVES AND ASSERTS ALL PRIVILEGES AND IMMUNITIES APPLICABLE TO THIS TRANSMISSION. If you are no the intended recipient, be aware that any disclosure, copying, distribution, or use of this communication is STRICTLY PROHIBITED. If you have received this electronic transmission in error, please notify us by telephone at **Redacted** Thank you.

-----Original Message-----
From: William Dozier **Redacted**
Sent: Tuesday, April 15, 2014 2:11 PM
To: Andrews, Chris
Cc: Brown, Douglas
Subject: Re: Sovaldi Data

Hi Chris,

Thanks, it will be discussed during a meeting in-house tomorrow.

Linda asked if it is possible to get data on where Sovaldi ranks in top spend by state?

Do you normally gather this or would you need to contact each state?

Best regards,

William

William E. Dozier, MBA
Senior Manager, National Accounts
Strategic Accounts East
Gilead Sciences
Redacted

----- Reply message -----
From: "Andrews, Chris" **Redacted**
To: "William Dozier" **Redacted**
Cc: "Brown, Douglas" **Redacted**

Subject: Sovaldi Data
Date: Tue, Apr 15, 2014 11:01 AM

I've attached the utilization information available to us for hepatitis C products. It is sortable by client and product. Please let us know what the next steps will be.

Chris

Confidentiality Notice

This electronic message transmission contains information belonging to Magellan Health Services that is solely for the recipient named above and which may be confidential or privileged. MAGELLAN HEALTH SERVICES EXPRESSLY PRESERVES AND ASSERTS ALL PRIVILEGES AND IMMUNITIES APPLICABLE TO THIS TRANSMISSION. If you are no the intended recipient, be aware that any disclosure, copying, distribution, or use of this communication is STRICTLY PROHIBITED. If you have received this electronic transmission in error, please notify us by telephone at **Redacted** Thank you.

-----Original Message-----
From: Brown, Douglas
Sent: Friday, April 11, 2014 12:16 PM
To: William Dozier
Cc: Andrews, Chris; Brown, Douglas
Subject: RE: Sovaldi Data

William,

We have access to pharmacy claims data but not medical data. The data we'll send to you will be the most recent 3 months of claims data for each customer. In most cases it will be Dec, Jan and Feb. (March data will not be available until the end of April.) We don't have unique recipients in the data set so you'll have to infer that from the utilization.

We'll start there and continue with our discussions.

Doug

-----Original Message-----
From: William Dozier **Redacted**
Sent: Friday, April 11, 2014 11:58 AM
To: Brown, Douglas
Cc: Andrews, Chris
Subject: Sovaldi Data

Hello Doug,

There is a meeting next week to begin discussions on your request.
Is it possible to provide me the following information by next tuesday COB?

Broken out by pool states, most recent data available:

1. Sovaldi utilization for Jan, Feb (March if available) 2. # of patients taking Sovaldi in Jan, Feb (March if available)
3. # of patients diagnosed with HCV

4. Rank in drug spend of Sovaldi year to date

I am copying Chris since you may already be on vacation.

Best regards,

William

William E. Dozier, MBA
Senior Manager, National Accounts
Strategic Accounts East
Gilead Sciences
Redacted

Exhibit 4

OFFICE OF THE DIRECTOR
Kate Brown, Governor

Oregon Health Authority

500 Summer St NE E20
Salem OR 97301
Voice: 503-947-2340
Fax: 503-947-2341
www.Oregon.Gov/OHA
www.health.oregon.gov

October 19, 2015

The Honorable Senator Ron Wyden
The Honorable Senator Chuck Grassley
221 Dirksen Senate Office Building
Washington, DC 20510

Dear Senators Wyden and Grassley:

Thank you for the opportunity to provide updated information on the challenges presented in Oregon by the incidence and prevalence of the Hepatitis C Virus (HCV) and the cost implications for health care reform. Thank you also for your work on this complicated and important issue.

The emerging HCV treatments of Sovaldi, Harvoni and Olysio contribute to the problem of rapidly increasing health care costs. When Sovaldi came to the market, Oregon Medicaid was both eager to provide access to the promising new treatment and shocked by the unpredicted price tag. Since then, we've seen Harvoni and Olysio, and still other new agents are on their way. Even with the promise of added competition, we have no cause to anticipate a lower, sustainable cost for HCV medications. Meanwhile, we struggle to provide appropriate coverage of other new specialty pharmaceuticals that also have high price tags. Some of these show much less promise in terms of meaningful therapeutic benefit.

Much has been said already about Sovaldi and the other recently-released HCV agents. It is a significant concern for all payers, but especially for Medicaid and Medicare. HCV patients are disproportionately beneficiaries of Medicaid or Medicare. This is true nationally, and Oregon is no different. What sets Oregon somewhat apart is that Oregonians have a higher incidence of hepatitis C than the national average. The mortality rate in Oregon from HCV was nearly twice the national average in 2011. Thus, Oregon is especially interested in life-saving, effective treatment, and is especially vulnerable to exceptionally high costs for that treatment.

We previously shared an analysis performed by Dr. Dan Hartung. This analysis identified 10,164 Medicaid clients as of September 2014 who appeared to be good potential candidates for the newly-available HCV treatment.

The gross cost of treatment was estimated to be between $84,000 and $150,000 per patient, depending on the treatment length indicated. Our entire gross drug spend for all drugs in 2014 was $591,191,199. This cost and demand meant that if we treated only half of the potential HCV candidates, we could end up more than doubling the previous year's entire drug spend.

With guidance from experts, we developed a strategy to target and prioritize treatment to those patients identified as the best candidates to successfully complete and benefit from treatment. Prescribing hepatologists and gastroenterologists help ensure treated patients are appropriate and prepared to successfully receive treatment. The Hartung analysis indicated that treating the more advanced patients was cost effective when compared to the previously available treatments. Based on historical utilization and assumptions regarding provider capacity, we concluded approximately 500 patients would be treated annually at a projected cost of up to $51 million per year for the first six years.

Since the new agents came on the market, total expenditure for these new HCV drugs continues to increase. Based on year-to-date expenditures, we expect to exceed $30 million in expenditure for 2015. Again, these appear to be well-tolerated, cost effective therapies that we anticipate will result in a reduction in costs for other services. However, the upfront costs to provide the treatment continue to drive substantial increases in the pharmaceutical budget.

The national attention paid to the new HCV treatments is well-deserved, but the concern over dramatic pharmacy budget increases is not limited to HCV. There are newer treatments for chronic conditions that, unlike the hepatitis drugs, do not provide a cure and will need to be taken by patients every year for the rest of their lives. For example, the PCSK9 inhibitors will be prescribed to treat high cholesterol and will result in a gross cost increase of approximately $14,000 to $29,000 per patient per year. New treatments for cystic fibrosis will exceed $250,000 per year for one patient. The estimated number of patients who meet current FDA-approved indications for the new cystic fibrosis treatment is very small but will still result in a significant financial impact of approximately $4 million per year. With the recent FDA approval of Orkambi (ivacaftor/lumacaftor), and anticipated expansion of FDA-approved indications, many more patients will likely qualify for treatment and the additional annual costs could be as high as $46 million.

What we face is not a drug cost problem; it is a drug price problem. State Medicaid programs are limited in our ability to control pharmacy benefit expenditure, particularly as federal law requires us to provide a pathway to coverage for all FDA-approved drugs, no matter how minimal the likely benefit per dollar spent. While federally mandated rebates help, they provide limited relief.
This limitation is especially evident for generics, for which we do not have the same rebate protections when the manufacturer raises their average price in excess of the Consumer Price Index.

Again, thank you for your work and attention on the financial impacts of these very expensive pharmaceuticals. Please let me know if you have any questions about this letter or would like further information. I can be reached by telephone at 503-945-6777 or via email at Lynne.Saxton@state.or.us.

Sincerely,

Lynne Saxton

Lynne Saxton
Director

CC: Jeremy Vandehey
Karmen Fore
Drew Johnston

Exhibit 5

STATE OF WASHINGTON
HEALTH CARE AUTHORITY
626 8th Avenue, SE • P.O. Box 45502 • Olympia, Washington 98504-5502

September 23, 2015

The Honorable Ron Wyden
The Honorable Chuck Grassley
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senator Wyden and Senator Grassley:

Specialty pharmacy drugs have long constituted a portion of total pharmaceutical costs. These medications have historically been used to treat a limited number of medical conditions that affect relatively small numbers of the U.S. population.

More recently, effective, safe and very expensive specialty pharmaceuticals have become available for a wider number of medical conditions. While some of these pharmaceuticals target less common conditions such as cystic fibrosis and multiple sclerosis, others are used to treat very common conditions such as chronic hepatitis C and high cholesterol.

Newer treatments for chronic hepatitis C that have come to market in the last two years have posed especially difficult challenges for payers. Hepatitis C is a chronic infection caused by the hepatitis C virus. It affects one percent of the U.S. population and is the leading cause of cirrhosis, liver cancer and liver transplantation in the U.S.

In Washington State, it is estimated that between 75,000 and 85,000 people harbor the hepatitis C virus; based on available epidemiologic and clinical data, the Washington State Health Care Authority (HCA) estimated that as of July 2014, more than 23,310 Medicaid clients were chronically infected with hepatitis C. The especially high prevalence of hepatitis C in the Medicaid population reflects the increased prevalence of risk factors for hepatitis C in this population.

In November 2013, the Food and Drug Administration (FDA) approved Sovaldi (sofosbuvir) in combination with ribavirin and interferon for the treatment of hepatitis C. Sovaldi, manufactured by Gilead Sciences, represents a major breakthrough in the treatment of hepatitis C because of its effectiveness and lack of toxicity. However, Sovaldi still needed to be used in combination with two older medications – ribavirin and interferon – both associated with a high degree of toxicity.

The State was aware of Sovaldi's impending approval, but had no way of knowing that Gilead would set the price at $1000 per pill (Sovaldi is taken daily for 12 weeks when used in the treatment of the most common type of hepatitis C virus; hence, the cost of treating 1 individual is $84,000, based on Average Wholesale Price at the time). Moreover, the State recognized that within 1 year of Sovaldi's market entrance, additional less toxic and safer hepatitis C regimens would likely become available; these regimens would not require ribavirin and interferon as part of treatment.

The HCA anticipated relatively modest utilization of Sovaldi in 2014 because it needed to be used in combination with more toxic medications; as well, the medical community was eagerly anticipating the availability of much less toxic treatment regiments by early 2015 and "warehousing" patients with the purpose of treating them when the superior regimens became available. Approximately 350 Medicaid patients were treated with Sovaldi in calendar year 2014, a small proportion of those estimated to qualify for treatment. In January 2015 a new less toxic drug, Harvoni was released and HCA has estimated approximately 8,000 individuals will be eligible for treatment.

Taking into account both the federal and Washington State rebate negotiated with Gilead, in FY 2016 alone, the State anticipates spending more than $242 million to treat eligible Medicaid patients ($60,680,000 State; $181,630,000 Federal). Of note, this estimate is based on Medicaid's current clinical policy, which does not provide treatment for those who are infected with hepatitis C and evidence a lower risk of developing severe liver disease or cirhhosis). HCA's current pharmacy budget including Fee for Service and Managed Care is a little over $1 billion. ***If HCA were to pay for hepatitis C treatment for all Medicaid clients infected with hepatitis C, the cost would be three times the current total pharmacy budget.***

The new hepatitis C medications represent the "tip of the iceberg" with respect to the potential impact of new, effective and extraordinarily expensive pharmaceuticals that have recently or will soon come to market. For example, the FDA just approved two new cholesterol-lowering medications. These drugs, known as "PCSK9" inhibitors have been priced at about $14,000 annually. Like the new hepatitis C drugs, these medications treat a common condition; however, whereas people with hepatitis C usually have their hepatitis C virus eliminated with a single 90-day course of treatment, those treated with these new and expensive cholesterol-lowering agents will require treatment on an ongoing basis, i.e. $14,000 will be a recurring annual cost over the course of an individual's lifetime. It is estimated that up to 25 percent of people who need cholesterol lowering treatment cannot tolerate currently available medications (so called "statins," which are pennies per pill). Therefore, the cost implications of the "PCSK9" drugs for payers and national health care costs are staggering.

It is important to note that the new and expensive specialty drugs, while effective in reducing the burden of disease, are priced as such that they do not produce a net savings over time. That is, while treatment costs for the underlying condition will be reduced over time, they are not reduced to the extent that the dollars saved exceed the dollars expended on the drug. While

"cost-effective," these newer agents are NOT cost saving; they will add to the total cost of health care in the U.S.

State Medicaid programs will continue to be challenged to cover these new and emerging treatments. States may be forced to make difficult choices related to coverage for other Medicaid services in order to afford these new and very expensive drugs. We are interested in continuing to work with Congress to find relief for states as more drugs come onto the market.

Please let me know if you have any questions about this letter or would like further information. I can be reached by telephone at (360) 725-1863 or via email at MaryAnne.Lindeblad@hca.wa.gov.

Sincerely,

MaryAnne Lindeblad, BSN, MPH
Medicaid Director
Washington State

cc: Bob Crittenden, Special Assistant, GOV
Peter Gartrell, Committee Staff, U.S. Senate

Exhibit 6

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF HUMAN SERVICES

OCT - 2 2015

The Honorable Ronald L. Wyden
The Honorable Charles E. Grassley
United States Senate
Senate Committee on Finance
Washington, D.C. 20510

Dear Senators Wyden and Grassley:

Thank you for the opportunity to describe Pennsylvania's experience with coverage of the newest Hepatitis C agents in the Pennsylvania (PA) Medicaid program. Sovaldi and Harvoni (manufactured by Gilead), Daklinza (manufactured by Bristol-Myers Squibb), and Viekira Pak and Technivie (manufactured by AbbVie) are all covered under the PA Medicaid program and available in both the fee-for-service (FFS) and the managed care delivery systems. All of the recently-approved drugs for the treatment of Hepatitis C are very costly. The high price of the newer Hepatitis C medications sparked national and international debate over fair pricing which, combined with several unknowns that made overall costs unpredictable, generated significant concern over potential cost of care and indirectly impacted policy decisions on coverage and access.

Cost Concerns and Potential Impact

The Department of Human Service's (Department's) clinical pharmacists routinely monitor the pipeline for new drugs coming to market. They were aware of the anticipated release of each of the new oral Hepatitis C drugs and their promise of higher cure rates with fewer side effects compared to previous treatment options. Like all new drugs, the pharmacists were not aware of costs until the drugs received final approval from the U.S. Food and Drug Administration (FDA) and became available in the market. When the prices were announced, PA Medicaid, like every other public and private third party payer in the nation, experienced "sticker shock."

Concerns about the cost of the new Hepatitis C drugs were exacerbated by a number of unknowns that made total cost unpredictable. The biggest unknown was the size of the target population due to the following:

- Pent-Up Demand – Many people diagnosed with Hepatitis C decided to delay treatment until the newer Hepatitis C drugs were available, as the new drug treatment regimens were entirely oral and were anticipated to increase effectiveness, decrease side effects, and shorten treatment time compared to previously-available regimens.

- Centers for Disease Control (CDC) Recommendation for Testing – In 2012, the CDC recommended that everyone born between 1945 through 1965, also known as baby boomers, get tested for Hepatitis C. People with Hepatitis C often have no symptoms and can live for decades without feeling sick. The only way to know if a person has Hepatitis C is to get tested. The CDC recommended testing for early diagnosis and treatment to help prevent serious health problems, including liver damage, cirrhosis, liver cancer, liver transplants, and even death.

- Direct to Consumer Marketing – Manufacturers used television and magazine advertisements to promote their Hepatitis C drugs, targeting the baby boomer population.

Typically, the expenses associated with high-cost drugs, such as drugs to treat HIV/AIDS and hemophilia, are spread out over time and are predictable. In this case, pent-up demand, increased testing, and greater consumer awareness of the new drugs, combined with a shorter treatment time of 8 to 12 weeks for most patients, creates the potential for a one-time immediate spike in demand for the recently-approved high-cost treatments and challenges traditional fiscal projections and planning.

The PA Medicaid program prepared a rough estimate of the cost impact if every PA Medicaid beneficiary infected with Hepatitis C was treated. According to that estimate, the cost could range from $2.87 billion to $3.05 billion paid to the dispensing providers, or $1.58 billion to $1.73 billion after the federal drug rebates are collected. The ranges reflect the difference in paid amounts and net costs and are dependent upon which drug is designated as preferred on the FFS Preferred Drug List (PDL).

The PA Medicaid managed care organizations (MCOs) voiced their concern about the high cost of the drugs and the unpredictability of demand. The Department's actuary included Hepatitis C drug costs when they developed the calendar year 2015 MCO rates. However, the MCOs remain skeptical that the rates are sufficient given the high demand for access to treatment. The Department continues to monitor MCO expenditures in response to MCO demands for further financial adjustment.

PA Medicaid Efforts to Mitigate Cost

Both the PA Medicaid FFS program and the MCOs immediately implemented strategies to manage utilization and mitigate cost impact. Those strategies included prior authorization of the new Hepatitis C drugs and reinforced emphasis on its already robust collection of federal drug rebates on these drugs. The FFS program also worked with its state supplemental rebate contractor to negotiate supplemental rebates for these products. (NOTE: Drugs paid for by PA Medicaid MCOs do not qualify for state supplemental rebates. The MCOs negotiate and collect their own market share

rebates.) Initially, Gilead offered a very modest supplemental rebate for Sovaldi on the condition of a guarantee of unfettered access: no prior authorization, and no requirements for prescriptions to be written by, or in consultation with a medical specialist. When Gilead introduced Harvoni and AbbVie introduced Viekira Pak to the market, Gilead claimed willingness to negotiate supplemental rebates but negotiations were unproductive. Currently, Viekira Pak is designated as preferred on the FFS PDL; Harvoni, Sovaldi, Daklinza and Technivie are designated as non-preferred. They are covered and available when determined to be medically necessary. All of the drugs, including Viekira Pak, require prior authorization.

Current Utilization and Cost

The following chart reflects the current utilization and spend for Hepatitis C drugs in both FFS and managed care in PA Medicaid. The total spend does not account for rebates collected by PA Medicaid.

Hepatitis C Drug Utilization and Spend in PA Medicaid January 1, 2014 through August 8, 2015			
	Recipient Count	Claim Count	Spend
Total	2,041	11,969	$186,116,252

Policy Impact

PA Medicaid provides coverage of all FDA-approved drugs of manufacturers who participate in the Federal Drug Rebate Program. Consistent with federal Medicaid requirements, PA Medicaid's policy is to provide coverage for all medically-accepted indications. Both FFS and the Medicaid MCOs rely on package labeling, national and international treatment guidelines, and peer-reviewed medical literature to identify the guidelines to determine medical necessity.

In this case, expert consensus panels published treatment guidelines that shifted the emphasis on determining medical necessity from the clinical merits of these breakthrough treatments to an accommodation of the exorbitant costs. Instead of focusing their guidelines on the clinical merits of the drugs and their medically-accepted indications, treatment guidelines recommended prioritizing treatment for the "sickest" patients due to potential cost and access issues. And, unlike other communicable diseases such as HIV/AIDS, there was no emphasis on reduction in transmission to stem the spread of the disease through education and intervention at the point of transmission. One positive outcome of the concerns about high cost for Pennsylvania was the development and adoption of consistent guidelines to determine medical necessity of the newer Hepatitis C drugs among FFS and all of the PA Medicaid MCOs to ensure equal access across delivery systems.

I hope that this information is helpful. If you need additional information, please contact Mr. Abdoul Barry, Director, Office of Legislative Affairs, at (717) 783-2554.

Sincerely,

Theodore Dallas
Secretary

c: The Honorable Robert P. Casey, Jr.

Exhibit 7

Iowa Department of Human Services

Terry E. Branstad, Governor
Kim Reynolds, Lt. Governor
Charles M. Palmer, Director

FEB 9 2015

Mr. Peter Gartrell
U.S. Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, D.C. 20510
Peter_Gartrell@finance.senate.gov

Dear Mr. Gartrell:

This letter is in response to your recent questions of the Iowa Department of Human Services (DHS) regarding Medicaid pharmaceutical expenditures.

The request was to provide a list of the top twenty-five drugs ranked by total amount paid for calendar year 2014. Additionally, the request was to include claim count, wholesale acquisition cost (WAC), drug quantity, days' supply and the number of unique recipients. It was also requested to include the same information for the drugs Sovaldi® and Harvoni™, if they were not included in the top 25 drugs by amount paid. Iowa Medicaid reimburses pharmacy claims based on a state specific average acquisition cost (AAC) and uses WAC when an AAC is not available. Therefore, the Iowa AAC has also been included in the data where applicable. Please note that both the WAC and AAC can change over time so the average WAC and AAC for calendar year 2014 is provided. The data requested is provided as an attachment.

All prescription drugs are through the fee for service (FFS) program, so the data provided represents all outpatient prescription drug expenditures. Iowa Medicaid currently covers 560,000 Iowans. Approximately 63,000 Medicaid members, or 11 percent of the total population, are covered by an HMO managed care plan (Meridian Health Plan of Iowa); however, pharmacy is carved out of the managed care plan.

Regarding the questions specific to Hepatitis C Virus (HCV), the state estimates 5,406 HCV patients in the Medicaid program. The Iowa DHS has not implemented any special funding provisions (special budget line items, etc.) for coverage of these drugs, but it has incorporated the cost of specialty drugs (including HCV medications) into its current and future Medicaid budget requests.

The Iowa Medicaid program participates in the Sovereign States Drug Consortium (SSDC) for supplemental drug rebates. To date, the program has not accepted a supplemental rebate for any of the HCV medications; however, the rebates offered are under consideration and will be discussed at the April Pharmaceutical and Therapeutics (P&T) Committee meeting.

If you have additional questions, please contact Susan Parker, Pharmacy Director, at sparker2@dhs.state.ia.us or (515)256-4634.

Sincerely,

Charles M. Palmer
Director

CMP:slp

Attachment:
1 – Iowa Medicaid Top 25 Drugs by Paid Amount CY2014

Exhibit 8

AHCCCS
Arizona Health Care Cost Containment System

Douglas A. Ducey, Governor
Thomas J. Betlach, Director

July 17, 2015

Mr. Peter Gartrell
U.S. Senate Committee on Finance
Ranking Member Ron Wyden (Oregon)
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Mr. Gartrell:

The AHCCCS Administration submits the requested information in response to your July 8, 2015 correspondence requesting a list of the top 25 drugs ranked by total amount paid for calendar year 2014. The attached spreadsheet includes the following:

Fields requested:	Field descriptions on the excel spreadsheet:
Claim count	Number of Prescriptions
Wholesale acquisition price (WAC)	Health Plan Paid Amount
Drug quantity	Quantity Dispensed
Days of supply	Days Supply
The number of unique recipients	Distinct Members

The first and second tabs on the spreadsheet are the Top 25 Drug by Cost for the Fee-For-Service (FFS) and Managed Care Organizations (MCOs) respectively. The third and fourth tabs are the specific reports for Sovaldi and Harvoni for the Fee-For-Service and Managed Care Organizations (MCOs) respectively.

The current AHCCCS enrollment is 1,746,175 members. Of these members, 1,471,809 are enrolled in MCOs and 116,747 are in the FFS program. An additional 50,483 are in Medicare Savings Programs and 107,136 are in a program that provides emergency services only. Excluding the Medicare Savings Program and emergency services populations, 92.7% of the remainder of the AHCCCS population is enrolled in MCOs and 7.3% is in FFS.

You also requested additional information and the Administration's responses are below.

Has the state agreed to any supplemental rebate with Gilead for Sovaldi or Harvoni? If so, when?

Yes. The effective date of our agreements is January 1, 2015.

Also, many states have had to make special budget line items or other special provisions for Sovaldi and other new HCV drugs because of the cost. Has your agency had to make any special funding provisions that your state has had to request or adopt to cover the cost of these drugs?

There was an existing $15 million in the MCO capitation rates for treatments that Sovaldi and Harvoni are replacing. These dollars were left in the rates to cover a portion of the costs of Sovaldi and Harvoni. Arizona added an additional $30 million in funding to the capitation rates to address the additional costs of Sovaldi and Harvoni, for total funding of $45 million.

Lastly, is there any estimate of the number of HCV patients in the Medicaid program?

There are approximately eighteen thousand identified HCV patients within the AHCCCS program. It should be noted that the national consensus among health care professionals is the number of Hepatitis C patients is understated due to lack of testing.

In the event that you have additional questions, please contact me at your convenience.

Sincerely,

Thomas J. Beltach
Director

Exhibit 9

RICK SCOTT
GOVERNOR

ELIZABETH DUDEK
SECRETARY

October 19, 2015

The Honorable Orrin G. Hatch
Chairman
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman and Ranking Member:

Thank you for asking about the Florida Medicaid Program's experience with the new generation of Hepatitis C drugs that became available beginning in December of 2013.
Florida Statute directs the Agency to implement a Medicaid prescribed-drug spending control program and the Agency utilizes a Preferred Drug List (PDL) as part of that program. The Preferred Drug List (PDL) is a listing of cost effective therapeutic options recommended by the state's Medicaid Pharmacy and Therapeutics Committee. The Pharmacy and Therapeutics Committee is an advisory committee of physicians and pharmacists that ensures that the drugs available on the PDL allow providers a selection that guarantees quality of care and cost containment.

In Florida, most Medicaid recipients are enrolled in the Statewide Medicaid Managed Care (SMMC) program. Under the SMMC program, the Agency negotiated capitation rates and entered into contracts with fully risk bearing health plans to provide services, including prescription drugs, to Medicaid enrollees beginning in May of 2014. Health plans are required to utilize the Agency's PDL and develop prior authorization criteria and protocols, which cannot be more restrictive than that used by the Agency, for reviewing requests for brand name drugs that are not on the Agency's PDL.

The Agency, working with the Pharmacy and Therapeutics Committee, established clinical criteria for the new Hepatitis C drugs as they became available on the market. Below is the original date the criteria was established. Please note, the medications used to treat Hepatitis C are an evolving group and guidelines for treatment may have been modified since the original posting date.

Medication	**Original Date of Criteria**
Harvoni	10/24/2014
Olysio	2/13/2014
Sovaldi	12/17/2013
Viekira Pak	1/20/2015

Medicaid health plans expressed concern that utilization of these new drugs would be high, and if the cost was high, the financial impact would be greater than anticipated in the capitation rates that were negotiated with the Agency. To address the rate impact, Agency staff and the Agency's contracted actuaries established a temporary "kick payment" for Hepatitis C drugs. A kick payment is a rate mechanism to manage the uncertainty of the number of people who will need high cost Hepatitis C Treatment. A kick payment allows the Medicaid program to pay the health plans based on expected costs for each enrollee who is prescribed the drugs for treatment. The goal was to help the plans cover the costs of the treatment until such time as utilization and expenditure data was available to incorporate the cost for these drugs into the capitation rate.

The Agency set new capitation rates for 2015-16 that became effective September 1, 2015 that included coverage for the new Hepatitis C drugs. One of the main drivers of the increase includes prescription drug trends and specialty drug growth. Kick payments for these drugs were discontinued, except for certain enrollees with a diagnosis of HIV/AIDs.

This data below represents expenditures under the fee-for-service program and managed care encounter data relating to the Hepatitis C drugs for the time period of January 1, 2014 – August 7, 2015. Expenditures reported here are gross costs as paid by FFS and as reported paid by the managed care plans; thus do not include offsets for rebates received.

Drug	FFS Claims	MCO claims	FFS Expenditure	MCO Expenditure	Total expenditure FFS + MCO
Harvoni	13	1027	$415,702.00	$31,570,787.99	$31,986,489.99
Olysio	232	309	$5,167,978.11	$6,880,999.86	$12,048,977.97
Sovaldi	958	1617	$26,944,190.01	$45,009,256.10	$71,953,446.11
Viekira	14	85	$394,706.48	$2,349,020.21	$2,743,726.69
Totals	**1,217**	**3,038**	**$32,922,576.60**	**$85,810,064.16**	**$118,732,640.76**

We hope this letter provides you with a high level understanding of Florida Medicaid's experience with the new generation of Hepatitis C drugs.

Sincerely,

Justin M. Senior
Deputy Secretary for Medicaid

JMS/ks

Exhibit 10

CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR MEDICAID SERVICES

Steven L. Beshear
Governor

275 E Main St, 6W-A
Frankfort, KY 40621
www.chfs.ky.gov

Audrey Tayse Haynes
Secretary

Lisa D. Lee
Commissioner

The Honorable Charles E. Grassley
Chairman
Committee on the Judiciary
United States Senate
135 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
221 Dirksen Senate Office Building
Washington, D.C. 20510

October 21, 2015

Re: High Cost Price of HCV Treatment

Dear Senators and Congressmen,

One of the most pressing concerns facing states and the nation's public health is hepatitis C. It is no secret that Kentucky has been challenged with the onslaught of heroin addiction, and we have been very aggressive legislatively with treatment to fight this problem. Heroin not only brings about a public health concern, but also the impact of newer hepatitis C virus (HCV) treatment options on state health care/Medicaid budgets. This is not only a problem for Kentucky but a national public health concern.

Kentucky's spending related to HCV has increased to about 7 percent of its total Medicaid budget, providing new hepatitis C drugs to a relatively small number of recipients. Sovaldi® has a list price of $84,000 for a typical 12-week course of treatment. Harvoni®, made by the same company, Gilead Sciences, has a list price closer to $100,000. Newer additions may be available but are also similarly high in cost. Although some manufacturers offer discounts to Medicaid programs, these do little to offset the cost of care.

We are concerned about the sharp rise in costs for Kentucky Medicaid beneficiaries diagnosed with hepatitis C. Our state's opiate problem and the increased testing of people who have injected drugs contribute to the upward trend.

Kentucky will soon start providing hepatitis C screening tests at all its county health departments, just as it does for H.I.V. Although precise estimates of the Medicaid population infected are not readily available, we would expect based upon the available data that the majority of infected individuals are of disproportionately low-income and Medicaid eligible status. Once members are HCV confirmed the question of when to initiate treatment must still be considered. Given the current cost of the newer treatment options and to remain fiscally responsible we will be forced to make difficult decisions regarding who does and does not get access to treatment medications upon diagnosis.

Kentucky is not alone in its concern. Through our multi-state rebate contract negotiating pool we have engaged HCV product manufacturers for various pricing level considerations. However, these efforts have been met with little to no success.

The evolving situation associated with such high cost breakthrough treatments has a great impact upon sensitive and strained health care budgets. Newer HCV products are often acclaimed as curative. Noteworthy here is that clinical trials are rarely focused on co-morbidities found most often among Medicaid recipients which often have a profound impact on treatment efficacy. Although we fully support innovation in treatments, policymakers must begin developing frameworks that address the comprehensive costs and value of treatments in public health insurance programs such as Medicaid. As a primary payer, Kentucky continues to use the limited tools available to manage the cost implications of emerging HCV products, such as prior authorizations, weighing the available scientific evidence to guide access, and continuing to pursue price competition and supplemental rebates despite the fact that the state is not well positioned to secure savings. The price charged by drug companies is the one item where the state has little control.

Drug manufacturers have been reluctant to competitively price these breakthrough therapies as they emerge and we have concerns regarding the increasing challenges which are likely to continue for many years. We welcome any opportunity for open dialogue regarding federal level policies that could create some balance between appropriate access to new treatment options and long-term fiscal sustainability of Medicaid programs.

Thank you for your time and attention to this important issue.

Kindest Regards,

Samantha McKinley, B.S., J.D., D.C., Pharm.D.
Department for Medicaid Services
Pharmacy Director
275 East Main Street, 6W-A, Frankfort, KY 40621
Office (502)564-9444 X 2194
Fax (502) 564-0223
samantha.mckinley@ky.gov

Exhibit 11

TEXAS HEALTH AND HUMAN SERVICES COMMISSION

August 14, 2015

CHRIS TRAYLOR
EXECUTIVE COMMISSIONER

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Charles E. Grassley
Senior Member
Committee on Finance
United States Senate
135 Hart Senate Office Building
Washington, DC 20510

Dear Senator Wyden and Senator Grassley:

Thank you for exploring the financial impact that Gilead Sciences, Inc.'s (Gilead) Sovaldi — and other second generation direct acting antiviral medications for the treatment of the Hepatitis C virus (second generation HCV drugs) — has on Medicaid programs. Unfortunately, the high cost of these drugs forced the Texas Health and Human Services Commission (HHSC) to carefully examine which Medicaid beneficiaries are truly in medical need of these products and required HHSC to implement strong prior authorization requirements.

The HHSC Pharmaceutical and Therapeutics (P&T) Committee first reviewed Sovaldi in January of 2014 and recommended a preferred status, contingent upon implementation of prior authorization criteria. HHSC began developing a medical necessity and prior authorization criteria for second generation HCV drugs, based on reliable and appropriate evidence. In July that same year, HHSC requested detailed clinical outcome data from Gilead (see Attachment 1). The associate director for medical sciences for this company, Michelle Puyear, was extremely helpful and provided and explained the data. In addition, HHSC enlisted the services of the Oregon Health Science University Medicaid Evidence Based Decisions Project to help review the data and assist with drafting appropriate prior authorization criteria. Texas Medicaid eventually determined that second generation HCV drugs are medically necessary for beneficiaries if they are diagnosed with the Hepatitis C virus and experience a METAVIR score of F3 or F4. The METAVIR test assesses the level of liver fibrosis on a scale of increasing severity from F0 to F4.

For most of 2014, HHSC program staff focused on the clinical aspects of the drugs, but the high drug cost remained a concern. Because Sovaldi was not yet on the Texas Medicaid formulary, Gilead leadership asked to meet with HHSC executive leadership, and a meeting was conducted on August 6, 2014. The Gilead executives and representatives in attendance were:

- Kacy Hutchison, Vice President of Government Affairs
- Coy Stout, Vice President of Managed Markets
- Justin Crum, Director, National Accounts, Strategic Accounts Central
- Tyler Hunter, Executive Manager, National Accounts

HHSC's former Executive Commissioner, Dr. Kyle Janek, expressed his displeasure with Gilead's pricing. He reminded the Gilead executives and representatives of the impact of their drug to the state budget. Given the size of the Texas Medicaid population, Dr. Janek also asked for a discounted rate. He referenced the drug's availability at a fraction of the price in other countries and the likelihood that it would be cheaper for Texas to fly Medicaid recipients to those countries for treatment than to treat them in the U.S. Gilead executives and representatives explained that the company limited access to the drug in other countries to citizens of those countries and then defended their pricing model. Gilead offered no meaningful discounts until January 2015 when two other second generation HCV drugs entered the market: Harvoni (also by Gilead) and AbbVie, Inc.'s (AbbVie) Viekira Pak.

In October 2014, HHSC's Preferred Drug List (PDL) vendor, Magellan Medicaid Administration, sent solicitation letters to all manufacturers of second generation HCV drugs. These letters solicited manufacturers to provide their supplemental rebate offers so the same could be presented to the P&T Committee in its January of 2015 meeting. During this period, but prior to the P&T Committee meeting, HHSC and Gilead discussed coverage criteria and drug price/rebates on multiple occasions. Attachment 2 lists the conversations HHSC held with representatives of Gilead in 2014 and 2015.

In early January 2015, news outlets reported that Express Scripts—the nation's largest pharmacy benefits manager—had signed an exclusive arrangement with AbbVie to make Viekira Pak its sole preferred second generation HCV drug. Shortly after that announcement, and leading up to the January P&T Committee meeting, Gilead met with Texas HHSC again and offered a more substantial supplemental rebate. The deadline for submitting supplemental rebate offers had expired, but HHSC made an exception because of the particular nature of the situation. To be fair, HHSC also allowed AbbVie to revise its offer (post-deadline) and AbbVie did.

Upon completion of their January 2015 review, the P&T Committee recommended Viekira Pak as the preferred product for recipients in both fee-for-service traditional Medicaid and managed care Medicaid. The committee's decision was based on the understanding that both Harvoni and Viekira Pak were effective treatments, but because AbbVie submitted more aggressive rebates to HHSC's PDL vendor, Viekira Pak was more cost effective.

In Texas, almost 90 percent of Medicaid recipients receive benefits through a managed care organization (MCO). When Sovaldi was the only U.S. Food and Drug Administration (FDA)

approved second generation HCV drug, there was much uncertainty about potential expenditures, and calculating an actuarially-sound MCO premium rate that took this drug into account was not possible. Therefore, HHSC was forced to develop an MCO contract amendment and obtain approval from the Centers for Medicare & Medicaid Services to reimburse MCOs for the cost of second generation HCV drugs through a separate non-risk-based payment process. In Texas' managed care Medicaid, second generation HCV drugs are the only products that are "carved-out" of the MCO premium rate. HHSC's policy has consistently required MCOs to assume the risk for all prescription drugs.

Like all states, Texas struggles with the challenge of trying to provide beneficiaries with maximum access to second generation HCV drugs without compromising its Medicaid program's solvency. In Texas, approximately 17,000 Medicaid recipients (primarily adults) were identified with a primary diagnosis of Hepatitis C. Based on HHSC's medical-necessity criteria, product indications, and HCV population demographics, HHSC forecasted potential utilization, and estimates that approximately 1,200 recipients per fiscal year will obtain second generation HCV drugs. The table below provides the estimated net costs per year after all rebates.

	FY 2015 (Apr - Aug)	FY 2016	FY 2017	FY 2018
All Funds*	**$ 20.1**	**$ 65.8**	**$ 53.4**	**$ 54.7**
Federal Funds*	$ 11.7	$ 27.1	$ 23.3	$ 23.9
TX General Revenue*	$ 8.4	$ 38.7	$ 30.0	$ 30.9

Notes

- ** All dollar amounts in millions*
- *Analysis is based on three Hepatitis C treatments: Viekira (12-week), Viekira + Ribavirin (12-week), and Sovaldi (24-week).*
- *Assumed effective date April 2015 with pent-up demand assumed in State Fiscal Year (SFY) 2015.*
- *HHSC System Forecasting, March 2015*

The state's experience with second generation HCV drugs prompted the 84th Texas Legislature to pass a rider on the state's appropriations act in June 2015. The rider requires HHSC to estimate the potential cost of all new outpatient drug products prior to covering the products. All products with an estimated annual cost of greater than $500,000 must be submitted to the Legislative Budget Board for review. This requirement may increase the amount of time between approval of a new treatment by the FDA and provision of that treatment to Medicaid clients.

In January 2015, Texas Medicaid began limited coverage of Sovaldi and Olysio (manufactured by Johnson and Johnson) on an exception basis for recipients with HCV and the most urgent medical needs. In April 2015, Texas Medicaid fully implemented its coverage of the second generation HCV drugs.

The rebate revenue from manufacturers lessens the impact of second generation HCV drugs on the state's Medicaid budget. However, given the exorbitant price of these medications, the rebates are insufficient and these drugs jeopardize the solvency of the state's Medicaid and public health programs. Manufacturers lowering the price at which these drugs are sold to providers would be more beneficial than rebates to the Texas Medicaid program and would also benefit its state-funded health programs.

HHSC is hopeful that as new HCV and other breakthrough drugs are approved, market forces will reduce costs. Otherwise, Texas and all other states will experience budgetary difficulties that could negatively affect the Medicaid program.

Your exploration of these issues is greatly appreciated. If you would like additional information or have additional questions, please contact me at 512-707-6142 or by email at Andy.Vasquez@hhsc.state.tx.us.

Sincerely,

Andy Vasquez
Texas Health and Human Services Commission
Medicaid/CHIP Deputy Director, Vendor Drug Program

Attachment 1

TEXAS HEALTH AND HUMAN SERVICES COMMISSION

KYLE L. JANEK, M D.
EXECUTIVE COMMISSIONER

July 29,2014

Ms. Stephanie Tran
Associate Manager, Medical Information
Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404

Ms. Tran:

We are writing to request clinical data from Gilead Sciences to answer pertinent questions on the Hepatitis C drugs, Sovaldi (sofosbuvir) and the combination drug, ledipasvir/sofosbuvir.

Chronic Hepatitis C is estimated to affect 3.2 million people in the United States and has a high prevalence rate in patients with income below the poverty line. Hepatitis C affects a large number of Texas Medicaid patients and, with the high cost of treatment, it will represent a significant cost to the state of Texas.

The preliminary clinical evidence prompted the FDA to grant Sovaldi a Priority Review and Breakthrough Therapy designation, which it awards products for indicating substantial improvement over available therapies for patients with serious or life threatening diseases, can cut the FDA review time from 10 months to 6 months. The FDA has also granted ledipasvir/sofosbuvir a Breakthrough Therapy designation. There is evidence of the benefits Sovaldi, and by extension ledipasvir/sofosbuvir, will bring to our Hepatitis C patients. However, the full extent of benefits, as well as potential deficits, remains out of reach. The state of Texas is dedicated to providing the most prudent, cost-efficient, and beneficial health care to our Texas Medicaid clients. We have been diligently reviewing clinical information, as well as several guidelines to help form an appropriate clinical edit. As we recommended by our Drug Utilization Board, we have been reaching out to stakeholders for additional input and concerns.

The available guidelines and reviews have been helpful in our draft of a clinical edit. In our review of both the guidelines and the available studies, questions have remained that need to be answered so we can guarantee every step of our clinical edit is founded on the most current and complete information. With such a significant impact on the state health care budget, there is

very little room for error. We appreciate that some information has been published and provided for both products, but there is still data that would be crucial to providing the most accurate representation of cost-effective treatment, based on available clinical evidence.

In order to help us address these items, we are asking Gilead Sciences for the following:

- All data on adverse effects from all studies that have been published, presented, and/or available for both Sovaldi and ledipasvir/sofosbuvir.
- All data to calculate incidence of relapse after SVR12 for all studies that have been published, presented, and/or available for both Sovaldi and ledipasvir/sofosbuvir.
- A flow diagram showing what happened to all people who were initially screened for enrollment in any study studies that have been published, presented, and/or available for both Sovaldi and ledipasvir/sofosbuvir.
    - Study investigators should complete a full CONSORT flow diagram (available at www.consort-statement.org/).
    - For each outcome reported there should be a clear indication of the numerator and denominator for each of the outcomes analyzed.
    - SVR12 and SVR 24 data for all studies that have been published, presented at a meeting, or available to the investigators or manufacturers.
    - Please include data that may have been incomplete from any studies that have been sent to HHSC staff.
- Quality of life data for all studies that have been published, presented, and/or available for both Sovaldi and ledipasvir/sofosbuvir..

We ask that all material be provided in a format that staff can employ to adjust our clinical edit criteria. We appreciate your continued cooperation and timeliness in this matter.

Please let me know if you have any questions or need additional information. Joshua Dominguez Pharm. D., Vendor Drug Pharmacist, serves as the lead staff on this matter and can be reached by telephone at 512-462-6390 or by email at Joshua.Dominguez@hhsc.state.tx.us.

Sincerely,

Andy Vasquez
Medicaid/CHIP Deputy Director, Vendor Drug Program

Attachment 2

Meetings between Health and Human Services (HHSC) staff and Gilead Sciences, Inc. regarding clinical and financial considerations of Texas Medicaid coverage of Sovaldi and Harvoni.

Meeting Date	Description
May 6, 2014	Discuss coverage status of Sovaldi. Gilead representatives include: Tyler Hunter
June 2, 2014	Discuss coverage status of Sovaldi. Gilead representatives include: Tyler Hunter
June 20, 2014	Clinical update on Sovaldi Gilead representatives include: Tyler Hunter, Michelle Puyear
July 29, 2014	HHSC letter to Gilead requesting detailed clinical data
Aug. 6, 2014	Meeting with HHSC executive commissioner requested by Gilead to discuss coverage of Sovaldi Gilead representatives include: Kacy Hutchison, Coy Stout, Justin Crum, Tyler Hunter
Aug. 13, 2014	Detailed discussion of HHSC's clinical data request. Gilead representatives: Michelle Puyear, Tyler Hunter
Oct. 21, 2014	Initial discussion regarding Harvoni; including clinical and rebate considerations Gilead representatives include: Tyler Hunter, Michelle Puyear
Nov. 14, 2014	Discuss Gilead rebate offers for Harvoni and Sovaldi. Note: HHSC conveyed our continued, serious concerns with Gilead's pricing structure and they committed to taking our request to their management with response expected by the next week. Gilead representatives include: Coy Stout, Justin Crum, Tyler Hunter, Erin Smith
Nov. 20, 2014	Discuss enhanced Gilead rebate offer. Gilead offered slight increase from original offer for Harvoni and extended offer to Sovaldi. Gilead representatives include: Justin Crum, Tyler Hunter, Erin Smith (Gilead Government Affairs)
Dec. 4, 2014	Touchbase meeting regarding HHSC evaluation of enhanced rebate offers. Gilead representatives include: Justin Crum, Tyler Hunter
Dec. 17, 2014	Touchbase meeting regarding HHSC evaluation of enhanced rebate offers. Gilead representatives include: Justin Crum, Tyler Hunter
Jan. 7, 2015	Touchbase meeting regarding HHSC evaluation of enhanced rebate offers. HHSC offers extension to supplemental rebate offer submission deadline based on Gilead commitment to submit a new, revised final offer. Gilead representatives include: Justin Crum, Tyler Hunter
Jan. 16, 2015	Pre-P&T Committee meeting discussion regarding Gilead's final, revised offer. Gilead representatives include: Coy Stout, Kimberly Hawkins, Justin Crum

Exhibit 12

GILEAD
Advancing Therapeutics.
Improving Lives.

Wednesday, July 1, 2015

Dear Community Partner,

Gilead has always been an advocate for patient access to therapies in the areas in which we work. I am writing to provide you with an update regarding Support Path, our patient support program for individuals living with chronic hepatitis C.

As you may be aware, Support Path is designed to help patients in the U.S. with high co- pays or who lack adequate insurance access Sovaldi or Harvoni. The Support Path program provides assistance to patients who are uninsured or who need financial assistance to pay for the medicine.

Key components of the program include:

- The Sovaldi and Harvoni Co-pay Coupon Program, which minimizes monthly out-of-pocket costs for eligible patients* to as little as $5 per month
- The Support Path Patient Assistance Program, which will provide Sovaldi or Harvoni at no charge for eligible patients

In the interest of facilitating patient access in the period immediately following the launch of Sovaldi and Harvoni, the Gilead Patient Assistance Program (PAP) made these medications available to virtually all patients who met financial and other program requirements. Gilead also implemented significant discounts for its HCV therapies across different payer groups. While many payers responded to these discounts by opening access broadly, some payers have continued to restrict access despite the discounts.

As a result, our PAP criteria enabled continued restrictions by some payers by providing a generous route for them to deny access and refer patients they have chosen not to cover. While we have approved many of these patients in the past, we feel it is necessary to establish more specific guidelines for patient eligibility. Our PAP was designed to help uninsured patients with the most need, and changes are necessary to remain true to that mission. We believe these changes also will help increase access among those payers who continue to restrict access.

With that in mind, effective July 1, 2015, the following changes will be implemented. Gilead anticipates these changes will not impact the majority of patients helped by our patient support programs.

Specifically, patients who are insured and who do not meet their payer's coverage criteria will no longer be eligible for support via Gilead's Patient Assistance Program. Patients who fall within the category of "Insured and Did Not Meet Payer Criteria" are patients whose insurance providers limit access to Sovaldi/Harvoni based on, but not limited to, the following:

- Fibrosis score restrictions
- Preferring or exclusively covering another product on formulary (i.e., Viekira Pak preferred)
- Limiting coverage to a maximum treatment duration or denying subsequent treatment after a patient has failed therapy
- Step-therapy requirements
- Clinical criteria (e.g., psychiatric requirements, drug and alcohol testing)

It is important to note that a very small number of patients fall into this category. Support Path experts will continue to treat each patient case individually and consider a number of variables when assessing patients for our free drug program.

**You are not eligible if you are enrolled in a government healthcare prescription drug program such as Medicaid or Medicare Part D*

For Sovaldi and Harvoni patients who are insured and have been denied coverage by their payer, Support Path can assist patients with the requirements for submitting appeals, peer reviews and understanding the process for in-person hearings if required.

Gilead continues to support open access to hepatitis C therapies – with prescribing decisions made by a physician in partnership with his or her patient. We will continue to work with payers to provide information that conveys the profile of our hepatitis C medications and the benefit of curing individuals living with the virus. We believe that payers should take the responsibility to provide coverage for their insured patients based on the treatment decisions of their healthcare providers.

Through Gilead's Support Path Program, which provides a comprehensive suite of patient assistance resources, we are committed to our mission of helping patients in financial need access our products, and to ensuring our patient assistance program reaches eligible uninsured patients.

As always, we appreciate the ongoing dialogue with our community partners and look forward to continuing to collaborate with you on efforts to expand access to life-saving therapies.

Best regards,

Coy Stout
Vice President, Managed Markets
Gilead Sciences, Inc.

Exhibit 13

HCV Fair Pricing Coalition Meeting
Thursday, October 3, 2013

Gilead Sciences
368 Lakeside Drive
Foster City, CA

9:30 a.m.	**Welcome and Introductions**	David Johnson *Sales and Marketing*
9:45 a.m.	**Sofosbuvir Clinical Update**	John McHutchison *Liver Disease Therapeutics*
10:15 a.m.	**Considerations in the Management of HCV**	Janice Tam *Medical Affairs*
11:15 a.m.	**Payer Landscape in HCV: Considerations for Sofosbuvir**	Coy Stout *Managed Markets*
12:15 p.m.	**Working Lunch**	
1:00 p.m.	**Discussion**	**All**
1:30 p.m.	**Patient Support Landscape**	Jim Drew *Business Operations*
2:15 p.m.	**Discussion**	**All**
3:00 p.m.	**Closing and Next Steps**	**All**

****

Additional Gilead Participants
Bill Guyer
Medical Affairs

Cara Miller
Public Affairs

Michele Rest
Public Affairs

FPC Participants
Bill Arnold
Community Access National Network

Bruce Burkett
Missouri Hep C Alliance

Ryan Clary
National Viral Hepatitis Roundtable

Lynda Dee
AIDS Action Baltimore

Michael Ninburg
Hepatitis Education Project

Murray Penner
NASTAD

Lorren Sandt
Caring Ambassadors

Exhibit 14

FPC Gilead 10-3-13 Meeting Agenda (FOR FPC ONLY)

WAC price of Incivek: $60,470 + $30,000

WAC price of Victrelis: $60,873 + $30,000

Argue only for a lower price than SOC. Arguments for a lower price:

Limited window before inf free DAA regimens are available

We believe Merck and Vertex will be lowering their prices to protect their market share. How low are you willing to go to obtain market share?

It's a new day. ACA Exchanges and other formularies are looking for lowest prices. Provide examples of state and private payer formularies, e.g., Oregon and United Healthcare that is prior authorizing their HIV FDC Stribild because of the cost. Volume, volume, volume is the key to them obtaining the highest market share. Acknowledge the cost-effectiveness of cost per cure, but also argue that pricing themselves out of the market will result in shooting themselves in the foot. What they do now will affect what portion of the market they will corner with their FDC in the future.

AbbVie is going to beat them to the inf free table. How they price sofosbuvir now will determine what their ultimate FDC of 7977 and 5885 will cost if they do the same thing in HCV as in HIV, i.e., charge the same for the component parts of the FDC as for the individual drug. Is that their plan for the HCV FDC? Will they continue to make sofosbuvir available as a stand alone drug?

What Phase IV studies do you have planned for sofosbuvir with other drugs, in the ACTG?

Request an update on their Expanded Access clinical trials, including the number of people enrolled and if they intend to initiate any other EAP trials for other populations, e.g. post-transplant patients and people with bleeding disorders. (Any other populations not now covered.)

Exhibit 15

Gilead 12-6-13 Call Notes

For the FPC: Ryan Clary, Lynda Dee, Michael Ninburg and Lorren Sandt

For Gilead: David Johnson, Bill Guyer, Coy Stout and Cara Miller

Price:

Sovaldi WAC is $84,000 for a 12 week regimen for GT 1, 2 and 4, not including $9,000 for 12 weeks of inf/r. The Sovaldi WAC is less than Olysio + 24 weeks of inf/r. ($84,360).

The price is double for a 24 week GT 3 regimen or $186,000. Gilead stated that they looked at capping the 24 week price, but that this was not possible because they would have had to use only one specialty pharmacy provider. This would mean out of network charges for many patients and an even higher price.

Gilead thinks the broad FDA indications for GT 1, 2, 3 and 4 as well as pre-transplant and co-infected patients and all oral Sovaldi 24 week regimens for inf intolerant patients will be helpful in ensuring payer reimbursement, even for the 24 week regimen, especially if the AASLD promulgates HCV Treatment Guidelines next year, hopefully in January.

Gilead will be shipping Sovaldi on Monday and it will be available in US pharmacies by mid-week, barring unforeseen weather conditions.

In response to disappointment expressed about price, Gilead discussed their access programs at length and said they are working with all payers and will do unbranded education about the need for people to see be tested and be treated. Gilead is speaking with state Medicaids, starting with problem states like Illinois that have budget crises.

Gilead access concessions are as follows: (They gave us every single thing we asked for and more.)

- The SupportPath patient assistance program (PAP) with a $100,000 maximum income requirement for a household of three and 500% of the federal poverty level (FPL) for larger households. See www.supportpath.com or also on the Gilead.com web sight accessible after a few clicks. Contact #: 855-769-7284 (855-7mypath). Gilead will have 40 counselors available for case management/benefits counseling who will investigate insurance options and program eligibility. There will also be warm transfer to other companies' PAPs.

- There will 24/7 nursing support and educational info on their web site.

- They send extensive E-communications to pharmacists regarding directions for Sovaldi ordering and access programs as well as the indications.

- The SupportPath™ Sovaldi™ co-pay coupon program will provide co-pay assistance for eligible patients with private insurance, including Affordable Care Act Marketplace exchange patients, who need assistance paying for out-of-pocket medication costs. Most patients will pay no more than $5 per co-pay. Co-pay assistance of up to 20% of the WAC price or $16,000 for Sovaldi can also be applied toward prescription deductibles and co-insurance obligations. These are huge victories for us!!!

- Gilead has made a substantial contribution to the Patient Access Network (PAN) for co-pay assistance for Medicare Part D clients.

- Gilead has initiated an emergency Sovaldi supply program for patients that may lose their prescriptions ala their HIV PEP program that has a lot of experience shipping HIV antivirals to HIV needle stick patients very quickly.

- Gilead has agreed to ensure access to its PAP or co-pay assistance programs for AIDS Drug Assistance Program (ADAP) patients who are co-infected with HIV, even in states with ADAP programs that will not include Sovaldi on their formularies. Gilead will not be lobbying state ADAPs to add Sovaldi to their formularies at least this year.

- Gilead WILL NOT be working with Harbor Path at this juncture.

Gilead is also working with payers to ensure Sovaldi is included in lower tiers and with the USP to ensure that HCV drugs are included in updated categories since state marketplaces are using them to develop formularies.

Miscellaneous Issues:

Lorren made the points that some states will not be including Sovaldi on their Medicaid formularies and will only be allowing specialists to prescribe Sovaldi. Gilead agreed to look into it this.

Michael asked questions about off-label use and a direct link to PAN on their web site. Gilead stated that while they were not promoting off-label use, they would not require anything but an Rx from a physician to supply a patient with Sovaldi SupportPath access, without requesting what actual regimen a person would be using. They also agreed to look into a PAN link.

I think it was Bill that asked about access for undocumented people. Gilead said although supplying a SSN will make the access process faster, they are not requiring legal alien status, only US residency is required.

Lynda made the point that Gilead needs to go the extra mile to disseminate their SupportPath access programs. She e-mailed them on 12-7-13, asking them to include the underinsured program information on their web site, have their salespeople have written SupportPath info when they visit docs and clinics and include the SupportPath link and contact info and their HIV access program info in their ads.

Gilead ended the call thanking us and agreeing to keep the lines of communication open so that we can continue to discuss future access issues as they occur.

Exhibit 16

FAIR PRICING COALITION

April 14, 2014

Coy Stout, Vice President, Managed Markets
Kristie Banks, Senior Director, Business Operations and Contract Compliance
Jim Drew, Director, Business Operations and Contract Compliance
Amy Flood, Vice President, Public Affairs
Michele Rest, Director, Public Affairs

Gilead Sciences
333 Lakeside Drive
Foster City, CA 94404

Dear Coy, Kristie, Jim, Amy and Michele:

Thank you for the March 25, 2014, call with the Fair Pricing Coalition. Please allow this letter to serve as a follow up to this important discussion, particularly the pressing issue of Sovaldi (sofosbuvir) pricing and access.

We want to address your claim that third-party payers have utilized the media's attention to Sovaldi's exorbitant price to negotiate with Gilead by proxy. We understand that Gilead was not expecting the payer backlash and the furor that has erupted. That said, we should remind you of our original warning that, even though new DAAs are a major improvement that may be cost-effective in the long run, our healthcare system lacks this particular downstream thinking. Both government and industry payer programs operate under short-term budget constraints that are incapable of absorbing the costs of Sovaldi for every patient they cover who needs access to this medication.

We had hoped Gilead would be satisfied with cornering the larger volume market. By all accounts, Gilead will dominate the DAA market for years to come. This has made Sovaldi's price all the more unconscionable. Gilead is already close to recouping the Pharmasset purchase price of Sovaldi, even before the fixed-dose combination with ledipasvir is on the market. We still hope Gilead will consider a larger volume market strategy—one that will make a respectable profit for the company, while being priced so that it is accessible for the millions of patients for whom Sovaldi is indicated.

To that end, in an effort to keep Sovaldi and Gilead's antiretrovirals affordable and accessible, we urge you to fulfill *all* of the following requests:

- Provide additional rebates for Sovaldi to state Medicaid programs over and above the legally required initial Medicaid rebate offering. Claims that this will slow the Medicaid formulary process are unfounded. We also encourage you to continue rebate agreements with state Medicaid programs for your antiretrovirals, similar to the recent agreement with the New York State Medicaid Director.

- Continue providing additional discounts/rebates to ADAPs over and above those required by the 340B program.

- Refrain from making any changes to current ADAP rebate policies until HRSA can craft sound guidance. We do not need yet another drug access crisis. This is especially relevant for Sovaldi. ADAP clients deserve the chance to access Sovaldi, with its label indication for people coinfected with HIV and HCV, despite Gilead's decision not to promote the inclusion of Sovaldi on ADAP formularies.

- Disclose the number of patients on all your HIV and HCV access programs and your eligibility formula for underinsured patients. This is our second request for this information and it is essential that you be transparent in these matters.

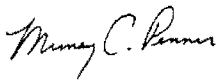
- Provide all underinsured HIV and HCV patients with 100% coverage of all out-of-pocket (OOP) costs, including co-pays, deductibles, co-insurance or any other related prescription costs for all Gilead HIV and HCV prescriptions. We make this request in light of reports from individuals throughout the U.S. who are not taking their medications because they cannot afford the OOP cost(s).

- Provide us with full details of information and data submitted to the Waxman Briefing.

- Institute a price freeze for all HIV and HCV drugs for the next two years and henceforth for a two-year period from the date of FDA approval of all new HIV and HCV drugs.

- Refrain from referring to the FPC when negotiating or discussing your drug prices or access programs. Even though you did not intend to use the FPC for cover, we have heard of your references to early negotiations with this coalition that are being misinterpreted to mean that FPC is supportive of the price established for Sovaldi. The only sure way to avoid this in the future is for you not to refer to the FPC, either publicly or privately, going forward.

Please contact us with your responses as soon as possible and thank you for your anticipated cooperation.



Murray Penner
On behalf of the FPC

Exhibit 17

From: William Dozier **Redacted**
Sent: Sunday, May 11, 2014 6:41 PM
To: Brown, Douglas M.
Cc: Eric Kimelblatt
Subject: Magellan Offer

Importance: High

Hello Doug,

Here are the terms as approved by our legal dept. Though there are minor edits, the structure and terms are exactly the same as we reviewed with you on the phone last week. Our Foster City team will be submitting these exact terms to your FTP site online by Monday morning.

- 6% discount- Parity status on PDL. Any PA criteria imposed on Sovaldi shall be no more restrictive than patients with F2-F4 fibrosis scores.

- 8% discount: Parity status on PDL. Any PA criteria imposed is consistent with and no more restrictive than the FDA approved label.

- 10% discount: Parity status on PDL. Any PA criteria imposed is consistent with and no more restrictive than the FDA approved label. Any PA criteria imposed shall not require prescriptions by Specialists.

- For all states that accept any discount level, they must immediately remove any current restrictions on Sovaldi that are more restrictive than the corresponding criteria listed above.

Best regards,

William

William E. Dozier, MBA
Senior Manager, National Accounts
Strategic Accounts East
Gilead Sciences
Redacted

1

xvuhXRyJAZroiSrJnbRdT7vrAf5HBaK5RABmEEwQIvkpZ/QRcWXdSFw5soKaF0F7qZeLO13mGBDpQsf5CoxVKHOt0Pctp2uvE
drzG/V+c5S3w/54HnPDIiQiGpPMETABoB2AAYd9MRAMMAvGmX+RcAyAoBVJ7gZQDtABworH4AHWmX+bOMZdkjCoXiUz
abvcAwzPSsob5p/VTNY9GcdpnxdmYZ9wJThSCtCr1e/4XjuNPd3d1KjUZzaGbl27ysqzGQoggAsLa1A7ehArrDxfDNr0oBlQB+
wmKxbJFEL968SxoamsjkHaPU9l9piUo6A0RE1DG2QCWdASrpDAzJM5kMi8XecdjVxfEl+K9dxFgsgUvvR6HyBKHyBAEATyKLe
GSsENuNcqk5kUjEGm7fzcYqr0ClVODl99+YXEvl6+c1amjVe+ahiGGYaUEQKnmeh91uL43rqheixjpdmzCL11er0PcjhrTLvMfUJ
syKYUSeyWQ6enp6tgCgrKxsfbP8bB8AdE1G89cOReMAgOv+Cag8QXRNRkXAsDwcDr+am5tLCYKA3t7eo2dG+1vVK/MfpRP
tA+MlReMYaKj+/xm9MilCx3EmpVL5wefzFavValis1u1vvHMkdfykCQC0kSGUTo+Ajmnx1dSC7lGD+UUCEYGlwLKsyWazrSeT
SSliMpnNf7TtzS+ec96fr7/VnE0mk+QfHMzV3WjcKH/4rEr05QGFIA6HY4llWRLPRER+v3/HYrFMFQSIkNra2tVQKJSlfcSyLO0L
ECFWq3XF6XRGA4HAptTsdrsXeZ6fEHtl+31nAOA4rkUulz/i5XL63dQGgHEAN8Ph8AYA/BsAt4ube4GblQIAAAAASUVORK5C
YII=]<https://webmail.gilead.com/OWA/?ae=Item&a=New&t=IPM.Note#>

Exhibit 18

From: Brown, Douglas M.
Sent: Monday, May 19, 2014 3:42 PM
To: Lennertz, Matthew D.
Cc: Brown, Douglas M.; Andrews, Christopher J.
Subject: Sovaldi Supplemental Rebate Offer

Our negotiations with Gilead have produced a supplemental rebate offer on Sovaldi. As states begin to ***actively*** manage access to this drug (with many states including fibrosis scores of F3 or greater and other aggressive criteria) Gilead has come forward with 3 offers. The three offers are as follows:

- **6% discount - Unique Position 1.** Any PA criteria imposed is consistent with and no more restrictive than the FDA approved label. Additional restriction for fibrosis score (Metavir) of F2-F4 is permissible. PA criteria may require prescriptions be written by Specialists (hepatologists or gastroenterologists, for example).

- **8% discount - Unique Position 2.** Any PA criteria imposed is consistent with and no more restrictive than the FDA approved label. PA criteria may require prescriptions be written by Specialists.

- **10% discount - Unique Position 3.** Any PA criteria imposed is consistent with and no more restrictive than the FDA approved label. Any PA criteria imposed shall not require prescriptions by Specialists. Of note, Gilead has stated that they are not detailing their hepatitis portfolio to non-Specialists.

I'm happy to have this offer in place for those states that cannot otherwise manage utilization in this category and are experiencing a sharp increase in total spend. However, I expect most states to forgo this offer and continue to actively manage this category. Our negotiations with Gilead continue, especially for those states that require fibrosis scores of F3 or greater as well as other PA criteria.

For those states that wish to accept the rebate offer, please consult with your contract analyst to commence invoicing and copy Chris Andrews and myself.

Let me know if you have any questions

Thanks,

Doug

Douglas M. Brown R.Ph., MBA
Sr. Director, Pharmacy Pricing and Value Based Solutions
Magellan Medicaid Administration

Redacted

Confidentiality Notice

This electronic message transmission contains information belonging to Magellan Health Services that is solely for the recipient named above and which may be confidential or privileged. MAGELLAN HEALTH SERVICES EXPRESSLY PRESERVES AND ASSERTS ALL PRIVILEGES AND IMMUNITIES APPLICABLE TO THIS TRANSMISSION. If you are not the intended recipient, be aware that any disclosure, copying, distribution or use of this communication is STRICTLY PROHIBITED. If you have received this electronic transmission in error, please notify us by telephone at **Redacted** . Thank you.

Exhibit 19

From: Brown, Douglas M.
Sent: Thursday, June 05, 2014 3:07 PM
To: Brown, Douglas M.; William Dozier; Andrews, Christopher J.
Subject: RE: Offer Update

William,

(additional info)

I would say that 20 of 25 states have no interest in the offer. CT looks to take the 10% offer. The other four are debating the offer (but not rushing their decision).

Doug

-----Original Message-----
From: Brown, Douglas
Sent: Thursday, June 05, 2014 12:56 PM
To: 'William Dozier'; Andrews, Chris
Subject: RE: Offer Update

CT is 10%. No word from NY.

-----Original Message-----
From: William Dozier **Redacted**
Sent: Thursday, June 05, 2014 12:50 PM
To: Brown, Douglas; Andrews, Chris
Subject: Offer Update

Hello Doug,

Have all states contacted you to accept/decline the offer?

CT accepted at 8% and NY is evaluating, correct?

Best regards,

William

William E. Dozier, MBA
Senior Manager, National Accounts
Strategic Accounts East
Gilead Sciences
Redacted

GVKw4bAAAAIGNIUk0AAHolAACAgwAA+f8AAIDpAAB1MAAA6mAAADqYAAAXb5JfxUYAAAKLSURBVHjadJPfS5NhFMe/21x
vuhXRyJAZroiSrJnbRdT7vrAf5HBaK5RABmEEwQIvkpZ/QRcWXdSFw5soKaF0F7qZeLO13mGBDpQsf5CoxVKHOt0Pctp2
uvEdrzG/V+c553w/54HnPDIiQiGpPMETABoB2AAYd9MRAMMAvGmX+RcAyAoBVJ7gZQDtABworH4AHWmX+bOMZdkjCoXiU
zabvcAwzPSsob5p/VTNY9GcdpnxdmYZ9wJThSCtCr1e/4XjuNPd3d1KjUZzaGbI27ysqzGQoggAsLa1A7ehArrDxfDNr0
oBlQB+wmKxbJFEL968SxoamsjkHaPU9l9piUo6A0RE1DG2QCWdASrpDAzJM5kMI8XecdjVxfEl+K9dxFgsgUvvR6HyBKH
yBAEATyKLeGSsENuNcqk5kUjEGm7fzcYqr0ClVOD199+YXEvl6+c1amjVe+ahiGGYaUEQKnmeh91uL43rqheixjpdmzCL
11er0PcjhrTLvMfUJsyKYUSeyWQ6enp6tgCgrKxsfbP8bB8AdE1G89cOReMAgOv+Cag8QXRNRkXAsDwcDr+am5tlCYKA3

t7eo2dG+1vVK/MfpRPtA+MIReMYaKj+/xm9MiICx3EmpVL5wefzFavValis1u1vvHMkdfykCQC0kSGUTo+Ajmnx1dSC7I
GD+UUCEYGIwLKsyWazrSeTSSIiMpnNf7Ttz5+ec96fr7/VnE0mk+QfHMzV3WjcKH/4rEr0SQGFIA6HY4llWRLPRER+v3/
HYrFMFQSIkNra2tVQKJSlfcSyLO0LECFWq3XF6XRGA4HAptTsdrsXeZ6fEHtl+31nAOA4rkUulz/I5XL63dQGgHEAN8Ph
8AYA/BsAt4ube4GblQIAAAAASUVORK5CYII=]<https://webmail.gilead.com/OWA/?ae=Item&a=New&t=IPM.Not
e#>

Exhibit 20

Ohio | Department of Medicaid

John R. Kasich, Governor
John B. McCarthy, Director

August 7, 2015

Mr. Peter Gartrell
U.S. Senate Committee on Finance
Ranking Member Ron Wyden (Oregon)
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Mr. Gartrell:

In response to your inquiry regarding any records of emails or meetings between Ohio Department of Medicaid (ODM) officials and Gilead where concerns were expressed about the price of the drug please see below:

June 26, 2014 conference call with Gilead and ODM: ODM staff included Margaret Scott, RPh, Michael Howcroft, RPh, Patricia Nussle, RPh, Anam Khan, college intern and Xerox State Healthcare (ODM contractor): Sandra Kapur, PharmD

David Kaufman
Manager, National Accounts
Strategic Accounts Central
Gilead Sciences
Cell: 919.791.8715
Office: 740.474.2142
VM: 800.915.3003 x 5306
david.kaufman@gilead.com

Justin Crum
Director, National Accounts
Strategic Accounts Central
Gilead Sciences
Phone: 650-522-2399
Justin.Crum@gilead.com

Sept. 24, 2014 In-person meeting with ODM Director John McCarthy, David Salisbury, Legislative Liaison, Margaret Scott, RPH, Debbie Saxe, Health Plan Policy Chief and Gilead representatives Rebecca O'Hara, Paul Miner, Justin Crum, local representation Joshua Sanders

Rebecca O'Hara
Associate Director
Government Affairs
Gilead Sciences, Inc.
Phone: 850-339-6211
Rebecca.O'Hara@gilead.com

Joshua R. Sanders, Esq.
Calfee, Halter & Griswold LLP
Phone 614-621-7763
jsanders@calfee.com

Paul Miner, PharmD, Assoc. Director
Medical Sciences
Managed Care & Government Accts.
Gilead Sciences, Inc.
810-333-5818 (c)
paul.miner@gilead.com

Sincerely,

John B. McCarthy, Director

50 W. Town Street, Suite 400
Columbus, Ohio 43215

An Equal Opportunity Employer and Service Provider

Exhibit 21

From: Janet Z Zachary-Elkind (health.ny.gov) **Redacted**
Sent: Tuesday, September 09, 2014 5:25 PM
To: 'Kacy.Hutchison@gilead.com'
Cc: Ttress@ **Redacted** Anthony V Merola (health.ny.gov); Barbara Rogler (health.ny.gov); Michael Colabufo (health.ny.gov)
Subject: Analysis
Attachments: Sovaldi projections.pdf

Hi Kacy:

Attached is our analysis regarding CHC prevalence in NY Medicaid and our estimates regarding number of beneficiaries that could potentially be treated with Sovaldi.

The first chart identifies the total number of beneficiaries with Chronic Hepatitis C (CHC) and anticipated spend, based on the % of beneficiaries potentially treated. As you can see, if all beneficiaries with CHC were to be treated with Sovaldi, our total spend (amount paid to pharmacies) would be greater than the total annual pharmacy spend in the NY Medicaid program (~$4.5B). The second chart identifies those beneficiaries that would meet the standardized criteria that we've developed. If all beneficiaries that meet our standardized criteria were to be treated, our total spend for Sovaldi would be equal to approximately 67%% of our total annual pharmacy spend. While we can't predict the total number of people that will be treated with Sovaldi, we estimate that it will be somewhere between 10 and 20% of 35,010 (the number of members identified in the second chart) for this calendar year.

Let me know if you have any questions or would like to discuss further.

Janet

Janet Zachary-Elkind, Deputy Director
Division of Program Development and Management
Office of Health Insurance Programs
NYS Department of Health
Redacted

Pharmacy Fiscal Analysis - Sovaldi
Based on claims with service dates December 13, 2013 through April 30, 2013.
Data Source: Medicaid Data Warehouse - data extracted by SUNY Buffalo on 6/3/14

All Chronic HCV Beneficiaries[1]		
Potential New Chronic Hepatic Infection Treatment	Estimated Number of Beneficiaries with Chronic Hepatitis C Infection (n=57,897)	Estimated Amount Reimbursed to Pharmacies ($)[3]
1%	579	$50,368,086
2%	1,158	$100,736,171
3%	1,737	$151,104,257
5%	2,895	$251,840,428
10%	5,790	$503,680,857
20%	11,579	$1,007,361,714
100%	57,897	$5,036,808,570

Total Possible Members 57,897

Chronic HCV Beneficiaries - Targeted Treatment Group[2]		
Potential New Chronic Hepatic Infection Treatment	Estimated Number of Beneficiaries with Chronic Hepatitis C Infection (n=35,010)	Estimated Amount Reimbursed to Pharmacies ($)[3]
1%	350	$30,457,307
2%	700	$60,914,613
3%	1,050	$91,371,920
5%	1,751	$152,286,533
10%	3,501	$304,573,066
20%	7,002	$609,146,132
100%	35,010	$3,045,730,660

Total Possible Members 35,010

Footnotes:

[1] See notes below on how Chronic Hep C was defined. Existing Sovaldi patients(1,754) are included in the totals.

[2] Targeted Treatment Group = Patients coinfected with HIV and/or HBV (n=14,070), patients with liver disease have progressed to a stage that requires HCV treatment to prevent further liver

[3] Total Cost of treatment calculated to be $86,992. Includes 84 day regiment of Sovaldi, Ribavirin and Peg Interferon at FFS reimbursement. Genotype 1 accounts for approximately 70% (OHSU) of people infected. The remaining 30% could utilize therapy for a longer duration.

Notes:

The 57,897 are patients with a diagnosis of chronic hepatitis C as identified by ICD-9 codes. The medications are only FDA approved for patients with a diagnosis of chronic hepatitis C (CHC). There are no other Compendia-supported indications for the drugs. 57,897 was then reduced to the 35,010 patients (e.g. patients with HIV/AIDS, chronic liver disease or extra hepatic manifestations per the suggested clinical criteria).

Chronic Hep C was identifed using the following codes:

ICD-9	Description
7044	CHRONIC HEPATITIS C WITH HEPATIC COMA
7054	CHRONIC HEPATITIS C WITHOUT MENTION OF H

Exhibit 22

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

March 20, 2014

Dr. John C. Martin, PhD
Chief Executive Officer
Gilead Sciences Inc.
333 Lakeside Drive
Foster City, CA 94404

Dear Dr. Martin:

We are writing to request a briefing from Gilead Sciences Inc. to answer important questions about the pricing of the company's recently approved Hepatitis C drug, Sovaldi.

A breakthrough treatment for Hepatitis C could result in significant public health benefits. Approximately 3.2 million Americans have a chronic Hepatitis C infection, and the illness causes approximately 15,000 deaths in the United States annually.[1] There is no vaccine for Hepatitis C, which causes fatal cirrhosis or liver cancer in up to 5% of affected individuals.[2]

There is evidence that Sovaldi could be a breakthrough treatment. According to FDA, "Sovaldi was effective in treating multiple types of the hepatitis C virus. ... demonstrat[ing] efficacy in participants who could not tolerate or take an interferon-based treatment regimen and in participants with liver cancer awaiting liver transplantation, addressing unmet medical needs in these populations."[3]

---

[1] CDC, Hepatitis C FAQs for the Public (2014) (online at http://www.cdc.gov/hepatitis/c/cFAQ.htm#statistics); New York Times, *Awareness: Hepatitis C Death Rate Creeps Past AIDS* (Feb. 27, 2014) (online at www.nytimes.com/2012/02/28/health/research/hepatitis-c-deaths-creep-past-aids-study-finds.html?_r=1&).

[2] CDC, Hepatitis C FAQs for the Public (2014) (online at http://www.cdc.gov/hepatitis/c/cFAQ.htm#statistics); New York Times, *Awareness: Hepatitis C Death Rate Creeps Past AIDS* (Feb. 27, 2014) (online at www.nytimes.com/2012/02/28/health/research/hepatitis-c-deaths-creep-past-aids-study-finds.html?_r=1&).

[3] FDA, FDA Approves Sovaldi for Chronic Hepatitis C (Dec. 6, 2013) (online at http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm377888.htm).

Our concern is that a treatment will not cure patients if they cannot afford it. Reports indicate that Gilead intends to sell Sovaldi at $84,000 per treatment.[4] In cases where Sovaldi is prescribed with other treatments the costs could be even higher. According to a recent Reuters report, "many doctors are requesting a $150,000 combination of Sovaldi ... and Olysio."[5]

These costs are likely to be too high for many patients, both those with public insurance and those with private insurance.[6] Because Hepatitis C is "concentrated in low-income, minority patients," the affordability problems are likely to be particularly acute for state Medicaid programs and those patients served by these programs.[7] Colorado and Pennsylvania have already announced that their Medicaid programs will be limiting use of the new drug to "only the sickest patients," such as those already suffering from liver disease.[8] California's Medicaid program is still considering how and when to reimburse for the drug.[9] The large pharmacy benefit manager Express Scripts has said it is "encouraging some doctors in its networks to delay prescribing Sovaldi."[10] Even in cases where public or private insurers pay for the medication, it will impose substantial costs on taxpayers and could cause premium increases for those with employer or individual coverage.

The extraordinarily high cost of your drug raises additional concerns because of the role of the federal government in speeding its approval. In April 2013, Gilead submitted a New Drug Application to the Food and Drug Administration for approval of Sovaldi for the treatment of Hepatitis C. As part of the request, Gilead filed for and received a Priority Review and Breakthrough Therapy designation, which reduces the FDA review goal date from ten to six

---

[4] Washington Post, *Costly Hepatitis Drug Sovaldi Rattles Industry* (Mar. 1, 2014) (online at http://www.washingtonpost.com/national/health-science/costly-hepatitis-drug-sovaldi-rattles-industry/2014/03/01/86cab0b4-a091-11e3-9ba6-800d1192d08b_story.html).

[5] Reuters, *Insurers, Medicaid fear multibillion-dollar hepatitis C drug tab* (Mar. 4, 2014) (online at www.reuters.com/article/2014/03/04/us-health-hepatitis-idUSL1N0M10Z720140304).

[6] Bloomberg, *At $84,000 Gilead Hepatitis C Drug Sets Off Payer Revolt* (Jan. 27, 2014) (online at http://www.bloomberg.com/news/2014-01-27/at-84-000-gilead-hepatitis-c-drug-sets-off-payer-revolt.html).

[7] Bloomberg, *Hepatitis C Drug Price Limiting State Medicaid Approvals* (Mar. 5, 2014) (online at www.bloomberg.com/news/2014-03-05/hepatitis-c-drug-price-limiting-state-medicaid-approvals.html).

[8] *Id.*

[9] Reuters, *Insurers, Medicaid fear multibillion-dollar hepatitis C drug tab* (Mar. 4, 2014) (online at www.reuters.com/article/2014/03/04/us-health-hepatitis-idUSL1N0M10Z720140304).

[10] Washington Post, *Costly Hepatitis Drug Sovaldi Rattles Industry* (Mar. 1, 2014) (online at http://www.washingtonpost.com/national/health-science/costly-hepatitis-drug-sovaldi-rattles-industry/2014/03/01/86cab0b4-a091-11e3-9ba6-800d1192d08b_story.html).

months.[11] This designation is awarded to medicines that meet certain criteria, including "that the drug may have substantial improvement on at least one clinically significant endpoint over available therapy."[12] The FDA approved Sovaldi on an expedited basis on December 6, 2013.[13]

This history raises many questions about Gilead's approach to pricing this drug and the impact the high cost may have on public health. In order to address these issues, we ask that you brief Committee staff on a number of key questions, including:

(1) The methodology used by Gilead to establish Sovaldi's pricing.
(2) The extent to which Gilead is providing discounts to low-income patients and to key government or private-sector purchasers of the drug.
(3) The value to the company of the expedited review provided under the Priority Review and Breakthrough Therapy designation and how any savings provided by the expedited review factored into pricing decisions for the drug.
(4) The public health impact of insurers' and public health programs' decisions not to cover Sovaldi for all patients with Hepatitis C.

We ask that you provide this briefing no later than April 3, 2014. Please contact Brian Cohen of the Committee staff at (202) 225-3641 if you have any questions.

Sincerely,

Henry A. Waxman
Ranking Member

Frank Pallone, Jr.
Ranking Member
Subcommittee on Health

Diana DeGette
Ranking Member
Subcommittee on Oversight and Investigations

[11] Food and Drug Administration, *Regulatory Information* (online at www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcact/significantamendmentstothefdcact/fdasia/ucm341027.htm).

[12] *Id.*

[13] Food and Drug Administration, *FDA Approves Sovaldi for Chronic Hepatitis C* (press release) (Dec. 6, 2013) (online at www.fda.gov/newsevents/newsroom/pressannouncements/ucm377888.htm).

Exhibit 23

Troyen A. Brennan, M.D., Chief Medical Officer, CVS Health; Alan Lotvin, M.D., Executive Vice President, CVS/specialty, CVS Health; William Shrank, M.D., Chief Scientific Officer, CVS Health

Background

Sovaldi® (sofosbuvir), a new treatment for Hepatitis C manufactured by Gilead, was launched on December 9, 2013 and immediately generated an intense public debate about cost and value in health care. The medication represents an extraordinary clinical breakthrough; in clinical trials, more than 95 percent of patients with Hepatitis C experience sustained viral response, essentially a cure, compared with the 40 percent cure rate observed with prior interferon-based therapies. Treatment tolerability was a main driver of the stunning improvement in the cure rate, as only two percent of patients discontinued therapy during the trial. Substantially higher discontinuation rates have been observed among patients who used previous Hepatitis C therapies.

Sovaldi is very costly, with a list price (Average Wholesale Price) of approximately $1,000 a pill and $84,000 for a 12-week course. More than three million Americans either have Hepatitis C-caused liver disease or are carriers of the disease, highlighting the enormous possible cost of treating this condition in the U.S. This extraordinary cost has stressed commercial, state and federal budgets. While the drug is extremely effective and may offer value in terms of reducing downstream costs, the short-term monetary outlays are considerable and were largely unexpected. The costs have led to an outcry from payors and policymakers, and resulted in widespread debates about the "fairness" of the medication's pricing.

The debate about Sovaldi's efficacy, price, and value has largely been based on the current price of the medication and the results of several clinical trials. The impressive clinical trial results rely on patients' adherence to the medication, and such adherence is often not replicated in real world settings where patients are not observed as closely and where patients are often sicker, older, or more complex than those participating in clinical trials.

To date, little evidence has been presented publicly that assesses Sovaldi adherence and therapy completion rates in real world populations. Similarly, we know little about correlates of therapy discontinuation. Specifically, there is little evidence to suggest whether patients who were previously treated for Hepatitis C and failed therapy (presumably sicker patients) are more likely to complete therapy than those who are naïve to therapy. We are also unaware of any studies of the relationship between the site of delivery of Sovaldi and rates of adherence to therapy. In this White Paper we present real-world evidence about trends in Sovaldi use, rates of therapy discontinuation, and correlates of non-adherence to treatment. We also discuss expected trends as new products become available in the marketplace.

© CVS Health. All Rights Reserved.

Sovaldi Use
In the nearly nine months since Sovaldi's release, 16,560 patients with pharmacy benefits through CVS/caremark filled prescriptions for the medication. More than 65 percent of the Sovaldi regimens prescribed have been interferon-free (Table 1).

Table 1. Utilization of Sovaldi and the Regimens Used

DRUG UTILIZATION (# OF MEMBERS)*	BOOK OF BUSINESS	
	N	%
Sovaldi (sofosbuvir)	16,560	76%
Olysio (simeprevir)	5,194	24%
Total	21,754	100%
Sovaldi utilization in combination with other drugs		
Sovaldi + ribavirin ONLY	7,070	43%
Sovaldi + ribavarin + pegylated interferon	5,599	34%
Sovaldi + Olysio ONLY	3,772	23%
Total	16,441	100%

*Results bases on paid claims data

Discontinuation Rates and Correlates of Discontinuation
To study discontinuation rates, we created a cohort of patients who were continuously eligible with CVS/caremark insurance for 44 months in order to establish previous use of any Hepatitis C regimen. We identified all patients who were continuously eligible and started a Hepatitis C regimen with Sovaldi on or before 5/15/14 in order to assess rates of discontinuation or completion of the regimen. A total of 1,965 patients met this eligibility criteria.

Among those patients who began Sovaldi in combination with other medications, Sovaldi discontinuation rates were approximately four times greater than the rates observed in clinical trials (Table 2): Sovaldi+Peg-IFN+RBV (10.2 percent of patients discontinued), Sovaldi+Olysio (4.2 percent), and Sovaldi+RBV (9.0 percent). Across regimens, treatment-naïve patients were 64 percent more likely to discontinue therapy with Sovaldi than treatment-experienced patients: 8.7 percent treatment-naïve patients discontinued therapy vs. 5.3 percent for treatment-experienced patients ($p<0.05$).

© CVS Health. All Rights Reserved.

Table 2: Discontinuation Rates, by Regimen

	N Utilizer*	N Treatment Competed	%	N Treatment Discontinued†	%	Discontinuation Rates in Clinical
Sovaldi+PegIFN/RBV	738	663	89.8%	75	10.2%	2.0%
Treatment-experienced‡	145	134	92.4%	11	7.6%	
Treatment-naïve§	593	529	89.2%	64	10.8%	
Sovaldi+Olysio	547	524	95.8%	23	4.2%	3.6%
Treatment-experienced	115	112	97.4%	3	2.6%	
Treatment-naïve	432	412	95.4%	20	4.6%	
Sovaldi+RBV	680	619	91.0%	61	9.0%	0–2.0%
Treatment-experienced	97	92	94.8%	5	5.2%	
Treatment-naïve	583	527	90.4%	56	9.6%	
All Sovaldi regimens¶	1,965	1,806	91.9%	159	8.1%	
Treatment-experienced	357	338	94.7%	19	5.3%	
Treatment-naïve	1,608	1,468	91.3%	140	8.7%	

*Members who initiated therapy between 12/1/2013 and 5/15/2014, with paid claims and continuous eligibility between 1/1/2011 and 8/24/2014.

†Patients who had refill gaps exceeding the allowable gap period of 15 days were classified as discontinuers.

‡Patients who were treated with a Hepatitis C drug between 1/1/2011 and 11/30/2013

§Patients who were not treated with a Hepatitis C drug between 1/1/2011 and 11/30/2013

¶Treatment-experienced vs. Treatment-naïve; $p<0.05$.

Discontinuation rates also varied by the site of delivery. We evaluated discontinuation rates in the CVS Health organization, where specialty patients receive the same counseling and ongoing patient-centered support services from central specialists whether they access their medications through home delivery or at CVS/pharmacy retail stores through our Specialty Connect™ program. We compared discontinuation rates for patients who filled Sovaldi regimens in CVS/pharmacy retail locations or CVS/caremark specialty pharmacies with patients who filled in non-CVS Health-related outlets. To conduct this analysis, we included members who initiated therapy between 12/1/2013 and 5/15/2014, with paid claims and continuous eligibility between 12/1/2013 and 8/24/2014

In general, discontinuation rates were considerably higher in non-CVS Health outlets. When patients filled their Sovaldi regimens at either CVS/pharmacy retail stores or CVS/caremark specialty pharmacies, through the Specialty Connect™ program, they discontinued their regimens 5.9 percent of the time. Patients who filled outside of CVS Health discontinued 8.5 percent of the time, a 44 percent increased rate of discontinuation compared with CVS Health sites. Discontinuation rates were 8.8 percent for non-CVS/pharmacy retail locations and 8.3 percent for non-CVS/caremark specialty pharmacies. (Table 3)

© CVS Health. All Rights Reserved.

Table 3: Discontinuation Rates, by Delivery Channel, Within CVS/caremark Beneficiaries

REGIMEN	PHARMACY CHANNEL	MEMBERS*	TREATMENT DISCONTINUATION BEFORE 12 WEEKS†, N(%)
Sovaldi + PegIFN/RBV	CVS/caremark specialty pharmacy**	1,171	85 (7.3%)
	Non-CVS/caremark specialty pharmacy‡	731	73 (10.0%)
	-Retail	572	*63 (11.0%)*
	-Specialty	129	*9 (7.0%)*
Sovaldi + Olysio	CVS/caremark specialty pharmacy**	768	35 (4.6%)
	Non-CVS/caremark specialty pharmacy‡	552	43 (7.8%)
	-Retail	389	*31 (8.0%)*
	-Specialty	146	*11 (7.5%)*
Sovaldi + RBV	CVS/caremark specialty pharmacy**	1,096	60 (5.5%)
	Non-CVS/caremark specialty pharmacy‡	767	59 (7.7%)
	-Retail	589	*43 (7.3%)*
	-Specialty	133	*14 (10.5%)*
All Sovaldi Regimens[1]	CVS/caremark specialty pharmacy**	3,035	180 (5.9%)
	Non-CVS/caremark specialty pharmacy‡	2,050	175 (8.5%)
	-Retail	1,550	137 (8.8%)
	-Specialty	408	34 (8.3%)

Sovaldi and Olysio launched on December 9, 2013

*Members who initiated therapy between 12/1/2013 and 5/15/2014, with paid claims and continuous eligibility between 12/1/2013 and 8/24/2014.

**Includes both CVS/caremark specialty pharmacy and CVS/pharmacy retail locations through the Specialty Connect program

†Patients who had refill gaps exceeding the allowable gap period of 15 days were classified as discontinuers.

‡ Includes "other" sites: home infusion therapy provider, long term care, and institutional pharmacies

[1]CVS/caremark specialty pharmacy vs. non-CVS/caremark specialty pharmacy; p<0.001

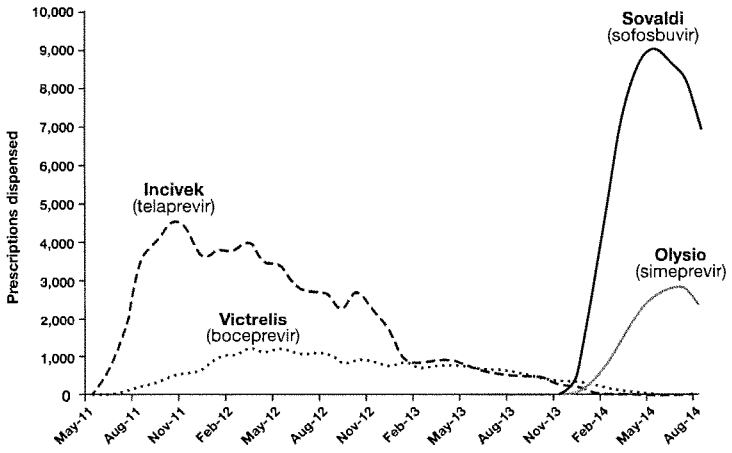
The analysis did not adjust for benefit plan design which may provide different incentives for members to complete treatment.

© CVS Health. All Rights Reserved.

Current and Future Utilization

The practice of "warehousing" patients, waiting to treat until new and improved therapy becomes available, has a rich history in Hepatitis C. In reviewing utilization data over the last four years, it is clear that hepatologists employed an elective approach to the timing of initiation of therapy for those patients without severe sequelae from Hepatitis C. In 2011, when Incivek® (telaprevir) and Victrelis® (boceprevir) were approved for the treatment of Hepatitis C, they represented an important improvement in the ability to treat the disease. As illustrated in Figure 1 below, when these drugs became available in May of 2011 there was a rapid peak in utilization which dissipated when news of the pending availability of a new and improved therapy, Sovaldi, began to circulate. Considering that approximately half of those with Hepatitis C are carriers and unaware they have the disease (approximately 1.5 million Americans) and that the majority of the 1.5 million Americans who are diagnosed with the disease have little or no symptoms, experts suggest that these patterns of peaked use when improved treatments become available will continue.

Figure 1: Utilization Trends of Hepatitis C Treatments (May 2011 – Aug 2014)



Beginning December 2013, when Sovaldi first became available, there was a massive rush to use the medication, with increasing numbers of patients beginning treatment each month (Figure 1). This was due to the fact that in the months leading up to the Food and Drug Administration's approval of Sovaldi, many patients with Hepatitis C who were not experiencing symptoms or adverse health effects had delayed pursuing any treatment until the new, highly effective drug became available. In contrast to the rapid uptake observed initially, CVS Health data show a plateau and then a downward trend in the number of new starters of Sovaldi during May – August 2014.

© CVS Health. All Rights Reserved.

Experts anticipate another substantial uptick in use in late September or October 2014, when Gilead, the manufacturer of Sovaldi, releases a new regimen for Hepatitis C that combines Sovaldi and ledipasvir into a single pill that is taken once a day. This regimen confers similar efficacy to multi-pill regimens and requires only an 8-week course of therapy compared with Sovaldi's current 12-week course. Experts believe that many hepatologists have been waiting for the release of this new single pill regimen and will initiate therapy for lower acuity patients when this medication becomes available. The pharmaceutical manufacturer Abbvie plans to release a similar all oral regimen at nearly the same time. The simplicity of these options may further reduce treatment discontinuation rates, although this cannot be determined at present. Additional peaks in use may be seen several months later, when new products from other manufacturers become available, which is likely to drive down costs.

Conclusions

CVS Health followed 1,965 patients who began Sovaldi to treat Hepatitis C during December 2013 – Aug 2014. We found that 8.1% of patients discontinued the drug during the recommended 12-week course, approximately a 4-fold increase in the discontinuation rates observed in clinical trials. Patients with less advanced Hepatitis C disease (those naïve to therapy) were markedly less likely to complete treatment than those who had previously received other Hepatitis C therapies. These findings underscore the well-recognized fact that real world adherence to medication is often poorer than that observed in clinical trials. It is reassuring to note that discontinuation rates were substantially lower in the CVS/caremark specialty pharmacy, where additional counseling and patient support is provided.

Sovaldi is an effective, curative therapy but also a costly one, and Sovaldi treatment discontinuation represents a substantial cost to the health care system without the corresponding clinical benefit and value. Our data suggest that all patients who receive Sovaldi should be followed closely by their providers to support adherence to therapy. Because treatment-naïve patients with less advanced disease discontinued Sovaldi more often, health care providers may choose to prioritize treatment for those who have more advanced disease. We anticipate upcoming spikes in Sovaldi use as new, simpler, and less expensive regimens become available. By anticipating these spikes in use, payors can augment current strategies to improve appropriate adherence in those who initiate therapy, and plan for the substantial cost outlays that will arise.

This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Health.

This document contains confidential and proprietary information of CVS Health and cannot be reproduced, distributed or printed without written permission from CVS Health.

This analysis was conducted in accordance with HIPAA and the PBM's business associate agreements.

© CVS Health. All Rights Reserved.

Exhibit 24

EDMUND G. BROWN JR.
GOVERNOR

State of California
HEALTH AND HUMAN SERVICES AGENCY

DIANA S. DOOLEY
SECRETARY

Aging
Child Support Services
Community Services and Development
Developmental Services
Emergency Medical Services Authority
Health Care Services
Managed Health Care
Public Health
Rehabilitation
Social Services
State Hospitals
Statewide Health Planning and Development

October 14, 2015

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
221 Dirksen Senate Office Building
Washington D.C. 20510

The Honorable Charles E. Grassley
Senior Member
Committee on Finance
United States Senate
135 Hart Senate Office Building
Washington D.C. 20510

Dear Senator Wyden and Senator Grassley:

Thank you for the opportunity to provide comments on California's experience with high-cost drugs, as you explore Gilead Sciences, Inc.'s pricing of the Hepatitis C drug Sovaldi. Our state Medicaid agency, the California Department of Health Care Services, previously provided your staff with more specific utilization and enrollment data for our state Medicaid program, called Medi-Cal, related to newly available Hepatitis C treatments. The purpose of this letter is to provide some context for California's efforts to understand and address the increased costs to the state and to consumers of these Hepatitis C treatments and high-cost drugs more broadly.

In January 2015, our proposed state budget specifically identified the high costs of newly available Hepatitis C treatments and noted that there are thousands of inmates in our state prisons, patients in our state mental hospitals, and participants in Medi-Cal and the AIDS Drug Assistance Programs who are infected with Hepatitis C. This budget proposal provided funding to cover these anticipated increased costs and tasked the California Health and Human Services Agency with convening a workgroup to refine these fiscal estimates and compare practices across our state departments and county governments.

Our agency convened several conversations with an internal workgroup consisting of state departments, county governments, and sheriffs, as well as with an external workgroup consisting of stakeholders representing consumers, organized labor, employers, health plans, providers, and the pharmaceutical industry. We have focused on three areas and have taken preliminary steps in these areas, by considering: what we can do through clinical guidelines, what we can do through procurement policies, and the value equation of high-cost drugs.

We are currently building our proposed budget for the next state fiscal year (July 1, 2016-June 30, 2017), which we will release in January 2016. Fiscal estimates for our departments will continue to account for the impact of these high-cost drugs. In addition, we'll continue to do what we can to manage these costs while providing high quality of care to the individuals in our public programs.

We appreciate your interest in the impact to states of the newly available Hepatitis C drugs, and look forward to continuing to work with our federal partners on these and other issues related to administering Medicaid and other important programs.

Sincerely,

Diana S. Dooley

Diana S. Dooley
Secretary

Appendix E

Exhibit 1

GILEAD LIVER DISEASE STRATEGY OVERVIEW

Introduction

Approximately 18 million patients in the US suffer from one of the three most common forms of chronic progressive liver disease - hepatitis C (HCV), hepatitis B (HBV), and non-alcoholic steatohepatitis (NASH). Liver disease is in the top 10 leading causes of death worldwide, with 1.3 million annual deaths due to complications of chronic liver disease. In coming decades, the incidence of cirrhosis, portal hypertension and primary liver cancer is expected to significantly increase highlighting the magnitude of disease burden. Treatment approaches that can cure the underlying etiology (eg, viral hepatitis) or prevent progression of liver damage will address this significant unmet medical need. Gilead's efforts are immediately focused on advancing therapy for patients with chronic hepatitis B, providing novel approaches for the treatment of chronic hepatitis C, and exploring new strategies to address liver fibrosis. Gilead will capitalize on its internal expertise in viral hepatitis to consolidate the company's efforts and expertise in HBV therapeutics, and in chronic hepatitis C infection. In addition, Gilead will explore new treatment strategies for patients with advanced liver fibrosis where there are currently no therapeutic options. These include diseases such as NASH and primary sclerosing cholangitis. This report discusses these ongoing and planned initiatives in liver diseases.

Hepatitis B

Introduction

The burden of disease due to chronic hepatitis B infection is the most significant global liver disease related problem. With over 400 million chronically infected individuals, and hepatitis B being the most common cause of liver cancer world wide, the opportunity to impact the lives and health of many patients and economies is obvious. There are currently two therapeutic approaches to treating HBV: chronic suppressive therapy with

Business Proprietary Information – Confidential Treatment Requested GS-0019261

oral antiviral drugs, and a 48 week course of interferon (IFN) therapy aimed at augmenting a blunted immune response to effectively regain immunological control over HBV virus replication. Although weekly injections of interferon therapy offers the opportunity for a cure (HBsAg sero-conversion), the 1 year cure rates are low (3%) and the therapy is poorly tolerated. Consequently, with availability of effective and well tolerated oral anti-viral therapies, interferon use is low in the US and declining in Europe.

While the first generation of antiviral drugs (Epivir-HBV®, Hepsera®, Tyzeka®) effectively suppressed the HBV virus, viral resistance to these drugs appeared after 2 years of therapy. Viread represents a significant improvement over these previous antiviral therapies. It provides potent, durable antiviral suppression, no resistance observed after five years on therapy, and is well tolerated. With Viread, and the competitive drug Baraclude® as options, the need for effective long-term suppressive anti-viral HBV therapy is largely met; both of these treatments are now considered the standard of care in current treatment guidelines and use of Viread has now surpassed Baraclude in the majority of regions where both treatments are promoted.

However, HBV remains vastly under-diagnosed and under-treated. In the US alone, recent estimates of the HBV prevalence are 2 million patients; with only about 15% of patients diagnosed and 15% of the diagnosed patients actually treated (similar figures in Europe). Reasons for these low diagnosis and treatment rates are numerous, from poor physician and patient awareness of HBV and the long term consequences of HBV infection, to complex guidelines about who to treat and when to initiate treatment. However, the prospect of life-long therapy is also a frequently mentioned barrier for patients to initiate antiviral therapy.

Opportunities

With Viread firmly established as first-line therapy, developing the HBV market through the expansion of diagnosis and treatment will benefit patients and extend the use of Viread. Clinical strategies aimed at exploring treatment at earlier stages of disease and

providing a stronger link between viral clearance and preventing liver cancer, along with support of updated treatment guidelines advocating earlier treatment, are significant opportunities for market expansion. The recent 5-yr long term data with Viread demonstrates that 75% of patients with cirrhosis showed regression of advanced fibrosis, highlighting the clinical benefit of virologic suppression with Viread. Furthermore, current efforts of expansion into high-prevalence HBV geographies, such as Asia, where Viread is currently unavailable, will offer significant opportunity for growth. The development of an alternative prodrug of tenofovir could also provide a more potent, lower dosage and potentially safer alternative for patients in US, EU and Asia.

The natural history of HBV and studies of patients on antiviral therapy have demonstrated that a cure is possible, albeit in a small proportion of patients. While current options offer high rates of viral suppression, the availability of a cure for HBV would address the most important unmet need described by physicians. Therapies that could permanently eradicate the virus and offer the prospect of finite therapy would increase the number of patients seeking treatment, improve the long-term clinical outcomes associated with "cure", and provide a strengthened economic rationale for treating the majority of infected patients.

Threats

Differentiation from Baraclude®, the main competitor of Viread, remains a significant priority with the perception of comparability of Baraclude® and Viread for first line therapy. The main opportunities for differentiation include the reliable efficacy and resistance profile of Viread in a broad range of patients (naïve and experienced) and the established safety profile of Viread in large patient populations including women of child-bearing age and young patients, where carcinogenicity issues with Baraclude® are a concern.

Business Proprietary Information – Confidential Treatment Requested GS-0019263

There is continued apathy on behalf of the medical community for changing the currently low levels of diagnosis, management and treatment of HBV despite ongoing efforts from Gilead and BMS.

The patent expiration of Baraclude® in 2015 in the EU followed by Viread in 2017 in the US will provide an enormous challenge to Gilead's HBV franchise unless a new therapeutic approach, such as a cure, can be established. The patent expirations of lamivudine in 2010 and Hepsera in 2014 are less likely to be relevant to the franchise.

Strategy

The strategy for the HBV franchise is focused on increasing the use of Viread for chronic therapy, and developing programs for direct acting antivirals and immunomodulatory compounds.

The prodrug of tenofovir (GS-7340) targets the liver at lower doses than Viread and this may translate to potential improved safety given the lower systemic exposure. This compound has demonstrated equivalent to greater HIV RNA reduction at lower doses when compared with TDF, and is being developed for the treatment of HIV-infected patients. Gilead will explore if a similar activity is also observed in HBV infected patients.

The role of the innate and adaptive immune system in HBsAg clearance or cure is an area of significant scientific interest. Research and development efforts will be advanced for immunomodulatory agents that are directed at both the innate and adaptive immune response. GS-9620 is the oral Toll-Like Receptor 7 (TLR7) agonist which targets gut associated lymphoid tissue innate immune activation. This approach provides pre-systemic liver activation with low oral doses, without the systemic effects associated with IFN administration. In parallel, compounds that can potentiate cognate HBV T-cell adaptive response (e.g., Globeimmune HBV tarmogens) are also being considered for in-licensing.

The combination of antiviral (Viread) and immunomodulatory (IFN) approaches are also being explored in a finite duration Phase 4 study. Findings from this study may inform future combination studies of direct antivirals (Viread, GS-7340) with the alternate immuno-modulatory approaches.

Current & upcoming initiatives

To achieve these strategic objectives, the HBV franchise will do the following:

- Continue to support Viread with ongoing clinical studies in various patient populations including the Phase 4 studies exploring finite regimens.
- Develop GS-7340 for use against chronic HBV infection with an early priority of development in Asia.
- Continue to develop GS-9620, an immunomodulatory TLR7 agonist, which is initiating early phase clinical trials in HBV patients. In addition, other external adaptive immunomodulatory approaches will be explored.
- Enhance Gilead's stake in successfully curing HBV infected patients with finite therapy by evaluating combinations of direct antivirals and immunomodulation.

Hepatitis C

Introduction

Chronic hepatitis C is the leading cause of chronic liver disease, cirrhosis and liver cancer in the United States, as well as the most common reason for liver transplantation in the Western world. The estimated number of individuals infected with HCV in the US, EU, and Japan is ~ 9 million, with only 1/3 of those infected actually diagnosed. The standard of care (SOC) for chronic hepatitis C up until mid-2011 was combination therapy with weekly injections of pegylated interferon (PEG) + daily oral ribavirin (RBV). The total world-wide HCV market for PEG and RBV products was $2.4 billion in 2008,

and is expected to increase significantly over the next decade and beyond with new changes in standard of care.

In May 2011, two direct acting antivirals, both protease inhibitors (Vertex's telaprevir (Incivek®) and Merck's boceprevir ((Victrelis®)), were approved for treatment of chronic HCV genotype 1 infection in combination with PEG + RBV. Both these new regimens cure significantly more patients than PEG + RBV alone (in all patient populations). Importantly, both agents allow a shorter treatment; telaprevir decreases therapy by half (to 24 weeks) in slightly more than half of all patients. The boceprevir treatment regimen requires a more complicated algorithm for 28 to 36 weeks including a 4 week lead-in PEG + RBV phase.

Both telaprevir and boceprevir have significant liabilities with safety/tolerability (rash and anemia) and dosing (three times per day). The discontinuation rates with these new regimens are two to three fold higher than current therapy, and those that do not respond will have developed resistant virus. It is unknown whether this will prevent these patients from successfully responding to similar agents in the same class in the future. For all these reasons, significant opportunities for safer, simpler, shorter regimens of equal or better efficacy clearly exist.

Another significant barrier to patients starting treatment for HCV is the side effect profile associated with interferon. Nearly half of the patients who qualify for treatment according to current guidelines are either unsuitable or unwilling to take PEG + IFN due to underlying co-morbidities, or the side effect profile. Physicians are also more hesitant to treat patients who historically have lower response rates (African-Americans, the elderly, those with HIV/HCV co-infection, obese/diabetic patients, prior treatment non-responders, those with psychiatric disorders, current injection drug users, the homeless, and those awaiting kidney or liver transplantation). Thus there is a significant unmet need for well tolerated and effective all-oral regimens that will benefit the 30-50% of all chronic HCV patients who are either intolerant or ineligible for PEG-based treatment regimens.

Business Proprietary Information – Confidential Treatment Requested GS-0019266

Following the commercialization of telaprevir and boceprevir, there are now over 50 novel agents from numerous manufacturers in the early stages of clinical development that target more than 8 different mechanisms. Several studies are underway that assess two direct acting oral antiviral agents in combination. In 2011, the feasibility of a PEG-free regimen was established with 2 direct acting (NS3 plus NS5a inhibitor) oral agents. High genetic barrier direct antivirals such as nucleotide NS5b inhibitors have been shown to provide high SVR rates when combined with PEG and are now being explored in PEG-free regimens. It is anticipated that ultimately a combination of two or more oral antiviral agents will replace PEG + RBV as the standard of care for the treatment of chronic HCV. Besides Gilead, six different manufacturers have initiated combination oral antiviral agent studies (BMS, Vertex, Roche, Abbott, BI, Tibotec). Results for many of these studies are expected in 2012.

Gilead currently has 7 agents with 6 different mechanisms of action in clinical development for chronic HCV. There are 5 ongoing Phase 2 studies with combination of 2 direct oral antiviral with PEG + RBV, and 3 ongoing Phase 2 studies exploring all-oral combination regimens. The compounds in development include:

- GS-9190 a non-nucleoside polymerase inhibitor in Phase 2b. Given 2 recent cases of severe pancytopenia, this compound will no longer be studied in combination with PEG + RBV and other direct anti-virals.
- GS-9451 and GS-9256, two protease inhibitors in Phase 2b. GS-9451 is now designated the preferred protease inhibitor based on cumulative clinical, toxicology and manufacturing data.
- GS-5885, a potent NS5a viral replication inhibitor in Phase 2b
- GS-6620, a nucleoside inhibitor of the HCV polymerase in Phase 1b
- GS-9669, a non-nucleoside polymerase inhibitor in Phase 1b
- GS-9620, an immunostimulatory TLR7 agonist, that could theoretically replace interferon, in Phase 1b

Business Proprietary Information – Confidential Treatment Requested GS-0019267

By the end of 2011, a minimum of two further molecules will be in early stage clinical development; a second HCV nucleoside inhibitor and a second potent NS5A viral replication inhibitor that is active against HCV genotypes 1-6. These molecules will provide the platform for an oral, pan-genotype regimen for the treatment of HCV.

Opportunities

Efficacy and tolerability are the key unmet needs in HCV therapy. Efficacy is defined as sustained virological response (SVR), the absence of serum HCV RNA six months following the cessation of therapy. Patients who obtain SVR are considered to be cured of their disease. SVR rates are particularly low in "difficult-to-treat" patients, which include those with a specific HCV genotype, high viral levels in the blood, advanced age, high body weight, diabetes, African American race, primary interferon non-responders, those with unfavorable genetic profiles (IL28B status) and HIV co-infection. PEG + RBV therapy is associated with a significant number of toxicities such as depression, anemia and marked flu-like symptoms that limit its effectiveness and acceptance by most patients.

The commercial opportunity for a non-interferon based, all oral therapy for the treatment of HCV is substantial. In addition to expanding the treatment naïve population, there are a growing number of patients who have previously failed current therapy who could benefit from combination antiviral therapy. The US and European Regulatory Agencies have recognized the importance of combination drug development for HCV and now are supporting innovative clinical research designs that study two or more different oral antiviral (OAV) classes (eg, protease inhibitor plus a polymerase inhibitor) in varying combinations with or without PEG + RBV, in different patient populations. Furthermore, regulatory agencies are encouraging development of therapies for the highest unmet needs which includes patients who are not eligible for the current standard of care. Other patient populations include those undergoing liver transplantation where HCV recurrence is 100%, and prevention of graft re-infection will be highly valued.

Business Proprietary Information – Confidential Treatment Requested GS-0019268

Gilead is aiming to capitalize on combination drug development by having several compounds in research and clinical development that could potentially be combined to create an all oral regimen, similar to ATRIPLA for HIV.

Threats

It is unknown if combinations of direct OAVs alone will be sufficient to cure most patients, or if therapy will require the addition of interferon or immunomodulatory agents in order to achieve a cure. In such a scenario, the tolerability profile of PEG + RBV would limit the overall benefit to patients. To be prepared for such an eventuality, Gilead has developed an interim strategy to reduce the dose and duration of interferon in these mutliple combination trials, and we are also developing a TLR7 agonist that could theoretically replace pegylated interferon.

Strategy

The Liver Disease Therapeutic franchise's primary long-term strategic objective and vision is to develop a broad genotypic all oral once a day antiviral combination therapy approach that will replace PEG + RBV. To achieve this objective, Gilead is developing multiple antiviral agents in parallel, with different mechanisms of action as well as non-overlapping resistance profiles to minimize the potential for the development of drug resistance.

Gilead has initiated three Phase 2 studies in 2011 to assess the potential of all oral regimens that contain Gilead antivirals. External licensing opportunities of development phase compounds would complement our internal pipeline and enhance our ability to achieve this long-term strategy.

Our interim IFN-sparing strategy is to create dual OAV combination regimens given with reduced duration/dose of PEG + RBV that would allow equivalent cure rates with shortened durations of therapy (16 and perhaps 12 weeks, rather than the current 24-48 weeks). Five Phase 2b studies addressing this interim goal are underway in 2011.

Proof of concept data from the 8 Phase 2 trials will be available throughout 2012 to inform subsequent decision making.

Current & upcoming initiatives

The progress of GS-9190, GS-9256, GS-9451 and GS-5885 in the clinic allows Gilead to now focus the clinical development plans:

- Five Phase 2 studies with 2 direct oral antivirals in combination with PEG + RBV are ongoing, though the focus is on GS-5885 + GS-9451 containing regimens.
  - GS-5885 + GS-9451 + PEG + RBV:
    - two studies in treatment naïve patients exploring response guided treatment duration of 12 weeks or 6 weeks (in a favorable *IL28B*-CC patient) respectively
    - one study in treatment experienced patients
  - GS-9451 + GS-9190 + PEG + RBV
    - One study in treatment naïve patients exploring response guided treatment shortening to 16 weeks. This study has stopped enrollment and GS-9190 is no longer part of this regimen.
  - GS-9256 + GS-9190 + PEG + RBV
    - One study in treatment naïve patients exploring response guided treatment shortening to 16 weeks. This study completed enrollment; GS-9190 is no longer part of this regimen.
- Three Phase 2 studies with all-oral regimens are ongoing in treatment naïve, treatment experienced and interferon ineligible or intolerant patients population.

- GS-5885 + GS-9451 + GS-9190 + RBV in treatment naïve exploring 12 or 24 weeks of treatment
- GS-5885 + GS-9451 + GS-9190 + RBV in treatment experienced exploring 24 weeks of treatment
- GS-5885 + GS-9451 + GS-9190 + RBV in IFN ineligible or intolerant exploring 24 weeks of treatment

- Phase 1b studies of GS-9620, a TLR7 agonist in HCV infected patients will be initiated in Q1 2012.
- R&D, in collaboration with Corporate Development will continue to explore all available in-licensing opportunities in HCV.

Liver Fibrosis

Introduction

Liver fibrosis represents the final common pathway whereby chronic liver injury results in the deposition of fibrous tissue and eventually cirrhosis. Progressive liver fibrosis leading to cirrhosis and its complications is currently the 6th leading cause of morbidity and mortality worldwide, and the disease burden is expected to significantly increase in the next few decades. While effective therapies are available for both hepatitis B and hepatitis C infected patients, the increasing prevalence of obesity and the metabolic syndrome is producing an epidemic of non-alcoholic fatty liver disease. This can progress to non-alcoholic steatohepatitis (NASH) which is predicted to become the leading cause of end-stage liver disease. There are other less common immune-mediated liver diseases like primary sclerosing cholangitis for which there are no effective therapies.

External environment

There are no currently approved therapies for liver fibrosis. Current approaches focus on addressing the causative etiologies of chronic liver disease. While NASH and viral

Business Proprietary Information – Confidential Treatment Requested GS-0019271

hepatitis account for the majority of patients with liver fibrosis, rapidly progressive immune-mediated diseases such as primary sclerosing cholangitis also represent high unmet need for which no effective treatment exist.

An estimated 25% of the industrialized world has fatty liver, an entity that has been termed non-alcoholic fatty liver disease (NAFLD). Simple hepatic steatosis is not associated with an excess liver related morbidity and mortality, but a subset of NAFLD patients have histological hepatitis referred to as NASH which is associated with inflammation, fibrosis and an increased risk of progression to cirrhosis, end-stage liver disease and hepatocellular carcinoma. NASH affects approximately 20-25% of all NAFLD patients. NASH is already a significant health problem and will likely become the leading cause of end-stage liver disease in the coming decade.

Weight reduction with diet and exercise is the only therapeutic strategy that has been shown to be beneficial in NASH. Several strategies have been tried experimentally, including insulin sensitizers (metformin and glitazones), antioxidants such as vitamin E, statins and other classes of lipid lowering agents, pentoxyfiline and omega-3 fatty acids. In general, none of these strategies has proven to be particularly effective, with some such as vitamin E and pioglitazone showing modest temporary reductions in inflammation but not fibrosis.

Primary Sclerosing Cholangitis (PSC) is a chronic disease of the bile ducts of unknown etiology which is characterized by a fibrosing cholangitis leading to inflammation, cholestasis and cirrhosis. The overall incidence of the disease is 0.77 per 100,000 person-years, with a median age at diagnosis of 41 years old and 2-to-1 male predominance. The disease is highly associated with inflammatory bowel disease (IBD). Within IBD, PSC is more likely to occur in patients with ulcerative colitis (UC) than in Crohn's disease (CD). There are approximately 30,000- 45,000 cases of PSC in the USA, and about one third-to-one half of these patients are affected with a more rapidly progressive disease. PSC also increases the risk of developing a rare ductal tumor, cholangiocarcinoma. Cholangiocarcinoma occurs in 10-15% of PSC patients, a rate 160 times that of the general population.

No specific treatment exists for PSC. Episodes of ascending cholangitis are managed with antibiotics in conjunction with therapeutic drainage. Treatment, optimally via sphincterotomy, balloon dilation and stenting is performed if the cholangitis is associated with a dominant stricture (a tight stenosis in either the common bile duct or one of the hepatic ducts). The only therapeutic option available to PSC patients is liver transplantation, although the disease does recur post-transplant in up to 25% of patients.

Opportunities

The development of a therapeutic agent with the ability to halt the progression of, or to reverse fibrosis will be viewed as an important advance in medicine. In particular, liver diseases with limited therapeutic options represent a high unmet medical need. These include patients with non-viral liver diseases such as NASH and other immune-mediated diseases such as primary sclerosing cholangitis.

Threats

Failure of all previous therapies in liver fibrosis, indicates that this represents a challenge for drug development. Lack of validated end points may necessitate the demonstration of benefit in clinical outcomes linked to histological end-points and subsequently longer duration of clinical trials. Finally, high rates of cure with future HCV regimens and high rates of viral suppression with HBV regimens, may obviate the need for anti-fibrotics in the majority of patients with viral hepatitis who are on effective treatment.

Strategy

The development program will focus on diseases with high unmet need where it is possible to demonstrate histologic and clinical benefit definitively given the rapid progression of disease. Examples will include advanced fibrosis in NASH patients and

Business Proprietary Information – Confidential Treatment Requested GS-0019273

rapidly progressing primary sclerosing cholangitis. The initial compound will be GS-6624 (anti-LOXL2 mAb) given the substantial body of scientific evidence indicating a "core" pathway role in fibrogenesis for LOXL2. In parallel, Gilead will continue to evaluate other compounds that are currently in preclinical development that target inflammation, in a variety of animal models of fibrosis.

Key current and upcoming initiatives in Q4 2011

Phase 1b safety studies of GS-6624 in patients with liver fibrosis will be initiated. Also, animal studies assessing different compounds in 4 different models of fibrosis are ongoing with preliminary data available this year.

Exhibit 2

From: "Matt.Young@barclayscapital.com"<Matt.Young@barclayscapital.com>
Subject: Re: Bristol-Inhibitex

From: Matt.Young@barclayscapital.com [Matt.Young@barclayscapital.com]
Sent: Saturday, January 07, 2012 9:59 PM
To: John McHutchison
Subject: Re: Bristol-Inhibitex

I totally agree. In my view that business is worth very little today, if ever. But they are running 12 phase 3s and need an answer that isn't as punitive to their current profitability. This is another zymogenetics.

Matthew Young
Barclays Capital
matt.young@barcap.com
650-289-6102 (w)
310-625-5519 (m)

----- Original Message -----
From: John McHutchison <John.McHutchison@gilead.com>
To: Young, Matthew: IBD (MLP)
Sent: Sat Jan 07 19:52:59 2012
Subject: Re: Bristol-Inhibitex

Thanks Matt

Yes I saw also

Think we got a bargain don't you

Perhaps desperation?

John

Sent from my iPhone

On Jan 7, 2012, at 10:51 PM, "Matt.Young@barclayscapital.com" <Matt.Young@barclayscapital.com> wrote:

> All -
>
> I wanted to make sure you saw this.
>
> It is unsurprising on one hand in that others need a complete, pan-genotypic portfolio approach, but given what we know about this asset, it is a risky move.

>
> Your premium was only 1/2 of 163%...

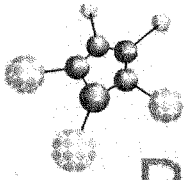
>
> I wanted to pass it along as I am sure you will get lots of questions. Let us know if you need anything.
>
> Best,
> Matt
>
> Subject: WSJ DEALS ALERT: Bristol to Buy Hepatitis C Drug Developer Inhibitex
>
> _____
> Deals Alert
> from The Wall Street Journal
>
>
> Drug giant Bristol-Myers Squibb Co. announced a deal to buy hepatitis C drug developer Inhibitex Inc. for $26 a share, or about $2.5 billion including options and warrants.

>
>
> The price represents a premium of about 163% based on Friday's closing price for Inhibitex shares of $9.87. The deal is the latest involving the exploding business of treating the hepatitis C virus. Gilead Sciences Inc. agreed in November to buy hepatitis C virus drug developer Pharmasset Inc. for about $11 billion.

>
>
> http://online.wsj.com/article/SB10001424052970203471004577147543747719460.html?mod=djemalertDEALS
>
>
>
> Matthew Young
> Barclays Capital
> matt.young@barcap.com
> 650-289-6102 (w)
> 310-625-5519 (m)
> ----------
> _____
>
> This e-mail may contain information that is confidential, privileged or otherwise protected from disclosure. If you are not an intended recipient of this e-mail, do not duplicate or redistribute it by any means. Please delete it and any attachments and notify the sender that you have received it in error. Unless specifically indicated, this e-mail is not an offer to buy or sell or a solicitation to buy or sell any securities, investment products or other financial product or service, an official confirmation of any transaction, or an official statement of Barclays. Any views or opinions presented are solely those of the author and do not necessarily represent those of Barclays. This e-mail is subject to terms available at the following link: www.barcap.com/emaildisclaimer. By messaging with Barclays you consent to the foregoing. Barclays Capital is the investment banking division of Barclays Bank PLC, a company registered in England (number 1026167) with its registered office at 1 Churchill Place, London, E14 5HP. This email may relate to or be sent from other members of the Barclays Group.

> _____

Exhibit 3



PHARMASSET

Board of Directors Meeting

Princeton, NJ

July 21, 2011

Confidential

303-A College Road East
Princeton NJ 08540 USA
Office 609 613 4100
Fax 609 613 4150
www.pharmasset.com

Pharmasset Meeting of the Board of Directors
Thursday, 21 July, 2011
8:00 am – 5:00 pm (EST)

Pharmasset
303-A College Road East
Princeton, NJ 08540

AGENDA

8:00 am **Administration**
- Review and Approval of Minutes

8:05 am **Report of Board Committees**
- Audit Committee
- Nominating and Corporate Governance Committee
- Compensation Committee

9:00 pm **Risk Management Update**

9:20 pm **Finance Update**
- Stock Split Recommendation
- Morgan Stanley Update

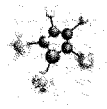
10:00 am **Discussion of Clinical Development Plans for 7977**
- Request for Budget to Accelerate P3
- Financing Plans

11:00 am **Pharmasset Strategy (with Working Lunch)**
- Global Commercial Strategy – Presentation by IMS
- U.S. Commercial Strategy
- Update of Research Strategy
- Global Financial Considerations

4:00 pm **Any Other Business**
- Authorization request: 938 Carcinogenicity Studies
- Authorization request: Quantum Study

4:15 pm **Executive Session**

5:00 pm **Adjourn**



Board Dinner (Incl Sr Execs)
Wednesday, 20 July 2011 at 7:00 pm EST
Blue Bottle Café
101 East Broad Street
Hopewell, NJ 08525

Future Board Meetings

- October 11, 2011 – New York City
- XXX

Business Proprietary Information – Confidential Treatment Requested

ADMINISTRATION

TAB

CONFIDENTIAL DRAFT
FOR DISCUSSION PURPOSES ONLY

Minutes of the Special Meeting of the
Board of Directors of Pharmasset, Inc.
Le Parker Meridien, New York, New York
March 23, 2011

Directors in attendance:
William J. Carney
Herbert Conrad
Elliot F. Hahn
Michael Inouye
P. Schaefer Price, President and CEO of the Company
Robert F. Williamson, III

Others in attendance at the invitation of the Board:
From the Company—
Michelle Berrey, Chief Medical Officer
Kurt Leutzinger, Chief Financial Officer
Mark Meester, Chief Administrative Officer
Michael Rogers, Chief Development Officer
Patrick Higgins, Executive Vice President, Marketing and Sales
Bryce Roberts, Vice President, Senior Counsel & Secretary
Richard E.T. Smith, Vice President Investor Relations
Michael McElhaugh, Director, Market Analytics and Business Development

From Morgan Stanley—
Jessica Chutter (via teleconference)
Steven Harr
Ashwin Pai

The Board of Directors (the "Board") of Pharmasset, Inc. (the "Company") held a regular meeting, pursuant to notice, on March 23, 2011 at the Le Parker Meridien hotel, New York, New York, commencing at 8:00 a.m. EDT. All members of the Board being present, Mr. Conrad called the meeting to order. Mr. Roberts acted as secretary for the meeting.

Approval of Minutes

Subject to certain ministerial corrections provided to Mr. Roberts, upon motion duly made, seconded and unanimously carried, it was

RESOLVED, that the minutes of the meetings of the Board held on January 13, January 18, and February 3, 2011 are hereby ratified and approved; and

FURTHER RESOLVED, that the minutes of the meeting of the Pricing Committee of the Board held on January 20, 2011 is hereby ratified and approved.

Business Proprietary Information – Confidential Treatment Requested

Board Committee Reports

Mr. Williamson reported that the Audit Committee met on February 4, 2011 to receive Grant Thornton's presentation of the results of the firm's review of the Company's financial statements for the quarter ended December 31, 2010.

Mr. Carney reported that the Nominating & Corporate Governance Committee had concluded a review of the Board's self assessment materials and distributed a summary of the collective responses to the members. Discussions were had, focusing on items that stood out to Mr. Carney in terms of the relative strength of the responses. Mr. Carney asked Mr. Leutzinger to address the members regarding the proposed revisions to the Company's Signature Authorization Policy. Mr. Leutzinger obliged and addressed questions of the members regarding same. Upon the conclusion of discussions, and upon motion duly made, seconded and unanimously carried, it was

RESOLVED, that the Board hereby approves the Company's revised Signature Authorization Policy in accordance with management's recommendations as provided to the Board at this March 23, 2011 meeting.

Mr. Carney reported that the Committee had initially discussed the size of the Board and the qualifications for any potential new members and led discussions with the full Board regarding the same. The Committee will conduct further research and report back to the full Board at a future meeting. Mr. Carney also proposed that the Board reappoint each member of each committee of the Board to serve on his respective committee. After discussions regarding same, and upon motion duly made, seconded and unanimously carried, it was

RESOLVED, that the Board hereby reappoints the following members to serve on the Committees of the Board opposite his name in the table below:

Name	Committees
William J. Carney	Audit, Nominating and Corporate Governance (Chair)
Herbert Conrad	Audit, Nominating and Corporate Governance
Elliot F. Hahn	Compensation, Nominating and Corporate Governance
Michael Inouye	Compensation, Nominating and Corporate Governance
Robert F. Williamson	Audit (Chair) Compensation (Chair)

Mr. Williamson reported that the Compensation Committee met on March 21, 2011. Mr. Williamson led discussions among the members regarding the recent ISS report and that the Committee would be conducting further research into compensation peer group benchmarking. Mr. Williamson led discussions regarding the Company's mid-year review of performance against objectives; specific discussions were had regarding the equity compensation component

Business Proprietary Information – Confidential Treatment Requested

for Company employees and the challenges facing the Committee in that regard. Mr. Price presented and led discussions regarding the proposed revised objectives for fiscal year 2011. Upon the conclusion of discussions, and upon motion duly made, seconded and unanimously carried, it was

> RESOLVED, that the Board hereby approves the Company's proposed objectives for fiscal year 2011 in accordance with management's proposal as presented to the Board at this March 23, 2011 meeting.

Mr. Williamson also presented the revised Charter of the Compensation Committee, which the Committee has approved and recommended for approval by the full Board. Mr. Williamson led discussions regarding the revisions, upon the conclusion of which, and upon motion duly made, seconded and unanimously carried, it was

> RESOLVED, that the Board hereby ratifies and approves the revised Charter of the Compensation Committee, as previously approved by the Compensation and Committee and presented to the Board at this March 23, 2011 meeting.

At approximately 8:55 a.m., the Chairman adjourned its meeting in order to attend the Company's 2011 Annual Meeting of Stockholders. At approximately 9:25 a.m., the Chairman reconvened this meeting and asked the representatives from Morgan Stanley, who had now joined the meeting at the invitation of the Board, to give their presentation.

The Morgan Stanley representatives distributed materials to the members and presented and led detailed discussions regarding same. Specific discussions were had regarding the Company's stock value over the past twelve months, anticipated value-creating events, HCV indicated drug candidates in development by third parties, Morgan Stanley's analysis of the Company and the HCV drug market, historical mergers and acquisition transactions, and related topics. At approximately 10:55 am, the Morgan Stanley representatives departed the meeting.

Clinical Update

The Chairman then asked Dr. Berrey to present the Company's clinical update to the Board. Dr. Berrey proceeded to present materials and lead discussions, including addressing questions from the members, regarding same. Specific discussions were had regarding clinical data presented at the 2011 EASL conference and the Company's on-going clinical studies, designs for future studies, and related topics. Dr. Rogers then addressed the Board regarding several specific planned studies and the planned designs and options for same.

Review and Approval of Budget

Mr. Maguire directed the members to materials previously provided regarding the review of the Company's updated budget for fiscal year 2011 and led detailed discussions regarding same. Mr. Maguire also presented the Company's original budget for the first half of fiscal year 2012 and led discussions and answered questions regarding same. Upon the conclusion of discussions, and upon motion duly made, seconded and unanimously carried, it was

Business Proprietary Information – Confidential Treatment Requested GS-0004494

RESOLVED, that the Board hereby approves and authorizes the updated budget for the Company's operations for the period ending September 30, 2011 in accordance with management's proposal as presented to the Board at this March 23, 2011 meeting.

Mr. McElhaugh then presented materials previously provided and led discussions concerning a proposal to potentially pursue an initial pivotal study strategy for PSI-7977 in HCV genotype 2/3 patients. Such presentation and discussions included, among other things, the potential risks, data and decision points, timelines, and potential clinical plans. The members asked detailed questions and extensive discussions were had among the members and Company management. The members concluded that management should continue to explore the proposed strategy and to follow up with the Board at its July 2011 meeting.

The Chairman then excused Company representatives from the meeting in order to conduct an executive session, which concluded at approximately 3:55 p.m., after which the meeting was adjourned.

Respectfully submitted,

_____
Bryce Roberts

Business Proprietary Information – Confidential Treatment Requested

AUDIT COMMITTEE

TAB

Minutes of the Regular Meeting of the Audit Committee of the Board of Directors of Pharmasset, Inc. May 5, 2011

Committee Members in attendance:
William J. Carney
Herb Conrad
Robert F. Williamson, III, Chairman of the Audit Committee

Others in attendance at the invitation of the Committee:
From the Company—
P. Schaefer Price, President, CEO and Director
Kurt Leutzinger, Chief Financial Officer
James Maguire, Vice President, Financial Reporting
Mark Meester, Vice President, Accounting and Administration
Bryce A. Roberts, Vice President, Senior Counsel & Secretary

From Grant Thornton LLP—
Wayne Kaplan
James Epperson
Cynthia Tjoa

The Audit Committee (the "Committee") of the Board of Directors of Pharmasset, Inc. (the "Company") held a regular meeting, pursuant to notice, on May 5, 2011 commencing at 2:00 p.m. EDT via teleconference. All members of the committee being present, Mr. Williamson noted that a quorum was present and called the meeting to order. Mr. Roberts served as secretary.

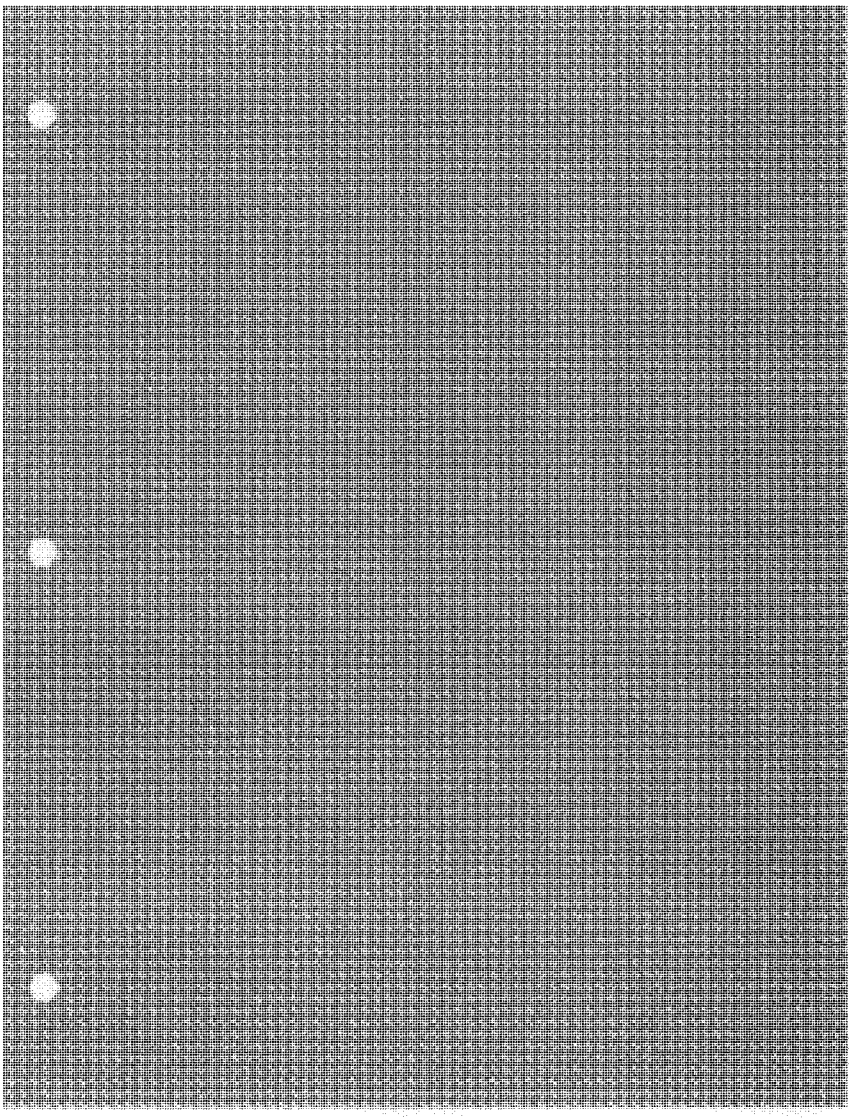
Redacted

At approximately 2:15 p.m., the Chairman asked members of management to depart the meeting so that the Committee could conduct its executive session with Grant Thornton, upon the conclusion of which the meeting was adjourned.

Respectfully submitted,

Bryce Roberts

Business Proprietary Information – Confidential Treatment Requested



Minutes of the Regular Meeting of the
Audit Committee of the Board of Directors of
Pharmasset, Inc.
April 22, 2011

Committee Members in attendance:
William J. Carney
Herb Conrad
Robert F. Williamson, III, Chairman of the Audit Committee

Others in attendance at the invitation of the Committee:
From the Company—
P. Schaefer Price, President, CEO and Director
Kurt Leutzinger, Chief Financial Officer
James Maguire, Vice President, Financial Reporting
Mark Meester, Vice President, Accounting and Administration
Richard Smith, Vice President, Investor Relations and Corporate Communications

From Grant Thornton LLP—
Wayne Kaplan
James Epperson

The Audit Committee (the "Committee") of the Board of Directors of Pharmasset, Inc. (the "Company") held a regular meeting, pursuant to notice, on April 22, 2011 commencing at approximately 11:00 a.m. EDT via teleconference. All members of the committee being present, Mr. Williamson noted that a quorum was present and called the meeting to order. Mr. Leutzinger served as secretary.

Mr. Williamson referred the members to the draft of the Company press release that was previously provided to the members and led discussions regarding same. Mr. Kaplan stated that Grant Thornton had reviewed the press release and had no changes. Mr. Kaplan also addressed a question from Mr. Carney regarding Grant Thornton's audit progress. Upon the conclusion of discussions and motion duly made, seconded and unanimously carried, it was

RESOLVED, that the Committee hereby approves the Company's press release regarding its quarterly results as presented to the Committee at this April 22, 2011 meeting and the release of same, which shall be effected prior to market open on April 25, 2011.

There being no further business, the meeting was adjourned at approximately 11:10 a.m.

Respectfully submitted,

Kurt Leutzinger

Business Proprietary Information – Confidential Treatment Requested

NOMINATION/

GOVERNANCE COMM.

TAB

Minutes of Telephonic Meeting
Nomination and Governance Committee
Pharmasset, Inc.
June 24, 2011

The Nomination and Governance Committee of Pharmasset met by conference call at 1:00 PM on Friday, June 24, 2011, pursuant to notice The committee had been notified by e-mail. Present were William Carney, Chair, Herb Conrad, Elliot Hahn and Michael Inouye, being all of the members of the committee. William Carney served as acting secretary for the meeting.

The meeting was called to discuss whether the Committee should search for one or more additional directors, and what the qualifications of that director should include. Mr. Carney referred to a memorandum of June 20, 2011, hereto as Exhibit A, reviewing issues of board size, current director competencies, potential board candidates and potential search firms.

The discussion centered its discussion of candidates on Dr. Scott Gottlieb, whose CV is attached hereto as Exhibit B. Mr. Conrad has made preliminary contact with Dr. Gottlieb, who indicated an interest in being considered as a board candidate. Dr. Gottlieb disclosed that he has recently served as a consultant for Vertex, and that his service has been completed.

After full discussion and upon motion duly made, seconded, and unanimously approved, it was

RESOLVED,

1. That the committee should recommend the addition of one board member at this time.

2. That the candidate should add to our competencies in areas including regulation, health policy and international activities.

3. That the Committee recommends to the board that we engage in vetting Dr. Scott Gottlieb, subject to the board's review and revision of director compensation policies.

There being no further business to come before the committee, the meeting was adjourned.

Respectfully submitted,

William Carney, Acting Secretary

EXHIBIT A

MEMORANDUM

TO: **Nominating and Governance Committee, Pharmasset**

FROM: **Bill Carney, Chair**

RE: **Draft presentation to the board concerning a director search.**

DATE: **June 20, 2011 - Revised**

CONTENTS

Executive Summary 2
Questions Addressed: 3
Size of Board 3
Current Skill Set of Board 4
Explanations of Skill Sets of Other Boards 8
Other Desirable Skill Sets 17
Candidates Mentioned to Date 18
Past Candidates Considered 21
Search Firms Investigated in the Past 24

Business Proprietary Information – Confidential Treatment Requested

Executive Summary

Board Size: In 2003 the average biotech board had eight members. A small survey of public biotechs reveals an average size of 10.% directors.

Current Skill Set of Board: The tables on pages 5 and 6 are currently incomplete, and need input from the committee and possibly from those directors not on the committee (Price and Williamson).

Explanations of Skill Sets of Other Boards: The boards of both Vertex and Idenix contain members with apparently relevant experience and skills. The Gilead board is far more diverse in its background, with more experience in public policy and public service not directly related to biotech.

Other Desirable Skill Sets: Thus far experience in product development and acquisition, to diversify our portfolio, international expertise, finance and virology public health have been mentioned.

Candidates Mentioned to Date: Mark Perry, CEO of Aerovance (formerly at Gilead); Melvin Sharoky, former CEO of several pharmaceutical companies, William D. Pruitt (accountant); Tamara Baum (investment banking) and Scott Gottlieb (Academic Medicine, FDA) have been mentioned by committee members.

Past Candidates Considered. Among candidates that we did not pursue in past searches are Donald J. Hayden, Jr. (former EVP at BMS); L. John Wilkerson (private equity partner); David M. Lawrence, M.D. (former CEO of Kaiser Foundation Health Plan, Inc.); Thomas A. Scully (lawyer and Administrator of Medicare).

Search Firms Investigated in the Past. In our 2007 search we looked closely at Egon Zender International, Mancino Burfield Edgerton (which we employed), Russell Reynolds Associates, and Heidrick & Struggles. A summary of their arrangements and of our reference checks is included. We also considered more briefly The Hennessy Group, Korn/Ferry International, and Levin and Company.

Business Proprietary Information – Confidential Treatment Requested

Questions Addressed

This report is intended to stimulate a thorough-going discussion of our needs for additional directors. It is longer than our committee's usual reports because of the breadth of the questions that need to be covered.

Size of Board

We now have a board of six members. The question is whether we should enlarge the board, and if so, to what extent. There is little formal study of board size in the academic or business literature, according to Carney's Google search. The only study we could identify was by Spencer Stuart, in 2003. Its survey of 25 biotech boards reported:

Biotech boards are smaller, but equally independent as S&P 500 boards

- The average biotech board has about eight members, versus 11 on S&P 500 boards.
- 76% of biotech boards have fewer than 10 members, compared to just 31% of S&P 500 boards.
- Biotech boards are on par with their S&P 500 counterparts in representation by outside directors. On average, biotech boards include 78% outside directors versus 80% on S&P 500 boards.
- More than half of biotech boards elect directors to three-year terms, virtually the same ratio as the S&P 500.

We also looked at a small sample of public biotech companies. This data comes from a 2010 study by MedTRACK, at http://www.medtrack.com/research/lstats.asp#list2. We have omitted one Japanese company from the list, and added Vertex, Idenix and Gilead. The data for the added companies is current as of June, 2011.

Company	Symbol	Market Value (millions)	Number of Directors
Amgen Inc.	AMGN	54,477.87	12
Kamada Ltd.	KMDA	22,204.43	7
Biogen Idec Inc	BIIB	22,177.00	12
CSL Limited	CSL	18,794.62	10
Life Technologies Corporation	LIFE	8,972.16	12
Elan Corp. Plc	ELN	6,121.21	12
Dendreon Corporation	DNDN	5,733.27	9
Human Genome Sciences Inc	HGSI	4,879.17	12
Vertex	VRTX	9,730	8
Idenix	IDIX	447.34	8
Gilead	GILD	31,450	13

Business Proprietary Information – Confidential Treatment Requested

This places Pharmasset on the low end of numbers of directors, suggesting enlargement would be appropriate over time, if not immediately.

Current Skill Set of Board

The Spenser Stuart Study contains the following information on the background of biotech directors:

New directors have a variety of functional backgrounds, but largely hail from biotech

- Just 17% of newly appointed biotech directors are active chairmen, presidents, CEOs, COOs or vice chairmen, compared to more than 30% of new directors on S&P 500 boards.
- Not surprisingly, nearly two-thirds of new directors of biotech companies come from the healthcare, pharmaceutical and biotech industries.
- New biotech directors also are from academia and the investment community, reflecting the importance of science and technology and the continued involvement of venture capitalists in biotech.
- The average age of new biotech directors is 52, compared to 56 for S&P 500 boards.

	2003 Biotech	2003 S&P
Active chair/pres/CEO/COO/vice chair	17%	32%
Finance management/CFO	17%	10%
Academics/not-for-profits	11%	10%
Division/subsidiary president/GM	11%	4%
Investment management/investors	11%	4%
Retired chair/pres/CEO/COO/vice chair	11%	12%
All others (incl. govt/military)	11%	4%
Accounting	6%	5%
Other corporate executives	6%	8%
Bankers/investment bankers	0%	4%
Consultants	0%	5%
Lawyers	0%	2%
Other retired	0%	1%

Business Proprietary Information – Confidential Treatment Requested

The Spenser Stuart study also reported:

Women underrepresented in the boardroom

- Women hold proportionately fewer director positions on biotech boards than on S&P 500 boards despite their gains in senior management within the biotech industry. 64% of biotech boards have at least one female director, compared to 85% of S&P 500 boards.
- Only two of the 25 biotech boards we surveyed have two or more women directors. By contrast, of the 413 S&P 500 companies with women directors, just under half have two or more female board members.
- Of the 18 new directors on biotech boards, three, or 17%, are women.

Russell Reynolds Associates has published a "Competency Model" that outlines qualifications useful for a biotech board. We have employed it to describe the competencies of our current members, as well as we can without further input from the full board. They are set out on the following pages.

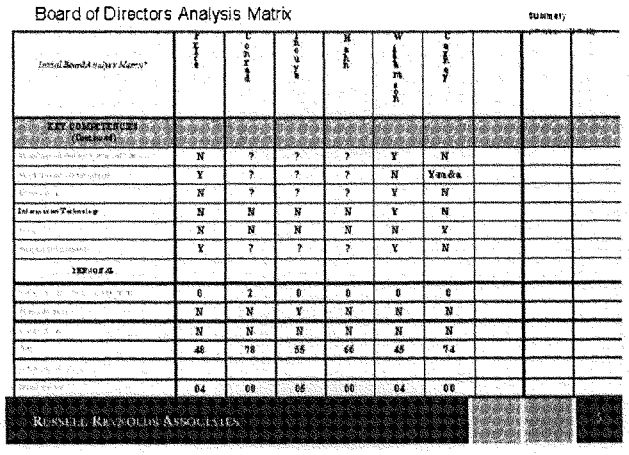
Board of Directors Analysis Matrix

COMPLIANCE DATA								
	N	Y	Y	Y	Y	Y		
	Y	Y	N	Y	Y	N		
	N	N	N	N	N	N		
KEY COMPETENCIES								
	Y	?	N	?	N	N		
	Y	?	N	?	Y	N		
	N	?	Y	?	N	N		
	N	N	N	?	Y	N		
	N	N	N	?	N	N		
	N	?	?	?	Y	N		

RUSSELL REYNOLDS ASSOCIATES

6

Board of Directors Analysis Matrix



Initial Board Analysis Matrix*	Price	Conrad	Inouye	Hahn	Williams	Laney			
KEY COMPETENCIES (Continued)									
	N	?	?	?	Y	N			
	Y	?	?	?	N	Yandra			
	N	?	?	?	Y	N			
Information Technology	N	N	N	N	Y	N			
	N	N	N	N	N	Y			
	Y	?	?	?	Y	N			
DEMOGRAPHIC									
	0	2	0	0	0	0			
	N	N	Y	N	N	N			
	N	N	N	N	N	N			
	48	78	55	66	45	74			
	04	08	05	00	04	00			
RUSSELL REYNOLDS ASSOCIATES									

Board of Directors Analysis Matrix

Summary

Y = Yes N = No

Initial Board Analysis Matrix*	Price	Conrad	Inouye	Hahn	Williams	Laney			
COMPETENCIES/EXPERIENCE									
Audit	N	Y	N	N	Y	Y			
Compensation	N	N	Y	Y	Y	N			
Marketing and Corporate Governance	N	Y	Y	Y	N	Y			
ADDITIONAL CURRENT PUBLIC BOARD COMMITTEE MEMBERSHIP									
Executive	0	0	0	0	0	0			
Audit	0	0	0	0	0	0			
Compensation	0	1	0	0	0	0			
Finance	0	0	0	0	0	0			
Governance/Nominating	0	1	0	0	0	0			
Other	0	0	0	0	0	0			
RUSSELL REYNOLDS ASSOCIATES									0

Finally, Korn/Ferry has produced a checklist of qualifications for biotech boards, set out below. We encourage each director to provide his own assessment of which categories are currently satisfied.

Life Sciences Board Composition -Needs Assessment

Category	Skills/Experience Required	Incumbents/Gaps
General Management		
	• Commercial/Strategic Marketing and Sales	
	• P&L	
	• Business Strategy	
	• Operations/ Manufacturing	
	• International	
	• Successful Entrepreneur	
	• Sitting Chief Executive Officer	
	• Business Development	
Finance		
	• Accounting/SEC reporting/SOX	
	• Public equity markets	
	• Investment banking	
	• M&A	
R&D		
	• Pharmaceutical Development	
	• Clinical development	
	• Therapeutic expertise	
	• Academic opinion leader/medicine	
	• Regulatory Affairs	
Legal & Governmental Affairs		

Business Proprietary Information – Confidential Treatment Requested

- Corporate Law _____
- Patent Law _____
- Reimbursement _____

Other Considerations

- Conflicts (therapeutic, time and independence)_____
- Board worthiness _____
- Board experience _____
- Diversity _____

Explanations of Skill Sets of Other Boards

We surveyed recent proxy statements to see what skills companies were listing for their directors, as now required by proxy rules. The relevant material has been italicized.

VERTEX:

Matthew W. Emmens

Mr. Emmens has been our Chairman, Chief Executive Officer and President since May 2009. He became our President in February 2009. Mr. Emmens also serves as the Chairman of the Board of Directors of Shire plc, a specialty biopharmaceutical company, and has been a member of Shire's board since March 2003. From March 2003 to June 2008, Mr. Emmens was also the Chief Executive Officer of Shire plc. Before joining Shire in 2003, Mr. Emmens served as President of Merck KGaA's global prescription pharmaceuticals business in Darmstadt, Germany. In 1999, he joined Merck KGaA and established EMD Pharmaceuticals, Inc., its United States prescription pharmaceutical business. Mr. Emmens held the position of President and Chief Executive Officer at EMD Pharmaceuticals from 1999 to 2001. Prior to this, Mr. Emmens held various positions, including Chief Executive Officer, at Astra Merck, Inc. as well as several positions at Merck & Co., Inc. Mr. Emmens was a member of the Board of Directors of Incyte Corporation from 2006 through February 2009. He received a B.S. degree in business management from Fairleigh Dickinson University.

Mr. Emmens provides our board with in-depth knowledge of our company through his day-to-day leadership of our executive team. Mr. Emmens also possesses strong leadership qualities that he has demonstrated and developed through his service as the CEO of a number of pharmaceutical and biotechnology organizations, including Shire. He also has substantial financial expertise and industry knowledge applicable to the current stage of our business, including significant experience leading commercial organizations.

Age: 51

Margaret G. McGlynn

Nominee to be Elected to Board in May 2011

Margaret G. McGlynn, R.Ph., has been nominated for election to our Board of Directors at our 2011 annual meeting. Ms. McGlynn served as President, Vaccines and Infectious Diseases of Merck & Co., Inc. from 2005 until her retirement in 2009. Ms. McGlynn joined Merck in 1983 and served in a variety of marketing, sales and managed care roles. Currently, Ms. McGlynn serves as a member of the board of directors for Air Products and Chemicals, Inc. and Amicus Therapeutics, Inc. She is also a member of the National Industrial Advisory Committee at the University at Buffalo School of Pharmacy and Pharmaceutical Sciences. Ms. McGlynn holds a B.S. in Pharmacy and an M.B.A. in Marketing

from the State University of New York at Buffalo.

Our board believes that Ms. McGlynn will be a valuable member of our board based on her significant commercial experience in the pharmaceutical industry and the leadership and financial expertise she has developed as an executive at a global pharmaceutical company, and as a member of the board and audit committee of Air Products and Chemicals, Inc., an international chemical manufacturer and distributor. As our newest board member, she would bring a fresh perspective regarding our company.

Wayne J. Riley, M.D., M.B.A.

Dr. Riley is President and Chief Executive Officer of Meharry Medical College, a position he has held since January 2007. In addition, he holds the academic rank of Professor of Internal Medicine at both Meharry and Vanderbilt University Schools of Medicine. From May 2004 to December 2006, Dr. Riley served as a corporate officer and member of the executive management team as Vice President and Vice Dean for Health Affairs and Governmental Relations and Associate Professor of Medicine at Baylor College of Medicine. He also served during that period as Assistant Chief of Medicine at Ben Taub General Hospital, Baylor's primary adult public hospital teaching affiliate. He was Assistant Dean for Education at Baylor College of Medicine from 2000 to 2004. Dr. Riley is a member of the Board of Directors of Pinnacle Financial Partners, Inc., a financial services firm. Dr. Riley earned a B.A. from Yale University, an M.P.H. in health systems management from the Tulane University School of Public Health and Tropical Medicine, an M.D. from the Morehouse School of Medicine and an M.B.A. from the Jones Graduate School of Business, Rice University.

Our board believes Dr. Riley is a valuable contributor to our board due to the leadership and management skills he has acquired through his experience as the CEO of Meharry Medical College and through his prior executive positions at Baylor College of Medicine and Ben Taub General Hospital. In addition, Dr. Riley has significant medical and academic experience in the health care field.

Jeffrey M. Leiden, M.D., Ph.D.

Director since 2009 Age: 55

Dr. Leiden has more than 20 years of experience in the biomedical and pharmaceutical sectors. Dr. Leiden was President and Chief Operating Officer of Abbott Laboratories, Pharmaceuticals Products Group and a member of the Board of Directors of Abbott Laboratories from 2001 to 2006. From 1987 to 2000, Dr. Leiden held several academic appointments, including positions as the Rawson Professor of Medicine and Pathology and Chief of Cardiology and Director of the Cardiovascular Research Institute at the University of Chicago, the Elkan R. Blout Professor of Biological Sciences at the Harvard School of Public Health, and Professor of Medicine at Harvard Medical School. He is an elected member of both the American Academy of Arts and Sciences and the Institute of Medicine of the National Academy of Sciences. Dr. Leiden is a Managing Director at Clarus Ventures, a life sciences venture capital firm he joined in 2006. Dr. Leiden also is a director and the non-executive Vice

Business Proprietary Information – Confidential Treatment Requested GS-0004510

Chairman of the Board of Shire plc, and a director of several private biotechnology companies. Dr. Leiden was a member of the Board of Directors of Millennium Pharmaceuticals, Inc. from October 2007 until it was acquired in June 2008. He received both his M.D. and Ph.D. degrees from the University of Chicago.

Our board determined that Dr. Leiden should serve as a director because he is a distinguished physician, scientist and teacher with a strong background as an executive in the pharmaceutical industry and as a life sciences venture capitalist. Dr. Leiden has significant strategic and biotech investment experience.

Bruce I. Sachs **Age: 51**

Director since 1998

Mr. Sachs is a General Partner at Charles River Ventures, a venture capital firm he joined in 1999. From 1998 to 1999, he served as Executive Vice President and General Manager of Ascend Communications, Inc. From 1997 until 1998, Mr. Sachs served as President and Chief Executive Officer of Stratus Computer, Inc. From 1995 to 1997, he served as Executive Vice President and General Manager of the Internet Telecom Business Group at Bay Networks, Inc. From 1993 to 1995, he served as President and Chief Executive Officer at Xylogics, Inc. Mr. Sachs was a director of BigBand Networks, Inc. from 2005 through June 2009. Mr. Sachs holds a B.S.E.E. in electrical engineering from Bucknell University, an M.E.E. in electrical engineering from Cornell University, and an M.B.A. from Northeastern University.

Our board believes that Mr. Sachs should serve as a director because of his strong business judgment and financial analytical skills, which are evidenced by his experience developing business strategy at a senior management level and his success in building companies and in venture capital. In addition, Mr. Sachs has extensive business leadership experience, including service as a CEO at a technology company.

Dennis L. Winger **Age: 63**

Director since 2009

Mr. Winger has over 30 years of experience as a financial executive, the majority of which has focused on the life sciences industry. He retired in 2008 from Applera Corporation, a life sciences company, where he had been Senior Vice President and Chief Financial Officer since 1997. He was previously Senior Vice President of Finance and Administration and Chief Financial Officer at Chiron Corporation. Before joining Chiron, Mr. Winger held various financial executive positions, including Chief Financial Officer of The Cooper Companies, Inc. Mr. Winger is currently a director of the following public companies: Accuray Incorporated, Cephalon Inc.; and Nektar Therapeutics. In addition, Mr. Winger was a member of the Board of Directors of A.P. Pharma, Inc. during 2005 and 2006 and a member of the Board of Directors of Cell Genesys, Inc. from 2004 until its merger with BioSante Pharmaceuticals in October 2009. He holds an M.B.A. from Columbia University Graduate School of Business and he earned his undergraduate degree from Siena College.

Mr. Winger's qualifications for our board include his extensive experience as a financial executive in the life sciences industry and his experience as a productive member of the board of directors of several public biopharmaceutical companies. Mr. Winger brings financial expertise to his role as our audit committee financial expert.

Business Proprietary Information – Confidential Treatment Requested GS-0004511

Class III Directors—Terms Expiring In 2013

Joshua Boger, Ph.D. **Age: 59**

Director since 1989

Dr. Joshua Boger is the founder of Vertex. He was our Chief Executive Officer from 1992 through May 2009. He was our Chair of the Board from 1997 until May 2006 and our President from our inception until December 2000, and from 2005 through February 2009. He was our Chief Scientific Officer from 1989 until May 1992. Prior to founding Vertex in 1989, Dr. Boger held the position of Senior Director of Basic Chemistry at Merck Sharp & Dohme Research Laboratories in Rahway, New Jersey, where he headed both the Department of Medicinal Chemistry of Immunology & Inflammation and the Department of Biophysical Chemistry. Dr. Boger holds a B.A. in chemistry and philosophy from Wesleyan University and M.S. and Ph.D. degrees in chemistry from Harvard University. Dr. Boger is the brother of Mr. Kenneth S. Boger, our Senior Vice President and Chief Legal Officer.

Dr. Boger's qualifications for our board include his extensive industry knowledge and leadership experience. In addition to his experience leading our company as CEO for 20 years and his distinguished scientific career, Dr. Boger brings an in-depth knowledge of issues facing our company and our industry as a result of both his experience and continued active participation in various industry-related organizations, including the Biotechnology Industry Organization.

Elaine S. Ullian **Age: 63**

Director since 1997

From 1996 through January 2010, Ms. Ullian served as President and Chief Executive Officer of Boston Medical Center, a private, not-for-profit, 626-bed, academic medical center with a community-based focus. From 1994 to 1996, she served as President and Chief Executive Officer of Boston University Medical Center Hospital. From 1987 to 1994, Ms. Ullian served as President and Chief Executive Officer of Faulkner Hospital. She also serves as a director of Thermo Fisher Scientific Inc. and Hologic, Inc. In addition, Ms. Ullian was a member of the Board of Directors of Valeant Pharmaceuticals, Inc. from 2005 through 2007. Ms. Ullian holds a B.A. in political science from Tufts University and an M.P.H. from the University of Michigan.

Our board has concluded that Ms. Ullian is a valuable contributor to our board due to the leadership and management skills she has acquired through her experience as the CEO of a number of large health care providers. This experience also has given her insight into the health care industry from the perspective of providers, payers and patients, who make up the target markets for our drug candidates.

IDENIX

Ronald C. Renaud has served as the President and chief executive officer of Idenix Pharmaceuticals, Inc. since October 2010. Prior to this, Mr. Renaud has served as the chief financial officer of Idenix Pharmaceuticals, Inc. since June 2007 and additionally as Chief Business Officer since June 2010. Mr. Renaud brings a unique mix of skills to this role with his finance experience at public biotechnology companies and on Wall Street, as well as his science background. Prior to joining Idenix, Mr. Renaud served as chief financial officer of Keryx Biopharmaceuticals. In this role he was responsible for the strategic planning

Business Proprietary Information – Confidential Treatment Requested GS-0004512

and development of the finance function to support the company's growth and its late-stage product candidate development. Prior to his position at Keryx, he spent several years as a senior biotechnology equity analyst for leading investment banks including Bear Stearns, Schwab SoundView and JP Morgan. Additional industry experience includes Mr. Renaud's more than five years at Amgen Inc., where he held positions in clinical research, investor relations and finance.

Mr. Renaud holds a Masters in Business Administration from the Marshall School of Business at the University of Southern California and a Bachelor of Arts from St. Anselm College in Manchester, NH.

Charles W. Cramb has served as a director since October 2003. In November, Mr. Cramb joined Avon Products, Inc., in the newly created position of executive vice president, finance and technology and chief financial officer. Until October 2005, Mr. Cramb served as the chief financial officer of The Gillette Company, a worldwide consumer products company, since July 1997. From July 1995 to July 1997, Mr. Cramb served as a corporate vice president and corporate controller of The Gillette Company. He is also a member of the board of directors of Tenneco Automotive Inc. Mr. Cramb holds a B.A. from Dartmouth College and a M.B.A. from the University of Chicago.

Wayne T. Hockmeyer, Ph.D. has served as a director since February 2002. Dr. Hockmeyer founded MedImmune, Inc., a biotechnology company, in April 1988 and served until October 2000 as the chief executive officer of MedImmune. In October 2000, Dr. Hockmeyer relinquished his position as chief executive officer and now serves as chairman of the board of directors, MedImmune, Inc. and president of MedImmune Ventures, Inc., a wholly-owned subsidiary of MedImmune, Inc. Dr. Hockmeyer also serves as a director of Advanced Pharmaceutical Corporation, GenVec, Inc., Tercica, Inc. and TolerRx, Inc. Dr. Hockmeyer was recognized, in 1998, by the University of Florida as a Distinguished Alumnus and in 2002 was awarded a Doctor of Science honoris causa from Purdue University. Dr. Hockmeyer holds a B.S. from Purdue University and a Ph.D. from the University of Florida.

Thomas R. Hodgson has served as a director since February 2002. From September 1990 to January 1999, Mr. Hodgson served as the president and chief operating officer of Abbott Laboratories. From 1983 to 1990, Mr. Hodgson served as the president of Abbott International and from 1978 to 1983, Mr. Hodgson served as the

president of the Hospital Products Division of Abbott Laboratories. Mr. Hodgson is a director of The St. Paul Travelers Inc. and Intermune, Inc. Mr. Hodgson holds a B.S. from Purdue University, an M.S. from the University of Michigan, an M.B.A. from Harvard Business School and an honorary doctorate degree in engineering awarded by Purdue University.

Tamar Howson has served as a director since March 2010. Prior to joining JSB-Partners, Ms. Howson was executive vice president of business development at Lexicon Pharmaceuticals where she led the company's partnering and licensing efforts. From 2001 to 2007, Tamar was senior vice president corporate and business development at Bristol Myers Squibb overseeing M&A, licensing and research collaborations across all businesses. In 2000 and 2001, Ms. Howson served as a business development and strategy consultant to biotechnology companies in the United States and in Europe. Ms. Howson worked at SmithKline Beecham from 1991 to 2000, where she was senior vice president and director of business development, responsible for worldwide in-licensing and business development. She also managed SR One, SmithKline Beecham's $100 million venture capital fund. Before joining SmithKline Beecham, Ms. Howson served as vice president, venture investments at Johnson Associates, a venture capital firm, and earlier as director, worldwide business development and licensing for Squibb Corporation. In 1999, Ms. Howson received the Healthcare Businesswomen's Association "Woman of the Year" Award. Ms. Howson currently serves on the board of S*Bio Pte Ltd., a consultant to Pitnago Venture Fund and is a member of the advisory board to

Trians Venture Partners. She previously served on the boards of Ariad Pharmaceuticals, SkyPharma, NPS Pharma, Targacept, and HBA.

Ms. Howson holds an M.B.A from Columbia University, a M.S. from City College of New York and a B.S. in Chemical Engineering from the Technion in Israel.

Robert Pelzer has served as a director since May 2003. Mr. Pelzer is President and Chief Executive Officer of Novartis Corporation. In this position, which he assumed in September 2008, he is responsible for the Novartis Group Companies in North America and the Novartis US Foundation. Previously, Mr. Pelzer was Global General Counsel and Head of Legal Services of Novartis Pharma AG, based in Basel, Switzerland. He also served as a member of the Novartis Pharma Executive Committee. Prior to joining Novartis in 2002, Mr. Pelzer was Senior Vice President and General Counsel at DuPont Pharmaceuticals based in Wilmington, Delaware. Mr. Pelzer also held a variety of positions within the DuPont organization, including Director and General Manager for the European oil and gas business and Vice President and General Counsel of Conoco Canada Limited in Calgary, Canada. He began his legal career at the law firm of MacKimmie Matthews in Calgary. A graduate of the University of Alberta in Alberta, Canada, Mr. Pelzer earned degrees in Commerce and in Law.

Denise Pollard-Knight, Ph.D. has served as a director since May 2003. From January 1999 to March 2004, Dr. Pollard-Knight served as head of Healthcare Private Equity at Nomura International plc, a leading Japanese financial institution. Since April 2004, Dr. Pollard-Knight has served as head of Nomura Phase4 Ventures, an affiliate of Nomura International plc. Prior to joining Nomura, Dr. Pollard-Knight was a member of Rothschild Asset Management Ltd., an investment management firm, from January 1997 to January 1999. Dr. Pollard-Knight held several research and development management positions at Amersham-Pharmacia and Fisons plc. In December 2005, Dr. Pollard-Knight became a member of the Board of Trustees of the British Heart Foundation. Dr. PollardKnight holds a Ph.D. and BSc (Hons) from the University of Birmingham in England. Dr. Pollard-Knight completed postdoctorate work as a Fulbright Scholar at the University of California, Berkeley.

Anthony Rosenberg has served as a director since June 2009. Mr. Rosenberg is Head of Business Development and Licensing of Novartis Pharma AG and a member of the Pharma Executive Committee. He joined Sandoz in 1980 in the UK where he held various leadership positions in sales and marketing, business development and strategic planning. In 1994 he moved to Basel, initially as international product manager (Clozaril), and undertook roles of increasing responsibility in Global Marketing, ultimately as Head Global Marketing Primary Care. In 2000 he became Global Head of the Transplant and Immunology Business Unit and began his current role in 2005. He has overseen several major in-licensing transactions in the respiratory, infectious disease, CNS areas. Tony Rosenberg has a BSc (Biological Sciences) University of Leicester, and an M.Sc (Physiology) University of London.

GILEAD

John C. Martin, PhD

Chairman and Chief Executive Officer, Gilead Sciences

Dr. Martin joined Gilead Sciences in 1990 and currently serves as Chairman of the Board of Directors and Chief Executive Officer. H Officer from 1996 through May 2008. Prior to joining Gilead, Dr. Martin held several leadership positions at Bristol-Myers Squibb an

Dr. Martin is a member of the Board of Directors of the California Healthcare Institute and Gen-Probe Incorporated. He also

serves on Board of Trustees.

Dr. Martin previously served as President of the International Society for Antiviral Research, Chairman of the Board of Directors of B Directors of the California Healthcare Institute. He served on the National Institute of Allergy & Infectious Diseases Council, the Bo Industry Organization, the Board of Trustees of the University of Chicago, the Board of Trustees of Golden Gate University and the E University of California School of Global Health. Additionally, Dr. Martin served on the Centers for Disease Control/Health R Committee on HIV and STD Prevention and Treatment and was a member of the Presidential Advisory Council on HIV/AIDS.

Dr. Martin holds a PhD in organic chemistry from the University of Chicago and an MBA in marketing from Golden Gate University. the American Chemical Society and the Gertrude B. Elion Award for Scientific Excellence from the International Society for Antiviral inducted into the National Academy of Engineering of the National Academies.

James M. Denny

Lead Independent Director, Gilead Sciences Board of Directors

Mr. Denny joined Gilead's Board of Directors in 1996 and was appointed Lead Independent Director in May 2008. He served as Chairman from 2001 until May 2008. Previously, he was Chief Financial Officer and Vice Chair at Sears, Roebuck & Co. and held oversight responsibility for many of the company's operations and staff functions.

Mr. Denny is currently Chairman of a privately held healthcare technology company. He is a past Chairman of Northwestern Memorial Hospital and the Northwestern Memorial Foundation and has held directorships at Astra AB, ChoicePoint, GATX Corporation Inc., The Principal Financial Group, The Allstate Corporation, and General Instruments, Inc.

Mr. Denny also served as Executive Vice President and Chief Financial and Planning Officer at G.D. Searle & Co., Chairman of Pearle Health Services, Inc. and Senior Advisor at William Blair Capital Partners, Treasurer at the Firestone Tire & Rubber Co. and associate counsel at Dewey, Ballantine, Bushby, Palmer and Wood in New York and Paris.

Paul Berg, PhD

Nobel Prize Winner, Chemistry

Cahill Professor, Emeritus, Stanford University

Dr. Berg joined Gilead's Board of Directors in 1998. He previously served as Professor and Chairman of the Department of Biochemistry and Director of the Beckman Center for Molecular and Genetic Medicine at the Stanford University School of Medicine.

Dr. Berg is currently a director and scientific advisor to Affymetrix Inc. He is a member of the U.S. National Academy of Sciences.

In 1980, Dr. Berg was awarded the Nobel Prize for his fundamental studies of the biochemistry of nucleic acids. He was awarded the National Medal of Science in 1983.

John F. Cogan, PhD

Senior Fellow, Hoover Institution, Stanford University

Business Proprietary Information – Confidential Treatment Requested

Dr. Cogan joined Gilead's Board of Directors in 2005. He is currently the Leonard and Shirley Ely Senior Fellow at the Hoover Institution and Professor of Public Policy at Stanford University, where his research focuses on U.S. budget and fiscal policy, social security and healthcare.

Dr. Cogan has held a number of positions in the U.S. government, including Assistant Secretary for Policy in the U.S. Department of Labor and Associate Director and Deputy Director in the U.S. Office of Management and Budget (OMB). Dr. Cogan is currently a director of Monaco Coach Corporation, Venture Lending and Leasing Inc., and a trustee of the Charles Schwab Family of Funds.

Etienne F. Davignon Minister of State Chairman, Genfina

Mr. Davignon joined Gilead's Board of Directors in 1990. He is currently Minister of State and serves as Chairman of Recticel, CMB, SN Air Holding and Genfina and as a director of Sofina. Previously, he served as Chairman of Société Générale de Belgique, a diversified financial and industrial company.

Mr. Davignon has served as the European Community's (EC) Commissioner for Industry and International Markets and as the EC's Vice President for Research, Industry and Energy Policies.

Carla A. Hills

Chair and Chief Executive Officer, Hills & Company, International Consultants

Mrs. Hills joined Gilead's Board of Directors in 2007. She is currently the Chair and Chief Executive Officer of Hills & Company, a firm providing advice to U.S. businesses on investment, trade and risk assessment issues outside the United States.

Mrs. Hills serves on the international advisory boards of J.P. Morgan Chase, Rolls Royce and the Coca-Cola Company. She is Chair of the National Committee on U.S.-China Relations and Co-Chair of the Inter-American Dialogue, the Council on Foreign Relations, and the International Advisory Board of the Center for Strategic and International Studies. Mrs. Hills is also a member of the Executive Committee of the Peterson Institute for International Economics and of the Trilateral Commission, and a member of the board of the International Crisis Group.

Mrs. Hills served as U.S. Trade Representative from 1989 to 1993 and was principal advisor on international trade to President George H. W. Bush. Under President Gerald Ford, Mrs. Hills served as Secretary of Housing and Urban Development.

Kevin E. Lofton

President and Chief Executive Officer, Catholic Health Initiatives

Mr. Lofton joined Gilead's Board of Directors in 2009. He is currently the President and Chief Executive Officer of Catholic Health Initiatives, a Denver-based healthcare system operating the full continuum of services from hospitals to home health agencies throughout the nation. He previously served as Chief Executive Officer of two university hospitals, the University of Alabama at Birmingham Hospital and Howard University Hospital in Washington, D.C. In 2007, Mr. Lofton served as Chairman of the Board of the American Hospital Association, the nation's largest hospital trade association.

Mr. Lofton also currently serves on the Board of Directors of the Morehouse School of Medicine, Atlanta, and the Georgia State University J. Mack Robinson College of Business, also in Atlanta.

John W. Madigan

Business Proprietary Information – Confidential Treatment Requested

Retired Chairman and Chief Executive Officer, Tribune Company

Mr. Madigan joined Gilead's Board of Directors in 2005. He is the retired Chairman and Chief Executive Officer of Tribune Company, a director and former chairman of the Robert R. McCormick Foundation and a director at Boise Cascade.

Mr. Madigan is also a former member of the Defense Business Board of the Department of Defense, an advisor to Madison Dearborn Partners and a director and former chairman of The Chicago Counsel on Global Affairs. He serves as a trustee of Northwestern University, Rush University Medical Center and the Paley Center for Media in New York.

Mr. Madigan is a member of the Council on Foreign Relations in New York, a member and former chairman of The Commercial Club of Chicago and a director of the Renaissance Schools Fund.

Gordon E. Moore, PhD

Retired Chairman and Chief Executive Officer, Intel Corporation

Dr. Moore joined Gilead's Board of Directors in 1996, after serving as a member of the company's Business Advisory Board from 1991 until 1996. Prior to joining Gilead's board, Dr. Moore co-founded Intel Corporation and served as Chairman, President and Chief Executive Officer.

Dr. Moore is a former Chairman and present Life Trustee of the California Institute of Technology, a member of the National Academy of Engineering and a Fellow of the Royal Society of Engineering (UK). He is the recipient of the National Medal of Technology and the Presidential Medal of Freedom, the United States' highest civilian honor.

Nicholas G. Moore

Retired Global Chairman, PricewaterhouseCoopers

Mr. Moore joined Gilead's Board of Directors in 2004. He is the retired global Chairman of PricewaterhouseCoopers, a professional services firm formed in 1998 by the merger of Coopers & Lybrand and Price Waterhouse. Prior to the merger, Mr. Moore was elected Chairman and Chief Executive Officer of Coopers & Lybrand (U.S.) in 1994 and Coopers & Lybrand International in 1997.

Mr. Moore is the lead independent director of NetApp Inc. and a director of Bechtel Group, Inc., Wells Fargo, Inc. and one private venture capital-backed technology company. He has also served as Chairman of the Board of Trustees of St. Mary's College of California.

Mr. Moore is an inactive member of the American Institute of CPAs, the California Bar Association and the California and New York Society of CPAs.

Richard J. Whitley, MD

Distinguished Professor, Loeb Scholar Chair in Pediatrics, Professor of Pediatrics, Microbiology,Medicine, and Neurosurgery, University of Alabama at Birmingham Dr. Whitley joined Gilead's Board of Directors in 2008. He is a Distinguished Professor, Loeb Scholar Chair in Pediatrics; Director, Division of Pediatric Infectious Diseases; Vice-Chair, Department of Pediatrics; Senior Scientist, Department of Gene Therapy; Senior Scientist, Cancer Research and Training Center; Associate Director for Clinical Studies, Center for AIDS Research; and Co-Director, Center for Emerging Infections and Emergency Preparedness (CEIEP) for the institution.

Business Proprietary Information – Confidential Treatment Requested

Dr. Whitley has held responsibility for the National Institute of Allergy and Infectious Diseases Collaborative Antiviral Study Group, is a past President of the International Society of Antiviral Research, chairs the Board of Scientific Councilors for the National Center for Infectious Diseases of the U.S. Centers for Disease Control and Prevention and is President of the Board of the Infectious Disease Society of America.

Gayle Edlund Wilson

Chair, Ralph M. Parsons Foundation

Mrs. Wilson joined Gilead's Board of Directors in 2001. Mrs. Wilson served as California's First Lady from 1991 1999. She is Chair of the Ralph M. Parsons Foundation, a non-profit organization that provides grants for higher education, social impact, civic, cultural and health issues.

Mrs. Wilson is also the Chair Emeritus of the Advisory Board of the California State Summer School for Math and Science (COSMOS), a member of the Board of Trustees of the California Institute of Technology (Caltech), as well as the board of the Society for Science and the Public and the Sanford Burnham Institute for Medical Research.

Per Wold-Olsen

Retired President, Human Health Intercontinental Division, Merck & Co., Inc.

Mr. Wold-Olsen joined Gilead's Board of Directors in 2010, after serving as the Chair of the company's Health Policy Advisory Board since 2007. From 2005 to 2006, Mr. Wold-Olsen served as President of the Human Health Intercontinental Division of Merck & Co., Inc., a leading global pharmaceutical company. From 1997 until 2005, he served as President of Human Health Europe, Middle East/Africa and Worldwide Human Health Marketing for Merck.

Mr. Wold-Olsen is currently Chairman of the Board of Lundbeck A/S, a pharmaceutical company focused in the field of central nervous system diseases and disorders. He is also Chairman of the Board of GN Store Nord A/S, a leading Danish-based company that develops and commercializes hearing aids and headsets. Mr. Wold-Olsen also serves on the Board of Directors of Exiqon A/S.

Mr. Wold-Olsen is a member of the Board of the Medicines for Malaria Venture (MMV), a non-profit initiative dedicated to the discovery, development and delivery of new medicines for the treatment of malaria.

Other Desirable Skill Sets

Mike Inouye mentioned several other desirable skills:

"A background in product development/acquisition, especially across various therapeutic areas. We seem to be deep in the HCV pipeline, with good back-up prospects if lead products encounter problems. However, based on the initial look at forecasts, it seems like we may peak in sales rather quickly, which necessitates having a well thought out plan for the next target(s) - that will need to have sufficient commercial potential to maintain EPS growth. Preferably, the candidate would have a scientific or medical background.

"A financial background, with more experience on internal growth management and

Business Proprietary Information – Confidential Treatment Requested

acquisitions versus financing - which leads to someone with experience in revenue environments versus development stage companies. Whether or not we continue to the market on our own or sell the company, someone with relatively recent experiences in both situations could be helpful.

"I liked Herb's comment on having someone with international expertise. While I had responsibility for international business at Gilead, that experience will be dated by the time our products enter those markets. If others support it, having someone in Europe with the above experiences would be really helpful (i.e., current first-hand knowledge)."

Bill Carney:

I'd like to have someone who can help us think strategically about our next product research and development targets. I'm in the process of contacting people in virology at the CDC to get names of thought leaders not employed by the government."

Candidates Mentioned to Date

Several committee members have mentioned potential candidates. Their recommendations are set out below:

Mike Inouye:

"I've given some thought to recruiting a new board member and think that **Mark Perry**, currently the CEO of Aerovance in the San Francisco Bay area may be a good fit for us. I worked for a number of years with, and ultimately for, Mark at Gilead Sciences. His background coming into Gilead was outside counsel at Cooley Godward (sp?), one of the two major law firms advising biotech companies.

"Over the course of his career at Gilead he played numerous senior management roles, including General Counsel, CFO and ultimately EVP of Operations (when I reported to him managing the Commercial group and international subsidiaries). I'm sure he would easily fit the criteria to head the Audit Committee. Other experience and qualities include corporate deal structuring, private/public financing, familiarity with the hepatitis field, good overall general management skills including CEO and board chairman experience.

"His personality would fit well with the current board. No ego, pleasant sense of humor, intelligent and a lot of integrity. Here is the link to his profile on the Aerovance website: http://www.aerovance.com/company/executive-team

Elliot Hahn:

Business Proprietary Information – Confidential Treatment Requested

Melvin Sharoky

"Dr. Sharoky was Insmed's Chairman of the Board from June 15, 2009 to December 1, 2010 and has been a member of the Insmed Board since May 2001.

"He is Director of Par Pharmaceutical Companies, Inc since 2007. From March 2007 to December 2007, he was a consultant with Somerset Pharmaceuticals, a research and development pharmaceutical company which markets Eldepryl® for the treatment of patients with late stage Parkinson's disease and developed EMSAM® for major depressive disorder, which is licensed to Bristol-Myers Squibb. From January 2002 until March 2007, he was President and CEO of Somerset Pharmaceuticals, Inc. He previously served as President of Somerset Pharmaceuticals from July 1995 to June 2001. From June 2001 to January 2002, Dr. Sharoky was retired. From July 1995 through January 1998, Dr. Sharoky was President of Watson Pharmaceuticals, Inc., a leading specialty pharmaceutical company, and from February 1993 to January 1998 he was also President and Chief Executive Officer of its wholly-owned subsidiary, Circa Pharmaceuticals, Inc., which develops, manufactures and markets solid dosage generic pharmaceutical products to wholesale distributors. Dr. Sharoky joined Circa Pharmaceuticals in July 1988 as Medical Director, served as Senior Vice President and Director of Research and Development from April 1991 to August 1992, and as Executive Vice President and Director of Research and Development from August 1992 to January 1993. Prior to this, from February 1986 to June 1988, he was Vice President and Chief Medical Officer of Pharmakinetics Laboratories, Inc.

"Dr. Sharoky received a B.A. in Biology from the University of Maryland in Baltimore County and an M.D. from the University of Maryland School of Medicine."

William D. Pruitt

"Mr. Pruitt is the President of Pruitt Enterprises, LP. From 1980 to 1999, Mr. Pruitt was the Managing Partner for Arthur Andersen LLP's Florida, Caribbean and Venezuela operations. During his career, Mr. Pruitt has served on the board of directors as a Chairman of the audit committee for several companies. Mr. Pruitt has been a board member of The PBSJ Corporation since July 2005, and has been the Chairman of the company's audit committee since 2003. Mr. Pruitt has been a director of MAKO Surgical Corp. since June 2008 and serves as the Chairman of its audit committee. Mr. Pruitt served as Chairman of the audit committee of KOS Pharmaceuticals, Inc., a fully integrated specialty pharmaceutical company until its sale to Abbott Laboratories in 2006. He was also Chairman of the audit committee for Adjoined Consulting, Inc., a full-service management

Business Proprietary Information – Confidential Treatment Requested

consulting firm, until it was merged into Kanbay International, a global consulting firm in February 2006. Mr. Pruitt has a Bachelor of Business Administration from the University of Miami and is a Certified Public Accountant.

"With regard to Bill Pruitt, he was the audit partner for Andrx and currently is on the Board of a joint venture company that Accu-Break Pharmaceuticals has established."

Tamara Baum

"With respect to Tamara Baum, I have not been able to find an updated bio for her but have been told by others that she is still "active". I thought that if she met the criteria we are looking for then Tamara would add diversity to the all male VRUS board.

"Her background (to the extent that I am aware) is as follows:

"Tamara A. Baum was a Director of Andrx beginning in April 2001 and became a Lead Director in March 2003 and a Member of Audit Committee. Since 1999, Ms. Baum was a private investor. Ms. Baum was Managing Director, Global Head of Health Care Finance for Warburg Dillon Read from 1994 through 1999. Ms. Baum was Managing Director, Co-Head Health Care Group for Kidder, Peabody & Co., Incorporated from 1989 through 1994, and the Director of Corporate Finance, Health ... Care for Prudential-Bache Capital Funding from 1983 through 1989."

Herb Conrad

Scott Gottlieb, M.D., a practicing physician, has served in various capacities at the Food and Drug Administration, including senior adviser for medical technology, director of medical policy development, and, most recently, deputy commissioner for medical and scientific affairs. Dr. Gottlieb has also served as a senior policy adviser at the Centers for Medicare & Medicaid Services.

Experience

Attending Physician, Tisch Hospital, New York University Medical Center, 2011-present

Clinical Assistant Professor, New York University Medical Center, 2011-present

Editorial Board Member, Value-Based Cancer Care, 2009-present

Editorial Board Member, Cancer Commons, 2009-present

Deputy Commissioner for Medical and Scientific Affairs, 2005-2007; Director of Medical Policy Development, 2004; Senior Adviser for Medical Technology to the Commissioner, 2003-2004, Food and Drug Administration

Resident Fellow, AEI, 2004-2005

Author, Forbes-Gottlieb Medical Technology Report; Columnist Forbes.com, 2004-2005

Senior Adviser to the Administrator, Centers for Medicare & Medicaid Services, 2004

Staff Writer, British Medical Journal, 1997-2005

Senior Editor, "Pulse," Journal of the American Medical Association, 1996-2001

Past Candidates Considered

Donald J. Hayden, Jr. (considered in 2007). Chairman of the Board, Insmed, Inc.; Lead Independent Director (formerly Executive Chairman), Amicus Therapeutics. He is Senior Advisor at Prospect Venture Partners. Donald J. Hayden, Jr. brings to Amicus the experiences, insights and perspective gained during a highly successful 25-year career in pharmaceuticals and related health care businesses with Bristol-Myers Squibb Company, including 15 years in senior executive positions. Mr. Hayden has a proven track record of innovative strategy development, growing successful products and businesses and building exceptional leadership teams. Mr. Hayden began his careeras a business intern with Bristol-Myers Squibb in 1981. His early career experiences included serving as director of new business development and planning for the U.S. Pharmaceutical Group, as director of marketing for Mead Johnson Pharmaceuticals and as a district sales manager within the BMS oncology division. Since 1991 Mr. Hayden has held a number of senior management positions including vice president and general manager of Mead Johnson Laboratories; president of Oncology and Immunology; senior vice president for Worldwide Franchise Management and Business Development; president of Intercontinental and senior vice president, Business Development, Pharmaceuticals; president of Worldwide Medicines; executive vice president of Strategy, e-business, Investor Relations and Competitive Intelligence; and executive vice president of the Health Care Group. For the past four years, Mr. Hayden served as executive vice president and president, Americas, overseeing two major pharmaceutical units and two healthcare businesses with combined annual sales in excess of $10 billion as well as global pharmaceutical manufacturing.

Mr. Hayden received his undergraduate degree from Harvard University and has an M.B.A. from

Business Proprietary Information – Confidential Treatment Requested

Indiana University.

Carney's notes indicate that Schaefer was to talk to him in 2007, when we identified him as a prospect. Carney's notes from a board discussion April 11, 2006 also asked "is he tainted by scandal?" While successive appointments to other boards suggest that isn't a problem, we should conduct careful due diligence before pursuing him further.

L. John Wilkerson (considered in 2007). John Wilkerson is a Founder, Senior Advisor at Galen Partners, a private equity firm focused on thehealthcare industry, which he co-founded in 1990. His entire career has been focused on healthcare. John was formerly the Chairman of the Wilkerson Group, a leadinghealthcare consultancy, which was acquired byIBM in 1998. Prior to the Wilkerson Group, John was a VicePresident at Smith Barney research, specializing in medical device industry analysis. John began his career as a Group Product Director for Ortho Diagnostics Inc., a Johnson & Johnson company.

John currently serves on the board of Galen portfolio companies Dow Pharmaceutical Sciences Inc., and TPS (d/b/a Advanced Pharmacy Services). He is the immediate past Chairman of Atlantic Health Systems, a New Jersey hospital system. He is a trustee and former President of the Museum of American Folk Art and founder of the E. L. Rose Conservancy.

John earned a Ph.D. from Cornell University, where he currentlyserves on their Council, and earned his B.A. at Utah State University.

David M. Lawrence, M.D., (considered in 2007) retired in 2010 as Chairman and Chief Executive Officer of Kaiser Foundation Health Plan, Inc. and Kaiser Foundation Hospitals after ten years of outstanding service and achievement.

Prior to being named CEO in 1991 and Chairman of the Board in 1992, Dr. Lawrence served KFHP/KFH as vice chairman and chief operating officer (1990-91); senior vice president and regional manager for Northern California (1988-89); vice president and regional manager in Colorado (1985-88); vice president and area medical director for Northwest Permanente in Portland (1981-85). Dr. Lawrencealso served as health officer and director of Human Servicesin Multnomah County, Oregon; on the faculty of Department of Health Services and Director of MEDEX in the School of Public Health and Community Medicine, University of Washington; as advisor to the Ministry of Health of Chile; and as Peace Corps Physician in the Dominican Republic and Washington, D.C.

Dr. Lawrence is a graduate of Amherst College (BA), the University of Kentucky (MD), and the

Business Proprietary Information – Confidential Treatment Requested

University of Washington (MPH). He is Board Certified in General Preventive Medicine (Johns Hopkins and UniversityofWA). He is a member of Alpha Omega Alpha (Medical Honorary Society) and the Institute of Medicine (National Academy of Sciences). He currently serves on the Boards of Agilent Technologies, Pacific Gas and Electric Company, Raffles Medical Group of Singapore, The Rockefeller Foundation, RAND Health Advisory Board, and is a Senior Fellow in Health Policy, Malcolm Wiener Center for Social Policy. He has received numerous honors and is author of the book From Chaos to Care – The Promise of Team-Based Medicine. Dr. Lawrence is nationallyknown for his advocacy improvements in the American health care delivery system. He served as a member of the Institute of Medicine's Committee on Qualityof Health Care in America that produced the landmark report on patient safety, "To Err is Human," and the blueprint for improving America's health care system, "The Quality Chasm."

Carney's notes from 2007 indicate that Steve Burrill described him as "really savvy, a reimbursement expert."

Thomas A. Scully (considered in 2007)is senior counsel in Alston & Bird's Washington, D.C., office, focusing his practice on health care regulatoryand legislative matters, as well as on advising clients on health policy and strategies for health care delivery.

Prior to joining the firm, Mr. Scully was appointed by President George W. Bush and confirmed by the U.S. Senate as the Administrator of the Centers for Medicare & Medicaid Services (CMS), where he served from 2001 to 2004. Formerly known as the Health Care Financing Administration, CMS is responsible for the management of Medicare, Medicaid, SCHIP, and other national health care initiatives. CMS controls more spending than any other federal agency—over $800 billion for fiscal year 2008.

At CMS Mr. Scully was noted for his instrumental role in passing Medicare reform and Medicare Rx legislation, as well as for changing the agency's culture and making the vast agency more open and accountable to the public. Mr. Scully initiated the first public reporting and disclosure for comparative quality among hospitals, nursing homes, home health agencies and dialysis centers.

Tom also initiated a broad public education campaign to improve seniors' awareness and utilization of their Medicare benefits.

Before joining CMS, Tom served as president and chief executive officer of the Federation of American Hospitals from January1995to May 2001. The Federation represents over 1700 privately owned and managed hospitals.

Tom is also a former partner in the Washington, D.C., law firm of Patton Boggs, LLP, where his

Business Proprietary Information – Confidential Treatment Requested

practice focused on regulatoryand legislative work in health care. Before joining the law firm, Tom worked at the White House in the first Bush Administration as deputyassistant to the president and counselor to the director of the Office of Management and Budget (OMB) from 1992-93; and as associate director of OMB for Human Resources, Veterans and Labor from 1989-92. In 1988, Tom worked on the Bush for President campaign. He was an attorney with Akin Gump from 1985-1988 and he worked for U.S. Senator Slade Gorton from 1980-1985.

Tom holds a Juris Doctor degree from Catholic University and a Bachelor's degree from the University of Virginia. In addition, he also serves on the advisory board of the George Bush Presidential Library, Executive Council of the Harvard School of Public Health, and he is a general partner with Welsh, Carson, Anderson & Stowe in New York City.

Carney's notes indicate he was identified byChris Bardon, then with MPM Capital, who said she got his name through Marwood Group and Ted Kennedy, Jr.

Search Firms Investigated in the Past

Here is a matrix on the search firms we looked at in detail in 2007:

Firm Name	Contact	Location of Contact	Fixed Fee?	Success Fee?	Other Inducements	Firm Size	Comments
Egon Zender Int'l	Peter Levin; (Al Prieto)	NYC	yes; approx. $100K + $4K admin. fee & out of pockets	No	200 life science board searches in last 4 years. After consulting us, produces 1 page summaries & discusses with us; then call top targets	350 consultants world wide	from Mike: international firm strong outside U.S. Good reputation in smaller circles w/in U.S. He's worked with them..
Mancino Burfield Edgerton	Gene Mancino	Princeton, NJ	$45,000 + expenses for each search.	No.	If a hired candidate quits within 12 mos., new search for expenses only.	3 principals	Provided references. Life science focus.

Business Proprietary Information – Confidential Treatment Requested

Firm Name	Contact	Location of Contact	Fixed Fee?	Success Fee?	Other Inducements	Firm Size	Comments
Russell Reynolds Associates	Anne Martin Simonds	Washington, DC	$80-$95K, depending on difficulty of search + $6,300 admin. fee and out-of pockets	No	Claims database of 1,000,000 individuals. They meet with candidates after we've reviewed their list and prioritized candidates	300 professionals world wide	fee seems inappropriate for director search; not tailored to our search 70% repeat business
Heidrick & Struggles	Erik Lundh (Graham Galloway)	San Francisco (NYC)	$100,000 (sounds like the fee for one director) + expenses	No	After we indicate a short list, they will interview & do due diligence checks. Time est: 3-6 mos.	Large	Has done more big pharma board searches

Attached are summaries of reference checks on these firms. We used Mancino Burfield Edgerton in our last search, that identified Herb. Schaefer used Russell Reynolds for two executive searches for Pharmasset.

Other firms mentioned included, but not pursued in depth, included:

- The Hennessy Group (Mike Inouye)
- Korn/Ferry International
- Levin and Company

Business Proprietary Information – Confidential Treatment Requested

Questions to Ask Reference: Martin Cleary ____ **Re Firm:**Mancino Burfield Edgerton

1. **What position were you searching for?**

He's used him for multiple searches over the years, both for senior executives and board members.

2. **How long ago?**

3. **Who led your search?**

When you hire Gene Mancino, you really get him. There is no back room doing most of the work. You don't have to worry about the quality of the investigation, or the contacts with candidates. He personally handles all the contacts and logistics. As a result, he handles a smaller number of clients.

4. **Any contact with our lead people?**

5. **Are you a repeat user of this firm?** Yes - multiple times.

6. **Did they produce a broad pool?**

Yes. He knows everyone in the industry. He has personal knowledge of an incredibly large number of execs, and a huge rolodex.

7. **Did candidates meet your specifications & expectations?** He generates an impressive list of candidates.

8. **How was their due diligence?**

Excellent.

9. **Any other comments? Comparison to other search firms you've used?**

He's known Gene Mancino for 25 years. He's been on the board of Cleary's current company.

Business Proprietary Information – Confidential Treatment Requested

He's used big search firms in the past, but switched to Gene. He still uses large firms for specialized searches.

Questions to Ask Reference: Al Altomari_____ **Re Firm:** Mancino Burfield____

1. **What position were you searching for?**

He was placed on a board by Gene Mancino.

2. **How long ago?**

3. **Who led your search?** Gene Mancino

4. **Any contact with our lead people?**

5. **Are you a repeat user of this firm?** Yes.

Why or why not? Mancino is good at follow-up – he'll meet with people he's placed 6 months & a year later to see how the appointment is working out. Macino really knows the high tech market in New Jersey in particular. He knows most of the retired executives in the state. He's a go-getter, and does an outstanding job selling the position.

6. **Did they produce a broad pool?**

7. **Did candidates meet your specifications & expectations?**

8. **How was their due diligence?**

9. **Any other comments? Comparison to other search firms you've used?**

Business Proprietary Information – Confidential Treatment Requested

Questions to Ask Reference: Ron Eastman_____ **Re Firm:** Mancino Burfield_____ By voice mail message

1. **What position were you searching for?**

He has been recruited by Gene Mancino and used his firm to recruit.

2. **How long ago?** - No information

3. **Who led your search?** Gene Mancino

4. **Any contact with our lead people?** - See # 3 above.

5. **Are you a repeat user of this firm?** Didn't say, but see below.

Why or why not? He's known Gene Mancino for many years, and holds him in the highest regard. He has the highest ethical standards, a great work ethic and a great Rolodex. He recruits very well for both board positions and senior executives. He has no reluctance to hire him again, and highly recommends him.

6. **Did they produce a broad pool?**

7. **Did candidates meet your specifications & expectations?**

8. **How was their due diligence?**

9. **Any other comments? Comparison to other search firms you've used?**

Business Proprietary Information – Confidential Treatment Requested

Questions to Ask Reference: Ashleigh Palmer **Re Firm:** Mancino, Burgield & Edgerton

1. **What position were you searching for?**

He was initially placed by Gene Mancino in 1992, and used Gene while working in mid-sized cos. over the years. He used Gene to build a management team for a start-up in 1998-2001. He hasn't used the firm for board searches.

2. **How long ago?**

3. **Who led your search?** Gene Mancino

4. **Any contact with our lead people?** Yes - Gene Mancino

5. **Are you a repeat user of this firm?** See # 1 above. He has used this firm almost exclusively except for some specialized searches Gene's firm doesn't do.

Why or why not? Gene's strength ins in serving companies that are building teams. He is less of a "packager" than the large firms, in that his written presentations will be less pretty. He really understands client needs, and matches candidates to those needs well.

6. **Did they produce a broad pool?** Yes. And he predicts that he would do so at the board level. Gene has been in the business a long time, and has built a huge network of trust and respect. Palmer has been at various industry meetings, where it's clear Gene knows everyone, up to the senior level execs at large pharmas.

7. **Did candidates meet your specifications & expectations?**

8. **How was their due diligence?**

Excellent. He doesn't just present you with a paper report, but puts a personal and emotional component into his searches.

9. **Any other comments? Comparison to other search firms you've used?**

He has an effective partnership. Elaine Burfield is good on the pharma side, and they use each

Business Proprietary Information – Confidential Treatment Requested

other's networks.

Questions to Ask Reference: Patrick Forteaux____ **Re Firm:** Russell Reynolds____

1. **What position were you searching for?** Officers, as he was building a management team.

2. **How long ago?** Over the past 2½ years, in four or five searches.

3. **Who led your search?** Anne Martin Simonds

4. **Any contact with our lead people?** Yes.

5. **Are you a repeat user of this firm?** Yes

Why or why not? She has a good understanding of sales and marketing, and of their business, its needs and its philosophy. She had the right profile for each of their searches.

6. **Did they produce a broad pool?** Yes, and she attracted candidates the company couldn't have attracted on its own. The company is located in Atlanta, which made searches more difficult.

7. **Did candidates meet your specifications & expectations?** Yes.

8. **How was their due diligence?** They gave the company good reports. As always, she sometimes saw different things in candidates than the search committee did.

9. **Any other comments? Comparison to other search firms you've used?** Hasn't used any other large firms.

She also helped on succession planning for the company.

Business Proprietary Information – Confidential Treatment Requested

Questions to Ask Reference: Abhijeet Lele_____ **Re Firm:** Russell Reynolds____

1. **What position were you searching for?** CEO for Medorex. They were delighted with the results.

2. **How long ago?**

3. **Who led your search?** John Archer, who was excellent, and Lele wouldn't have felt that way without Archer's leadership.

4. **Any contact with our lead people?** Yes, Anne Simonds did some candidate interviews and background checks.

5. **Are you a repeat user of this firm?** No.

   Why or why not?

6. **Did they produce a broad pool?** Yes. They know the industry very well, and know the market well.

7. **Did candidates meet your specifications & expectations?** Yes, they brought good candidates to be considered. They know who's out there, and their assessment matched that of the search committee.

8. **How was their due diligence?** Excellent. They did good background checks.

9. **Any other comments? Comparison to other search firms you've used?**

Business Proprietary Information – Confidential Treatment Requested

Questions to Ask Reference: Schaefer Price **Re Firm:** Russell Reynolds

1. **What position were you searching for?**

CFO and Director of Regulatory Affairs

2. **How long ago?** 2005

3.

4. **Who led your search?** Anne Simonds led the search for Loni Da Silva, and someone from the Boston office for Kurt. Anne was the initial contact for both searches.

5. **Any contact with our lead people?** See above.

6. **Are you a repeat user of this firm?** Twice

Why or why not?

7.

8. **Did they produce a broad pool?** Yes, in Loni's case. It was a long search. In Kurt's case we only looked at about three candidates at the outset, and quickly contacted Kurt and negotiated with him.

9. **Did candidates meet your specifications & expectations?**

Yes.

10. **How was their due diligence?** Fair. They missed some things on Kurt that they could have picked up on. With Loni, Pharmasset did its own reference check because we knew people at Roche who gave us good information.

Business Proprietary Information – Confidential Treatment Requested

11. **Any other comments? Comparison to other search firms you've used?**

Anne is good at her job.

Questions to Ask Reference: Jim Mullen, Biogen Idec **Re Firm:** Heidrick & Struggles_

1. **What position were you searching for?** Mullen chairs a search for a director on another board, and is looking at using Heidrick & Struggles for a director search at his own firm.

2. **How long ago?** See above

3. **Who led your search?** Richard Idinger

4. **Any contact with our lead people?** Graham Galloway is also on the team.

5. **Are you a repeat user of this firm?** Yes.

Why or why not? In addition to current discussions with Heidrick & Struggles, he's talking to Egon Zender. I got the distinct impression that he saw a great deal of similarity in the large search firms.

6. **Did they produce a broad pool?** Yes.

7. **Did candidates meet your specifications & expectations?** Yes.

8. **How was their due diligence?** Apparently they met with candidates before presenting them to the search committee. They can take care of verification of education, employment, and, if desired, a criminal background check, which he recommends.

9. **Any other comments? Comparison to other search firms you've used?**

Business Proprietary Information – Confidential Treatment Requested

Questions to Ask Reference: Randy Thurman_____ **Re Firm:** Heidrick & Struggles_

1. **What position were you searching for?** Both directors and executives

2. **How long ago?**

3. **Who led your search?** Graham Galloway

4. **Any contact with our lead people?** See above

5. **Are you a repeat user of this firm?** Yes, many times

Why or why not? Graham Galloway is a pro's pro. As good as they come. He's known Galloway for many years, including at Spencer Stuart, where he was before. He's one of the best. He's professional, ethical, and very aggressive, in terms of pushing his clients to get on with the process, to be certain they get the search completed in a timely manner. He'd be one of the first, if not the first, search person he'd call.

6. **Did they produce a broad pool?** Galloway's reach and network are excellent.

7. **Did candidates meet your specifications & expectations?** Yes.

8. **How was their due diligence?** Very comprehensive. He checked carefully for conflicts.

9. **Any other comments? Comparison to other search firms you've used?**

Business Proprietary Information – Confidential Treatment Requested

Questions to Ask Reference: Robert Chess **Re Firm:** Egon Zender

1. **What position were you searching for?** Two directors

2. **How long ago?**

3. **Who led your search?** Lou Casin, from the Chicago office, who heads up health care.

4. **Any contact with our lead people?** No.

5. **Are you a repeat user of this firm?** Yes.

Why or why not?

There are four or five firms that all do good work. He mentioned Russell Reynolds and Korn Ferry as comparable. When I asked if they all produced the same lists of candidates, he said that probably 60% of the candidates would be obvious, and thus on everyone's list. It's the other 40% where a firm adds value, and that depends on the knowledge and contacts of the person doing the search. Ultimately he didn't suggest that Egon Zender was distinguishable from other firms.

6. **Did they produce a broad pool?** Yes.

7. **Did candidates meet your specifications & expectations?**

8. **How was their due diligence?** They did good background checks, and produced nice books on each candidate. Importantly, they can sell your company to candidates and get you access to them.

9. **Any other comments? Comparison to other search firms you've used?** See #5 above.

Business Proprietary Information – Confidential Treatment Requested

Questions to Ask Reference: Peter Tombros_____ **Re Firm:** Egon Zender_____

1. **What position were you searching for?** Director.

2. **How long ago?**

3. **Who led your search?**

4. **Any contact with our lead people?**

5. **Are you a repeat user of this firm?** Yes.

   Why or why not?

6. **Did they produce a broad pool?** All the large search firms seem to have the same names in their pool, but Egon Zender uncovered a different list of candidates the other search firms hadn't located.

7. **Did candidates meet your specifications & expectations?** Yes. They screened out inappropriate candidates.

8. **How was their due diligence?** Excellent. They were good at follow-up. They moved things along by pushing the process.

9. **Any other comments? Comparison to other search firms you've used?**

They get very high marks. His approach at Alpharma was to interview multiple candidates for a single board position, rather than interview them sequentially. While search firms sometimes resist this approach, he thinks its important.

Business Proprietary Information – Confidential Treatment Requested

Questions to Ask Reference: Susan Wolf_____ **Re Firm:** Egon Zender_____

1. **What position were you searching for?** When she became corporate secretary in 2004 Schering Plough had been engaged in a search for two directors for about a year and a half without success, using one of the big search firms, which wasn't delivering well-qualified candidates, either because of antitrust or other conflicts. Subsequently, with Egon Zender, they have filled a total of four directors' positions.

2. **How long ago?** Since 2004

3. **Who led your search?** Kai Halst

4. **Any contact with our lead people?** Al Prieto assisted Halst, by providing leads to him. Their team system leads to cooperation rather than competition among various search professionals.

5. **Are you a repeat user of this firm?** Yes

Why or why not? She could not be more pleased with Egon Zender's services. They have provided candidates who are a perfect fit.

6. **Did they produce a broad pool?**

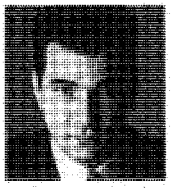
7. **Did candidates meet your specifications & expectations?** They were careful to learn what Schering Plough needed, and to submit candidates who met the specifications. Once in a while she would receive a call saying "I know this candidate doesn't precisely fit your specs, but you might want to look at him anyway." These were generally could calls by the search firm.

8. **How was their due diligence?** They do thorough background checks. They screened very well for conflicts, both in terms of independence, working for competitors (antitrust problems) and not having been tainted by serving on boards of companies that have had law compliance difficulties or scandals.

9. **Any other comments? Comparison to other search firms you've used?** When Schering Plough rejected a candidate, they were thoughtful in probing why a candidate was rejected, both to improve service to Schering Plough and to the candidate.

Business Proprietary Information – Confidential Treatment Requested

EXHIBIT B



Scott Gottlieb, MD

Resident Fellow, American Enterprise Institute;

Former Deputy Commissioner for Medical and Scientific Affairs, U.S. Food and Drug Administration

Scott Gottlieb, MD is a practicing physician and Resident Fellow at the American Enterprise Institute, a nonpartisan, not-for-profit institution dedicated to research and education on issues of government, politics, and economics. A leading expert in health policy, Dr. Gottlieb's work focuses on providing insights into the economic, regulatory and technological forces driving the transformation of healthcare today.

From 2005-2007, Dr. Gottlieb served as FDA Deputy Commissioner and before that, from 2003-2004, as a senior advisor to FDA Commissioner Mark McClellan and as the FDA's Director of Medical Policy Development. He left FDA in the spring of 2004 to work on implementation of the new Medicare Drug Benefit as a Senior Adviser to the Administrator of the Centers for Medicare and Medicaid Services (CMS), where he supported the agency's policy work on quality improvement and coverage and payment decision-making, particularly related to new medical technologies.

Dr. Gottlieb is the author of more than 300 articles that have appeared in leading medical journals as well as The Wall Street Journal, The York Times, USA Today and Forbes Magazine. Dr. Gottlieb has held editorial positions on the British Medical Journal and the Journal of the American Medical Association and appears regularly as a guest commentator on the cable financial news channel CNBC. He is an invited contributor to POLITICO.com. He is an editorial board member of the journal Value Based Cancer Care, the Food and Drug Law Institute's Policy Forum, and is a member of the board of advisers of Cancer Commons. Dr.

Gottlieb also serves as an advisor to the National Comprehensive Cancer Network, and a member of NCCN's working groups.

Previously Dr. Gottlieb worked as a healthcare analyst for the investment bank Alex Brown & Sons and was author of the Forbes-Gottlieb Medical Technology Letter published by Forbes Magazine and the Gilder Biotech Report; published by futurist George Gilder.

A noted authority on pathways to successful development of new medical products, Dr. Gottlieb has testified as an expert witness on health and regulatory matters before the United States Senate and the House of Representatives. The Wall Street Journal identified him as a "forward thinker" on health policy and Congressional Quarterly as an "original thinker with a strong Libertarian streak."

Dr. Gottlieb is a member of the Scientific Advisory Board of the Rutger's Brain Health Institute, a Director of CombiMatrix, a medical diagnostics company focused on cancer; MedaVante, a private company focused on neuroscience drug development; and previously, Bravo Health, a Medicare Advantage plan that was sold to HealthSpring. He is a Venture Partner at the venture capital firm New Enterprise Associates and a Partner to Arcoda Capital, a healthcare investment firm.

Dr. Gottlieb is a Clinical Assistant Professor at the New York University Medical Center and an Attending Physician at NYU's Tisch Hospital in Manhattan. He completed a residency in internal medicine at the Mount Sinai Hospital in New York and is a graduate of the Mount Sinai School of Medicine and of Wesleyan University, in Middletown, Connecticut, where he studied Economics.

COMPENSATION COMMITTEE

TAB

CONFIDENTIAL DRAFT
FOR DISCUSSION PURPOSES ONLY

Minutes of the Regular Meeting of the Compensation Committee of the Board of Directors of Pharmasset, Inc. March 21, 2011

Directors in attendance:
Elliot F. Hahn
Michael K. Inouye
Robert F. Williamson III, Chair

Others in attendance:
From the Company:
P. Schaefer Price, President & CEO
Mark W. Meester, Chief Administrative Officer
Bryce Roberts, Vice President, Senior Counsel and Secretary
Lisa Griffin, Director, Human Resources

The Compensation Committee (the "Committee") of the Board of Directors (the "Board") of Pharmasset, Inc. (the "Company") held a regular meeting, pursuant to notice, on March 21, 2011 via teleconference commencing at 4:00 p.m. EDT. Role was taken and, a quorum being present, Mr. Williamson called the meeting to order. Mr. Roberts acted as secretary for the meeting.

Mr. Williamson reviewed the agenda for the meeting and the materials provided to the members in advance of the meeting. The members reviewed the minutes from the Committee's prior meeting on January 7, 2011; the members had no comments to the minutes and upon motion duly made, seconded and unanimously approved, it was

RESOLVED, that the minutes from the meeting of the Committee dated January 7, 2011 are hereby approved.

The members discussed the report recently issued by Institutional Shareholder Services (ISS), in particular discussions considering whether the Company should develop additional language for the proxy regarding stock compensation. The members asked Company management to further consider and research this issue and report back to the Committee at a later date. Discussions were also had about the ISS comment regarding the treatment in the proxy of the Company's stated plan to move from the 50th to the 75th percentile in the Radford survey data and the members asked Company management to consider clarifying revisions to this language for the 2012 proxy.

Mr. Williamson called the Committee's attention to materials previously provided regarding the Company's progress against its 2011 first half objectives. The members provided comments to and asked questions of Company management, which were addressed by Mr. Price who also presented the Company's 2011 second half objectives. Discussions were also had regarding the need for Company management to begin to accrue year end bonuses at above

Business Proprietary Information – Confidential Treatment Requested

target levels, primarily based on the progress against objectives to date and also due to certain accounting needs in the event year end bonuses are above target. The members agreed that Company management should accrue at a higher rate (greater than 100%) of target for the second half of 2011 and directed the Company to make calculations and work with the Chair regarding how this should be done from an accounting perspective.

Mr. Meester led discussions regarding the performance of the Company's stock in comparison to compensation peer group companies, primarily demonstrating that the Company does not have a comparable in terms of stock performance. Ultimately, this results in a compensation plan that provides on-going stock grants to Company employees and new hire grants that may be inadequate to provide the incentives that the stock component of such plan is designed to provide. The Committee directed Company management to consider the effect on such stock compensation of a stock split in order to provide for greater stock incentive compensation. Company management will report back to the Committee on these topic at its next meeting.

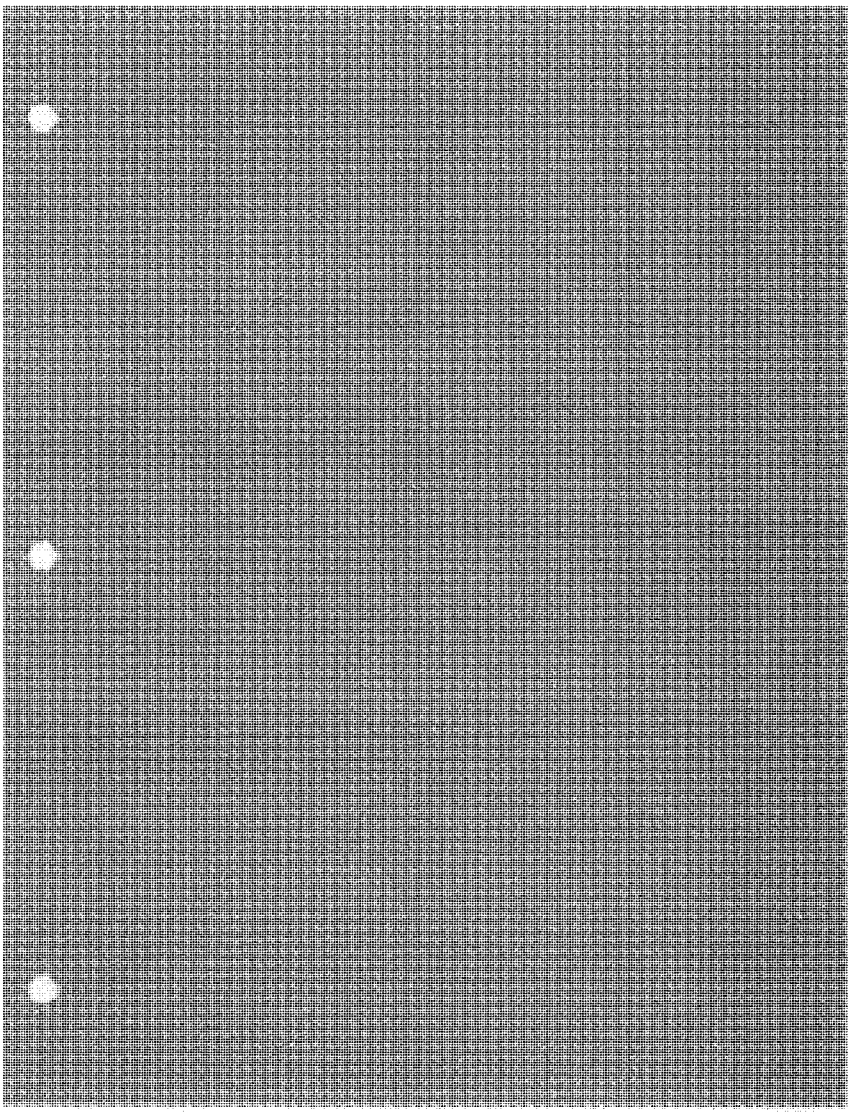
There being no further business, upon motion duly made, seconded and unanimously approved, Mr. Williamson adjourned the meeting at approximately 4:55 p.m. EST.

Respectfully submitted,

_____

Bryce A. Roberts

Business Proprietary Information – Confidential Treatment Requested



303-A College Road East
Princeton NJ 08540 USA
Office 609 613 4100
Fax 609 613 4150
www.pharmasset.com

MEMORANDUM

To: Compensation Committee

From: Mark W. Meester, Lisa Griffin

Date: July 20, 2011

Subject: External compensation consultant and study review

Recommendation

Review Radford's compensation committee support proposal for 2011-12 and make any modifications as deemed appropriate.

Background

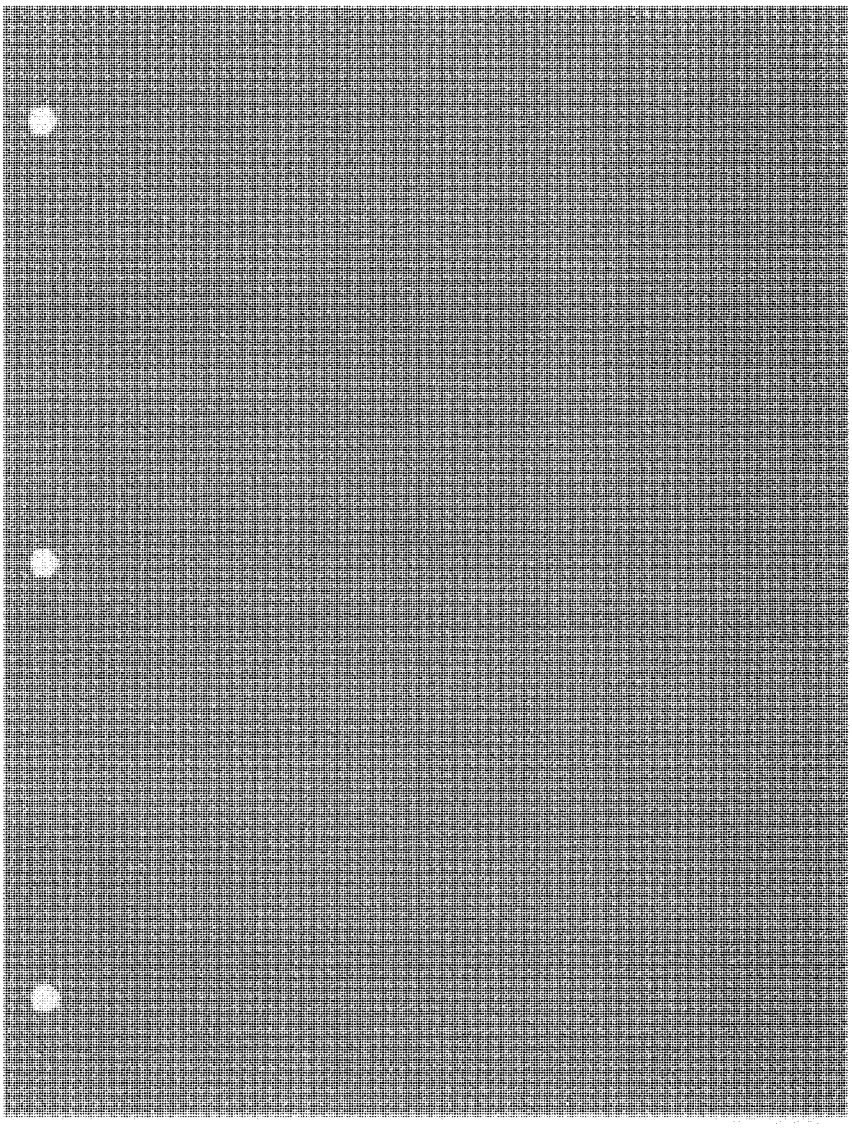
An executive compensation and equity review should be conducted annually based on public company best practices and Radford's recommendations. Currently 95% of Radford's clients perform annual updates. In this current regulatory environment as it relates to compensation, we believe the practice of annual updates for the next few years is justifiable. Pharmasset's executive compensation study was last completed in September 2010.

In addition to best practices, if stock price increases 30% or greater since the prior study was conducted, an updated study should be performed. Radford's FY11 Proposed Equity Guidelines conducted September 2010 were based on Pharmasset's 30-day average share price of approximately $26.00. As Pharmasset's stock price has far exceeded and remained above 30%, this reinforces the decision to perform an annual update for all areas.

Board and committee compensation review should be conducted every two years based on public company best practices and Radford's recommendations. Pharmasset's most recent review was completed September 2009, so we are on target for review during this current cycle.

Radford's cost to conduct the studies, which includes peer group analysis review and approval, will be capped at approximately $65,000.

Refer to Radford's proposal for 2011-12 attached.



Compensation Committee Support:
Radford's Proposed Scope of Work for 2011-12

June 13, 2011

Radford An Aon Consulting Company

PHARMASSET

Contents

- Introduction
- Proposed work plan
- Fee estimates
- Team biographies

Radford

Business Proprietary Information – Confidential Treatment Requested

Business Proprietary Information – Confidential Treatment Requested

Introduction

We are pleased to again have the opportunity to provide compensation consulting support to Pharmasset and serve as advisor to the Compensation Committee for the 2011 - 2012 year.

We believe that Radford continues to be uniquely qualified to advise Pharmasset as a trusted partner for the Compensation Committee. Our efforts over the past several years have been comprehensive.

As a result of rising optimism about Pharmasset's hepatitis drugs, the Company's stock has risen significantly in value over the past year, climbing from the $26-$27 range at the time of last year's compensation assessment to a current trading range around $120 per share. The Company is now subject to considerable more investor scrutiny as a much more valuable and high-profile company. In addition, the significant growth in the company's market capitalization has implications for the go-forward structure of Pharmasset's equity compensation programs.

These factors will be a significant factor in our analysis and recommendations for the coming year. We have considered both the current state of the company and the results of work completed last year in this year's work plan.

We thank you for the opportunity to present the following work plan and look forward to continuing our relationship with Pharmasset.

Sincerely,

Edward J. Speidel, Senior Vice President, Radford

Radford

GS-0004549

Proposed Scope of Work for 2011 - 2012

Radford

Business Proprietary Information – Confidential Treatment Requested

Summary of Historical Scope of Work and Suggested Frequency

On the following pages, we outline the following areas of support Pharmasset has requested over the next several months:

Scope of Previous Years' Work	Associated Work Completed		Recommended Frequency	Part of Proposed FY 2012 Work
	Last Completed	Outcome		
Review Pharmasset's pay philosophy and peer group to ensure appropriateness for 2011-12	July 2010	Current Peer Group approved by Compensation Committee for use during the past year Pharmasset's board has approved a 5-year plan to transition from market 50th to 75th percentile exec comp philosophy	Annually	YES
Assess Executive compensation program and develop recommendations covering salary, bonus and long-term incentive compensation	Sept. 2010	Approved executive cash adjustments and equity grants	Annually	YES
Assess Director compensation program and develop recommendations to ensure alignment with market competitive practices, both cash and equity	Aug. 2009	No changes made to Director s' annual cash or equity compensation; initial appointment grant increased to 40,000 options	Every 2 years	YES

Radford

GS-0004551

Business Proprietary Information – Confidential Treatment Requested

Summary of Historical Scope of Work and Suggested Frequency

On the following pages, we outline the following areas of support Pharmasset has requested over the next several months:

Scope of Previous Years' Work	Associated Work Completed		Recommended Frequency	Part of Proposed FY 2012 Work
	Last Completed	Outcome		
Assess broad-based equity programs below the senior executive level and develop recommendations regarding adjustments to go-forward guidelines	Oct. 2009	Annual and new hire option guidelines established targeting the market 50th percentile	Every 2-3 years	YES
Review market practices with respect to Executive and Director stock ownership guidelines and/or holding requirements, and assess appropriateness/potential structure for implementation at Pharmasset	N/A	N.A	As needed	YES
Review Compensation Disclosure & Analysis and other proxy disclosures to ensure consistency with disclosure requirements and governance best practices	Early 2011	Completed	Annually	YES
Redacted				
ISS Share request Analysis	September 2010 Updated December 2010	Fungible 2M share Request Recommended	As Needed	NOT ANTICIPATED

Radford

GS-0004552

Business Proprietary Information – Confidential Treatment Requested

Peer Group Review and Development

Phase	Work Steps	Outcomes
Review Total Rewards Philosophy	> Conduct meeting with Compensation Committee Chair, CEO and HR to gather intelligence about roles and current programs > Through our initial discussions with the above, we will work to determine: - Labor competitor profile - Program objectives - Desired competitive positioning > Draft pay philosophy statement > Finalize philosophy statement based on feedback received	• Understanding of the organization's strategy, executive roles, responsibilities, and duties, and perceived peers • Understanding of past practices and why current programs exist • Assessment of areas of concern with respect to compensation • Articulate pay philosophy statement for use as cornerstone of program design and future decision making
Review Existing Peer Group	> Review existing peer group and recent Analyst reports > Identify the "pool" of U.S.-based public companies > Target a specific financial/business profile - Industry segment - Revenue levels - Market cap - Business model - Number of employees > Evaluate qualitative factors	• Arrive at core comparator companies approved by the Compensation Committee and Management • Key learnings from past experiences: - Buy-in of all parties (Compensation Committee and Management) is a worth-while investment - Some inputs carry more weight than others - Industry, revenue and headcount are the primary drivers of executive compensation • The process will highlight key issues regarding: - Business Strategy - Compensation Philosophy

Radford

GS-0004553

Business Proprietary Information – Confidential Treatment Requested

Executive Compensation Assessment

Phase	Work Steps	Outcomes
Competitive Pay Analysis	> Understand the roles and responsibilities of executives > Perform analysis of pay practices, using peer group proxies and the Radford Executive Survey > Present competitive total compensation market analysis and recommend 2011 pay structure - Base salary - Short-term incentive opportunities - Total cash compensation - Long-term incentives - Total direct compensation - Pay mix (base / cash incentives /equity) > Summarize findings into report format and review initial findings with Pharmasset internal team	> Detailed analysis of competitive market position for: - Base salary - Annual incentives - Long-term incentives (stock options, restricted stock, etc.) > Understanding of executive compensation competitiveness vis-à-vis the market based upon the desired pay philosophy > Recommendations for potential adjustments and course of action
Executive "Pay for Performance" Analysis	> Determine the relationship between CEO compensation and corporate performance, typically defined as total shareholder return or other relevant metrics of publicly available information - Base salary - Total cash - Total direct compensation > Review Institutional Shareholder Services (ISS) and Glass Lewis pay-for-performance test and other commentary to understand potential risks/outcomes of their assessment	> Understanding of the linkage between pay and performance and the appropriateness of compensation levels and performance levels against the public peer companies > Understand unique or problematic pay practices as identified by ISS and Glass Lewis

Radford

GS-0004554

Business Proprietary Information – Confidential Treatment Requested

Executive Compensation Assessment *(cont'd)*

Phase	Work Steps	Outcomes
Short-term Incentive Program Review	> Based on the approved peer and the peer group profile we will examine the design of incentive plans to determine market competitiveness and reasonableness in support of the business strategy > In addition to targets, we will provide information on metrics, weightings of metrics, funding mechanisms, plan leverage, historical peer growth rates and any other relevant information required to ensure the program is consistent with the company philosophy and broader market practices	> Incentive plan review including assessment of target incentives and plan leverage > Recommendations for any plan design changes including costing
Long-term Incentive Plan Review	> Evaluate executive vested and unvested equity holdings to determine the retention value of the current equity program > Evaluate peer practices regarding long-term incentive vehicles: - Potential value - Prevalence of different vehicles - Plan terms and conditions > Analyze aggregate equity usage, including annual burn rate and total overhang, compared to peer companies	> Assessment of retentive value of current equity holdings particularly > Comprehensive executive equity plan strategy that reflects market best practices and motivates executives to enhance shareholder value > Particular emphasis will be placed on the significant increase in Pharmasset's stock
Update on Market Trends	> Provide the Compensation Committee with an update on current/emerging market trends with respect to executive compensation > Current topics of interest would include - Changes in bonus and equity plan design given current environment - Government influence on executive compensation - Say-on-Pay - Changes to Executive employment agreements - ISS, Glass Lewis and major institutional investors policies	> Committee gains understanding of market and external factors influencing executive pay to assist in decision making process

Radford

GS-0004555

Board of Directors Compensation Assessment

Phase	Work Steps	Outcomes
Board of Director Compensation Competitive Analysis	Examine the Board compensation practices of the peer group (same as for the executives) Perform benchmark analysis of Board compensation practices using the most recent public SEC filings Summarize and present market competitive findings from a number of perspectives: - Annual retainer - Board and committee meeting fees - Chairperson premiums - Initial and annual equity awards - Average Director compensation - Aggregate Board compensation - Market prevalent practices - Equity vesting periods and frequency	Develop an understanding of Board of Director process, roles and governance to align competitive Board cash and equity compensation practices Examine changes in Board compensation practices from past years to understand the most up to date trends - Role-based versus activity based compensation - Term Limits, age limits or rotation policies
Board Compensation Program Design	Place market competitive data into the context of the fast-changing regulatory and investor environment Provide Board compensation strategies and recommendations to consider going forward with emphasis placed upon: - Market practices - ISS -preferred best practices with respect to Board compensation Develop alternatives to cash and equity delivery under both an activity based and role based approach Provide equity recommendations using options, restricted stock or a combination of both Finalize program design based on feedback the Committee	Alternative program designs to deliver cash and equity compensation outlining the advantages and disadvantages of each design alternative

© Radford

Business Proprietary Information – Confidential Treatment Requested

Business Proprietary Information – Confidential Treatment Requested

Employee Equity Guidelines Assessment

Phase	Work Steps	Outcomes
Equity Review	> Radford will evaluate Pharmasset's current equity program and assess it against the market for the broader employee population - Long-term incentive values / numbers / percent of company - Retention analysis as needed to key performers or limited to the executive team - Participation rates for competitiveness - Dilution levels including burn rate and overhang - Vehicle mix (options, RSU's, Performance Shares) - Stock-based compensation expense > Gather best practices and market trends to determine any changes to past practices > These analyses, in conjunction with the compensation philosophy, will provide the framework in which Radford will develop equity guidelines including: - New hire vs. ongoing practices - Eligibility and participation - Targeted burn rate - Equity vehicle usage (e.g., restricted shares vs. options vs. performance equity) - Grant size / Grant frequency / Vesting - Domestic versus International guidelines	> A comprehensive understanding of alternative long-term incentive vehicles and their implications for the company > Summary report of peer stock granting practices in terms of quantity and mix of vehicles > Competitive market based new hire and annual stock guidelines > Full understanding of dilutive impact and expense associated with the program annually > Projections based on staffing plans to ensure the current pool is sufficient or to plan for a shareholder request

Radford

GS-0004557

Business Proprietary Information – Confidential Treatment Requested

Stock Ownership Guidelines

Phase	Work Steps	Outcomes
Ownership Guidelines Review	> Review market practices with respect to the adoption of stock ownership guidelines and holding/retention requirements for Executives and Directors > Design range of potential structures/approaches for Pharmasset - Structure of programs - Magnitude of ownership requirements - Time to comply - Eligible forms of equity ownership - Enforcement mechanisms - Evaluate Executives' and Directors' projected time to be in compliance with any program that is adopted	> Understanding of market prevalence and practices with respect to Executive and Director stock ownership requirements > Final proposal for Pharmasset's consideration in conjunction with the 2011 equity compensation program

Radford

GS-0004558

CD&A Review

Phase	Work Steps	Outcomes
CD&A Review	> Review CD&A against outcomes of Radford modeling, SEC disclosure requirements, and best practice disclosures	> Minimize need for additional responses to SEC comment letters

Radford

Business Proprietary Information – Confidential Treatment Requested

Business Proprietary Information – Confidential Treatment Requested

Radford's Recommended Activity for 2011 and Fee Estimates

Areas of Service/ Support	Timing	Detail of Key Elements/Services	Fee Estimate
Peer Group Review	July 2011	> Review peer group to be used in this year's Executive and Director compensation assessments, and recommend additions/deletions to the existing peer group as appropriate	$3,000 to $5,000
Executive Compensation Assessment	August 2011	> Review and provide recommendations regarding executive compensation based on market competitive cash and equity compensation data	$35,000-$40,000
Board Compensation Assessment	August 2011	> Review and provide recommendations regarding Pharmasset's current non-employee Board of Directors compensation practices based on market competitive data collected from peer group companies	$12,000 - $15,000
Equity Guidelines	Sept 2011	> Review market trends in equity compensation utilization, vehicles, practices > Develop go-forward annual ongoing and new hire guidelines	$12,000 to $15,000
Ownership Guidelines	September 2011	> Review and provide recommendations with respect to the possible implementation of stock ownership guidelines or holding requirements for executives and directors	$8,000 to $10,000
CD&A Review	~Jan. 2012	> Review CD&A and proxy disclosures in context of SEC rules and Radford analysis conclusions – up to 8 hours, with additional hours billed at hourly rates if needed	At hourly rates as needed
Total Fees:			**$70,000 - $85,000**

> In recognition and appreciation of our continuing relationship with Pharmasset, we are willing to cap our fees for all of the above mentioned services at **$65,000**

Radford

GS-0004560

Business Proprietary Information – Confidential Treatment Requested

Radford's Fee Estimates

- For any additional ad-hoc work requested, Radford would provide a fee-estimate ahead of time that would be reviewed and approved by the Compensation Committee and/or management
- Such additional services would be billed at an hourly rate based on the time required to complete the quality deliverable using resources qualified to perform the services, plus out of pocket expenses for travel and document development
  - Hourly billing rates range from $150 to $675 per hour
- We bill on a monthly basis and invoices are due on receipt

Radford

GS-0004561

Business Proprietary Information – Confidential Treatment Requested

Radford's Proposed Engagement Team

Name	Contact Information
Ed Speidel Senior Vice President	espeidel@radford.com (w) 508-628-1552 (m) 617-872-0905
Robert Surdel Assistant Vice President	rsurdel@radford.com (w) 508-628-1551 (m) (617) 835-5656
Ram Kumar Assistant Vice President	rkumar@radford.com (w) 212-441-2007 (m) 917-941-3404

GS-0004562

Business Proprietary Information – Confidential Treatment Requested

Ed Speidel – Senior Vice President

Ed Speidel has nearly 30 years of experience in executive and equity compensation, corporate governance and employee benefits consulting. Prior to joining Radford, Ed was a Principal and National Executive Compensation Practice Leader for Mellon Human Resources & Investor Solutions. Before Mellon, Ed was Managing Director of the Northeast Compensation Practice for PricewaterhouseCoopers.

Ed works with clients which vary in size and complexity in a wide array of industries. He maintains a strong focus on technology and life science community with particular emphasis in e-commerce, semiconductors, software and biotechnology firms.

He has written and spoken frequently on emerging issues in executive and equity compensation. Ed has a JD from the New England School of Law, an LLM in Taxation from Boston University Law School, an MBA from Lehigh University, and a BA in economics/government from the University of Delaware. In addition, he is a Certified Compensation Professional, Certified Benefits Professional, Certified Equity Professional and has a Certificate in Human Resource Management. He is based in Boston.

GS-0004563

Business Proprietary Information – Confidential Treatment Requested

Robert Surdel – Assistant Vice President

Robert Surdel (AVP) has more than 10 years of compensation consulting experience on a broad range of human resources issues, including short- and long-term incentive design, executive compensation and sales effectiveness. In his current role, Rob consults with global organizations at various stages of development and maturity, with a focus on high technology and life sciences, as well as across general industry. Rob adds significant project value through his innovative quantitative analysis and extensive project management experience.

Prior to joining Radford, Rob held consulting positions at Pearl Meyer & Partners, Buck Consultants (formerly Mellon's HR & Investor Solutions) and iQuantic.

Rob earned a bachelor of arts in economics and environment sciences from Bowdoin College, graduating cum laude. He is currently pursuing a master of business administration from the Franklin W. Olin Graduate School of Business at Babson College. Rob speaks on various executive compensation topics and holds designations from WorldatWork as a Certified Compensation Professional (CCP) and Global Remuneration Professional (GRP). He is periodically published in industry journals. Rob is based in Boston.

Rob Surdel
Assistant Vice President
508-628-1551
rsurdel@radford.com

Radford

GS-0004564

Business Proprietary Information – Confidential Treatment Requested

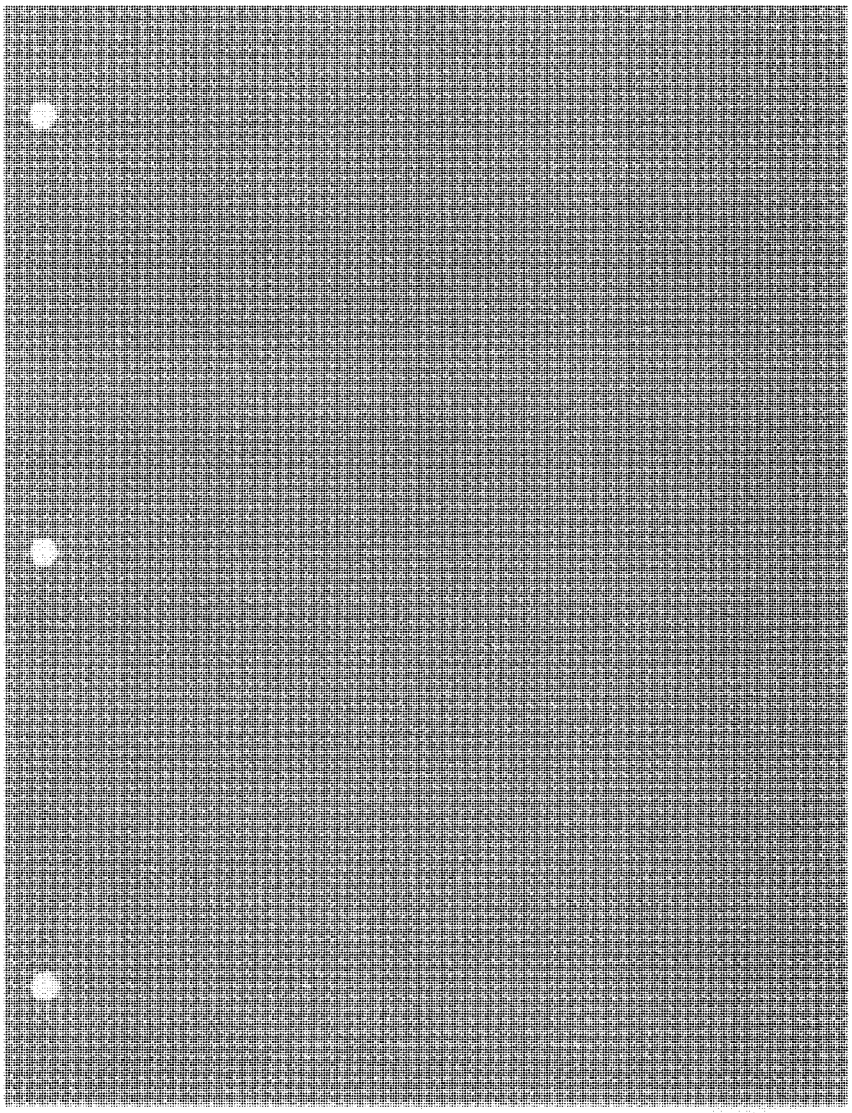
Ram Kumar – Assistant Vice President

Ram Kumar has over 10 years of experience in the governance and compensation industry. He is primarily focused on helping companies evaluate and resolve compensation plan design issues in the context of emerging standards of corporate governance and the perspectives of investors and proxy advisors.

Prior to joining Radford, Ram was an assistant vice president in the executive compensation practice of Aon Consulting. Prior to Aon, Ram worked in the corporate governance industry for more than six years, including four years at the prominent proxy advisory firm, Institutional Shareholder Services (ISS). While at ISS, he led the US research group charged with analyzing all public US companies and making proxy recommendations to institutional investors.

Ram earned a bachelor of arts from Johns Hopkins University. He is based in New York.

GS-0004565



PHARMASSET

WHERE INNOVATION IS VIRAL

303-A College Road East
Princeton NJ 08540 USA
Office 609 613 4100
Fax 609 613 4150
www.pharmasset.com

MEMORANDUM

To: Compensation Committee

From: Mark W. Meester, Lisa Griffin

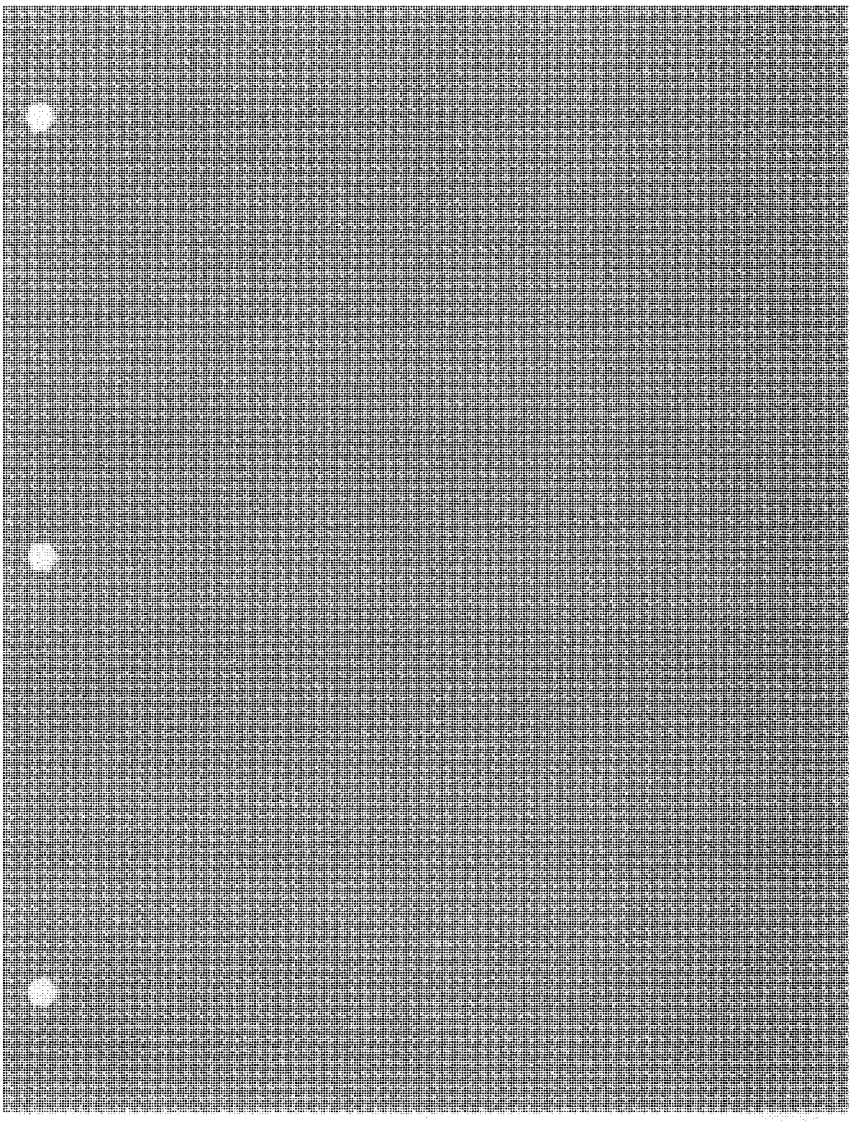
Date: July 20, 2011

Subject: Compensation and benefits program update

During fiscal year 2012 we have recruited candidates for various positions throughout the organization and have hired approximately 17 employees. Human Resources is continuously assessing the competitiveness of our benefits and compensation programs through various means, including the feedback from candidates, recruiters and employees. In order to retain and attract top talent we need maintain competitiveness in these key areas.

Our overall benefits program continues to be well received by current employees and candidates, including those coming from large pharma. However, the one area where we are not as competitive is with the 401(k) match. Our current match, which was put in place back in 2006 when we upgraded the Plan, is .50 on the dollar up to 6% of pay, with an annual maximum of $3,500. According to Radford, the industry trend for biotech and pharmaceutical companies is currently .50 on the dollar up to 6% of pay with no annual maximum. During our recruiting process, Human Resources has found that a number of companies have matches that are higher than .50 on the dollar and a few of the larger pharmaceutical companies that have recently ended their pension program have increased their match to dollar for dollar up to a certain percentage of pay, again with no annual maximum. We are reviewing this further and plan to make a change to our match calculation for the upcoming calendar year in order to remain competitive.

Our compensation program, for positions below the executive level, has also been quite competitive overall and for the most part have been able to attract top talent for our open positions. However, one of the areas where we are not as competitive, and that we are currently evaluating, is the bonus target incentives for positions below CEO direct reports. We are in the process of reviewing and evaluating industry compensation data, and will make changes as appropriate, based on the same principles that have been reviewed and approved for Schaefer's direct reports.



PHARMASSET, INC.

PROPOSED RESOLUTIONS OF THE COMPENSATION COMMITTEE OF THE BOARD OF DIRECTORS

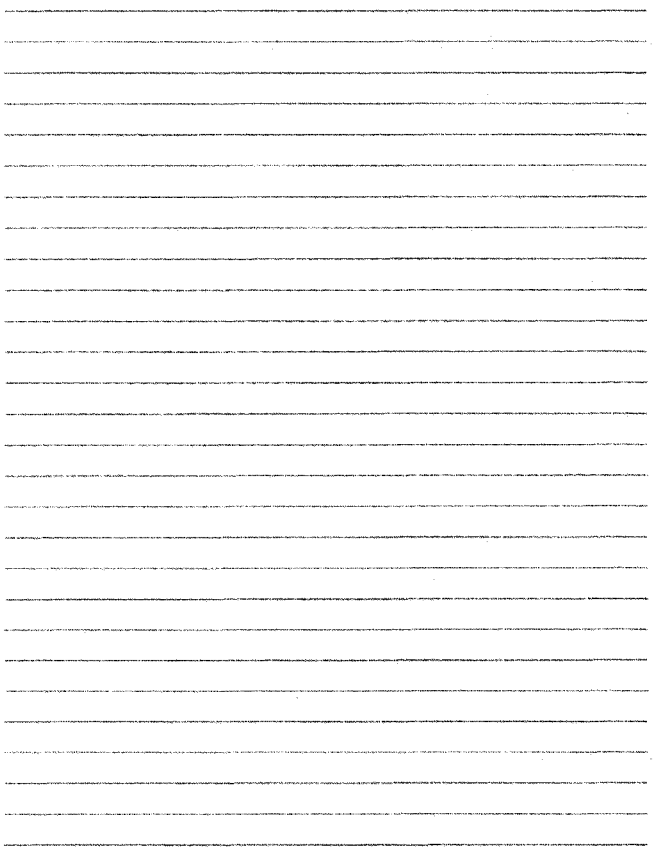
WHEREAS, the Board of Directors (the "***Board***") of Pharmasset, Inc. (the "***Company***") is contemplating a two-for-one stock split in the form of a stock dividend of one share of the Company's common stock, par value $0.001 per share (the "***Common Stock***"), for each share of Common Stock outstanding; and

WHEREAS, the Company's 1998 Stock Plan, as amended, (the "***Plan***") provides that such actions as are necessary shall be taken to make appropriate equitable adjustments in order to preserve the value of outstanding and future awards made pursuant to the Plan in the event of certain corporate actions such as the actions contemplated by these resolutions.

NOW, THEREFORE, BE IT RESOLVED, that the Compensation Committee of the Board hereby recommends that the Board take such action to authorize or make appropriate equitable adjustments in order to preserve the value of outstanding awards under the Plan, including adjustments to: (i) the number of shares and the option price per share specified in any stock option agreement with respect to any unpurchased shares, and (ii) the number of and exercise price for stock appreciation rights.

RISK MANAGEMENT

TAB



FINANCE

TAB

PHARMASSET

WHERE INNOVATION IS VIRAL

MEMORANDUM

To: Board of Directors

From: Kurt Leutzinger

Date: July 14, 2011

Subject: Stock split

Recommendation: Effective August 31, 2011, execute a 2 for 1 split of all our shares outstanding as of July xx, 2011 (the record date) using a stock dividend.

Discussion: Our stock price has reached a level where almost all companies execute a stock split. As every rationale investor knows, a stock split does not change the market value of the company or the investors' position in the company's stock. However, many investors have an irrational preference for more shares of lower priced stock. We have been hearing from such investors that they would buy more of our stock if we split it. Since we want as many investors as possible buying our stock, we should split it to increase support from these investors. Irrationality is a real force in the stock market, a fact proven by Professor Daniel Kahneman, for which he won the Nobel Prize in Economics. Among his many contributions, he discovered the phenomenon of "anchoring", in which an irrational consensus develops among investors that a particular price is the "right" price for a stock. Once such an anchor price has been established for a stock, a split can harness the force of irrationality to driving the stock back toward its anchor price. Pharmasset's price has been above $100 per share for most of the last three months, long enough to have become anchored at that level in the minds of the many investors. Splitting on August 31, just before a period of data releases that are expected to significantly increase our fundamental value, could greatly reduce resistance to a rise in our stock price that fully captures that increase in fundamental value. Instead of being held back by irrationality, we can make it work for us.

Our assumptions are supported by a recent analysis conducted by Citibank on a number of healthcare companies with market capitalizations of between $2.0 billion and $10.0 billion (see Figure 1). In each case the companies on average maintained a stock price above $83 for three months prior to a two-for-one stock split. While their short term stock performance was improved, longer term stock performance varied between the companies. We anticipate that based on the timing of our proposed stock split, there will be a number of medium term opportunities to update investors and support the stock.

Business Proprietary Information – Confidential Treatment Requested

PHARMASSET

WHERE INNOVATION IS VIRAL

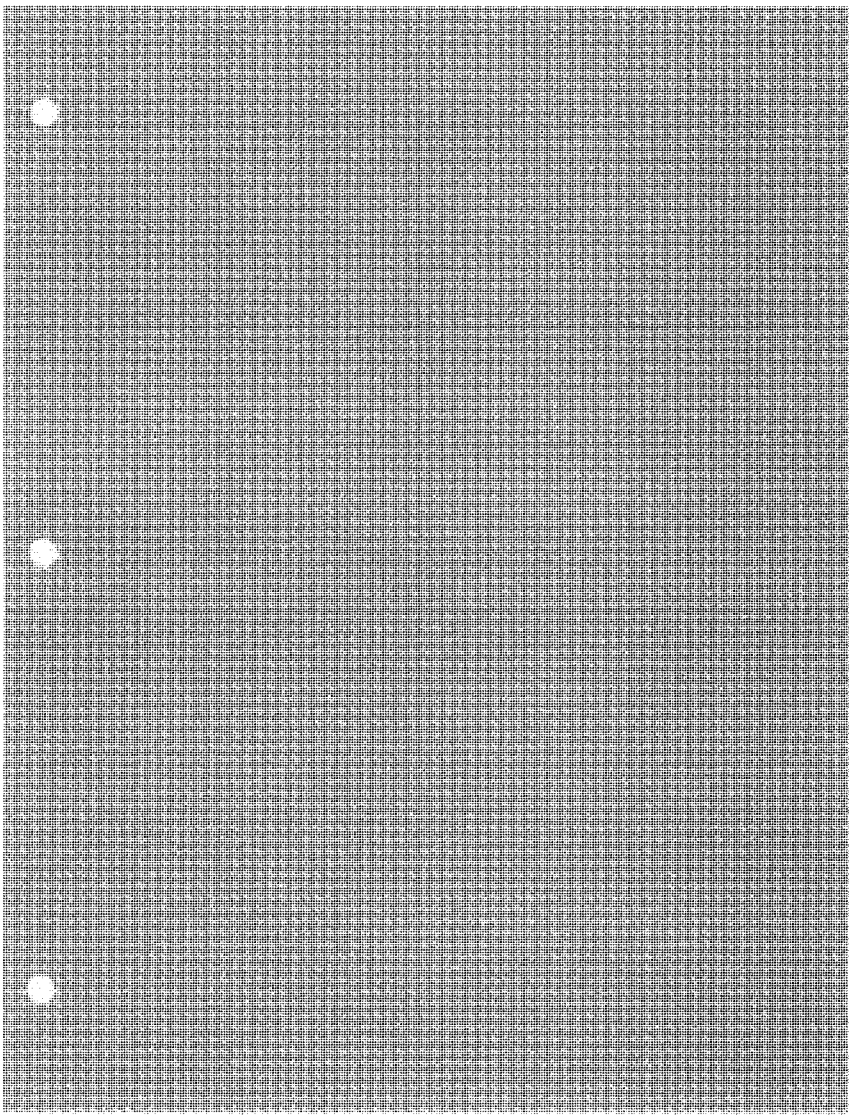
303-A College Road East
Princeton NJ 08540 USA
Office 609 613 4100
Fax 609 613 4150
www.pharmasset.com

Figure 1

Relevant Healthcare Stock Split Precedent Transaction

Precedent Stock Splits
Healthcare Issuers With Market Cap Between $2BN - $10BN

																First Announcement				Effective			



PHARMASSET, INC.

PROPOSED RESOLUTIONS OF THE BOARD OF DIRECTORS

WHEREAS, the Board of Directors (the "***Board***") of Pharmasset, Inc. (the "***Company***") has reviewed and considered the Company's existing capital structure; and

WHEREAS, the Board has determined that it is in the best interests of the Company's stockholders to declare a two-for-one stock split in the form of a stock dividend of one share of the Company's common stock, par value $0.001 per share (the "***Common Stock***"), for each share of Common Stock outstanding on the Record Date (as defined below); and

WHEREAS, the Company's 1998 Stock Plan, as amended (the "***1998 Plan***"), and 2007 Equity Incentive Plan, as amended (the "***2007 Plan***", and together with the 1998 Plan, the "***Plans***") provide, and the Compensation Committee of the Board recommends, that such actions as are necessary shall be taken to make appropriate equitable adjustments in order to preserve the value of outstanding and future awards made pursuant to the Plans in the event of certain corporate actions such as the actions contemplated by these resolutions.

NOW, THEREFORE, BE IT RESOLVED, that the Board hereby declares a two-for-one stock split of the Common Stock in the form of a dividend of one share of Common Stock for each outstanding share of Common Stock outstanding at the close of business on August 22, 2011 (the "***Record Date***"); and be it further

RESOLVED, the Chief Executive Officer and Chief Financial Officer of the Company (each an "***Authorized Officer,***" and, collectively, the "***Authorized Officers***") be, and each of them hereby is, authorized, empowered and directed to take all actions necessary such that on August 31, 2011 each shareholder of the Company as of the Record Date shall be issued one additional share of Common Stock for each share of Common Stock owned of record by such shareholder as of the Record Date; and be it further

RESOLVED, that as of the Record Date (i) the number of shares of Common Stock subject to outstanding awards made pursuant to the Plans, (ii) the number of shares of Common Stock reserved for future issuance pursuant to the Plans, (iii) the number of shares of Common Stock subject to the limitation in Section 5.2(a)(i) of the 2007 Plan and (iv) the number of shares of Common Stock that shall be issued pursuant to Section 11.1(a) of the 2007 Plan following the date hereof, are hereby doubled, and that the Authorized Officers are hereby authorized, empowered and directed, in the name and on behalf of the Company, to take any and all actions necessary or required to implement this resolution; and be it further

RESOLVED, that as of the Record Date the purchase price of outstanding options and stock appreciation rights is hereby reduced by 50%, and that the Authorized Officers are hereby authorized, empowered and directed, in the name and on behalf of the Company, to take any and all actions necessary or required to implement this resolution; and be it further

RESOLVED, that any Common Stock issued pursuant to these resolutions, upon issuance and payment therefor, shall be validly issued, fully paid and nonassessable, and upon such issuance, the sum of $0.001 per share of Common Stock shall be credited to the Company's stated capital account; and be it further

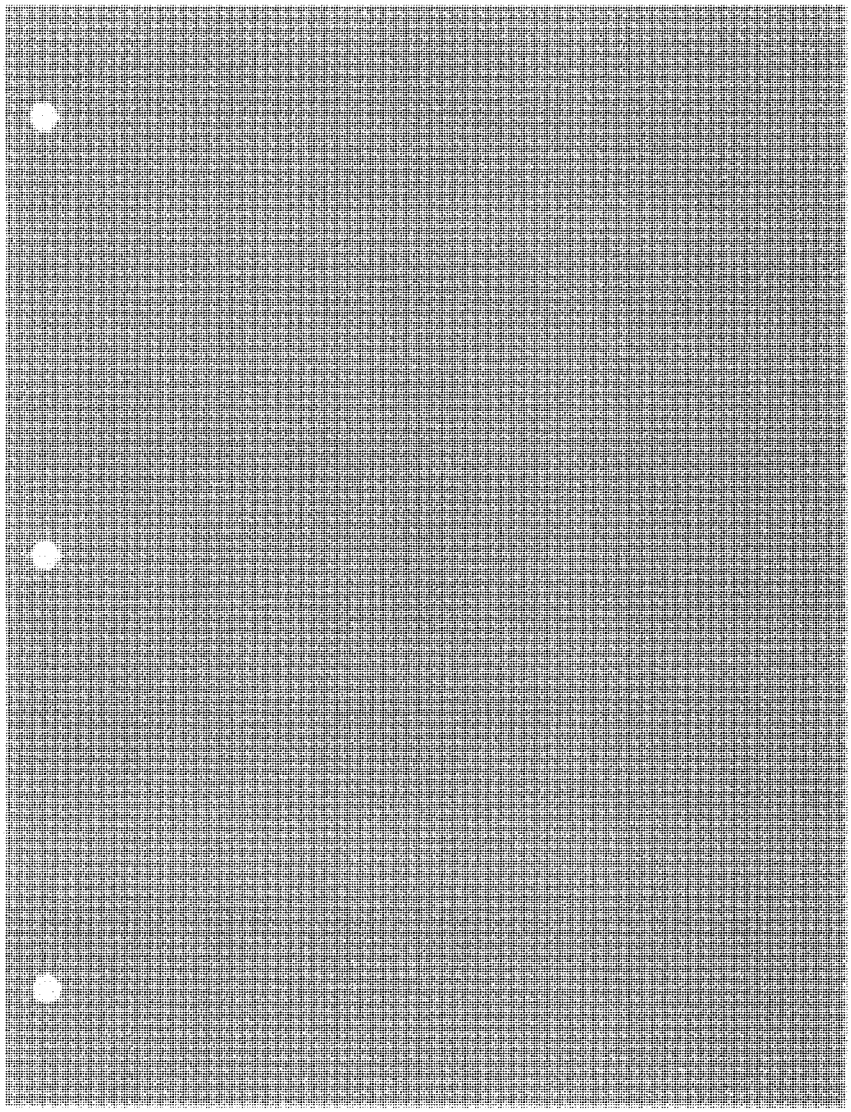
#14527337 v3

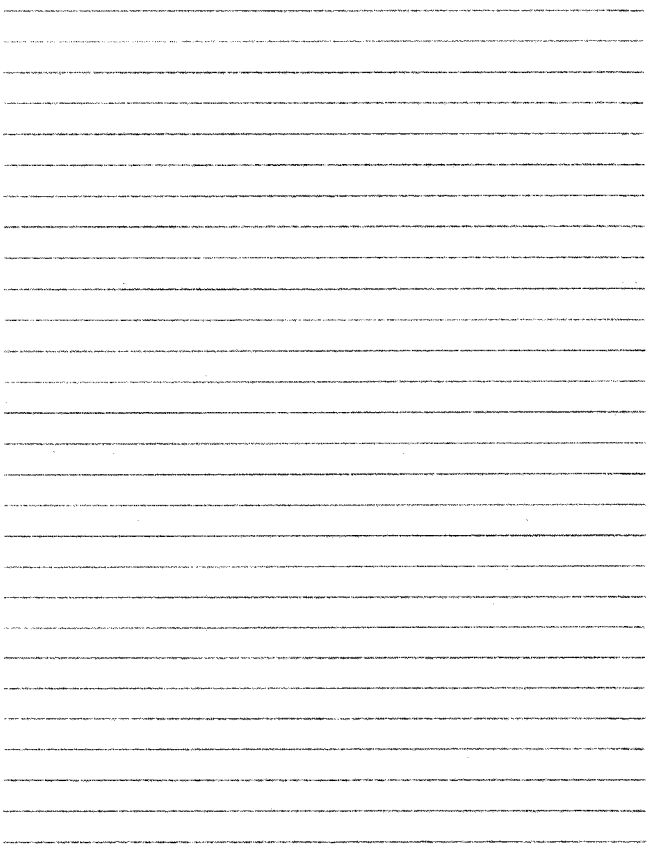
RESOLVED, that the Authorized Officers are, and each of them hereby is, authorized, empowered and directed, on behalf of the Company, to provide any and all required notices and documents on behalf of the Company to list any Common Stock issued pursuant to these resolutions on The NASDAQ Stock Market, LLC or any other market on which the Common Stock is listed (the "***Exchange***"); and be it further

Resolved, that each Authorized Officer be, and each of them hereby is, authorized, in the name and on behalf of the Company, to perform all such acts and execute, deliver and/or file all such agreements, notifications, documents and instruments (including, without limitation, any filings or notifications required by the rules and regulations of the Securities and Exchange Commission or the rules of any Exchange on which the Common Stock is listed), make any public announcements and pay any and all fees and expenses in connection therewith, as such Authorized Officer shall deem necessary, desirable or appropriate to effectuate the intent and purposes of the foregoing resolutions, including, without limitation, the payment of legal, accounting, printing and regulatory fees, such determination to be conclusively evidenced by the performance of such acts, the execution delivery or filing of such agreements, documents and instruments and the payment of any such fees; and be it further

Resolved, that all actions previously taken by any director, officer, employee or agent of the Company in connection with or related to the matters set forth in or reasonably contemplated or implied by the foregoing resolutions be, and each of them hereby is, adopted, ratified, confirmed and approved in all respects as acts and deeds of the Company.

Business Proprietary Information – Confidential Treatment Requested GS-0004577





CLINICAL DEVELOPMENT

TAB

PHARMASSET

WHERE INNOVATION IS VIRAL

303-A College Road East
Princeton NJ 08540 USA
Office 609 613 4100
Fax 609 613 4150
www.pharmasset.com

MEMORANDUM

TO: Board of Directors

FROM: Mike Rogers and Kurt Leutzinger

DATE: July 14, 2011

RE: Request for Funds to Accelerate the PSI-7977 Phase 3 Genotype 2/3 Program

---

Recommendation

Management recommends the board authorize the remainder of the full multi-year project budget for accelerating and completing the phase 3 genotype 2/3 development of PSI-7977. We have estimated this in the past and reported it to the board in our multi-year projections, but since we will be signing multi-year contracts with a CRO and others, it is good internal control practice to approve the project as a whole rather than in pieces as they fall into future fiscal period budgets. The proposed accelerated plan will cost $87.3 million in addition to the $7.9 million (including API, bioequivalence, and stability batches) that has been previously approved, $1.9 million of which would be spent in FY 2011, $40.0 million in FY 2012, $34.7 million in FY 2013, and the remaining $10.7 million in FY 2014. This would increase the total authorized expenditures for the PSI-7977 phase 3 studies (including API and a required relative bioequivalence study) to $95.2 million. We are also requesting another headcount in accounting to support the increased administrative work associated with the phase 3 contracts and payment processing. The annualized cost for this headcount will be approximately $124K.

Background

At the last board meeting, we prepared a paper on our phase 3 development plan for PSI-7977. This paper described the market opportunity for a genotype 2/3 indication, the competitive landscape and possible plans for phase 3 with estimates of the financial impact. Please review this paper to re-familiarize yourself with these points. Previously, we described two issues which could prevent us from pursuing a genotype 2/3 path; one was data and the other was lack of regulatory support. In this paper, we provide you with positive data emanating from our genotype 2/3 studies which we believe fully support our plans. In addition, we will provide you with the detailed plans for our phase 3 studies. At present, we are preparing for our end of phase 2 meeting with the FDA which is scheduled for August 18.

Introduction

After an assessment of regulatory paths to approval, clinical risks and commercial potential, we propose to pursue an initial indication for PSI-7977 in combination with PEG/RBV for the treatment of patients infected with genotype 2 or 3. This would ideally be followed by a supplemental application for genotype 1 using an interferon-free regimen. The purpose of this memo is to request funds for the genotype 2/3 program and describe details of the program.

We have identified a dose, duration and regimen of PSI-7977 that delivers a high degree of sustained virologic response (SVR) in patients infected with HCV genotype 2 or 3. In fact, to date, the SVR at 12 weeks post-therapy (SVR12) is 100% in evaluable patients in two studies. The proposed dose and duration of 400 mg once per day for 12 weeks is supported by a robust clinical pharmacology program, efficacy from the PROTON and ELECTRON studies and safety from ~500 patients from the PROTON, ELECTRON and ATOMIC studies.

Our assessment is that there are three near-term Phase 3 approaches for approval of PSI-7977:

1) Studies in patients infected with genotype 1 demonstrating non-inferiority of a regimen of PSI-7977 given for 12 weeks with PEG/RBV followed by an additional 12 weeks of PEG/RBV ("12 + 12") to the new SoC regimen of a protease inhibitor in combination with PEG/RBV. This approach has been piloted in the PROTON study. Preliminary SVR data from the PROTON study suggests an SVR12 response rate in the 90-95% range. Although this is a positive and competitive result, the regimen is not ideal commercially because it requires six months of interferon, a significant barrier to use. This approach allows for an NDA submission date in the second quarter of 2015.
2) Wait for the results of the ATOMIC study which is assessing the more commercially attractive regimen of PSI-7977 given for 12 weeks with PEG/RBV and then stopping all treatment ("12 + 0"). Unfortunately, the results from ATOMIC will not be available for at least a year and we cannot be certain of the results at this point in time. It should also be noted that the results of this 12 + 0 interferon-containing regimen will be available in roughly the same timeframe as our study of interferon-free regimens (the QUANTUM study). If the QUANTUM results are comparable to the results in the assessment of interferon-containing regimens, we would choose to pursue an interferon-free regulatory strategy. Thus, we think it is prudent to wait for data from ATOMIC (interferon-containing) and QUANTUM (interferon-free) before pursuing an indication for genotype 1. This approach allows for an NDA submission date in the third quarter of 2015.
3) Studies in patients infected with genotype 2 or 3 using the 12 + 0 regimen which has been shown to be safe, well-tolerated and highly effective in two pilot studies. Our assessment is that we currently have an adequate data package to support progression into a genotype 2/3 Phase 3 program. Studies in this patient population are inherently shorter than in the genotype 1 population because the SoC treatment regimen that is used as a control in Phase 3 studies is 24 weeks for genotype 2/3 and 48 weeks in genotype 1. This approach allows for an NDA submission date in the fourth quarter of 2013.

Given that activity against genotypes 2 and 3 is a key differentiator for PSI-7977 and our internal assessment is that this is the fastest path to market, considerable value could be created if an early approval and indication for the treatment of HCV genotypes 2 and 3 is achieved. Once approved, a

Business Proprietary Information – Confidential Treatment Requested GS-0004582

12 week regimen of PSI-7977 + PEG/RBV would become the new "SoC" for genotypes 2 and 3. This would create a situation that would require all competitive compounds to conduct non-inferiority studies versus our 12 + 0 regimen. This would be a very high hurdle for our competition thus effectively blocking them from this market niche. Although genotypes 2 and 3 are not the predominate genotypes in the US, their prevalence in the global market is significant.

Data to Support Progression into Phase 3

Efficacy data from two studies, PROTON and ELECTRON, will be used to justify progression into Phase 3 for HCV genotypes 2 and 3:

PROTON

The PROTON study has two parts: Part A is designed to assess the safety and efficacy of two doses of PSI-7977, 200 and 400 mg, in treatment naïve patients infected with genotype 1 treated for 12 weeks with PEG/RBV, followed by 12 additional weeks of PEG/RBV (12+12); and Part B assesses 12 weeks of 400 mg of PSI-7977 with PEG/RBV (12+0) in 25 treatment naïve patients infected with genotype 2 or 3. Safety data from both parts and efficacy data from Part B will be used to support our phase 3 proposal. The study schematic is presented in the Appendix.

Of the 25 patients enrolled in Part B, one was lost to follow-up after Day 1 of the study. Thus, there were 24 evaluable patients at the SVR24 assessment and all had undetectable HCV levels from Week 4 on, yielding an SVR24 of 100% (Table 1).

Table 1: Antiviral Responses in the PROTON study

	Week 2	Week 4	Week 12	*SVR12*	*SVR24*
n (evaluable)	**24**	**24**	**24**	**24**	**24**
HCV RNA < LOD	21	24	24	24	24
% Response	88%	100%	100%	100%	100%
Lost to follow-up	1	1	1	1	1
% Response (ITT)	84%	96%	96%	96%	96%

There were no SAEs or AEs leading to any premature treatment discontinuations in this patient cohort and the PSI-7977 regimen was generally safe and well-tolerated.

ELECTRON

The objective of the ELECTRON study was to assess how much, if any, interferon is required in a 12 week regimen of PSI-7977 + RBV used to treat patients infected with HCV genotype 2 or 3. Thus, there were four arms with 0, 4, 8, and 12 weeks of interferon in combination with 12 weeks of PSI-7977 and ribavirin. The study schematic is presented in the Appendix.

Business Proprietary Information – Confidential Treatment Requested GS-0004583

Preliminary results from the ELECTRON study are presented in Table 2. In Arm A (no interferon) three of ten patients have reached the SVR12 assessment and all have undetectable levels of virus. In Arm B (4 weeks of interferon), three of nine patients have reached the SVR12 assessment and all have undetectable levels of virus. In Arm C (8 weeks of interferon), three of ten patients have reached the SVR12 assessment and all have undetectable levels of virus. Finally, in Arm D (12 weeks of interferon), four of eleven patients have reached the SVR12 assessment and all have undetectable levels of virus. Thus, all evaluable patients that have reached the week 12 post-therapy assessment have had undetectable levels of virus.

Table 2: Preliminary Results from the ELECTRON study

ARM	End of Treatment	SVR4	SVR12
A: 12 weeks of 7977/RBV (no IFN)	10/10 undetectable	5/5 undetectable 5 pending	3/3 undetectable 7 pending
B: 12 weeks of 7977/RBV w/ 4 weeks of IFN	9/9 undetectable	6/6 undetectable 3 pending	3/3 undetectable 6 pending
C: 12 weeks of 7977/RBV w/ 8 weeks of IFN	7/7 undetectable 3 pending	6/6 undetectable 4 pending	3/3 undetectable 7 pending
D: 12 weeks of 7977/RBV w/ 12 weeks of IFN	8/8 undetectable 3 pending	7/7 undetectable 4 pending	4/4 undetectable 7 pending

There were no SAEs or AEs leading to discontinuation in this study and the PSI-7977 regimen was generally safe and well-tolerated. Also, there were no Grade 3/4 AEs or Grade 3/4 laboratory abnormalities in the interferon-free arm (Arm A) vs eight Grade 3/4 laboratory abnormalities (neutropenia) in the 12 week interferon-containing arm (Arm D).

Proposed Plan and Design Considerations

Our desired indication for PSI-7977 is the treatment of chronic infection with HCV genotype 2 or 3. PSI-7977 would be used in combination with PEG/RBV in treatment naïve patients and in combination with ribavirin only for the treatment of patients infected with genotype 2 or 3 who cannot take interferon. To support an approval for this indication we propose to conduct three studies as follows: Two would be in treatment naïve patients and a third would be in patients who cannot take interferon. The two treatment naïve studies would be identical in design and would demonstrate that the safety and efficacy of 12 weeks of PSI-7977 in combination with PEG/RBV is superior to a control regimen of 24 weeks of PEG/RBV (Design 1). A third regimen in these studies would be exploratory and would test an interferon-free regimen of 12 weeks of PSI-7977 in combination with ribavirin only. The third study would demonstrate the superiority of an interferon-free regimen of 12 weeks of PSI-7977 in combination with ribavirin to a placebo control in patients who cannot take interferon (Design 2). The placebo control is justified because there is no treatment option for these patients. We think only one study will be required in this population because of the urgent medical need for an effective treatment for patients who cannot take interferon. However, this will be a point of negotiation for the FDA.

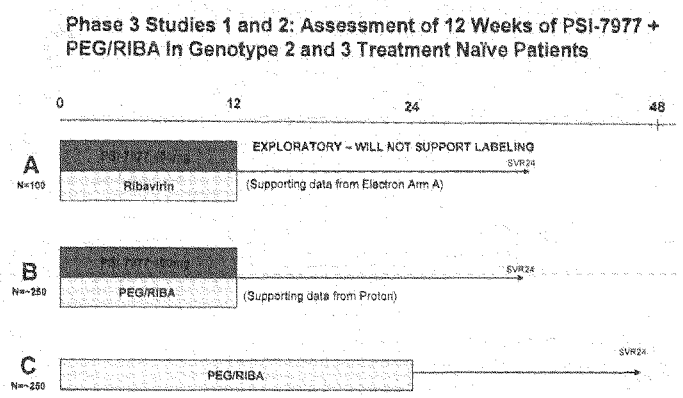
Business Proprietary Information – Confidential Treatment Requested

A key element in this strategy is that the two treatment naïve studies carry the least risk of clinical failure and thus, in our view, have the highest probability of regulatory approval of the various options we have considered. We conclude this because of the outstanding efficacy and safety of PSI-7977 demonstrated in this population in our pilot studies to date. Since the efficacy and safety of the 24 week SoC regimen in the genotype 2/3 population has been well-described, we can, with some precision, design a study demonstrating a statistically superior outcome of the PSI-7977 12 week regimen relative to the 24 week SoC regimen. We estimate that the control arm will have an SVR24 outcome of no greater than 77% and the PSI-7977 arm will have an SVR24 outcome of no less than 88%. We applied these predicted outcomes to standard statistical models and conclude that we will need 250 patients per arm in the treatment naïve studies (see Design 1) plus an additional 100 patients in the interferon-free exploratory arms. A study with this sample size and our predicted outcome will have 95% statistical power. This is more power than we need for regulatory approval and allows some flexibility in the outcome estimates. For the two treatment naïve studies, this comes to a total sample size of 1200 patients. The study in patients who cannot take interferon can be much smaller and will require no more than 200 additional patients. Thus, 1400 patients will be studied in this Phase 3 program.

The design of these studies and target patient population should support a global registration strategy. HCV genotypes 2 and 3 are a significant medical problem in the US but are not the predominant genotype. This is in contrast to Europe and Asia where genotypes 2 or 3 are more prominent and in some countries can be the dominant genotype. Thus we anticipate that the medical and regulatory communities in European and Asian countries will have significant interest in our program and will support approval in their countries.

Business Proprietary Information – Confidential Treatment Requested

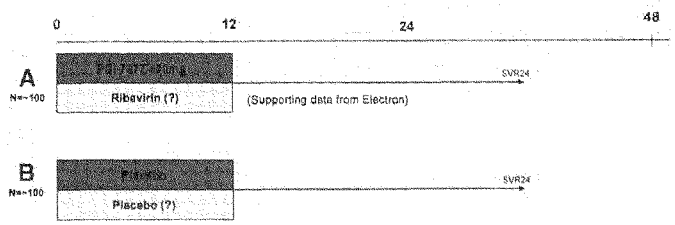
Design 1: Assessment of PSI-7977 in Patients Naïve to Treatment Who Are Infected with Genotypes 2 or 3



PHARMASSET

Design 2: Assessment of PSI-7977 in Patients Infected with Genotypes 2 or 3 Who Cannot Take Interferon

Phase 3 Study 3: Assessment of PSI-7977 +/- Ribavirin in Genotype 2 and 3 patients contraindicated, or intolerant, to interferon (may require two studies)



Placebo subjects roll-over to active

PHARMASSET

Regulatory environment

It is clear from the recent approvals of telaprevir and boceprevir that the FDA and regulatory authorities worldwide are open to innovative approaches to the treatment of chronic HCV infection. The recent approval of Pharmasset's IND for the QUANTUM study is a perfect example of a forward-looking, data driven regulatory environment. However, these approvals highlight the need to adhere closely to conventional regulatory guidance and to support your position with strong clinical data. In the case of our proposed phase 3 program, the studies should satisfy FDA guidance on the need for two well-controlled studies in an area of unmet medical need. However, although the quality of our data is very high, the quantity of data in terms of patient exposure is minimal. The total efficacy data to date is 24 patients in the PROTON study and 40 ongoing patients in the ELECTRON study. This relatively small database is likely to be an area of concern for the FDA and represents an area of risk to starting our program this year. We have hired a regulatory consultant (Dr. Heidi Jolson) who was a senior medical reviewer in the Antiviral Division. She has reviewed our program and believes it is sound and underpinned with encouraging data. She advised that the

database may be considered relatively small to start phase 3 and may be a point of discussion. Interestingly, Dr. Jolson felt that the FDA's opinion on the QUANTUM study design might provide insight into their level of enthusiasm for PSI-7977. If so, the recent approval of the QUANTUM IND may be construed as encouraging.

Budget

The current budget, approved at our March 23, 2011 board meeting, covering the period from October 1, 2010 through March 31, 2012, projected a cash balance of $93.9 million at the end of that period if we did not accelerate the development of 7977. We noted then that, if we did accelerate the program, we expected to spend an additional $10 million, most likely within the quarter ended March 31, 2012, ending the period with $83.9 million in cash. We have since found ways to accelerate the program more than we anticipated last March. Assuming agreement with the FDA, we could begin Phase 3 clinical trials of 7977 as soon as November 15, 2011, which would add $17.4 million to our approved budget through March 31, 2012, with $1.9 million falling in the quarter ended September 30, 2011, $5.7 million falling in the quarter ended December 31, 2011 and $9.8 million falling in the quarter ended March 31, 2012. We would thus be left with $76.5 million at March 31, 2012. Though we could continue to delay the next financing beyond that date, there is little reason to do so, as the stock has reached a more reasonable (though still undervalued) price level that minimizes the dilution of new stock sales. We expect to announce clinical data this Fall and during the AASLD conference ending on Wednesday, November 8, 2011 that should stimulate demand for our stock. Therefore, the following week, beginning Monday, November 14, 2011, should be a favorable time to launch a financing, assuming receptive market conditions. That is also the week before investors start disappearing for the Thanksgiving holidays. Since we have adopted the practice of issuing our earnings release when the numbers are final and audited/reviewed by Grant Thornton rather than wait until the rest of the financial statements have been prepared, we will be able to sell stock after the end of October, whether or not our 10K has been filed yet.

We have updated our multi-year projection of the company's cash flow with the costs of accelerating the 7977 program as well as the initial build out of a global commercialization organization. This model estimates that the amount of cash we will need to raise with stock sales before we reach break-even is $345 million, $245 million of it in fiscal 2012. Therefore, our November financing should raise $245 million to maintain a cash balance that is high enough to cause investors who want our stock to buy it on the open market, pushing our price up, rather than wait for a financing in order to get a discount.

We have discussed with the board the possibility of using an ATM form of financing to continuously replace cash used in each quarter, but our clinical data has been generated so rapidly and continuously, in open label studies that make the data known to the company, that we would have had to report incomplete data prematurely and be barred from AASLD (because of their embargo policy) in order to finance with an ATM in the period before AASLD. Now that we should raise $245 million soon after AASLD, a traditional underwritten offering is a better tool than the longer process of an ATM. Also, now that our market value has risen to a reasonable (though still undervalued) level, the discount and commission of an underwriting are significantly less dilutive than in our previous financings. Furthermore, an underwriting can provide a reward and future

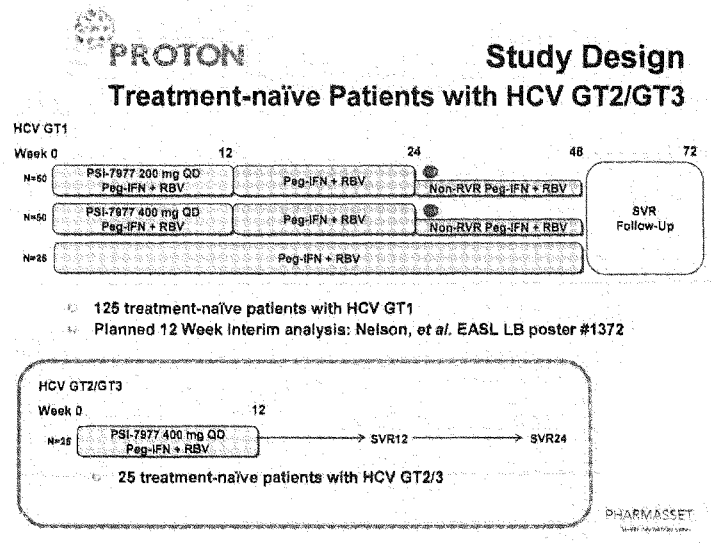
Business Proprietary Information – Confidential Treatment Requested

incentive to several analysts who have supported our stock at critical times, refuting negative rumors and endorsing the case for significantly higher stock prices in the next 12 months.

Preparations for a standard financing in November would begin in early October with appointment of lead bankers so there will be sufficient time for diligence by a new underwriters' counsel.

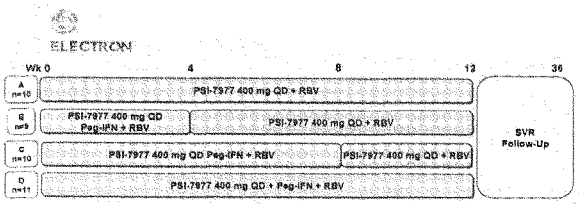
Business Proprietary Information – Confidential Treatment Requested

APPENDIX



Business Proprietary Information – Confidential Treatment Requested

PSI-7977: ELECTRON



PHARMASSET

PHARMASSET STRATEGY

TAB

WHERE INNOVATION IS VIRAL

303-A College Road East
Princeton NJ 08540 USA
Office 609 613 4100
Fax 609 613 4150
www.pharmasset.com

MEMORANDUM

TO: Board of Directors

From: Schaefer Price and Mike McElhaugh

DATE: July 21, 2011

RE: **Pharmasset Strategic Update**

In addition to executing on development and commercialization of our current pipeline products, Pharmasset must develop an appropriate long-term strategy and must act in the near term in order to continue to drive future value for shareholders.

The board has asked for an update of our research and development strategy, in addition to our commercial HCV strategy at this meeting.

Background – Last year we assessed Diversification Opportunities

Last summer at our strategy meeting with the board, we did an in depth analysis of diversification opportunities. In research, we looked at non-HCV viral targets and other indications for nucleosides such as cancer, metabolic and inflammatory diseases. While there was no obvious new target to pursue from this effort, we did conclude that we would begin a diversification effort by initiating a screening program in influenza and dengue. At the board meeting, Mike Otto will provide an update on these efforts to date. When considering these early stage efforts, it is important to remember that even if we discovered the next blockbuster from this effort, commercialization and revenue recognition from these programs are still about a decade in the future.

In addition to research diversification, we also assessed clinical development diversification opportunities at last year's board strategy meeting. We looked at both potential opportunities with our internal HCV programs and the attractiveness of external programs. One of the internal analyses was a discussion regarding an initial hepatitis C indication in transplant patients. At that time, we concluded that the risks of moving forward with this indication would not provide meaningful upside and was therefore not a priority for development. One external program that was identified as interesting was Herpes Zoster. We continue to watch for Zoster opportunities but have not yet found an appropriate program for in-licensing.

Pharmasset's current size and makeup limits the likelihood of success from research or development diversification. This is because it would require us, in areas where we are presently not expert, to identify and in-license appropriate opportunities and then execute flawlessly in development and commercialization. As such, our current optimal strategic path is to remain focused on our current pipeline in HCV and not get distracted. What we do know is that PSI-7977 has performed spectacularly in clinical trials and, based on safety and efficacy data to date, appears to be approvable and is rapidly progressing towards phase 3 trials. Given this progress, our present strategy should focus on maximizing our HCV opportunity and, once successful in this area, look once again for diversification opportunities.

What is the Strategy for Maximizing our HCV Opportunity?

An exclusively HCV-specific drug pipeline necessitates an HCV strategic focus until such time as it is appropriate to add diversity to our pipeline. To maximize the opportunity inherent in our HCV franchise, we are focused on getting to market as quickly as possible. As discussed at our last board meeting, this means initiating phase 3 trials in genotype 2 and 3 patients. Mike Rogers will be providing an update on our current plans and efforts at the board meeting.

Commercially, our focus has historically been on the US opportunity. It is strategically obvious that we will commercialize in the United States, given the market opportunity and our internal expertise. Pat Higgins has been responsible for building successful hepatology organizations in the US and is prepared to do so once again. He will describe an overview of the plan of action for commercializing in the US at the board meeting.

While most of the current HCV value is in the United States, Japan and the EU5 (France, Germany, Italy, Spain and the United Kingdom), it is important to realize that this opportunity is finite. Due to a better understanding and increased attention to modes of transmission, the incidence of HCV has declined dramatically in the US, Japan and EU5 in recent years. This, coupled with increased diagnosis and treatment rates, and significant improvements in efficacy from small molecules, means that the US, Japan and EU5 HCV markets will likely have a parabolic shape with an anticipated peak in the 2016-2020 range. As such, an HCV strategy needs to consider how to follow up an early commercial success in the US, Japan and EU5 with the cultivation of global markets to provide commercial longevity.

The global market is changing rapidly. There is a burgeoning middle class in many of the emerging markets (e.g. Brazil, Russia, India and China), and there is a higher incidence and prevalence of HCV in the markets outside of the US, Japan and EU5. We need to understand the intricacies of markets and the appropriate metrics to compare them with and to enable us to choose one path over another in a given country. We need to decide where we will have a commercial presence and how to best structure that presence for continued success. Pharmasset has engaged IMS Consulting to help us understand where and how Pharmasset could commercialize our HCV drugs. Our decisions will be based upon the time, expense and

Business Proprietary Information – Confidential Treatment Requested

probability of achieving commercial success in each country. We will need to decide whether to build organically in a country or to buy into an established infrastructure.

IMS Consulting will also provide us with their views of countries which could have future commercial interest to us, but in which we would not have a near term commercial presence. We will have to decide whether it is better to out-license to an established, multi-national pharmaceutical company operating in such a country or to preserve future internal commercialization by partnering with a distributor or a contract sales organization initially.

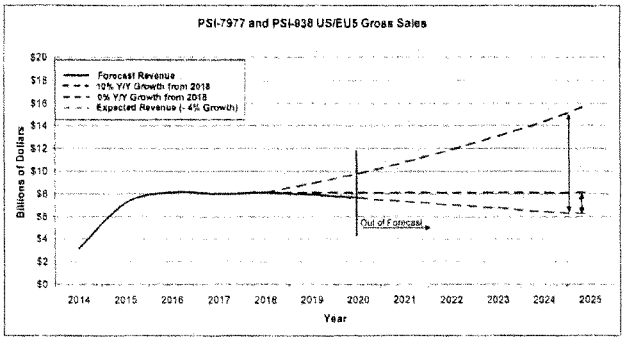
As we consider these global commercialization issues, we need to reflect on the fact that we may be building subsidiaries in several countries. This is important as it provides an opportunity to re-examine our corporate structure. Global pharmaceutical companies typically have an Executive Team comprised of a CEO, CFO, GC, Global Manufacturing head, and Commercial heads. As we consider building an Executive Team with global responsibilities, we face a decision about where these individuals should be located. Should Pharmasset have a Swiss European headquarters or Singaporean Pacific Rim headquarters? In addition to the benefits of being in proximity to local markets and cultures, there may be additional legal or financial reasons to open subsidiaries to oversee country-specific operations. Kurt Leutzinger will share some preliminary considerations on this topic with the board.

We are now considering building a multi-national pharmaceutical company from a single molecule discovered in our laboratories. While this seems ambitious, it is contextually important to remember that most major pharmaceutical companies have been built upon the blockbuster success of a single drug. Our own internal projections for US and EU5 sales exceed $8B at peak, which is consistent with some current analyst projections. These forecasts support the vision of Pharmasset growing into a multi-national pharmaceutical company. If the board is in favor of global expansion, many very large strategic decisions need to be considered and agreed prior to the launch of our first drug.

Is now the time to start planning for a future revenue decline?

As evident from the above discussion, one of the most important strategic issues facing Pharmasset in the mid-term is HCV commercial longevity. Pharmasset US/EU5 sales are expected to plateau beginning in 2016 with sales of about $8B. After a few years, these revenues are expected to decline. In order to maintain our total revenue, we anticipate needing significant additional revenue in the 2020-2025 timeframe to maintain growth at 0%, and significantly more to satisfy investor desires for 10% annual growth. (See graph and table below). There are several potential ways to address this issue. Diversify via novel research programs, diversify by in-licensing development or commercial programs, expand globally to continue to address remaining hepatitis C opportunities, or some combination of these possibilities.

Business Proprietary Information – Confidential Treatment Requested



Year	Revenue Replacement for 0% Growth Y/Y ($B)	Revenue Replacement for 10% Growth Y/Y ($B)
2019	$ 0.21	$ 0.81
2020	$ 0.49	$ 1.70
2021	$ 0.80	$ 2.69
2022	$ 1.09	$ 3.77
2023	$ 1.37	$ 4.96
2024	$ 1.64	$ 6.26
2025	$ 1.90	$ 7.70

The Pharmasset research group currently has ongoing projects in dengue and influenza viral infection. Both of these projects are early-stage and, statistically speaking, have a low probability of success. Historically, many companies have unsuccessfully spent significant resources attempting to address these areas with limited success, suggesting that these targets are particularly difficult. It is unlikely that either of these two opportunities will successfully offset declining HCV sales in the future. In fact, given the substantial time from research program initiation to product launch, it is unlikely that any *de novo* research program will provide the necessary revenue in the required timeframe.

The outcome from IMS Consulting will provide us direction regarding appropriate countries for expansion, but also information about the appropriateness of a given model in a particular country. There are several options available to us in any given country; build a subsidiary, buy an existing company, partner with a distributor or CSO or out-license to a multi-national company with expertise in that country. Each has its advantages and disadvantages, for example, licensing rights to a multi-national pharma company can occur rather quickly, but the Pharmasset

Business Proprietary Information – Confidential Treatment Requested

opportunity is then limited to royalty income. Strategically, we must fully consider countries where the recommendation is to commercialize by ourselves and then determine whether it is more advantageous to build or acquire a local operating company.

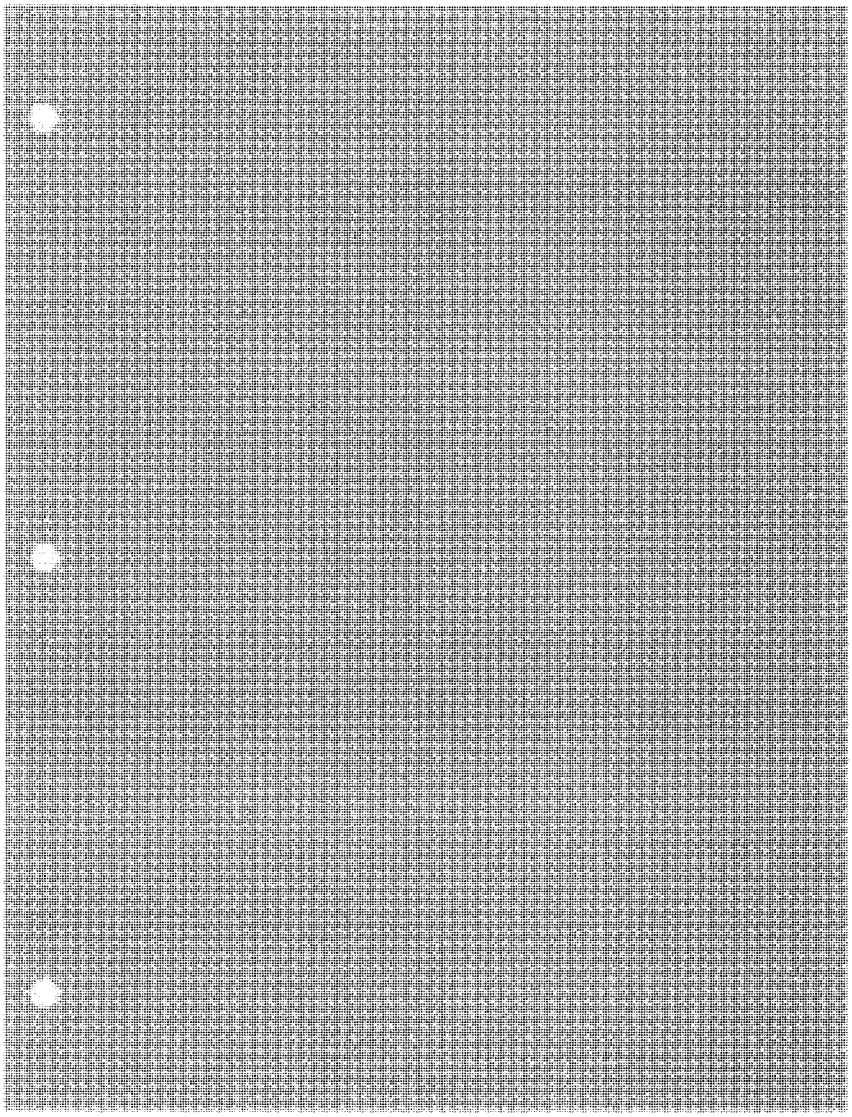
As we contemplate the build or buy decision on a country by country basis, or region by region, there are many variables to be mindful of. While typically one would assume that to acquire a company would allow for a faster commercial presence to be built, we should consider whether it is the right commercial infrastructure. Acquiring a company with mediocre products and mediocre employees may result in many poor decisions being made which could cost us time overall or result in lost opportunities. If we did find an acquisition opportunity that provided us access to an excellent team and a pipeline of commercial products in a different therapeutic area, we could also opportunistically acquire pipeline diversification.

While building *de novo* an operating company in a country or region appears to be more laborious, it may result in the best outcome. We would have the opportunity to assemble a team with quality comparable to the opportunity inherent in our HCV pipeline. As BMS, GSK and Gilead have hepatitis B global franchises and significant resources in HIV; we could build around key high level individuals selectively recruited from these organizations, as we will be doing in the US.

Questions for board consideration:

- Is the board committed to building a multi-national pharmaceutical company?
- What is the appropriate timing for building out commercial infrastructure?
- In a specific country/region, is it better to out-license, partner locally, build or buy?
- When is it appropriate to add to our pipeline?

Business Proprietary Information – Confidential Treatment Requested



PHARMASSET

WHERE INNOVATION IS VIRAL

303-A College Road East
Princeton NJ 08540 USA
Office 609 613 4100
Fax 609 613 4150
www.pharmasset.com

MEMORANDUM

To: Board of Directors

From: Michael J. Otto, Ph.D.

Date: July 21, 2011

Subject: Research Diversification Strategy Update

Analysis & Recommendations from 2010

Last year we undertook an extensive analysis of our research strategy. We evaluated a number of research areas that might allow us to expand our research beyond HCV but still build on our core expertise in nucleosides. These areas included additional viral target, cancer and metabolic diseases. Based on these analyses, our recommendation was to expand into other viruses, including respiratory viruses (e.g., influenza, respiratory syncytial virus), herpes viruses (e.g., HCMV, VZV) and emerging viruses (e.g., dengue, West Nile).

Influenza Virus

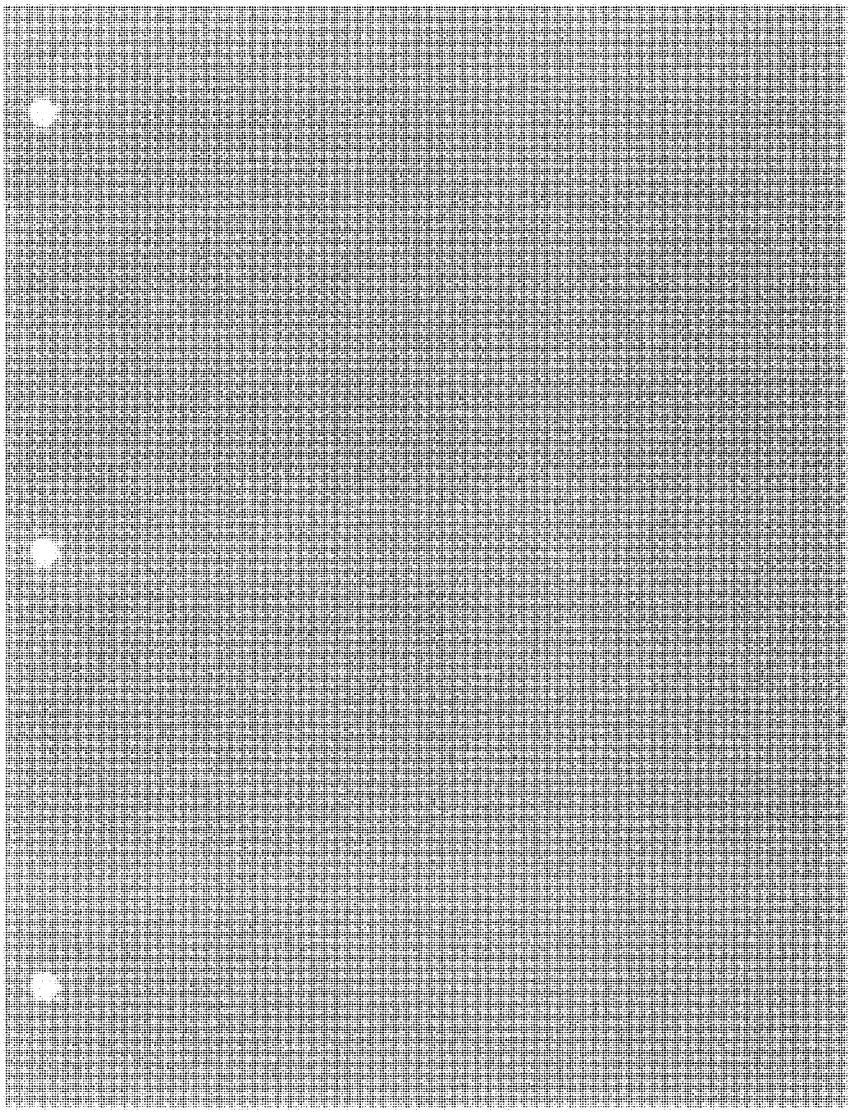
Influenza virus is an attractive target especially if we focus on the polymerase. This takes advantage of our nucleoside/tide expertise in chemistry and our ability to build antiviral assays. Currently there are two drugs, Tamiflu and Relenza, for treatment and prophylaxis of influenza virus infections. Both drugs target the viral neuraminidase and inhibit fusion of the virions to cells. Resistance development is a problem for both drugs and new nucleoside drugs targeting the polymerase with their higher barrier to resistance should provide complementary or better treatment options. To this end we have established cell-based assays in house. We have analyzed our library of nucleosides and selected an initial 800 nucleosides/tides for testing. The testing, which has just begun, should identify initial hits for further testing. Confirmed active compounds will be basis for chemistry optimization and SAR development. As we move forward, Pharmasset will need to identify collaborators or CROs to perform testing in animal models in order to understand the effect these antivirals have on disease progression or prophylaxis.

Dengue virus

Dengue virus causes significant morbidity and mortality worldwide and is a major national health care issue in many developing and developed countries. Recently infections have been documented in both Florida and Texas. There are currently no treatments for the virus and

vaccine development has been very difficult. One reason for this is that a prior infection by any one of the 4 serotypes and subsequent development of immunity to that serotype makes the individual susceptible to acute dengue hemorrhagic fever upon infection with a second serotype. The dengue virus polymerase is an attractive target as it is related to the HCV polymerase and should be inhibited by nucleoside-triphosphate analogs. To this end we have initiated a collaboration with an academic laboratory at the University of Rio de Janiero in Brazil. We have sent selected compounds that represent a variety of structures to Brazil for testing and have obtained some preliminary data which support the idea of using nucleosides for treating this disease. In addition, we have begun discussions with the Novartis Institute for Tropical Diseases, a not-for-profit research institute located in Singapore and supported by Novartis and the Singapore Economic Development Board. With these two collaborations we believe that we can leverage our research expertise by engaging partners who have the ability to move the programs forward in areas where dengue virus in endemic.

Business Proprietary Information – Confidential Treatment Requested



PHARMASSET

WHERE INNOVATION IS VIRAL

303-A College Road East
Princeton NJ 08540 USA
Office 609 613 4100
Fax 609 613 4150
www.pharmasset.com

MEMORANDUM

To: Board of Directors

From: Kurt Leutzinger

Date: July 14, 2011

Subject: Global Financial Considerations

Recommendation

Management is not recommending anything at this time, but will continue to study an opportunity to lower our US tax on ex-US sales, as described below. Should our further investigations of this opportunity warrant a recommendation to the board, we will have one for the October board meeting.

Background

Today, Pharmasset is a development stage company domiciled in the US. Our 78 employees operate entirely within the US, engaged primarily in discovery and clinical research. We contract for research services that are conducted on our behalf outside the US. However, Pharmasset is expected to evolve into a very different company. The HCV market that our product candidates address is a global market and we have decided to retain ownership of them and commercialize them with a minimum of involvement by third parties. This may result in an organization of several hundred Pharmasset employees engaged primarily in commercial activities such as sales, marketing, distribution, medical affairs, reimbursement and manufacturing management. Since a large part of our sales will occur outside the US, a large part of our organization may eventually reside and operate outside of the US. Thus, a large part of the company's future value will undoubtedly be generated outside of the US.

Each of the countries in which we sell product will tax the earnings we generate within the borders of their country. Some of these countries have higher rates of taxation than other countries. If we structure our global organization so that the parts that operate in low tax countries sell to the parts that operate in high tax countries at transfer prices that we can defend, we can minimize our tax liability to countries outside of the US by maximizing the earnings generated in low tax countries. As a US company, however,

the US will claim the right to tax our ex-US earnings in addition to the taxes paid to the countries in which these earnings were generated. The amount payable to the US will be the difference between US tax rates, the highest in the developed world, and the rates charged by the countries in which the earnings were generated. If our foreign subsidiary has enough economic substance, we will not have to pay this tax to the US until it transfers the earned cash to the US parent. Therefore, we may be able to defer the application of high US tax rates for possibly several years, by which time tax reform in the US may have lowered corporate tax rates.

The US is the only developed country in the world, except Canada, that taxes a significant portion of the earnings its companies make outside of its borders. Because of this, US companies are at a competitive disadvantage relative to their European and Asian counterparts. This is widely recognized in the business community and both political parties have promised tax reform sometime in the indeterminate future. If reform results in lower rates effective for the year 2014, when we expect to have our first taxable profit, we may never have to pay the current high rates. If reform goes even further, and confines US tax rates to income generated in the US, then all the income we are able to generate in low tax countries through defensible transfer pricing may benefit permanently from low ex-US rates.

However, our political process is prone to gridlock, and tax reform, if it occurs at all, may not arrive before our taxable earnings begin. Therefore, we should consider actions within our control that could position us to defer as much US tax as possible until reform becomes effective. This would require us to either establish a subsidiary with economic substance in a low tax country or to merge with a company incorporated in a low tax country such that at least 40% of the stock held by our current stockholders is transferred to new owners.

Giving up 40% of our value may be a very expensive thing to do, considering that we could become the next Gilead within the next 10 years, meaning that what is today worth $1.9 billion could become worth $16 billion. The future tax benefits to our continuing stockholders may not be worth this transfer of value to new stockholders.

Rather, our stockholders may get more benefit at less cost to them by establishing a subsidiary with economic substance in a low tax country. How much economic substance will be required to satisfy the IRS is not defined in either the tax code or Treasury regulations, but it will certainly require that many, if not all, senior management functions reside and operate in the chosen low tax country.

The company we are evolving into may be more efficiently managed from a headquarters that is located closer to the geographic center of our markets than Princeton, NJ. Switzerland is central to a part of the world that is expected to account for a large portion of our sales, including Italy, France, Russia, Spain, Germany, Turkey, Romania and the UK. Switzerland's time zone is 6 hours behind Shanghai and 6 hours

Business Proprietary Information – Confidential Treatment Requested

ahead of New York, facilitating global communication with our future markets in both Asia and the Americas. Furthermore, the combined Federal and Cantonal corporate tax rate in Switzerland is 10% to 20% compared to 41.5% net for a US corporation located in New Jersey.

The other counties we have considered are Ireland and Singapore. Both have very low corporate tax rates of 12.5% and 17%, respectively, but Singapore is far from the markets that will generate the bulk of our sales in the next 10 years, and Ireland is being bailed out by Germany and France, which may pressure Ireland to raise its corporate tax rate to their own levels of 30% and 33%, respectively.

Deferring income from US taxation will not be as easy, however, for companies that have legitimate business purposes in operating outside of the US, there is a path along which to migrate that potentially avoids prohibitive exit taxes and minimizes future income taxes.

The first stage would be to establish the legal framework. This structure is diagrammed at the end of this memo. Pharmasset (USco) would establish a wholly-owned subsidiary incorporated in Switzerland (Swissco). Transfers of IP and exchanges of stock from USco to Swissco would trigger prohibitively large exit taxes, however, USco could license all of our current IP to Swissco for an arm's length fair market royalty. The sooner we do this, the better, since compounds still in phase 2 clinical trials can be licensed for a lower royalty than those same compounds in phase 3 clinical trials. Swissco and USco would enter an R&D contract under which USco provides its research and clinical development services exclusively to Swissco, which in turn pays a fee that covers all of USco's expenses plus an appropriate profit. Swissco, not USco, would become the party to all manufacturing and external CRO (Quintiles) contracts. Furthermore, Swissco, not USco, would be the owner of future INDs filed with non-US regulators. Swissco would pay for all future development of all molecules, using cash contributed to it by USco out of the proceeds of sales of USco stock. If Swissco can then become, in the second stage below, the group's "entrepreneurial risk-taker", Swissco should be entitled to significant profit on sales made to our sales organizations in each country, while the sales organizations would receive a routine return.

The second stage is to establish economic substance in Switzerland so that Swissco is accepted by the IRS, as well as the taxing authorities in other countries, as the global "entrepreneurial risk-taker" for the Pharmasset group. Those senior management members who will be making decisions about, and held responsible and accountable for, the income that we want to defer US taxation on, must reside and operate in the chosen low tax country. This foreign-based management would have decision-making authority over spending decisions, budget creation and approval, clinical trial design and conduct, regulatory communications and management, manufacturing management, sales and marketing strategy and management. Functions that we could have simply outsourced will not count in passing the economic substance test. They must be

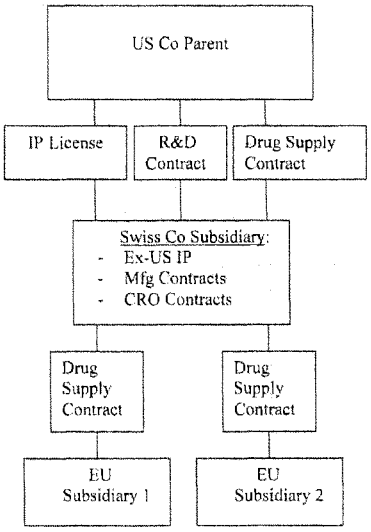
Business Proprietary Information – Confidential Treatment Requested

functions we would entrust only to senior level employees. At our present stage of development, this probably means that our current positions of CEO, CFO, CDO, CMO, manufacturing head and sales/marketing head would have to reside and operate in Switzerland. Three years from now, when we are a much larger and more complex organization, are cash flow positive and no longer selling stock, and our clinical development activities have wound down and are no longer the driver of our value that they now are, then perhaps the CEO, CFO, CDO and CMO functions could return to the US, leaving in place a general manager and finance director with appropriate authority, though reporting to the US. However, manufacturing and sales/marketing will have to continue to be directed from Swissco to support the rationale for high margins at Swissco. The ex-US organization can be built by internal development, acquisition, or both. Any acquired companies must have operations that do not cause the Swissco to fail the test of having economic substance in Switzerland. One recent example of successful expatriation through acquisition is the Alkermes reverse merger with a spinout from Elan.

The USco structure described above could be worth the considerable effort involved in setting it up. If US tax reform enables us to permanently benefit from low Swiss tax rates on the income we accumulate there, the NPV per share at 9.30.11 rises from $157 to $223. The NPV per share at 9.30.12 rises from $323 to $510. This assumes a structure in which our parent company remains our current US company, which has a wholly owned Swiss subsidiary, which in turn has multiple subsidiaries with sales organizations in several countries. The USco parent receives 20% royalties on global sales from the Swissco sub for the IP that has been created to date. The USco parent has a sales organization and pays all selling costs and buys its product from its Swissco sub at a transfer price that gives the USco parent a 10% pretax profit on its product sales. The USco parent retains its R&D organization and contracts all of its services to the Swissco sub for a fee that gives it a 10% pretax profit on its R&D services. The EU subsidiaries have sales organizations in their countries, pay all sales costs, and buy the product from their parent, Swissco, at a transfer price that gives them a 10% pretax profit on product sales. All of the residual profit goes to Swissco.

Business Proprietary Information – Confidential Treatment Requested

Below is a diagram of the structure discussed above:



Business Proprietary Information – Confidential Treatment Requested

ANY OTHER BUSINESS

TAB

PHARMASSET

WHERE INNOVATION IS VIRAL

303-A College Road East
Princeton NJ 08540 USA
Office 609 613 4100
Fax 609 613 4150
www.pharmasset.com

MEMORANDUM

To: Board of Directors

From: Bill Symonds and Kurt Leutzinger

Date: July 14, 2011

Subject: Approval of 24-Month Carcinogenicity Studies for PSI-938

Recommendation

The approval of eight proposals with BASi for Carcinogenicity Studies in Rats and Mice for PSI-938, for a total of $3.7 million. Following are the specific proposals:

- BASi Proposal #8924 for $1,579,500
- BASi Proposal #8930 for $25,736
- BASi Proposal #8932 for $6,175
- BASi Proposal #8931 for $22,800
- BASi Proposal #8925 for $2,018,000
- BASi Proposal #8927 for $25,736
- BASi Proposal #8929 for $6,175
- BASi Proposal #8928 for $22,800

Background

Your authorization is required for this work to proceed due to the timing of budgeted amounts and the total amounts quoted in the proposals. We note that the board approved the start of the two year PSI-938 Carcinogenicity Studies with the prior budget submission in March 2011, including the initial spending for those studies for a total of $982K during the period April 2011 to March 2012. In order to stay Sarbanes Oxley (SOX) compliant, we need your formal approval of the total expense that will occur over a two year period for the studies in order to proceed. The work to be performed is detailed below:

BASI Quote 8924
GLP 24 –Month Oral Carcinogenicity Study of PSI-938 in CD-1 Mice

BASI Quote 8930
GLP Analysis for 24 Month Oral Carcinogenicity Study of PSI-938 in Mice

BASI Quote 8932
TK Report for 24 Month Oral Carcinogenicity Study of PSI-938 in Mice

BASI Quote 8931
Dose Formulation for 24 Month Oral Carcinogenicity Study of PSI-938 in Mice

BASI Quote 8925
GLP 24 –Month Oral Carcinogenicity Study of PSI-938 in Sprague Dawley Rats

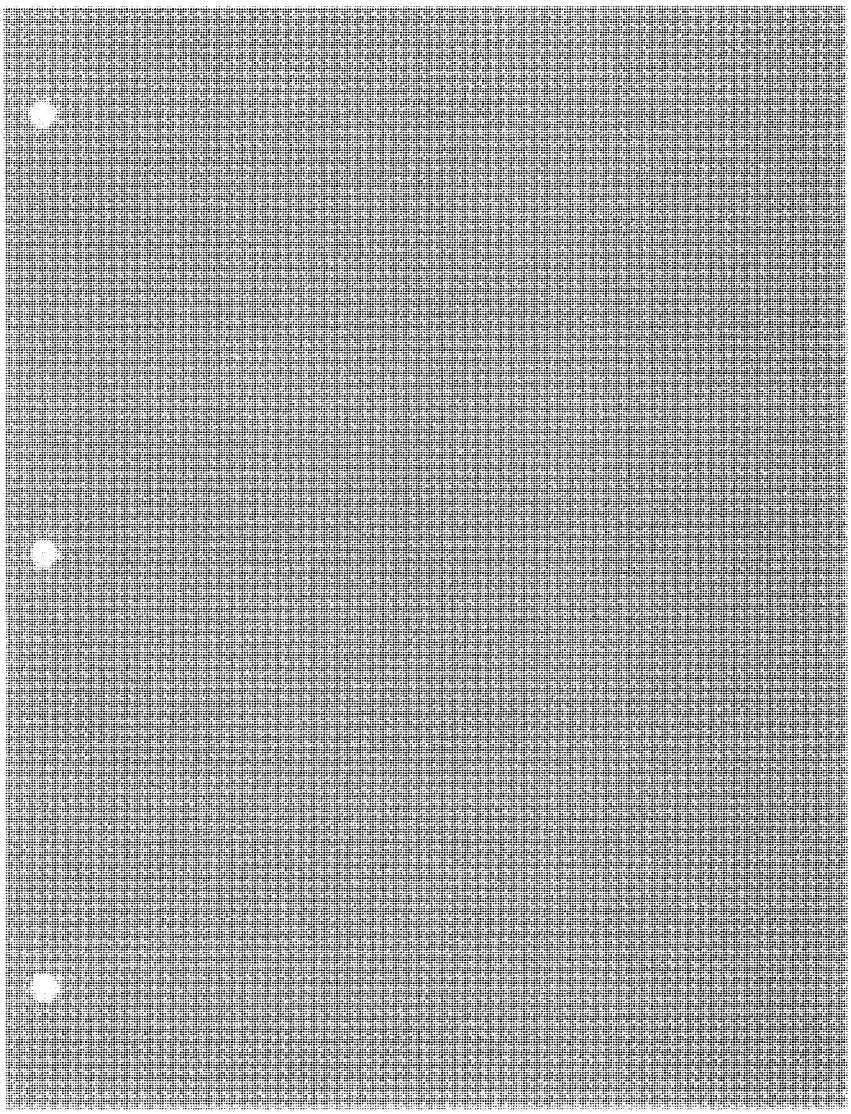
BASI Quote 8930
GLP Analysis for 24 Month Oral Carcinogenicity Study of PSI-938 in Rats

BASI Quote 8932
TK Report for 24 Month Oral Carcinogenicity Study of PSI-938 in Rats

BASI Quote 8931
Dose Formulation for 24 Month Oral Carcinogenicity Study of PSI-938 in Rats

In the future, our budgeting process will identify where there are expenditures related to distinct studies that are beyond the 12 month window that we typically budget for. The long term forecasts presented to the Board of Directors have always incorporated the full cost of the studies, but the formal budget that was approved was limited to the 12 month time period. Your approval of these future costs in addition to the 12 months forward will help us maintain SOX compliance without making repeated requests to the Board of Directors to proceed with elements of a particular study.

Business Proprietary Information – Confidential Treatment Requested



PHARMASSET

WHERE INNOVATION IS VIRAL

303-A College Road East
Princeton Nj 08540 USA
Office 609 613 4100
Fax 609 613 4150
www.pharmasset.com

MEMORANDUM

To: Board of Directors

From: Mark Meester and Kurt Leutzinger

Date: July 21, 2011

Subject: Approval of Quantum Combination Study for PSI-938 and PSI-7977

Recommendation

Management recommends the approval of the total budget for the Quantum combination study for PSI-938 and PSI-7977 in the amount of $45.5 million. We have estimated this amount in the past and reported it to the board in our multi-year projections. With the recent FDA safe to proceed letter for this study, we anticipate signing multi-year contracts with a CRO and others. It is good internal control practice to approve the project as a whole rather than in pieces as they fall into future fiscal period budgets. Below, we provide our line item estimates of the various components of the entire Quantum study, based on our latest vendor assumptions. As we receive updated contracts from our vendors, we will provide budget updates to our estimates in our semi-annual budget requests.

Background

Your authorization is required for this work to proceed due to the timing of budgeted amounts and the total amounts quoted in the proposals. We note that the board approved the start of the PSI-938 Quantum Study with the prior budget submission in March 2011, including the initial spending for those studies for a total of $21.8 million during the period April 2011 to March 2012. In order to stay Sarbanes Oxley (SOX) compliant, we need your formal approval of the total expense that will occur during the duration of the studies in order to proceed. The work to be performed is detailed below:

Quintiles
Project Management, Clinical Monitoring, Site Management, Investigator Expense Pass throughs, and Regulatory support ($30.3 million)

Quintiles or Cenetron
Central lab work and sample analysis ($5.8 million)

Standard of Care Drug Supply
Including PEG/RBV ($5.7 million)

QPS
Bioanalysis ($0.8 million)

IDDI
Electronic Data Capture / Data Management ($0.8 million)

Investigator Meetings
US and EU meetings ($0.8 million)

Fisher
Drug packaging and distribution ($0.7 million)

DDL
Phenotyping / genotyping and sequencing ($0.2 million)

Pharstat
Statistics ($0.2 million)

All Other ($0.2 million)

In addition to the Quantum study, there will be a rollover study that will include patients treated with placebo and treatment failures from the Quantum study. We do not have an estimated budget for that study at this time, and expect to request additional approval from the board in the future, to proceed with that study.

Business Proprietary Information – Confidential Treatment Requested

Exhibit 4

DRAFT
11/19/11

GILEAD

Advancing Therapeutics.
Improving Lives.

Gilead to Acquire Harry

November X, 2011

CONFIDENTIAL * DRAFT

Business Proprietary Information – Confidential Treatment Requested

Safe Harbor Disclaimer

Statements included in this presentation that are not historical in nature are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Gilead cautions readers that forward-looking statements are subject to certain risks and uncertainties, which could cause actual results to differ materially. These risks and uncertainties include: Gilead's ability to consummate the acquisition of Harry and advance Harry's product pipeline as planned; Gilead's ability to successfully develop its HCV franchise; Gilead's ability to develop an all oral antiviral regimen for HCV; and Gilead's ability to achieve its anticipated full year 2011 financial results. Gilead directs readers to its Quarterly Report on Form 10-Q for the third quarter ended September 30, 2011 and subsequent current reports on Form 8-K. Gilead claims the protection of the Safe Harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

This announcement is neither an offer to purchase nor a solicitation of an offer to sell shares of Harry. At the time the offer is commenced, Gilead will file a Tender Offer Statement on Schedule TO with the U.S. Securities and Exchange Commission, and Harry will file a Solicitation/Recommendation Statement on Schedule 14D-9 with respect to the offer. Harry stockholders and other investors are urged to read the tender offer materials (including an Offer to Purchase, a related Letter of Transmittal and certain other offer documents) and the Solicitation/Recommendation Statement because they will contain important information which should be read carefully before any decision is made with respect to the tender offer. The Offer to Purchase, the related Letter of Transmittal and certain other offer documents, as well as the Solicitation/Recommendation Statement, will be made available to all stockholders of Harry at no expense to them. The Tender Offer Statement and the Solicitation/Recommendation Statement will be made available for free at the Commission's web site at www.sec.gov.

Agenda

		Page
1.	Harry Acquisition Highlights	4
2.	HCV Landscape	8
3.	Overview of Harry HCV Portfolio	16
4.	Gilead – Harry's Combined HCV Opportunity	22

521

GILEAD

Harry Acquisition Highlights

Business Proprietary Information – Confidential Treatment Requested

Terms of the Agreement

GILEAD

[Insert HARRY Logo]

- Cash tender offer at $XX.XX per share
- Transaction value of $XX.X B
- Tender offer expected to close within QX XX
  - Subject to minimum tender requirement
  - Hart-Scott-Rodino (antitrust) clearance
  - Other customary conditions

523

GILEAD

Business Proprietary Information – Confidential Treatment Requested

Strategic Rationale

- Accelerates Gilead's strategy to develop the first all-oral regimen for the treatment of HCV
  - PSI-7977 is the most potent, advanced nucleotide in clinical development
  - Phase 3 clinical studies of PSI-7977 in combination with ribavirin open to enrollment
  - Targeted U.S. FDA approval in 2014

- Since HCV can be cured, there will be a significant benefit to the first all-oral, well tolerated regimen

- Opportunity for significant revenue growth and diversification in 2014 and beyond
  - Composition of matter patent protection for PSI-7977 into 2029

- Harry is a strategic fit with Gilead's areas of operational excellence

524

GILEAD

CONFIDENTIAL * DRAFT

Business Proprietary Information – Confidential Treatment Requested

GS-0009184

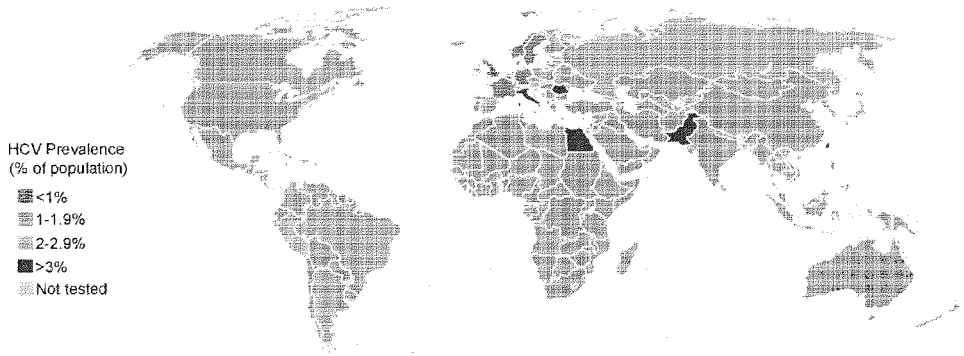
Fit with Gilead's Areas of Operational Excellence

- Established expertise and commitment to liver disease
- Preclinical, clinical development and regulatory expertise
  - Five HIV and two hepatitis products
  - Viread regulatory approvals in approximately 140 countries
  - Established team: Quad NDA filing in six weeks after last patient, last visit
- Expertise in process research and development, and established worldwide API and product manufacturing network
  - Have developed 1 fixed-dose combination and 3 single-tablet regimens in HIV
  - Manufacture tenofovir DF at >110 metric tons per year
- Established commercial operations in 23 countries worldwide, with expanding presence in Asia

HCV Landscape

Business Proprietary Information – Confidential Treatment Requested

Global Prevalence of HCV is Estimated to be 160 Million Individuals(1)



HCV Prevalence in Core and Emerging Markets (M)

Region	US[2]	EU-Core 5[2]	Japan[2]	Europe Other[3]	Asia[3]	Latin America[3]
All GT	2.9	3.7	0.6	6.7	70.8	5.4
GT1 (%)	73%	63%	70%	65%	39%	68%

Sources: 1) Lavanchy, et al. 2011. 2) Gilead Forecast (2011 prevalence estimate). 3) Cornberg, Sievert, and Kershenobich, *et al* 2011. Country populations from 2009 World Bank estimates

GILEAD

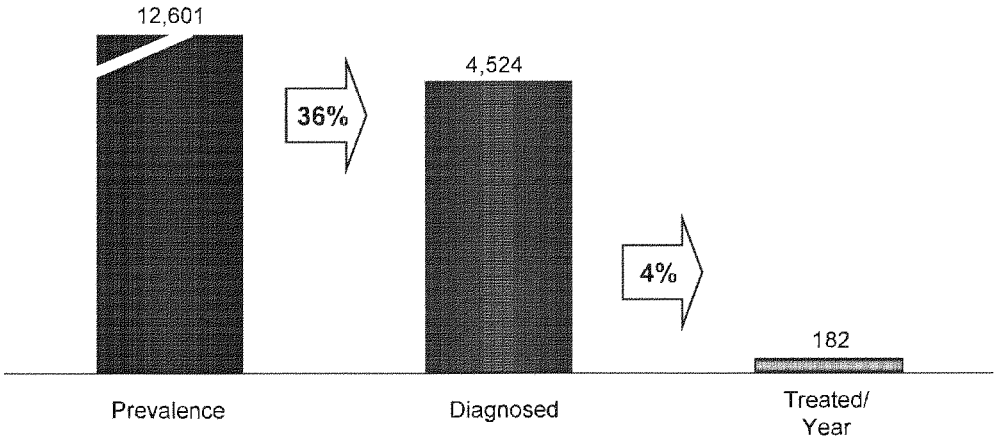
CONFIDENTIAL * DRAFT

Business Proprietary Information – Confidential Treatment Requested

HCV: A Significant Unmet Medical Need

Over 12 Million Infected Individuals in Major Markets[1] with Fewer than 200,000 Treated per Year

Patients in thousands



1. Major markets include US, EU-5, Japan, Australia, Austria, Brazil, Denmark, Finland, Greece, Ireland, Norway, Poland, Portugal, Sweden, Switzerland, Turkey, Canada

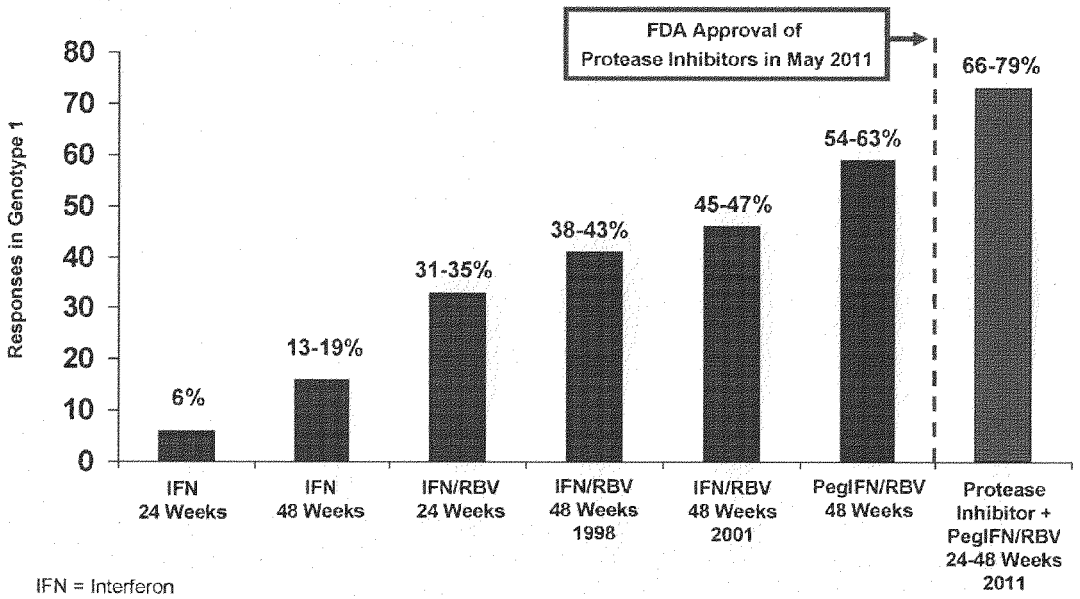
Sources:
Prevalence – KantarHealth Core-5 EU epidemiology analysis (2010), NHANES (1999-2006), Armstrong (2004), Hepatology, 40(4:S1):176a, Chak (2011), Liver Intl., 8, 1090-1101, Cornberg (2011), Liver Intl., 31 (s2), 31-60, Kershenobich (2011), Liver Intl., 31 (s2), 18-29
Diagnosed – KantarHealth Core-5 EU epidemiology analysis (2010), Armstrong (2004) Hepatology, 40(4:S1):176a, Culver (2000), Transfusion 40:1176
Treated – IMS MIDAS (2004 – 2009), Synovate chart audits (2007), Roche and Schering Plough annual reports (2009)

GILEAD

CONFIDENTIAL * DRAFT

Business Proprietary Information – Confidential Treatment Requested

HCV Treatment Evolution



IFN = Interferon
RBV = Ribavirin
PegIFN = Pegylated Interferon

GILEAD

CONFIDENTIAL * DRAFT

Business Proprietary Information – Confidential Treatment Requested

Challenges of Current PI-based Treatment Remains

- Additional safety issues and exacerbation of side effects (rash and anemia)
  - Discontinuation rates significantly increased on PIs
- Lower response rates in sub-populations (previous IFN/RBV non-responders, cirrhotics)
- Burdensome for patients and practitioners
  - PIs dosed 2-3 times per day, plus ribavirin and a self-administered injection
  - Time intensive adverse event management, complexity of response guided therapy

530

GILEAD

CONFIDENTIAL * DRAFT

Business Proprietary Information – Confidential Treatment Requested

Ultimate Goal in HCV Therapy

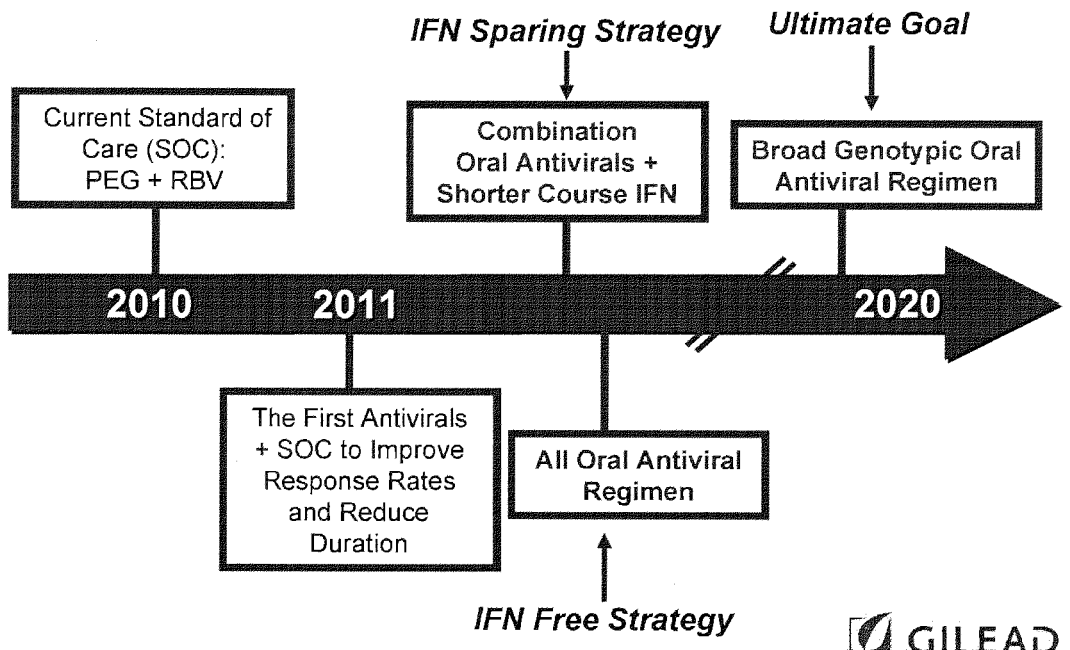
- Once a day
- Pan-genotype
- No clinical resistance
- No response guided therapy
- Short duration
- Safe with manageable side effects
- High cure rates
- Suitable for all populations

- Easier for doctors and patients
- Leads to increased diagnosis and treatment
- Potential to cure many more patients
- Lowers cost to healthcare system due to prevention of end-stage liver disease

Ideal HCV Therapy Most Likely Achieved through a Combination of Two or More Drugs

GILEAD

The Evolution of HCV Therapy: 2010

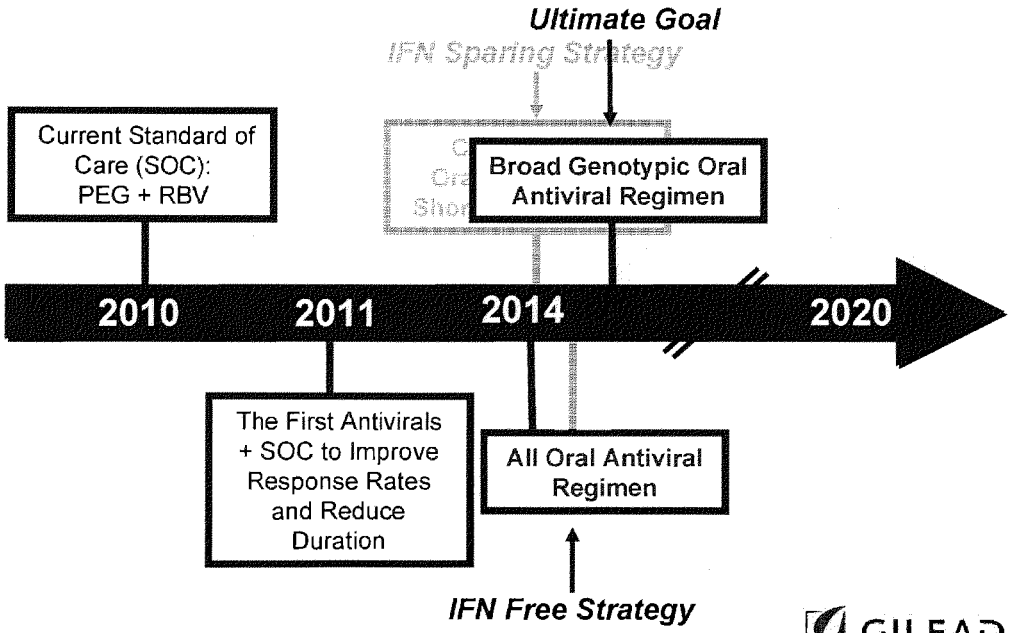


GILEAD

CONFIDENTIAL * DRAFT

Business Proprietary Information – Confidential Treatment Requested

The Competitive Nature and Speed of Development Have Significantly Accelerated the Timelines



GILEAD

CONFIDENTIAL * DRAFT

Business Proprietary Information – Confidential Treatment Requested

Overview of Harry HCV Portfolio

Business Proprietary Information – Confidential Treatment Requested

Harry's HCV Nucleotide Portfolio

PSI-7977

- 3.6 log HCV RNA↓ with 400 mg QD over 3 days
- Phase 3 in combination with ribavirin open to enrollment
- Highest on treatment and SVR rates to date
- Unpartnered with worldwide rights

PSI-938

- 3.6 log HCV RNA↓ with 300 mg QD over 3 days
- Phase 2
- 14 day data, with ongoing 12 week studies
- Unpartnered with worldwide rights

Redacted

GILEAD

PSI-7977: Harry's Lead Pyrimidine Nucleotide Analogue

- **Excellent safety profile**
  - 250 patients at 8 weeks or more
  - 1,500 patients by May 2014
- **High rates of cure in genotype 2/3**
  - 100% (10/10) with ribavirin
  - 60% (6/10) without ribavirin
- **Studies in genotype 1 ongoing**
  - Expecting Phase 2 SVR12 data early 2012
- **Multiple expanding data sets from studies in different patient populations**

CONFIDENTIAL * DRAFT

Business Proprietary Information – Confidential Treatment Requested

GS-0009196

PSI-7977: Genotype 2/3 Phase 2 Results
(ELECTRON)

Time (Weeks)	PSI-7977 RBV 12 weeks PEG	PSI-7977 RBV NO PEG	PSI-7977 NO PEG NO RBV
	n/n (%) < LOD	n/n (%) < LOD	n/n (%) < LOD
2	8/11 (82%)	8/10 (80%)	8/10 (80%)
4	11/11 (100%)	10/10 (100%)	10/10 (100%)
12	11/11 (100%)	10/10 (100%)	10/10 (100%)
SVR4	11/11 (100%)	10/10 (100%)	6/10 (60%)
SVR12	11/11 (100%)	10/10 (100%)	n/a

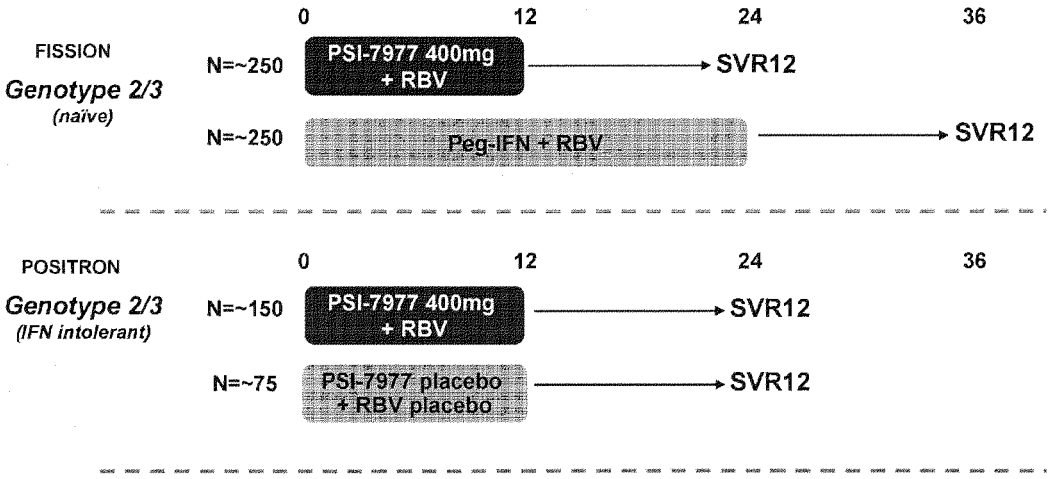
n/a – not yet available

GILEAD

CONFIDENTIAL * DRAFT

Business Proprietary Information – Confidential Treatment Requested

Harry's Phase 3 Program
(Announced November 1, 2011)



- A third Phase 3 study to be initiated in Genotype 1 patients in 1H 12
- Targeted U.S. FDA approval in 2014

GILEAD

CONFIDENTIAL * DRAFT

Business Proprietary Information – Confidential Treatment Requested

Key Remaining Questions in the Treatment of HCV

- Will one regimen work for all genotypes or will different regimens be required for different genotypes?
- How many molecules or mechanisms do you need?
- Can ribavirin be replaced?
- What is the minimum duration of therapy?
- Can HCV be cured with once-daily therapy?

Gilead's Combined HCV Opportunity

Business Proprietary Information – Confidential Treatment Requested

Harry and Gilead Combined HCV Efforts Position Us to Answer These Questions

- High barrier to resistance/pan-genotypic compounds will be an important component for any all-oral regimen
  - Harry's PSI-7977 is the most advanced, pan-genotypic compound with a high barrier to resistance
  - Ongoing efforts to identify other pan-genotypic compounds
- Complimentary portfolio accelerates potential for oral regimens
  - Includes direct acting antivirals with four different mechanisms in Phase 2/3 clinical development
  - Potential to pursue different combinations to then answer the question of duration of treatment and necessity of ribavirin
- Complimentary portfolios cover a number of opportunities for once-daily regimens
  - Potential for co-formulation

GILEAD

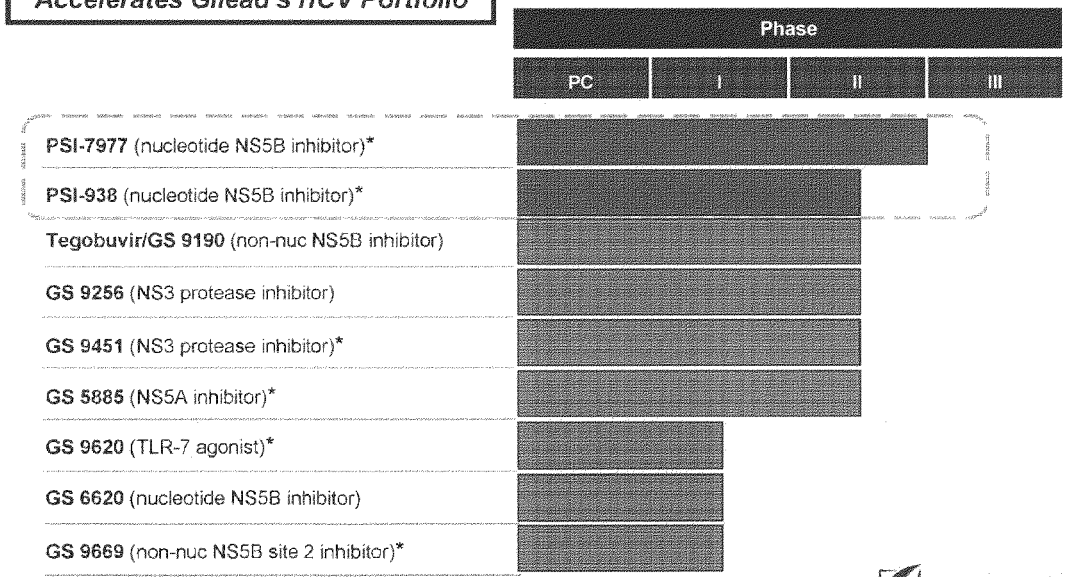
CONFIDENTIAL * DRAFT

Business Proprietary Information – Confidential Treatment Requested

GS-0009201

Combined HCV Clinical Portfolio

Harry Acquisition Compliments and Accelerates Gilead's HCV Portfolio



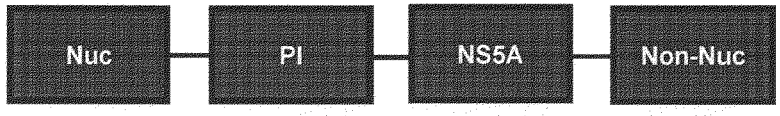
* Once-daily dosing

GILEAD

CONFIDENTIAL * DRAFT

Business Proprietary Information – Confidential Treatment Requested

All-Gilead Portfolio Increases the Chance of Developing Oral Therapies across Genotypes



Nuc	PI	NS5A	Non-Nuc
PSI-7977 PSI-938	GS 9451	GS 5885	GS 9190 GS 9669

Combination Therapies with High Potency May Further Shorten Duration and Eliminate Ribavirin

2012 Key HCV Milestones

- Initiate and integrate Harry's Phase 3 programs
  - GT 2/3 programs: no change
  - GT 1: Phase 2 data will determine strategy
- Initiate clinical trial with PSI-7977 to define minimum treatment duration in GT 2/3 patients
- Initiate multiple enabling drug-drug interaction studies with Gilead and Harry assets
- Explore combinations that exclude ribavirin
- Initiate programs in pre-transplant and HIV co-infected populations
- SVR data from Gilead's all-oral Phase 2 Study 120 at EASL

CONFIDENTIAL * DRAFT

Business Proprietary Information – Confidential Treatment Requested

GS-0009204

In Summary

- Accelerates Gilead's strategy to develop the first all-oral regimen for the treatment of HCV
- Since HCV can be cured, there will be a significant benefit to the first all-oral, well tolerated regimen
- Harry is a strategic fit with Gilead's areas of operational excellence
- Opportunity to change revenue trajectory starting in 2014

545

GILEAD

CONFIDENTIAL * DRAFT

Business Proprietary Information – Confidential Treatment Requested

GS-0009205

Gilead's Business Prospects

- Strong confidence in our core business
  - LTM HIV revenues of ~$6.4B in a total ~$13.0B market
  - LTM ~$1billion in revenues coming from products outside HIV

- Anticipate major HIV product launches in 2012
  - New revenue sources through partnerships to follow

- More Phase 2/3 programs across therapeutic areas than ever before
  - HIV, liver disease, oncology/inflammation/fibrosis, respiratory and cardiovascular

Note: LTM = last twelve months

Financial Impact of Harry Acquisition

- Cash flows from business will allow us to finance transaction
- Expect to use existing cash and $5.5 billion in incremental debt
- Committed to retaining investment grade credit rating
  - Debt/EBITDA ratio to return to ≤1.5x in closing + 1 year
- Transaction expected to be dilutive initially and significantly accretive beyond 2015
  - Increased interest expense associated with $X.X billion in new debt
  - Share repurchases to offset dilution as debt is repaid

GILEAD

CONFIDENTIAL * DRAFT

Business Proprietary Information – Confidential Treatment Requested

Transaction Summary

- Unique opportunity to dramatically change HCV disease burden worldwide
- Potential to extend leadership in liver disease to HCV
- Opportunity to parallel the commercial success in HIV
- Redefines revenue growth potential in 2014 and beyond

GILEAD

CONFIDENTIAL * DRAFT

Business Proprietary Information – Confidential Treatment Requested

DRAFT
11/19/11

GILEAD

Advancing Therapeutics.
Improving Lives.

Gilead to Acquire Harry

November X, 2011

CONFIDENTIAL * DRAFT

Business Proprietary Information – Confidential Treatment Requested

Exhibit 5

GILEAD

Questions:

1) As a gut check on whether payers will allow 9% of patients to receive SOF/LDV for 24 weeks, what percentage of patients received 24 weeks of SOF (on average) during Wave 1?

- Slide 2 shows that approximately 12 – 14% of patients in 1H 2014 are on 24 week regimen per IMS LRx calculations. This number is derived by calculating the ratio of total starts for each duration per June LE
- Slide 3 is the same info with the estimated costs of regimens added indicating that the average cost per treatment in Q2 is ~$120k.

2) Remind me, for the 9% at 24 weeks, what's the assumed split between GT-1 and GT-3?

- All 24 week duration for LDV/SOF is GT1; 12 weeks for GT3

3) Confirm my assumption that we'd face little competition in those buckets from AbbVie (particularly in GT-3, but also for any GT-1's who are PI-experienced).

- You are correct – no competition from AbbVie in GT3 or TE/C PI experienced patients
- In TE/C non-PI experienced GT1a patients (~5% of all GT1), we anticipate 24 weeks for both of us. In TE/C non-PI experienced GT1b patients (2% of all GT1), we will have 24 weeks and they will have 12 weeks.
- Slide 4 has the breakouts in detail

4) For the IPSOS assumptions, I need the following:
Brief description of sample size, methodology, and timeframe for the estimate
Clarification on whether this is currently available/syndicated/referenceable

- Assumed here that you are referring to the VL data (< 6MIU/mL)? See slide 5 all the data on the slide is available/syndicated/referenceable because it has been published by IPSOS. The sample size and methodology are on the slide. Note: Only Q2 IPSOS data is embargoed at this time.

Business Proprietary Information – Confidential Treatment Requested

Wave 1 regimen allocation based on IMS LRx

GILEAD

Regimen Allocation (IMS LRx)	Q1 2014[3]		Q2 2014[3]	
PegIFN + RBV	5.07%		2.10%	
Incivek-Based Regimens[1]	0.87%		0.30%	
Victrelis-Based Regimens[1]	0.67%		0.15%	
Sovaldi + RBV Regimens (12 week)[2]	61.7% → 39.57%	25.48%	62.0% → 34.80%	22.48%
Sovaldi + RBV Regimens (24 week)[2]	38.3%	*14.09%*	38.0%	***12.32%***
Sovaldi + PegIFN/RBV Regimens	33.80%		26.80%	
Sovaldi + Olysio Regimens	19.07%		34.25%	
Olysio-Based Regimens[1]	0.93%		1.60%	

Assumptions:

[1] PI + Peg-IFN/RBV regimen prices averaged across the duration range

[2] We estimate the split between 12- and 24-week SOF + RBV by calculating the ratio of total starts for each duration per June LE:

- 12-week SOF + RBV = total starts for GT2 = 27.3% (Q1), 27.8% (Q2) of total starts (June LE)
- 24-week SOF + RBV = total starts for GT3 + total starts for GT1 IFN-intolerant = 16.9% (Q1), 17.1% (Q2):
  - GT3: 10.8% (Q1), 11.0% (Q2) of total starts (June LE)
  - GT1 IFN-intolerant: 61.6% (Q1), 60.8% (Q2) GT1 (June LE) * 10% IFN-intolerant GT1 = 6.2% (Q1), 6.1% (Q2) of total starts
- Q1: 27.3% (12-wk), 16.9% (24-wk) → 61.7% / 38.3% split; Q2: 27.8% (12-wk), 17.1% (24-wk) → 62.0% / 38.0% split

[3] Quarterly allocations averaged across monthly data (Q2 does not yet include June).

[4] Prices reflect reported WAC prices from Q2 2014

Business Proprietary Information – Confidential Treatment Requested

Today, the weighted Average Cost per Treatment Regimen for HCV patients is above $100,000

GILEAD

Regimen Allocation (IMS LRx)	Regimen Price (WAC)[4]	Q1 2014[3]	Q2 2014[3]
PegIFN + RBV	$22,186	5.07%	2.10%
Incivek-Based Regimens[1]	$88,341 - $110,527	0.87%	0.30%
Victrelis-Based Regimens[1]	$66,004 - $117,926	0.67%	0.15%
Sovaldi + RBV Regimens (12 week)[2]	$85,190	61.7% → 25.48% (39.57%)	62.0% → 22.48% (34.80%)
Sovaldi + RBV Regimens (24 week)[2]	$170,380	38.3% → 14.09%	38.0% → 12.32%
Sovaldi + PegIFN/RBV Regimens	$95,093	33.80%	26.80%
Sovaldi + Olysio Regimens	$151,550	19.07%	34.25%
Olysio-Based Regimens[1]	$88,546 - $110,732	0.93%	1.60%
Average Cost per Treatment		$111,066	$120,599

Assumptions:

[1] PI + Peg-IFN/RBV regimen prices averaged across the duration range

[2] We estimate the split between 12- and 24-week SOF + RBV by calculating the ratio of total starts for each duration per June LE:

- 12-week SOF + RBV = total starts for GT2 = 27.3% (Q1), 27.8% (Q2) of total starts (June LE)
- 24-week SOF + RBV = total starts for GT3 + total starts for GT1 IFN-intolerant = 16.9% (Q1), 17.1% (Q2):
  - GT3: 10.8% (Q1), 11.0% (Q2) of total starts (June LE)
  - GT1 IFN-intolerant: 61.6% (Q1), 60.8% (Q2) GT1 (June LE) * 10% IFN-intolerant GT1 = 6.2% (Q1), 6.1% (Q2) of total starts
- Q1: 27.3% (12-wk), 16.9% (24-wk) → 61.7% / 38.3% split; Q2: 27.8% (12-wk), 17.1% (24-wk) → 62.0% / 38.0% split

[3] Quarterly allocations averaged across monthly data (Q2 does not yet include June).

[4] Prices reflect reported WAC prices from Q2 2014

Business Proprietary Information – Confidential Treatment Requested

Competitive Durations

GILEAD

GT1 Breakout (88% of TN, NC <= 6m IU/ml)

Based on IPSOS data

GT1	% of GT 1					% GT 1	Duration LDV/SOF	Duration Abb	Duration BMS
TN, NC	55%	<= 6m IU/L	88%			48%	8	12	8
		> 6m IU/L	12%			7%	12	12	12
TN, C	15%					15%	12	12	12
TE, NC	21%					21%	12	12	12
TE, C	10%	PI experienced	33%			3%	24	n/a	24
		Non PI exp.	67%	1a	70%	5%	24	24	24
				1b	30%	2%	24	12	24

Summary for GT1 &.GT3:

Patient Sub-Type		LDV/SOF 24 (TE, C) & 8 (TN, NC)	AbbVie 24 (TE, C)	BMS 24 (TE, C) & 8 (TN, NC)
GT 1	TN, NC*	8; 12	12	8; 12
	TN, C	12	12	12
	TE, NC	12	12	12
	TE, C	24	n/a; 12; 24**	24
GT 3		12	n/a	12

Business Proprietary Information – Confidential Treatment Requested

Ipsos HCV Therapy Monitor Data - Viral Load Distribution

GILEAD

Distribution of patients latest viral load (weighted)

Base: All naïve/experienced untreated patients with known latest viral load

Quarter	Quarterly Trended % of patients <=6m IU/mL (n)	
	Naïve	Exp
Q1'14	89% (544)	86% (156)
Q4'13	90% (489)	87% (187)
Q3'13	89% (534)	82% (173)
Q2'13	87% (518)	89% (220)
Q1'13	90% (499)	87% (188)
Q4'12	86% (427)	88% (174)
Q3'12	93% (328)	85% (129)

Seven Quarter Average % of patients <=6m IU/mL (n) (Q3'12 – Q1 '14)	
Naïve	Exp
~88% (3339)	~86% (1227)

Ipsos Methodology notes:

- ~150 HCV treating physician sample size per quarter with >85% Q-on-Q retention. Sample representative of targets (80% Gastro/Hep, 20% ID/IM) with KOL representation
- ~2100 patients/quarter overall
- Each physician completes 10 prospective forms to reflect HCV patient caseload + additional 4 patient records on recent initiations (starting Q4'13)
- Survey is fielded through the end of each quarter, representing 3 months of activity

Business Proprietary Information – Confidential Treatment Requested

Summary LDV/SOF US Pricing

August 5, 2014

Business Proprietary information – Confidential Treatment Requested

Executive Summary

GILEAD

- **Gilead enjoys modest pricing power for the LDV/SOF, although avoiding restrictions with all accounts will be difficult to achieve**
  - Physicians still strongly prefer the Gilead regimen and research suggests demand will remain relatively robust even in the face of some restrictions
  - A majority of payers indicate that 1 of 1 arrangements are unattractive, and most seek to make at least two options available
  - A minority of payers will seek more restrictive arrangements at all prices, such as 1 of 1 access
  - Broad discounts do not offer offsetting share benefits for Gilead; however, this does not mean there are not some payers where discounting will be profitable
- **AbbVie will likely have different pricing strategies that will be driven by final label language granted by FDA**
  - In most cases, AbbVie is incented to match LDV/SOF WAC and discount modestly to gain pockets of share
  - Assuming Gilead's discounts will have a high spill-over effect on other accounts, it will likely be in Gilead's interest to cede some portion of these wins to AbbVie
  - If AbbVie is granted a very different label than Gilead, they may be incented to launch with a significantly lower WAC (on a weekly basis)[*Unlikely*]
- **BMS offers Gilead some protection against revenue loss to AbbVie**

Business Proprietary Information – Confidential Treatment Requested

Executive Summary (Cont.)

GILEAD

- **NS5B is an important backbone**
  - Overall, physicians allocate between 78% and 84% of patients to a sofosbuvir-based regimen
  - As a consequence, if LDV/SOF is priced at a significant premium to the alternatives, physicians will allocate a substantial share of prescriptions to the DCV+SOF combination

Business Proprietary Information – Confidential Treatment Requested

Summary of Durations for Base Case and Alt Scenarios (includes GT1 & GT3)

GILEAD

Base Case Duration Assumptions for LDV/SOF and Franchise

Patient Sub-Type (F0-F4)		LDV/SOF	Gilead Franchise
GT 1	TN, NC	8; 12	8; 12
	TN, C	12	12
	TE, NC	12	12
	TE, C	24	24
GT 2		n/a	12
GT 3		12	12
GT 4/5/6		n/a	12

	Base Case (88% of TN, NC <= 6m IU/mL receive 8 weeks)		Alt Scenario 1 (100% of TN, NC receive 8 weeks)		Alt Scenario 2 (100% of TN, NC receive 8 weeks & 50% on 24 weeks shift to 12 weeks)		Alt Scenario 3 (100% of TN, NC receive 8 weeks & 50% on 24 weeks shift to 12 weeks + 50% of SOF/LDV GT3 moves to SOF+DCV)	
Patient Sub-Type (F0-F4)	LDV/ SOF	Gilead Franchise	LDV/ SOF	Gilead Franchise	LDV/ SOF	Gilead Franchise	LDV/ SOF	Gilead Franchise
% of Patients by duration								
% @ 8Wks	46%	33%	52%	37%	52%	37%	54%	37%
% @ 12Wks	45%	61%	39%	56%	43%	59%	42%	59%
% @ 24Wks	9%	7%	9%	7%	5%	3%	5%	3%
% of Revenue by duration								
% @ 8Wks	32%	23%	38%	26%	40%	27%	41%	27%
% @ 12Wks	48%	63%	42%	60%	50%	65%	48%	65%
% @ 24Wks	19%	14%	20%	14%	10%	7%	11%	7%
Wt Duration	**11.3**	**11.5**	**11.0**	**11.3**	**10.5**	**10.9**	**10.4**	**10.9**

559

LDV/SOF's weighted average price will vary based on the label and the fibrosis restrictions which are in place

GILEAD

LDV/SDF Weighted Average Price Under Different Scenarios

	% of Patients		Base Case			Alt Scenario 1			Alt Scenario 2			Alt Scenario 3		
% @ 8Wks	55%		40%	30%	20%	52%	38%	23%	52%	38%	23%	54%	41%	24%
% @ 12Wks	45%		45%	51%	57%	39%	46%	54%	43%	53%	65%	42%	52%	64%
% @ 24Wks	0%		9%	15%	23%	9%	14%	23%	5%	7%	11%	5%	7%	12%
Wt Duration	9.8		11.3	12.4	13.9	11.0	12.1	13.8	10.5	11.3	12.4	10.4	11.5	12.6
12 Wk WAC ($K)	**8 Wk WAC ($K)**	**24 Wk WAC ($K)**	**WAC per Pill**	**WAC per Bottle* ($K)**	**Wt Ave WAC ($K)**	**Wt Ave WAC ($K)**			**Wt Ave WAC ($K)**			**Wt Ave WAC ($K)**			**Wt Ave WAC ($K)**		
$72	$48	$144	$857	$24	$59	$68	$74	$83	$66	$73	$83	$63	$68	$75	$63	$68	$75
$84	$56	$168	$1,000	$28	$69	$79	$86	$97	$77	$85	$97	$73	$79	$87	$73	$79	$87
$96	$64	$192	$1,143	$32	$78	**$90** *Parity*	$99	$111	$88	$97	$110	$84	$90	$100	$83	$90	$100
$102	$68	$204	$1,214	$34	$83	$96	$105	$118	$94	$103	$117	$89	$96	$106	$89	$96	$106
$106.5	$71	$213	$1,268	$36	**$87** June LE	$100	$110	$124	$98	$108	$123	$93	$100	$110	$92	$100	$111
$108	$72	$216	$1,286	$36	$88	$101	$111	$125	$99	$109	$124	$94	$102	$112	$94	$101	$112
$120	$80	$240	$1,429	$40	$98	$113	$124	$139	$110	$122	$138	$105	$113	$124	$104	$113	$125

Base Case

*Note: Assumes 28 Pills per bottle

Scenarios with a weighted average WAC below the June LE are marked in Red

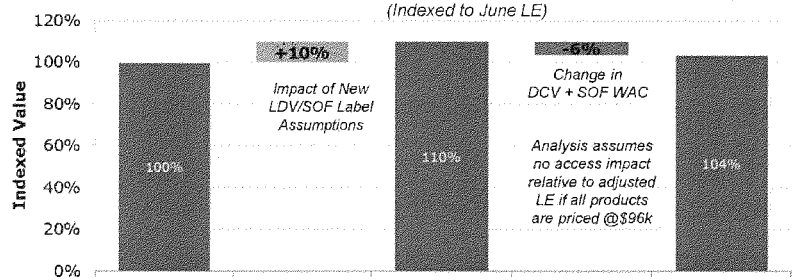
Business Proprietary Information – Confidential Treatment Requested

Base Case Assumptions have changed since the June LE (1 of2)

GILEAD

Change in Gilead HCV Franchise Net Revenue 2015 – 2017

(Indexed to June LE)



	June LE	Updated durations	Parity @ $96k
12 Week WAC Launch Price			
LDV/SOF	106.5	106.5	96
Weighted Average WAC Launch Price			
LDV/SOF	87	100	90
2015 GT1 Share			
Other SOF	0%	0%	0%
LDV/SOF	59%	59%	59%
DCV+SOF	15%	15%	15%
Other DCV	2%	2%	2%
AbbVie	24%	24%	24%
% Patient Split by Duration (LDV/SOF)			
8 Weeks	52%	46%	46%
12 Weeks	48%	45%	45%
24 Weeks	0%	9%	9%

*Includes revised GTN assumptions updated July 2014 by Gilead finance, impact <1%

-11-

Business Proprietary Information – Confidential Treatment Requested

Base Case Assumptions have changed since the June LE (2 of 2)

GILEAD

The "Parity @$96k has been used as the point of comparison for alternative WAC and competitive scenarios. This case assumes no access impact relative to adjusted LE if all products are priced @$96k

	Net Revenue ($ MM)			Treated Pts (000s)		
	2015	2016	2017	2014	2015	2016
June LE Forecast		Redacted				Redacted
Sovaldi	$2,715			39	35	
LDV/SOF	$5,944			92	79	
DCV+SOF (Gilead)	$1,790			31	26	
Total	**$10,450**			**162**	**140**	
Updated Durations*	11,557			162	140	
Delta from June LE:	*1,107*			-	-	
Parity @ $96k	10,879			162	140	
Delta from Updated Durations:	*(678)*			-	-	

*Impact of New LDV/SOF Label Assumptions Includes revised GTN assumptions updated July 2014 by Gilead finance, impact <1%

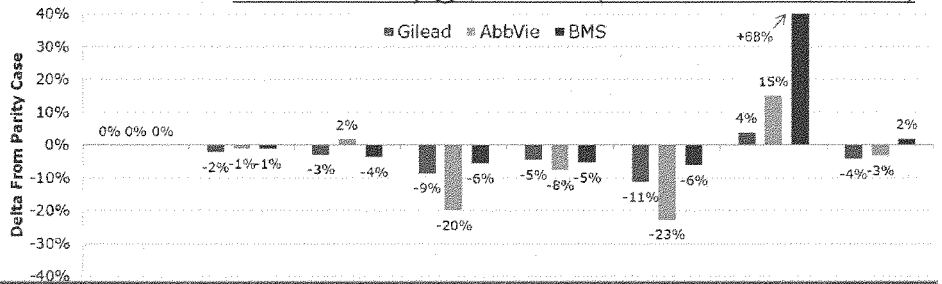
Source: IMSCG analysis based on primary market research and Gilead June LE 2014 forecast. Note: IMSCG did not develop and has not validated Gilead patient forecast

Business Proprietary Information – Confidential Treatment Requested

Cross Scenario Summary
Change from Parity Case for Gilead Franchise Net Revenue

GILEAD

Delta from Parity @ $96k Case (2015 – 2017 Net Revenue)



	Parity @ $96k	AbbVie - 10% WAC	AbbVie - 10% net	Gilead discounts w/ AbbVie	AbbVie - 20% net	AbbVie @ $60k	LDV/SOF @ $108k	LDV/SOF @ $108k; Abb $60k
Weight Average WAC Launch Price								
LDV/SOF	90	90	90	90	90	90	101	101
DCV	18	18	18	18	18	18	29	18
DCV+SOF	97	97	97	97	97	97	108	97
AbbVie	101	88	101	75	101	63	101	63
Launch Contracting Assumption								
LDV/SOF	Redacted							
DCV								
AbbVie								
2015 GT1 Share								
LDV/SOF	59%	57%	56%	59%	55%	55%	56%	46%
DCV+SOF	15%	15%	14%	14%	14%	14%	15%	16%
Other DCV	2%	2%	2%	2%	2%	2%	2%	2%
AbbVie	24%	27%	27%	25%	29%	29%	27%	35%

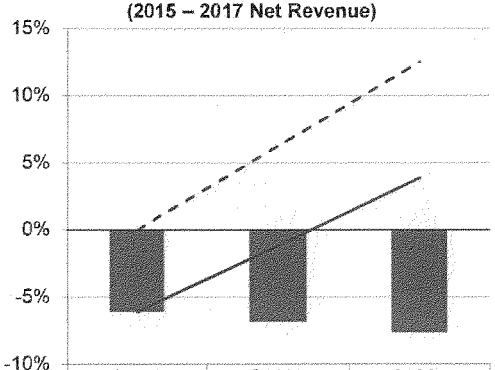
Business Proprietary Information – Confidential Treatment Requested

Payer restriction on LDV/SOF are more impacted by the relative price when compared to AbbVie than by the absolute WAC price

GILEAD

Impact of WAC pricing and AbbVie pricing on revenue and patients

Delta from Parity @ $96k Case (2015 – 2017 Net Revenue)



	$96k*	$102k	$108k
Change in Patients	-6%	-7%	-8%
Change in WAC	0%	6%	13%
Change in Net Revenue	-6%	-1%	4%

*LDV/SOF 12 Week WAC Price

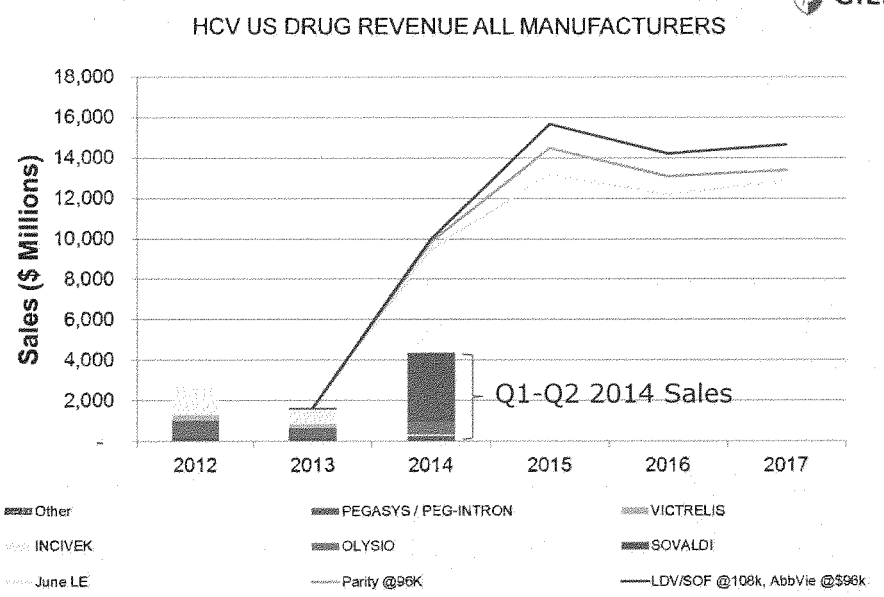
Conclusions

- All cases assume AbbVie sets their 12 week WAC price 20% below Gilead
- Assuming AbbVie prices 20% below Gilead's WAC. Gilead's WAC price does not significantly change demand

Business Proprietary Information – Confidential Treatment Requested

The Wave 2 launches will add significantly to the total spend on HCV

GILEAD



Source: IMS MIDAS US HCV SALES, Note: Merck is not included in the sales figures but does impact share calculations

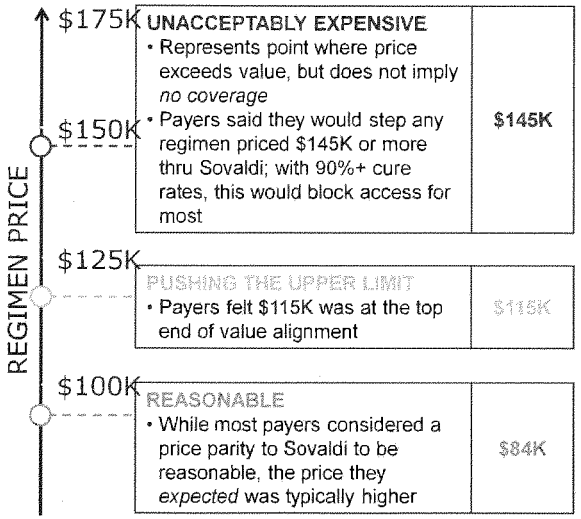
GILEAD

Appendix

Business Proprietary Information – Confidential Treatment Requested

Payers' unaided expectations for Wave 2 pricing were surprisingly high, possibly due to COSMOS' influence

GILEAD



- While most payers' stated price comparator for Wave 2 products is Sovaldi (8 of 15) a notable number will benchmark against COSMOS (3 of 15)
- Most payers base their initial LDV/SOF price expectations around the 12-week regimen, but would be interested in further analysis based on the distribution between eligible TN and TE lives

Reg. MCO

"COSMOS price would be unacceptable because this would be the second or third interferon-free regimen to the market"

*Payer price thresholds reflect a high-level assessment of expectations across both LDV/SOF and AbbVie regimens

Findings from Physician Research

GILEAD

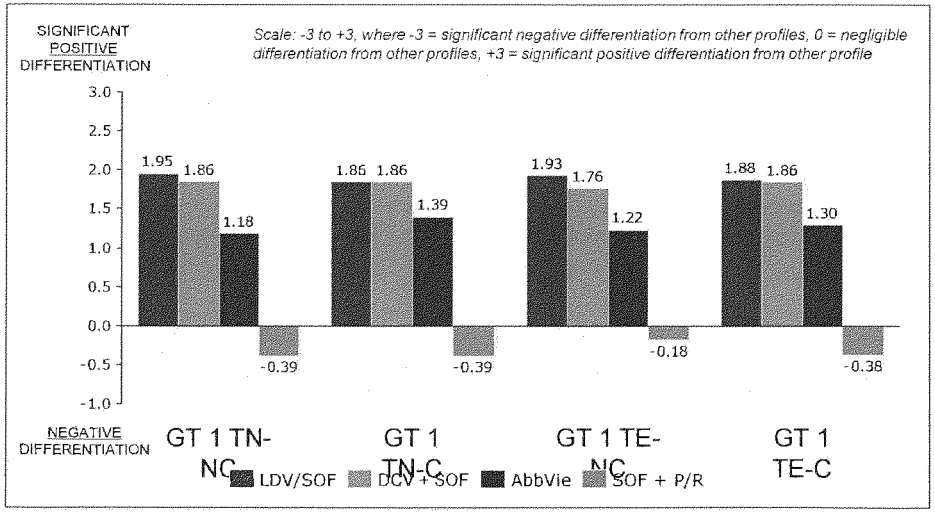
- At parity, physicians strongly prefer LDV/SOF, followed by the DCV + SOF regimen, with AbbVie a distant third
- Physician demand for LDV/SOF is likely to remain robust even in the face of soft restrictions or OOP disadvantages (LDV/SOF retains ~90% of share)
- Given hard restrictions, physician demand for LDV/SOF falls ~33%, with share going to both BMS and AbbVie; this reinforces that AbbVie will likely require help from payers to gain meaningful volume
- Despite some variation in physician allocation between 8, 12, and 24-week regimen durations, overall share for each brand remains largely consistent across subpopulations
- The access- and revenue-maximizing pricing strategies are likely to be very different price points
- At a 20% premium to AbbVie, ~18% of payers will implement a hard step or block LDV/SOF (Range 10-30%)
- AbbVie's labeled duration remains a key uncertainty

Business Proprietary Information – Confidential Treatment Requested

Among Wave 2 regimens, physicians see LDV/SOF as most differentiated, followed closely by BMS with AbbVie lagging behind

GILEAD

Please rate each of the following regimens on the level of clinical differentiation you perceive in its profile.



N = 76 physicians

Putting AbbVie in Context

GILEAD

- What revenue do they need from their HCV assets?
  - Humira revenues exceeded $10 billion in 2013, representing more than 50% of AbbVie's global sales
  - Analysts estimate that they need $2B+ worldwide, with at least 50% coming from US market
- Assuming similar duration in their label (12/24 weeks) – they must compete and win in the 12 week pool (relative size of 24 patient pool is too small to achieve financial goals)
  - We anticipate that they will come to market a little below LDV/SOF WAC and identify payers where they will negotiate to achieve 1 of 1 position or preferred status.Based on the quant study, they are at risk of achieving their financial goals with a parity position across payers.
  - A significant discount below WAC does not necessarily create enough volume to achieve AbbVie's financial goals.
- What can they hope to achieve with HCP targets or DTC/P efforts?

Payer	Must identify and win preferred status in a sub-set of payers without prompting Gilead to respond
HCP	Opportunity to influence HCPs with a) MOA/resistance profileb) SVRs in sub-populations c) robust clinical trials in difficult populations (perception in mkt)d) (easy) access experience e) greater number of field support
Patient	Opportunity to out-spend GILEAD and create a seamless transfer between diagnosis and treatment with Orasure

Business Proprietary Information – Confidential Treatment Requested

Launch Excellence Implications for AbbVie

GILEAD

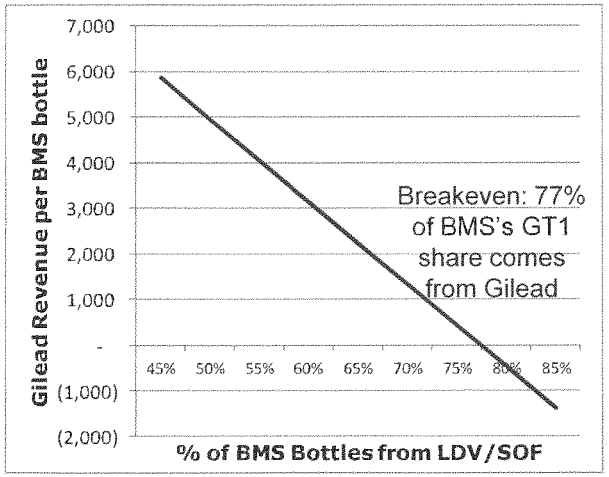
	Strength of value proposition/differentiation	Competitive intensity	Need to educate/change daily practice
Assessment of AbbVie position at launch	• Differentiation limited to secondary features – trial size, alternate mechanism	• Expected to be very high	• High: SOF established as backbone; complex admin requires patient training
Critical success factors	• Postulate market space and claim it • Promote secondary product benefits • Offer product services • Achieve optimal tier status/ offer co-pay card • Facilitate competition and parity access • Ensure broad sales force coverage and excellence in execution • Conduct comprehensive customer profiling to understand and address their needs • Target the optimum patient segment • Provide compelling long-term data • Create reasons to engage prescribers well before launch	• Optimize multi-stakeholder engagement model • Setup formulary access program • Conduct patient journey and ensure engagement at all leverage or possible leakage points • Achieve broad sales force coverage for high share of voice • Provide sampling • Establish brand loyalty	• Establish partnerships (scientific working groups) • Support inclusion in guidelines • Engage in public affairs • Set up unbranded physician education • Ensure strong publication strategy • Conduct patient journey to identify barriers, drivers and prescriber-influencers • Understand impact of changes to daily practice on provider/practice operations and identify ways to mitigate • Achieve high share of voice and have specialized field force in place • Provide education, services, other support to reduce barriers to trial and use
Implications for strategy	• Secondary benefits, including services, will be key	• Execution and targeted access investments	• Wrap-around services to offset VP weaknesses

Business Proprietary Information – Confidential Treatment Requested

However, BMS's impact on Gilead will be breakeven or better if less than 77% of BMS's share comes from Gilead

GILEAD

Incremental Gilead Net Revenue per BMS bottle



- If only 50% of BMS's GT1 share comes from Gilead; BMS's impact on Gilead would be +$400 M (~$5k per BMS bottle)
- Assumes:
  - June LE pricing
  - BMS GT1 share ~17%
  - 6% of BMS not SOF based
  - 3% of BMS's share comes from legacy regimens
  - 20% (included in the 77%) comes from other SOF based regimens
  - 31% of BMS revenue comes from GT2,3&4
  - All GT2,3&4 BMS revenue is from DCV + SOF at the expense of LDV/SOF

Business Proprietary Information – Confidential Treatment Requested

Impact of WAC pricing and competitive scenarios on revenue and patients

GILEAD

Gilead HCV Franchise

	Net Revenue ($ MM)			Treated Pts (000s)		
	2015	2016	2017	2014	2015	2016
Parity @ $96k	10,879	Redacted		162	140	Redacted
AbbVie -10% WAC	10,598			158	137	
Delta from Parity @ $96	*(281)*			*-3%*	*-2%*	
AbbVie -10% net	10,495			156	136	
Delta from Parity @ $96	*(383)*			*-4%*	*-2%*	
Gilead discounts w/ AbbVie	9,932			160	139	
Delta from Parity @ $96	*(946)*			*-1%*	*-1%*	
AbbVie -20% net	10,305			153	135	
Delta from Parity @ $96	*(574)*			*-5%*	*-4%*	
AbbVie @ $60k	9,612			154	135	
Delta from Parity @ $96	*(1,267)*			*-5%*	*-3%*	
LDV/SOF @ $108k	11,264			157	136	
Delta from Parity @ $96	*386*			*-3%*	*-2%*	
LDV/SOF @ $108k; Abb $60k	10,279			144	127	
Delta from Parity @ $96	*(600)*			*-11%*	*-9%*	

Source: IMSCG analysis based on primary market research and Gilead June LE 2014 forecast. Note: IMSCG did not develop and has not validated Gilead patient forecast

-23-

Business Proprietary Information – Confidential Treatment Requested

Impact of WAC pricing and competitive scenarios on revenue and patients

GILEAD

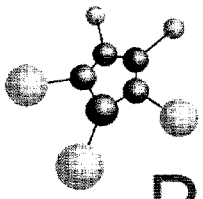
Gilead LDV/SOF Only

	Net Revenue ($ MM)			Treated Pts (000s)		
	2015	2016	2017	2014	2015	2016
Parity @ $96k	6,184	Redacted		92	79	Redacted
AbbVie -10% WAC	5,934			88	76	
Delta from Parity @ $96	*(250)*			*-4%*	*-3%*	
AbbVie -10% net	5,882			87	76	
Delta from Parity @ $96	*(302)*			*-5%*	*-3%*	
Gilead discounts w/ AbbVie	5,346			92	79	
Delta from Parity @ $96	*(837)*			*0%*	*1%*	
AbbVie -20% net	5,725			85	74	
Delta from Parity @ $96	*(459)*			*-7%*	*-5%*	
AbbVie @ $60k	5,048			87	76	
Delta from Parity @ $96	*(1,136)*			*-6%*	*-4%*	
LDV/SOF @ $108k	6,562			87	75	
Delta from Parity @ $96	*378*			*-6%*	*-5%*	
LDV/SOF @ $108k; Abb $60k	5,577			74	65	
Delta from Parity @ $96	*(607)*			*-20%*	*-17%*	

Source: IMSCG analysis based on primary market research and Gilead March LE 2014 forecast. Note: IMSCG did not develop and has not validated Gilead patient forecast

Business Proprietary Information – Confidential Treatment Requested

Exhibit 6



PHARMASSET

Board of Directors Meeting

Princeton, NJ

July 21, 2010

Confidential

PHARMASSET

WHERE INNOVATION IS VIRAL

303-A College Road East
Princeton NJ 08540 USA
Office 609 613 4100
Fax 609 613 4150
www.pharmasset.com

Board of Directors Meeting

Wednesday, July 21, 2010
8:00 am – 1:00 pm (EST)

Location: Pharmasset Offices

Teleconference Dial-In
US Access: 1-877-326-2337 — International Access: 1-303-928-3232
Access Code: 4249413

AGENDA

8:00 am	**Administration** – Review and approval of previous meeting minutes
8:15 am	**Report of Board Committees** – Audit Committee – Nomination/Governance Committee – Compensation Committee
9:15 am	**Risk Management**
10:00 am	**PSI-7977 Update** - Update on 7977 program - Update on business development discussions - Financial analysis of opportunity
11:00 am	**Pharmasset Strategy**
Lunch	
12:45 pm	**Executive Session**
1:00 pm	**Adjourn**

Board Dinner

Tuesday, July 20, 2010 at 7:00 pm EST
Peacock Inn
20 Bayard Lane
Princeton, NJ 08540
Phone: (609) 924-1707

Future Board Meetings

- October 14, 2010 – NYC
- ?
- ?
- ?

Business Proprietary Information – Confidential Treatment Requested

CONFIDENTIAL DRAFT
FOR DISCUSSION PURPOSES ONLY

Minutes of the Regular Meeting of the Board of Directors of Pharmasset, Inc.
New York, New York
March 18, 2010

Directors in attendance:
G. Steven Burrill, Chairman of the Board
William J. Carney
Herbert J. Conrad
Elliot F. Hahn
Michael K. Inouye
P. Schaefer Price, President and CEO of the Company
Robert F. Williamson III

Others in attendance at the invitation of the Board:
From the Company—
Kurt Leutzinger, Chief Financial Officer
Paul Lubetkin, Executive Vice President, General Counsel, and Secretary
Jim Maguire, Vice President, Finance
Mark Meester, Vice President of Accounting & Administration
Bryce Roberts, Assistant Secretary
Michael Rogers, Chief Development Officer
Richard Smith, Vice President, Shareholder Communications and Investor Relations

The Board of Directors (the "***Board***") of Pharmasset, Inc. (the "***Company***") held a regular meeting, pursuant to notice, on March 18, 2010 at Le Parker Meridien, 118 West 57th Street, New York, New York, commencing at 7:00 a.m. PST. All members of the Board being present, the Chairman called the meeting to order. Mr. Lubetkin acted as secretary for the meeting.

Approval of Minutes

Upon motion duly made, seconded, and unanimously carried, it was

RESOLVED, that the Minutes of the meeting of the Board held on January 14, 2010 and February 4, 2010 and the Pricing Committee held on January 27, 2010 are ratified and approved.

Mr. Burrill reported that the Audit Committee met on March 10, 2010 to review management's budget memorandum. After discussion, the Audit Committee authorized the release of the memorandum to the Board, with suggestions intended to increase the clarity of presentation. Upon motion duly made, seconded, and unanimously carried, it was

RESOLVED, that the Minutes of the meeting of the Audit Committee of Board held on March 10, 2010 are ratified and approved.

Business Proprietary Information – Confidential Treatment Requested GS-0014973

Amendment to the Bylaws

Mr. Carney, on behalf of the Nominating and Corporate Governance Committee, recommended that the Board amend Section 3.08 of the Second Amended and Restated Bylaws of the Company, as amended (the "***Bylaws***") (which gives the Board the power to form committees of the Board) to provide that the Board shall have the power to appoint a chairman of any committee of the Board. After discussion, upon motion duly made and seconded, the Board unanimously carried the following:

WHEREAS, upon the recommendation of the Nominating and Corporate Governance Committee, the Board desires to amend Section 3.08 of the Bylaws (which gives the Board the power to form committees of the Board) to provide that the Board shall have the power to appoint a chairman of any committee of the Board.

NOW, THEREFORE, BE IT HEREBY RESOLVED, that Section 3.08 of the Bylaws is hereby replaced in its entirety with the following:

> Section 3.08. Committees of the Board. The Board may, by resolution passed by a majority of the whole Board, designate one or more committees, each committee to consist of one or more directors. The Board may designate a chairman of each such committee. The chairman of a committee may call meetings of such committee and, if present, shall preside over such meetings and have such other authority as may from time to time be assigned to him or her by the Board or these Bylaws. The Board may also designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of such committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not he, she or they constitute a quorum, may unanimously appoint another director to act at the meeting in the place of any such absent or disqualified member. Any committee of the Board, to the extent permitted by law and to the extent provided in the resolution of the Board designating such committee, shall have and may exercise all the powers and authority of the Board in the management of the business and affairs of the Corporation, and may authorize the seal of the Corporation to be affixed to all papers which may require it. Unless the Board otherwise provides, each committee designated by the Board may make, alter and repeal rules for the conduct of its business. In the absence of such rules each committee shall conduct its business in the same manner as the Board conducts its business pursuant to this Article III. Each committee of the Board shall keep regular minutes of its proceedings and report the same to the Board when so requested by the Board.

Mr. Carney reported that the Nominating and Corporate Governance Committee met most recently on March 17, 2010. During that meeting, the committee reviewed the results of the Board's self-assessment and each Board committee self-assessment, and Mr. Carney summarized such results. Discussion ensued. Mr. Carney noted, on behalf of the Nominating and Corporate Governance Committee, that Fredric D. Price's resignation from the Board

Business Proprietary Information – Confidential Treatment Requested

became effective on March 17, 2010, resulting in a vacancy from the Audit Committee. After discussion, the Board unanimously accepted the recommendation of the Nominating and Corporate Governance Committee to elect Mr. Carney to fill the vacant seat on the Board's Audit Committee, effective immediately. The Nominating and Corporate Governance Committee also reviewed and discussed the Board's role in, and the evolving disclosure obligations in connection with, risk management. Discussion ensued, at the conclusion of which the Board unanimously accepted the recommendation of the Nominating and Corporate Governance Committee to direct management to summarize the principal aspects of the Company's risk management programs and policies to the Board at its July 2010 regular meeting.

Mr. Williamson reported about the March 9, 2010 meeting of the Compensation Committee. The agenda of that meeting included the potential future application of new Securities and Exchange Commission ("***SEC***") proxy disclosure rules regarding the Company's compensation and management's update on progress toward performance objectives. After a presentation by management and discussion, the Compensation Committee approved certain revisions to the performance objectives, which Mr. Williamson described, and authorized the Company to accrue for performance based bonuses based on meeting objectives and paying target amounts of bonuses. Discussion ensued.

Mr. Roberts updated the Board about the arbitration with the University of Georgia Research Foundation and Emory University. Among other things, he described, and the Board discussed, the status of discovery; the April, 2010 Markman-style hearing; the background and experience of the expert witnesses, panel members, and outside counsel; the management and coordination of counsel; and other related matters. Discussion ensued.

Mr. Rogers summarized the Company's development programs, focusing on the PSI-7977 clinical studies. The Board reviewed preliminary, partial data from the currently ongoing Phase 2a study. Discussion ensued regarding, among other things, the Company's strategy for further development of PSI-7977 and other nucleosides; the evolving regulatory environment for the developing of direct acting antivirals; the nature of the Company's competition and the impact of competitors' activities on the Company's strategy; and other related matters.

Mr. Leutzinger summarized the memoranda provided to the Board in which management proposed a roll-forward budget through March 31, 2011. Among other things, he highlighted variations and material changes in the budget; the Company's advancement of the planned development programs; management's analysis and plans for obtaining additional financing through the capital markets, strategic license agreements, or both; and alternative research and development strategies based on future financing or licensing developments.

In connection with a potential financing, the Board discussed the evolving perception of the Company, noting that Roche's R&D Day presentation included a reference to a pending Redacted Mr. Leutzinger suggested that the Board consider a public offering after the April 2010 EASL meeting, with the objectives of attempting to raise money from institutional shareholders who had not earlier participated in the Company's offerings, increase

Business Proprietary Information – Confidential Treatment Requested

the liquidity of the Company's common stock, and, if reasonable and appropriate, obtain sufficient funds to complete the Phase 2b development of PSI-7977. Discussion ensued.

At approximately 8:50 a.m., the Board adjourned its regular meeting to attend the 2010 Annual Meeting of Stockholders (the "***Annual Meeting***"). At approximately 9:40 a.m., after the conclusion of the Annual Meeting, the Board reconvened to continue its regular meeting. Mr. Steven Sands and Mr. Ian Woo, of Lazard Ltd., joined the meeting at the invitation of the Board.

The Lazard representatives reviewed their analysis of the Company's strategic financing alternatives and recommended, among other things, that the Company proceed to a public financing. The Lazard representatives summarized their firm's capabilities. Discussion ensued. At approximately 10:05 a.m., Mr. Price and Mr. Smith departed from the meeting. Further discussion ensued about market perception of the Company, the hepatitis C market and evolving competitive environment, and other related matters. At approximately 10:15 a.m., Messrs. Sands and Woo departed from the meeting.

Public Offering

Discussion ensued about the potential of a public offering of the Company's common stock, including the timing, potential size, lead underwriter, and other aspects of such offering. The Board directed management to provide an analysis of timing of an offering and to select a lead underwriter. In addition, the Board directed management to continue all business development and research and development programs in accordance with the Company's objectives and in the long term best interests of shareholders. After further discussion, upon motion duly made, seconded, the following resolutions were unanimously carried:

WHEREAS, the Board previously authorized the Company's preparation, execution, and filing with the SEC of a Registration Statement on Form S-3 (SEC File No. 333-164744) (the "***Shelf Registration Statement***") in accordance with the requirements of the Securities Act of 1933, as amended (the "***Securities Act***"), to provide for the registration and subsequent sale and issuance of certain securities of the Company from time to time on a immediate, continuous, or delayed basis pursuant to Rule 415 under the Securities Act, for a total public offering price of up to an aggregate of $150,000,000; and

WHEREAS, the Company has not completed any offerings of the securities available for issuance under the Shelf Registration Statement, such that the full $150,000,000 in aggregate total public offering price of such securities is currently available for offer and sale; and

WHEREAS, under Rule 462(b) under the Securities Act, the Company may prepare, execute, and file with the SEC a new Registration Statement on Form S-3 (a "***462(b) Registration Statement***" and, collectively with the Shelf Registration Statement, the "***Registration Statements***"), to provide for the registration of additional securities of the Company with a total public offering price of up to an aggregate amount equal to 20% of the $150,000,000 available for sale and issuance under the Shelf Registration Statement (or

Business Proprietary Information – Confidential Treatment Requested GS-0014976

$30,000,000) to be issued and sold by the Company in an offering with the securities remaining under the Shelf Registration Statement; and

WHEREAS, the Board deems it advisable and in the best interests of the Company for the Company to offer for sale to the public pursuant to the Registration Statements, shares (the "***Shares***") of the Company's common stock, par value $0.001 per share (the "***Common Stock***") for an aggregate purchase price of up to $180,000,000 (the "***Maximum Amount***") in a public offering (the "***Offering***") through one or more investment banks (each an "***Investment Bank***") to be led by an investment bank to be chosen by the Authorized Officers (as that term is defined below); and

WHEREAS, the Board deems it advisable and in the best interests of the Company to reconstitute the Pricing Committee of the Board (the "***Pricing Committee***") with G. Steven Burrill, P. Schaefer Price and Robert F. Williamson III as the sole members of such Pricing Committee.

NOW, THEREFORE, BE IT HEREBY RESOLVED, that, in connection with the Offering, the Pricing Committee of the Board be, and it hereby is, reconstituted with G. Steven Burrill, P. Schaefer Price and Robert F. Williamson III appointed to serve as the sole members of the Pricing Committee; and it was further

RESOLVED, that the Pricing Committee shall be authorized to act upon the affirmative vote of two out of three members of such Pricing Committee, and that two out of three members of such Pricing Committee shall constitute a quorum thereof, with full power to act pursuant to and in order to carry out the purpose and intent of these resolutions; and it was further

RESOLVED, that the Offering be, and it hereby is, authorized and approved in all respects, and shall take place at such time and upon such terms and conditions as are authorized by the following resolutions or as may hereafter be fixed or authorized, consistent with then-prevailing market conditions, by either the Board or the Pricing Committee; and it was further

RESOLVED, that the Pricing Committee shall have any and all authority of the Board in connection with setting the number of Shares to be offered for sale (provided the aggregate purchase price of the Shares to be offered for sale shall not exceed the Maximum Amount), in setting the offering price of the Shares and in taking all other actions described in any and all of the other resolutions adopted on the date hereof relating to the Offering or otherwise; and it was further

RESOLVED, that in the event the Board or the Pricing Committee determines that a 462(b) Registration Statement is required to be filed in connection with the Offering, the Board or the Pricing Committee shall direct the Chief Executive Officer, Chief Financial Officer, or General Counsel of the Company (each, an "***Authorized Officer***") to cause to be prepared, executed and filed with the SEC a 462(b) Registration Statement; *provided, however*, that the aggregate amount of the securities registered under the 462(b) Registration Statement may not exceed $30,000,000, and any director or officer of the Company required to sign such 462(b) Registration Statement on behalf of the Company be and hereby is authorized to have his or her

Business Proprietary Information – Confidential Treatment Requested GS-0014977

name affixed thereto by the holder of a power of attorney previously executed and delivered for such purpose; and it was further

RESOLVED, that meetings of the Pricing Committee may be called upon two hours prior notice (including by telephonic or electronic transmission) by any member of the Pricing Committee and that the unanimous consent or approval of at least two of the members of the Pricing Committee present in person or by telephone conference at a meeting of the Pricing Committee shall constitute the valid action of the Pricing Committee; and it was further

RESOLVED, that the Authorized Officers be, and each of them hereby is, authorized and directed, in the name and on behalf of the Company, to negotiate terms, conditions, and provisions of such agreements as may be necessary or appropriate to carry out the Offering, including, but not limited to, an underwriting agreement or a placement agency agreement, as the case may be (an "***Investment Bank Agreement***"), as well as any related subscription or purchase agreements and escrow agreement and any other documents, agreements, or instruments contemplated by any of the foregoing (collectively, the "***Additional Documents***") and, upon completion of such negotiation and approval of the Investment Bank Agreement and any Additional Documents by the Board or the Pricing Committee, the Authorized Officers are, and each of them hereby is, authorized to execute and deliver the Investment Bank Agreement and Additional Documents as approved by the Board or the Pricing Committee on behalf of the Company; and it was further

RESOLVED, that the Authorized Officers be, and each of them hereby is, authorized and directed, in the name and on behalf of the Company, to execute and deliver to the transfer agent of the Company any and all documents required by the transfer agent to effectuate the delivery of the Shares issued in connection with the Offering and that any and all Shares issued in connection with the Offering, upon issuance and payment therefor, shall be validly issued, fully paid, and nonassessable; and it was further

RESOLVED, that the Authorized Officers be, and each of them hereby is, authorized and directed to prepare, procure all necessary signatures to, execute and file in the name and on behalf of the Company, all documents relating to or necessary to effect the Offering with the SEC under the Securities Act, including, without limitation, any amendments to either or both of the Registration Statements, any free writing prospectus, or any prospectus supplements to either or both of the Registration Statements filed pursuant to Rule 424 of the Securities Act, each with such changes or modifications as shall be deemed necessary or advisable and in the best interests of the Company by such Authorized Officer executing the same, his determination to be evidenced conclusively by his execution thereof; and it was further

RESOLVED, that the Authorized Officers be, and each of them hereby is, authorized and directed to execute and deliver, in the name and on behalf of the Company, any and all such documents required to be filed, or to supply the Investment Banks with all necessary information to make such filings, and to pay all filing fees, in connection with any matter relating to any requirement of the Financial Industry Regulatory Authority ("***FINRA***") in connection with the Offering, and the Authorized Officers shall have authority to make such changes in, or take any further action with respect to, any document or matter relative thereto as may be necessary to conform with requirements for review by FINRA; and it was further

RESOLVED, that the Authorized Officers be, and each of them hereby is, authorized and directed to execute and deliver, in the name and on behalf of the Company, any and all such documents required to be filed and to pay all filing fees, in connection with any matter relating to any requirement of The NASDAQ Stock Market, LLC ("***NASDAQ***") in connection with the Offering, and the Authorized Officers shall have authority to make such changes in, or take any further action with respect to, any document or matter relative thereto as may be required by NASDAQ; and it was further

RESOLVED, that the Authorized Officers be, and each of them hereby is, authorized and directed, in the name and on behalf of the Company, to take any and all actions that such Authorized Officer may deem necessary or advisable in order to obtain a permit, to register, or to qualify the Shares for issuance and sale or to request an exemption from registration of the Shares or to register or obtain a license for the Company as a dealer or broker under the securities laws of such of the states of the United States of America or other jurisdictions as such Authorized Officer may deem advisable, and in connection with such registrations, permits, licenses, qualifications, and exemptions to execute, acknowledge, verify, deliver, file, and publish all such applications, reports, issuer's covenants, resolutions, irrevocable consents to service or process, powers of attorney, and other papers and instruments as may be required under such laws or may be deemed by such Authorized Officer to be useful or advisable to be filed thereunder, and that the form of any and all resolutions required by any such state or other governmental authority in connection with any such application, report, issuer's covenant, irrevocable consent to service of process, power of attorney, and other paper and instrument be, and each of them hereby is, adopted and approved, if (i) in the opinion of any Authorized Officer so acting, the adoption of such resolutions is necessary or advisable, and (ii) the Secretary or any Assistant Secretary of the Company evidences such adoption by filing with these Resolutions adopted by the Board (these "***Resolutions***") copies of such other resolutions, which shall thereupon be deemed to be adopted by the Board and incorporated in these Resolutions as a part thereof and with the same force and effect as if included herein; and it was further

RESOLVED, that the Authorized Officers be, and each of them hereby is, authorized and directed to take any and all further actions that any such Authorized Officer may deem necessary or advisable in order to maintain such registration in effect for as long he may deem such registration to be in the best interests of the Company, such determination to be evidenced conclusively by the taking of such actions; and it was further

RESOLVED, that the Authorized Officers be, and each of them hereby is, authorized and empowered, in the name and on behalf of the Company, to select a financial printer to undertake filing and printing responsibilities in connection with the Offering and to pay such charges in connection therewith as such Authorized Officer shall deem appropriate; and it was further

RESOLVED, that the Authorized Officers be, and each of them hereby is, authorized and empowered to cause to be paid by the Company any and all expenses and fees payable by the Company arising in connection with the Offering, including without limitation, the reasonable fees and disbursements of the Company's counsel and accountants, the filing fees of the SEC, FINRA, NASDAQ, any fees and expenses of counsel to the Investment Banks

Business Proprietary Information – Confidential Treatment Requested

required by the Investment Bank Agreement (including, without limitation, as incurred in connection with the qualification of the Shares under the various blue sky laws) and such other fees and expenses as may be reasonably incurred by the Company for the consummation of the Offering; and it was further

RESOLVED, that the Company be, and it hereby is, authorized and empowered to use the net proceeds from the Offering for general corporate purposes, which may include, but not be limited to, the acquisition of assets or businesses that are complementary to the Company's existing business, the funding of clinical trials and the funding of in-licensing agreements for product candidates, additional technologies or other forms of intellectual property.

Approval of Budget through March 31, 2011

The Board reverted to its earlier discussion of management's proposed budget. Among other things, the Board discussed how decisions might be structured and made with respect to the potential future need to restrain development expenses, the framework for choosing among potentially competing product candidates, and other related issues. After discussion, upon motion duly made, seconded, and unanimously carried it was

RESOLVED, that the Board hereby approves and authorizes the budget for the period ending March 31, 2011 in accordance with management's proposal as presented to the Board for consideration at this March 18, 2010 regular meeting.

Reduction in Board Size and Board Realignment

Mr. Carney, on behalf of the Nominating and Corporate Governance Committee, described the appropriate need, in light of Fredric D. Price's resignation from the Board, for the Board to reduce its size from eight to seven members. In addition, he noted that the Board classes are no longer as equal in number as possible, as the Company's Bylaws require. In light of this, the Nominating and Corporate Governance Committee recommends that the Board accept the resignation of Michael K. Inouye as a Class I director and simultaneously elect Mr. Inouye to the Board as a Class III director. Discussion ensued, at the conclusion of which the Board unanimously carried the following:

WHEREAS, Fredric D. Price has resigned as a member of the Board of the Company effective March 17, 2010 leaving a vacant seat on the Board; and

WHEREAS, with the resignation of Fredric D. Price, Herbert J. Conrad is the sole Class III director on the Board while there are three of each of Class I and Class II directors; and

WHEREAS, upon the recommendation of the Nominating and Corporate Governance Committee of the Board, and in accordance with the provisions of the Company's Third Amended and Restated Certificate of Incorporation ("***Charter***") and the Bylaws, the Board desires to (i) reduce the number of directors from eight to seven and (ii) to make the number of

Business Proprietary Information – Confidential Treatment Requested

directors in each class as even as possible in light of the number of directors on the Board by moving Michael K. Inouye from Class I to Class III; and

WHEREAS, the Board has received the written resignation of Michael K. Inouye as a Class I director and member of the Board effective upon his appointment as a member of the Board as a Class III director.

NOW, THEREFORE, BE IT HEREBY RESOLVED, that effective upon the adjournment of this meeting, the number of directors constituting the entire Board shall be fixed at seven members until such time as changed by the Board in accordance with the Charter and Bylaws; and it was further

RESOLVED, that effective upon the close of this meeting, Michael K. Inouye is hereby appointed to be a member of the Board as a Class III director until the next annual meeting of stockholders in which Class III directors are to be elected and until his successor is elected and qualified, subject to his earlier death, resignation, or removal; and it was further

RESOLVED, that the intent of the Board is (i) for the service of Michael K. Inouye as a member of the Board to be continuous for all purposes, including, but not limited to, the vesting and retention of any awards previously made to Mr. Inouye under the Company's 2007 Equity Incentive Plan (the "***Plan***"), (ii) that Mr. Inouye shall be considered for all purposes to be, and have been, a member of the Board since his initial appointment to the Board in June 2005, and (iii) that Mr. Inouye shall remain eligible for any awards under the Plan and any other compensation or benefits provided by the Company as a continuing member of the Board but shall not, as a result of the actions taken in these resolutions, be entitled to receive any awards under the Plan or other compensation or benefits provided by the Company to "new" members of Board solely due to their status as a "new" member of the Board.

General Resolutions

RESOLVED, that, in connection with the foregoing resolutions, the Authorized Officers are, and each of them hereby is, authorized, empowered and directed, in the name and on behalf of the Company, to (i) make, enter into, execute, deliver, file, and record any and all other agreements, consents, certificates and other documents and instruments with the corporate seal of the Company affixed thereto and attested by the Secretary or any Assistant Secretary of the Company or unattested or without such seal, (ii) pay or cause to be paid any and all expenses and fees and disburse such other funds of the Company, (iii) to prepare and file with the Securities and Exchange Commission a Current Report on Form 8-K or any other document deemed by any such Authorized Officer to be necessary or advisable to effect compliance with the Securities Exchange Act of 1934, as amended, and any rules and regulations promulgated thereunder, and (iv) take any and all such other actions as any such Authorized Officer may determine in his discretion to be necessary or advisable to carry out the terms, provisions, purposes, or intent of the foregoing resolutions and the actions contemplated thereby, the taking of any such action to constitute conclusive evidence of the exercise of such discretionary authority; and it is further

RESOLVED, that the Authorized Officers are, and each of them hereby is, authorized to seek and obtain the approval, consent, or waiver of any third party, or the amendment to any document to which the Company is a party, in order to carry out the terms, provisions, purposes or intent of the foregoing resolutions and the actions contemplated thereby; and it was further

RESOLVED, that the Company be, and it hereby is, authorized, through its Authorized Officers, to enter into and perform all of its covenants and obligations under the terms of the various documents, agreements, and instruments referred to herein or otherwise contemplated hereby, with such amendments or modifications thereto, or in respect thereof, as any such Authorized Officer shall deem necessary or desirable in order to carry out the terms, provisions, purposes or intent of the foregoing resolutions and the actions contemplated thereby; and it was further

RESOLVED, that, any and all actions of the Authorized Officers taken prior to the date hereof to carry out the purposes of the foregoing resolutions and the actions contemplated thereunder, the taking of any such action to constitute conclusive evidence of the exercise of such discretionary authority, are hereby ratified, approved, and confirmed in all respects.

The members of management departed from the meeting at approximately 11:00 a.m., after which the Board held an executive session, after which the meeting was adjourned.

Respectfully submitted,

_____
Paul Lubetkin

Business Proprietary Information – Confidential Treatment Requested

MINUTES OF PRICING COMMITTEE OF THE BOARD OF DIRECTORS OF PHARMASSET, INC.

MAY 13, 2010

Directors in attendance:
G. Steven Burrill
P. Schaefer Price
Robert F. Williamson, III

Other in attendance at the invitation of the Committee:
From the Company—
Kurt Leutzinger, Chief Financial Officer
Paul Lubetkin, Executive Vice President, General Counsel, and Secretary
Richard Smith, Vice President, Shareholder Communications and Investor Relations

From Pepper Hamilton LLP—
Steven Abrams

The Pricing Committee (the "***Committee***") of the Board of Directors (the "***Board***") of Pharmasset, Inc. (the "***Company***") held a telephonic meeting commencing at 5:30 p.m. E.D.T. on May 13, 2010. All members of the Committee being present, a quorum was established. Mr. Lubetkin acted as Secretary. After discussion among the Committee members, members of management, and representatives of Citigroup Capital Markets, and upon motion duly made, seconded, and unanimously carried, the Board adopted the following resolution:

WHEREAS, on February 5, 2010, the Company filed a Registration Statement on Form S-3 (Registration No. 333-164744) (the "***Shelf Registration Statement***") in accordance with the requirements of Rule 415 promulgated under the Securities Act of 1933, as amended (the "***Securities Act***"), to provide for the registration and subsequent sale and issuance of certain securities of the Company from time to time on a immediate, continuous, or delayed basis pursuant to Rule 415 under the Securities Act;

WHEREAS, on March 18, 2010, the Board of Directors of the Company (the "***Board***") approved (i) the preparation and filing of a new Registration Statement on Form S-3 in accordance with the requirements of Rule 462(b) promulgated under the Securities Act (the "***462(b) Registration Statement***" and together with the Shelf Registration Statement, the "***Registration Statements***"), to provide for the registration and subsequent sale and issuance of additional securities of the Company to be issued and sold by the Company in an offering with the securities remaining under the Shelf Registration Statement, (ii) the offering for sale to the public pursuant to the Registration Statements of shares of the Company's common stock (the "***Shares***") for an aggregate purchase price of up to $180,000,000 (the "***Maximum Amount***") in a public offering (the "***Offering***"), and (iii) the negotiation and execution of such agreements as may be necessary or appropriate to carry out the Offering, including, but not limited to, an underwriting agreement or a placement agency agreement, as well as any related subscription or purchase agreements and escrow agreement and any other documents, agreements, or instruments contemplated by any of the foregoing;

WHEREAS, the Board delegated the authority to the Committee to take any and all of the following actions:

1. setting the number of Shares to be offered for sale, *provided, however*, that the aggregate purchase price of such Shares to be offered for sale shall not exceed the Maximum Amount; and

2. setting the offering price of the Shares; and

3. taking all other actions described in any and all of the other resolutions adopted by the Board relating to the Offering or otherwise; and

WHEREAS, the Committee has considered the above matters and desires to take all of the actions as directed by the Board.

NOW, THEREFORE, BE IT HEREBY RESOLVED, that the Committee unanimously approves and authorizes the offering and issuance by the Company of 3,680,000 Shares, including 480,000 Shares for which the underwriters have been granted an overallotment option, at a price of $29.00 per Share to the public and a per Share discount to the underwriters of $1.45.

There being no further business, the meeting was adjourned.

Respectfully submitted,

Paul Lubetkin
Secretary

MINUTES OF PRICING COMMITTEE OF THE BOARD OF DIRECTORS OF PHARMASSET, INC.

APRIL 23, 2010

Directors in attendance:
G. Steven Burrill
P. Schaefer Price
Robert F. Williamson, III

Other in attendance at the invitation of the Committee:
From the Company—
Kurt Leutzinger, Chief Financial Officer
Paul Lubetkin, Executive Vice President, General Counsel, and Secretary
Richard Smith, Vice President, Shareholder Communications and Investor Relations

The Pricing Committee (the "***Committee***") of the Board of Directors (the "***Board***") of Pharmasset, Inc. (the "***Company***") held a telephonic meeting, pursuant to notice, commencing at 9:00 a.m. E.S.T. on April 23, 2010. All members of the Committee being present, a quorum was established. Mr. Lubetkin acted as Secretary. Mr. Price summarized the agenda, which was to consider management's recommendation for sole book runner, co-lead, and co-managers of a potential offering of the Company's common stock (the "***Offering***") in accordance with the Board's resolutions and directions at its March 18, 2010 meeting. After discussion, the Committee approved management's recommendation, subject to obtaining reasonable and appropriate terms and conditions, to engage Citigroup as sole book running manager, J.P. Morgan as co-manager or co-lead, and up to three additional co-managers of the Offering. The final selection of additional co-managers will be made by management, whose decision will reflect, among other factors, the ability of co-managers to reach different audiences, the economics of the transaction, and the relationship of the co-managers with the Company.

Mr. Leutzinger provided the Committee with a schedule of events leading to the Offering. The Committee encouraged management to move forward expeditiously in the best interests of shareholders. The Committee discussed the objectives and marketing of the Offering, and management undertook to review these matters with Citigroup. The Committee also discussed, among other things, current market conditions for biotechnology stocks and Company shares, upcoming industry events, the Company's recent business development, partnership, and development activities, and other related matters.

There being no further business, the meeting was adjourned at approximately 9:40 a.m.

Respectfully submitted,

Paul Lubetkin
Secretary

Minutes of the Regular Meeting of the
Audit Committee of the Board of Directors of
Pharmasset, Inc.
April 30, 2010

Committee Members in attendance:
G. Steven Burrill, Chairman of the Audit Committee
William J. Carney
Robert F. Williamson

Others in attendance at the invitation of the Committee:
From the Company—
Kurt Leutzinger, Chief Financial Officer
Paul Lubetkin, Executive Vice President, General Counsel and Secretary
James Maguire, Vice President, Financial Reporting
Mark Meester, Vice President, Accounting and Administration
P. Schaefer Price, President, Chief Executive Officer, and director

From Grant Thornton—
Immanuel John K.
Laura Iacona
James Epperson

The Audit Committee of the Board of Directors of Pharmasset, Inc. (the "Company") held a regular meeting, pursuant to notice, on March 10, 2010 commencing at 1:00 p.m. Eastern Daylight Time via teleconference. Mr. Lubetkin served as secretary.

Mr. John summarized Grant Thornton's Audit Committee Presentation, a copy of which was previously provided to the Audit Committee. Grant Thornton has completed, subject to receipt of a management representation letter, its SAS 100 review of the Company's Form 10-Q for the quarter ended March 31, 2010. Among other things, Mr. John reported that Grant Thornton did not identify any adjustments to the financial statements or disclosures therein and provided required communications with the Audit Committee. The members of the Audit Committee confirmed that they had nothing to report to Grant Thornton with respect to the financial statements. Discussion ensued regarding Grant Thornton's presentation. The Audit Committee considered, among other things, the Company's disclosures of certain potential risks and contingencies. Management discussed bases for management's conclusion that its disclosures are appropriate and reasonable and Mr. John described the bases for Grant Thornton's views regarding such disclosure. Based on this discussion, the Audit Committee concluded that the Company's disclosures are appropriate and reasonable.

Mr. John summarized the remainder of Grant Thornton's presentation including, among other things, an accounting update, SEC and corporate governance update, and audit standard update. Discussion ensued, concluding Grant Thornton's formal presentation.

The Audit Committee discussed the draft Form 10-Q, at the conclusion of which the Audit Committee unanimously approved the Form 10-Q, after it has been finalized with forthcoming clinical trial data and such other revisions or changes as management believes may be necessary and appropriate.

At approximately 1:20 p.m., the Company representatives (other than Mr. Lubetkin) departed from the meeting, and the Audit Committee conducted an executive session with Grant Thornton. Mr. John reported that he had nothing to add to his earlier report.

Business Proprietary Information – Confidential Treatment Requested GS-0014986

There being no further business, the meeting was adjourned at approximately 1:30 p.m.

Respectfully submitted,

Paul Lubetkin, Secretary

Business Proprietary Information – Confidential Treatment Requested GS-0014987

Minutes of the Regular Meeting of the Compensation Committee of the Board of Directors of Pharmasset, Inc. July 13, 2010

Directors in attendance:
Michael K. Inouye
Robert F. Williamson III, Committee Chairman

Others in attendance:
From the Company:
Lisa Griffin, Director, Human Resources
Mark W. Meester, Vice President, Accounting and Administration
P. Schaefer Price, President, CEO, and a director

The Compensation Committee (the "Committee") of the Board of Directors (the "Board") of Pharmasset, Inc. (the "Company") held a regular meeting, pursuant to notice, on July 13, 2010 via teleconference commencing at 10:05 a.m. (New York time). Committee members Messrs. Inouye and Williamson were present; Ms. Griffin and Messrs. Meester and Price attended at the invitation of the Committee. Ms. Griffin acted as secretary for the meeting.

Mr. Williamson called the meeting to order, conducted a roll call, determined a quorum was present, and reviewed the previously circulated proposed agenda.

Management and the Committee discussed the need for retaining an independent consulting firm to perform an updated executive compensation and equity study, and the timing for the next Board and Committee compensation analysis. The Committee reviewed, discussed, and unanimously approved the retention of Radford Consulting, an independent firm, to perform certain executive compensation and equity analysis, including a review and recommendation of peer company comparators. After further discussion, the Committee approved to conduct the next Board and Committee compensation review during the fourth quarter of FY2011.

The Committee reviewed the need for replenishment of the Company's 2007 Equity Incentive Plan and, after further discussion, agreed to report on this matter and recommend that the Board prepare for a shareholder vote to increase the stock option pool at the next annual meeting.

There being no further business, upon motion duly made, seconded, and unanimously carried, the meeting was adjourned at approximately 10:35 a.m.

Respectfully submitted,

Lisa Griffin

Business Proprietary Information – Confidential Treatment Requested

PHARMASSET

WHERE INNOVATION IS VIRAL

303-A College Road East
Princeton NJ 08540 USA
Office 609 613 4100
Fax 609 613 4150
www.pharmasset.com

MEMORANDUM

To: Compensation Committee

From: Mark W. Meester, Lisa Griffin

Date: July 8, 2010

Subject: Updated compensation study / External compensation consultant review

---

Recommendation

Update Pharmasset's executive total cash (base/bonus) compensation study originally completed in September 2009. Conduct an updated equity study if Pharmasset's stock price remains at or above $24.26 through August 2010, with results to be used for annual grants in October 2010.

Background

Based on public company best practices and Radford's recommendations, an executive compensation and equity review should be conducted annually. Currently 95% of Radford's clients perform annual updates. In this current regulatory environment as it relates to compensation, we believe the practice of annual updates for the next few years is justifiable.

In addition to best practices, if stock price increases 30% or greater since the prior study was conducted, an updated study should be performed. Radford's FY10 Proposed Equity Guidelines conducted September 2009 were based on Pharmasset's 30-day average share price of $18.66. If Pharmasset's stock price remains at or above $24.26 (30% increase), this reinforces the decision to perform an annual update.

The estimated cost to conduct an updated executive compensation and equity study would be approximately $35,000, based on last year's fee structure.

The peer group analysis discussed in an additional memo will be reviewed by an external consultant as part of the annual update.

PHARMASSET

WHERE INNOVATION IS VIRAL

303-A College Road East
Princeton NJ 08540 USA
Office 609 613 4100
Fax 609 613 4150
www.pharmasset.com

MEMORANDUM

To: Compensation Committee

From: Mark W. Meester, Lisa Griffin

Date: July 8, 2010

Subject: Peer Company Comparators update

Recommendation

Review and approve peer company comparators, to be used for an updated executive compensation and equity study.

Background

Radford's Executive Assessment completed in October 2009 used 21 peer comparator companies approved by the Compensation Committee. The selected peers included some historical peers as well as new peers that range from approximately 1/3 to 3x Pharmasset's size in headcount and market value and are at a similar stage of development.

Refer to **Attachment A** for updated peer company comparator data. Peer changes related to the criteria noted above are highlighted on the attachment. Pharmasset continues to outperform our peer group (with the exception of two) in all categories related to shareholder value.

ATTACHMENT A

	Pharmasset - Peer Comparator Company List - 2010					Most recent Fiscal Year							Market data as of: 6/22/10 (VRUS as of 6/30/10)					
	Company		Location	Prior FY	Stage of development	Prior FY	# of Employees	# diff	% change	Revenue	Net Income	R&D expense	Stock price	Total common shares outstanding	Prior FY	Market Cap. ($M)	# diff	% change
1	Acadia Pharmaceuticals	ACAD	San Diego, CA	Phase 3	same	63	27	-36	-57%	6.4	(45.1)	41.6	1.22	38,336,377	75.8	46.8	-29.0	-38%
2	Allos Therapeutics	ALTH	Westminster, CO & Princeton NJ	Phase 2	Market	81	170	89	110%	3.6	(73.6)	32.6	6.34	105,229,081	672.2	667.2	-5.0	-1%
3	Alnylam Pharma	ALNY	Cambridge, MA	Phase 2	same	170	178	8	5%	100.5	(47.6)	108.7	15.25	41,961,028	904.7	639.9	-264.8	-29%
4	Antigenics	AGEN	Lexington, MA	Phase 3	same	80	54	-26	-33%	3.3	(30.3)	16.9	0.68	94,231,519	176.6	82.6	-94.0	-53%
5	Ardea Biosciences	RDEA	San Diego, CA	Phase 2	Phase 2b	81	62	-19	-23%	22.9	(30.9)	42.2	22.31	22,778,274	347.6	508.2	160.6	46%
6	Ariad Pharma	ARIA	Cambridge, MA	Phase 3	same	150	149	-1	-1%	8.3	(60.0)	63.4	3.27	110,681,230	245.9	361.9	116.0	47%
7	Arqule	ARQL	Woburn, MA	Phase 2	same	107	111	4	4%	25.2	(36.1)	49.5	4.92	44,786,656	243.5	220.4	-23.1	-9%
8	Cytokinetics	CYTK	South SF, CA	Phase 2	Phase 2a	110	111	1	1%	81.5	24.5	39.8	2.61	64,389,446	194.5	168.1	-26.4	-14%
9	Geron	GERN	Menlo Park, CA	Phase 2	same	159	172	13	8%	1.7	(70.4)	57.6	5.03	98,181,475	629.2	493.9	-135.3	-22%
10	Idenix	IDIX	Cambridge, MA	Market	Phase 2b	173	144	-29	-17%	12.6	(53.2)	41.9	4.80	72,857,018	183.7	349.7	166.0	90%
11	Idera	IDRA	Cambridge, MA	Phase 2	same	37	40	3	8%	34.5	7.5	18.6	3.71	23,489,000	178.7	87.1	-91.6	-51%
12	Incyte	INCY	Wilmington, DE	End Ph 2	Phase 3	212	221	9	4%	9.3	(211.9)	119.4	12.06	121,133,647	651.2	1460.9	809.7	124%
13	InterMune	ITMN	Brisbane, CA	Market	same	130	121	-9	-7%	48.7	(116.0)	88.1	9.31	55,362,626	716.1	515.4	-200.7	-28%
14	Mexygen	MAXY	Redwood City, CA	Phase 2	same	72	64	-8	-11%	14.5	(18.4)	41.9	5.84	31,070,569	279.4	175.2	-104.2	-37%
15	Medivation	MDVN	San Francisco, CA	Phase 3	same	59	98	39	66%	69.3	(54.8)	87.7	9.52	34,008,485	847.1	323.8	-523.3	-62%
16	Micromet	MITI	Bethesda, MD	Phase 2	same	104	140	36	35%	21.0	(57.7)	53.4	6.89	80,831,555	477.4	556.9	79.5	17%
17	Novavax	NVAX	Rockville, MD	Phase 2	same	59	93	24	35%	0.3	(38.4)	25.8	2.21	100,468,543	530.4	222.1	-308.3	-58%
18	Optimer Pharma	OPTR	San Diego, CA	Phase 3	same	55	69	14	25%	0.9	(42.1)	33.7	9.25	38,241,264	424.4	353.7	-70.7	-17%
19	Poniard Pharma	PARD	South SF, CA	Phase 3	same	59	22	-37	-63%	-	(45.7)	25.7	0.77	47,073,262	273.1	36.2	-236.9	-87%
20	Targacept	TRGT	Winston-Salem, NC	Phase 2	Phase 3	113	116	3	3%	25.1	(38.4)	40.2	21.19	28,486,073	375.1	603.6	228.5	61%
21	Theravance	THRX	South SF, CA	NDA filed	(same) Phase 3	191	194	3	2%	24.4	(65.3)	77.5	14.38	63,761,505	1001.0	916.9	-84.1	-8%
	Pharmasset	VRUS	Princeton, NJ	Phase 2b	same	67	62	-5	-7%	13.3	(55.6)	52.6	27.34	33,968,441	539.1	928.7	389.6	72% 27.34
							1/3 = 20									1/3 = 309		
							3x = 166									3x = 2,780		

X:\Board & Comp Committee info\Peers Company Comparator update 7-10.xls

Business Proprietary Information – Confidential Treatment Requested

PHARMASSET

WHERE INNOVATION IS VIRAL

303-A College Road East
Princeton NJ 08540 USA
Office 609 613 4100
Fax 609 613 4150
www.pharmasset.com

To: Compensation Committee

From: Mark W. Meester, Lisa Griffin

Date: July 8, 2010

Subject: Board and Committee Compensation review

Recommendation

Schedule the independent review of board and committee compensation during the fourth quarter of FY11.

Background

Based on public company best practices and Radford's recommendation, board and committee compensation review should be conducted every two years. Pharmasset's most recent review of board and committee compensation was conducted in September 2009, therefore the next review should take place during 2011.

PHARMASSET

WHERE INNOVATION IS VIRAL

303-A College Road East
Princeton NJ 08540 USA
Office 609 613 4100
Fax 609 613 4150
www.pharmasset.com

MEMORANDUM

To: Compensation Committee

From: Mark W. Meester, Lisa Griffin

Date: July 8, 2010

Subject: Stock Option Pool Update as of June 30, 2010

Recommendation

Prepare for a shareholder vote to increase the stock option pool at the next annual meeting.

Background

Our prior increase was to ensure there were enough options in our pool for approximately two years through FY11. As of June 30, 2010, the remaining option pool is 712,346. Based on the historical amount of options which will be utilized for current Employees (425,000) and Directors (120,000) for the annual grants in October 2010 the remaining pool will be reduced to 167,346. In addition, we anticipate the positions that will be recruited and hired prior to the next annual meeting require approximately 45,000 additional options reducing the pool to 122,346. The March 2011 Director Restricted Shares (12,000) will further reduce the pool to 110,346. Therefore, we believe that increasing the pool at the next annual meeting will be required.

Below outlines our current option and restricted share position.

Refer to **Attachment A** for the following:

Issued Option Equity Overhang (calculated without using outstanding options in the denominator)
As of June 30, 2010, the total number of outstanding options and restricted shares is 2,937,428, which makes the current Issued Option Equity Overhang 8.60%.

Total Option Equity Overhang (calculated without using outstanding options in the denominator)
As of June 30, 2010, the total number of outstanding options, restricted shares and remaining available options equals 3,649,774, which makes the current Total Option Equity Overhang 10.68%.

Refer to **Attachment B** for the following:

Issued Option Equity Overhang (calculated using options in the denominator)

As of June 30, 2010, the total number of outstanding options and restricted shares is 2,937,428, which makes the current Issued Option Equity Overhang 7.77%.

Total Option Equity Overhang (calculated using options in the denominator)
As of June 30, 2010, the total number of outstanding options, restricted shares and remaining available options equals 3,649,774, which makes the current Total Option Equity Overhang 9.65%.

The overhang percentages calculated above compare very favorably to the ISS guidelines (used in the September 23, 2009 report) that were utilized to analyze Pharmasset's request for an increase in the option pool in September 2009. The following table shows a comparison with Pharmasset's four-digit GICS group of Pharmaceuticals, Biotechnology & Life Sciences (comparator group as of September 23, 2009). The GICS percentages are calculated using the method used to calculate Pharmasset, Inc. **B.**

	Total Potential Dilution (fully diluted shares Outstanding)
Pharmasset, Inc. **A**	10.68%
Pharmasset, Inc. **B**	9.65%
GICS median	14.99%
GICS average	16.71%
GICS 75th percentile	20.01%

Based on this analysis, Pharmasset could increase our pool by 2,380,000 (**Refer to Attachment C**) resulting in our overhang being 15% (GICS median being 14.99%). We believe that the compensation committee and the company should prepare for a shareholder vote for an increase (amount to be determined) in the option pool at the upcoming Annual Shareholder Meeting.

Business Proprietary Information – Confidential Treatment Requested

Attachment A

Options	Total Options Outstanding 06.30.10	% of Fully Diluted Shares as of 06.30.10	Vested Options 06.30.10	% of Fully Diluted Shares as of 06.30.10
Employees				
Section 16 Filers	1,172,357	3.43%	818,211	2.39%
Current Staff (excluding Section 16 Filers)	1,132,175	3.31%	547,354	1.60%
Current Directors	553,292	1.62%	385,792	1.13%
Former Staff	9,605	0.03%	9,605	0.03%
Former Directors	3,334	0.01%	3,334	0.01%
Consultants	0.00	0.00%	0.00	0.00%
Licensing	-	0.00%	-	0.00%
	2,870,762	8.40%	1,762,296	5.16%

Restricted Stock	Total Restricted Shares Outstanding 06.30.10	% of Fully Diluted Shares as of 06.30.10	Vested Restricted Shares 06.30.10	% of Fully Diluted Shares as of 06.30.10
Employees	-		-	
Current Directors	40,000	0.12%	28,000	0.08%
Former Staff	-		-	
Former Directors	-		-	
Consultants	26,666	0.08%	23,332	0.07%
Licensing	-		-	
	66,666	0.20%	51,332	

TOTAL OPTIONS & RESTRICTED SHARES:	2,937,428	8.60%	1,813,628	5.31%
Remaining Option Pool Prior to Increase	712,346	2.09%		
Requested Option Pool Increase	-	0.00%		
TOTAL:	3,649,774	10.68%	1,813,628	

Total Outstanding Shares * as of 06/30/10	34,162,356

* Shares = Total Outstanding Shares +Outstanding Restricted Shares + Outstanding Warrants

Attachment B

Options	Total Options Outstanding 06.30.10	% of Fully Diluted Shares as of 06.30.10	Vested Options 06.30.10	% of Fully Diluted Shares as of 06.30.10
Employees				
Section 16 Filers	1,172,357	3.10%	816,211	2.16%
Current Staff (excluding Section 16 Filers)	1,132,175	2.99%	547,354	1.45%
Current Directors	553,252	1.46%	385,792	1.02%
Former Staff	9,605	0.03%	9,605	0.03%
Former Directors	3,334	0.01%	3,334	0.01%
Consultants	0.00	0.00%	0.00	0.00%
Licensing	-	0.00%	-	0.00%
	2,870,762	7.59%	1,762,286	4.66%

Restricted Stock	Total Restricted Shares Outstanding 06.30.10	% of Fully Diluted Shares as of 06.30.10	Vested Restricted Shares 06.30.10	% of Fully Diluted Shares as of 06.30.10
Employees	-		-	
Current Directors	40,000	0.11%	28,000	0.07%
Former Staff	-		-	
Former Directors	-		-	
Consultants	26,666	0.07%	23,332	0.06%
Licensing	-		-	
	66,666	0.18%	51,332	

TOTAL OPTIONS & RESTRICTED SHARES:	**2,937,428**	**7.77%**	**1,813,618**	**4.80%**
Remaining Option Pool Prior to Increase	712,346	1.88%		
Requested Option Pool Increase	-	0.00%		
TOTAL:	3,649,774	9.65%	1,813,618	

Total Outstanding Shares * as of 06/30/10	37,812,130

* Shares = Total Outstanding Shares +Outstanding Restricted Shares + Outstanding Warrants + Share Allocation from plans

Attachment C

Options	Total Options Outstanding 06.30.10	% of Fully Diluted Shares as of 06.30.10	Vested Options 06.30.10	% of Fully Diluted Shares as of 06.30.10
Employees				
Section 16 Filers	1,172,357	2.92%	816,211	2.03%
Current Staff (excluding Section 16 Filers)	1,132,175	2.82%	547,354	1.36%
Current Directors	553,282	1.38%	385,792	0.96%
Former Staff	9,605	0.02%	9,605	0.02%
Former Directors	3,334	0.01%	3,334	0.01%
Consultants	0.00	0.00%	0.00	0.00%
Licensing	-	0.00%	-	0.00%
	2,870,752	7.14%	1,762,296	4.38%

Restricted Stock	Total Restricted Shares Outstanding 06.30.10	% of Fully Diluted Shares as of 06.30.10	Vested Restricted Shares 06.30.10	% of Fully Diluted Shares as of 06.30.10
Employees	-		-	
Current Directors	40,000	0.10%	28,000	0.07%
Former Staff	-		-	
Former Directors	-		-	
Consultants	26,666	0.07%	23,332	0.06%
Licensing	-		-	
	66,666	0.17%	51,332	

TOTAL OPTIONS & RESTRICTED SHARES:		2,937,428	7.31%	1,813,628	4.51%
Remaining Option Pool Prior to Increase		712,346	1.77%		
Potential Option Pool Increase		2,380,000	5.92%		
	TOTAL:	6,029,774	15.00%	1,813,628	

Total Outstanding Shares * as of 06/30/10	40,192,130

* Shares = Total Outstanding Shares +Outstanding Restricted Shares + Outstanding Warrants + Share Allocation from plans

Pharmasset
Risk Management and the Role of the Board of Directors

July 21, 2010

PHARMASSET
WHERE INNOVATION IS VIRAL

Business Proprietary Information – Confidential Treatment Requested

Introduction

- **Why is the role of the Board of Directors of a publicly traded company as it relates to risk management important today?**
  - The public and political perception that undue risk-taking was central to the breakdown of the financial and credit markets has fueled extensive legislative, regulatory, and even judicial focus on risk management and prevention
  - The SEC recently enacted disclosure rules that require discussion in proxy statements of the board's role in overseeing and managing risk and the relationship between a company's overall employee compensation policies and risk management
  - Risk management is also likely to receive heightened focus by shareholder activists and other "corporate governance" proponents

PHARMASSET
WHERE INNOVATION IS VIRAL

Business Proprietary Information – Confidential Treatment Requested

- **What is the proper role of the board in corporate risk management?**
  - The board cannot and should not be involved in actual day-to-day risk management
  - Directors should through their risk oversight role, satisfy themselves that the risk management processes designed and implemented by the company's management are consistent with the company's corporate strategy and are functioning as directed, and that necessary steps are taken to foster a culture of risk-aware and risk-adjusted decision-making throughout the organization
  - Establishing the right "tone at the top" of the corporation is one of the most important factors in ensuring that a board functions effectively and is able to meet all of its responsibilities, particularly with respect to risk oversight

609

PHARMASSET
WHERE INNOVATION IS VIRAL

Business Proprietary Information – Confidential Treatment Requested

- **How should an effective company risk management system function?**
  - A company's risk management system should bring to the board's attention the company's most material risks and permit the board to understand and evaluate how those risks interrelate, how they affect the company, and how management addresses those risks
- **What organizational structures should the board consider to give risk oversight sufficient attention at the board level?**
  - Does the board need a separate risk management committee or subcommittee?
  - Can it be effective by scheduling the review of risk management as a dedicated and periodic agenda item for an existing committee such as the audit committee, coupled with a periodic review at the full board?
  - Can it be effective by allocating responsibilities among existing committees as long as the committees coordinate their risk management efforts and share information appropriately with each other and with the full board?

- While no "one size fits all," risk management is a board priority; a system for risk oversight appropriate to the company must be in place

PHARMASSET
WHERE INNOVATION EVIRAL

Business Proprietary Information – Confidential Treatment Requested

Recommendations for Effective Risk Oversight

- Risk management should be tailored to Pharmasset. In general, an effective risk management system will:
  - Adequately identify the material risks that Pharmasset faces in a timely manner
  - Implement appropriate risk management strategies that are responsive to Pharmasset's risk profile, business strategies and specific material risk exposures
  - Integrate consideration of risk and risk management into business decision-making throughout Pharmasset
  - Include policies and procedures that adequately transmit necessary information with respect to material risks to senior executives, and as appropriate, to the board or relevant committees

609

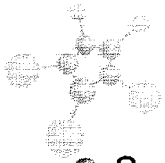
Recommendations for Effective Risk Oversight

- **Specific recommendations:**
  - Having the right "tone at the top" of the corporation
    - Transparency, consistency, and communication are key
  - Board should give serious and thoughtful attention to Pharmasset's risk management process and system, the nature of the material risks the company faces, and the adequacy of the company's policies and procedures designed to respond to and mitigate these risks.
  - Board should consider taking the following actions:
    - Review with management the company's risk appetite and risk tolerance, the ways in which risk is measured on an aggregate, company-wide basis, and the setting of aggregate and individual risk limits (quantitative and qualitative, as appropriate), and the actions taken if those limits are exceeded
    - Review with management the categories of risk the company faces, including any risk concentrations and risk interrelationships, as well as the likelihood of occurrence, the potential impact of those risks, and mitigating measures

610

PHARMASSET
WHERE INNOVATION IS VIRAL

Business Proprietary Information – Confidential Treatment Requested



Recommendations for Effective Risk Oversight

- Specific recommendations (continued):
  - Review with management the board's expectations for risk oversight and management of specific risks to ensure a shared understanding as to accountabilities and roles
  - Review the risk policies and procedures adopted by management, including procedures for reporting to the board and appropriate committees and providing updates, to assess whether they are appropriate and comprehensive
  - Review management's implementation of risk policies and procedures, to assess whether they are being followed and are effective
  - Review with management the quality, type and format of risk-related information provided to directors
  - Review the steps taken by management to ensure adequate independence of the risk management function and the processes for resolution and escalation of differences that might arise between risk management and business functions

PHARMASSET
WHERE INNOVATION IS VIRAL

Business Proprietary Information – Confidential Treatment Requested

Recommendations for Effective Risk Oversight

- Specific recommendations (continued):
  - Review with management the design of the company's risk management functions, including potential coverage gaps and reporting lines of authority, the qualifications and backgrounds of senior executives, and the personnel policies applicable to risk management, to assess whether they are appropriate given the company's size and scope of operations
  - Review with management the means by which the company's risk management strategy is communicated to appropriate groups within the company so that it is properly integrated into the company's business strategy
  - Review reports from management, independent auditors, legal counsel, regulators, stock analysts, and outside experts as appropriate regarding risks the company faces and company's risk management function

612

PHARMASSET
WHERE INNOVATION IS VITAL

Business Proprietary Information – Confidential Treatment Requested

Recommendations for Effective Risk Oversight

- **Other things to consider that may help the board in carrying out its risk oversight role:**
  - Board training
  - Board and committee composition
  - Lines of communication and information flow
  - Legal compliance programs
  - Mechanisms for anticipating future risks

PHARMASSET
WHERE INNOVATION IS VIRAL

Business Proprietary Information – Confidential Treatment Requested

Risk Management at Pharmasset

- **Pharmasset has established an environment and organizational structure where risk management oversight and risk mitigation are critical business components**
  - Board of Directors
    - Audit Committee
    - Nomination and Governance Committee
    - Compensation Committee
    - Special Committees as needed
  - Chairman of board separate from CEO position
  - Executive Team
    - Disclosure Committee
    - Other compliance mechanisms
  - Clinical Development Plan Team
  - Project Review Team
    - Project Teams
  - Candidate Selection Team
  - Research Team

PHARMASSET
WHERE INNOVATION IS VIRAL

Business Proprietary Information – Confidential Treatment Requested

Establishing the "Tone at the Top"

- **Pharmasset has established an environment of transparency, consistency and communication**
  - Board of Directors
    - Quarterly board meetings
      - Committee meetings
      - Development project updates
      - Business development updates
      - Finance updates
      - Research updates
    - Periodic written board updates
      - Provide updates on performance objectives
        - » % completion
        - » Explanation for not being on target
        - » Proposed changes if necessary
    - Ad hoc board calls with management as necessary
    - Special meetings as needed

PHARMASSET
WHERE INNOVATION IS VIRAL

Business Proprietary Information – Confidential Treatment Requested

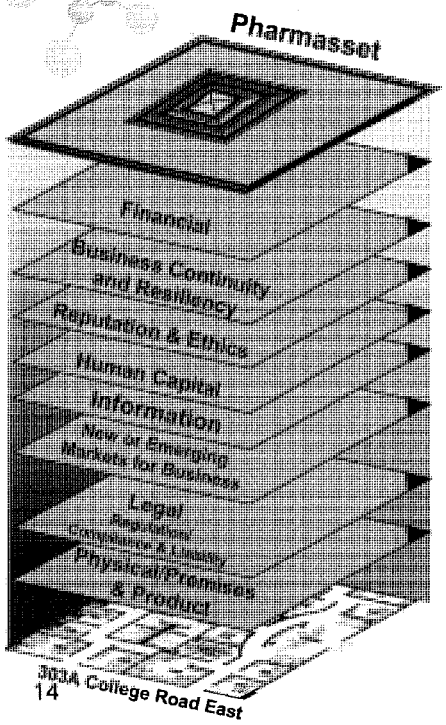
Establishing the "Tone at the Top"

- **Pharmasset has established an environment of transparency, consistency and communication**
  - Quarterly R&D Strategy Meetings
    - Multi-functional participation
    - Key opinion leader participation
  - Semi-annual Objectives Meeting
    - Participation by all company employees
    - Update objective status
    - Propose future/changed objectives
      - Identify go/no go decisions when required
      - Request additional resources if necessary
      - Identify pros and cons of objectives

PHARMASSET
WHERE INNOVATION IS VITAL

Business Proprietary Information – Confidential Treatment Requested

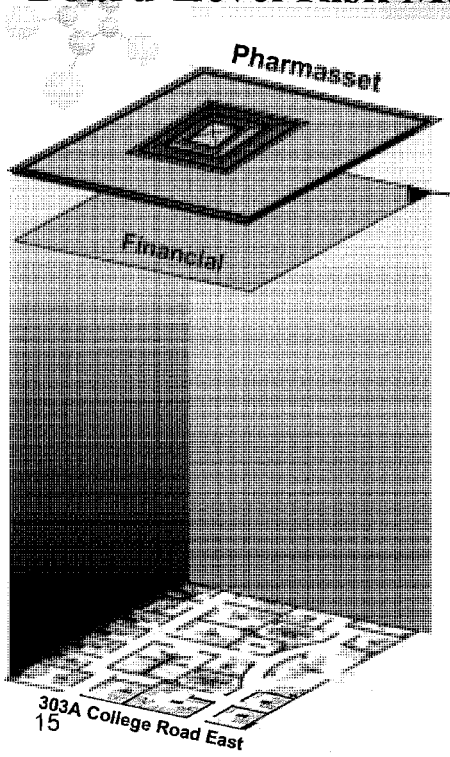
Board-Level Risk Management Program Elements



PHARMASSET
WHERE INNOVATION IS VIRAL

Business Proprietary Information – Confidential Treatment Requested

Board-Level Risk Management Program Elements

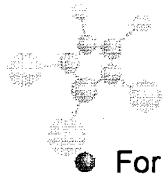


- Assets Management
- Accounting & Reporting
- Market Fluctuations

- Asset protection
- Exceptions management
- Violation detection and reporting
- Allegation of manipulation investigations
- Regulatory inquiries

PHARMASSET
WHERE INNOVATION IS VIRAL

Business Proprietary Information – Confidential Treatment Requested



Risk Management – Financial

- For Pharmasset, risk management processes covering financial areas of the Company consist of:
  - Asset Management
  - Accounting and Reporting, including the reporting of clinical trial results
  - Market Risk Management
- Asset Management
  - Maintenance, protection, and defense of intellectual property
  - Safeguarding of cash and investments
    - Maintenance of Signature Authorization, Check Signing, and Investment Policies
  - Security policies covering…
    - Information Systems
    - Access to Facility and Lab areas, and
    - Access to R&D Operations
  - Employee Recruiting, Retention and Development
    - Maintenance of Compensation and Professional Development policies

PHARMASSET
WHERE INNOVATION IS VIRAL

Business Proprietary Information – Confidential Treatment Requested

Risk Management – Financial

- Accounting and Reporting, including the reporting of clinical trial results
  - SEC Reporting (includes 10-Qs and 10-Ks)
    - Effective maintenance of day-to-day internal controls over financial reporting and reporting of operating (clinical trial) results
    - Detailed review of SEC filings performed by Financial Management and outside auditors (Grant Thornton)
    - General review of SEC filings performed by Disclosure Committee, outside counsel (Pepper Hamilton), and Audit Committee (10-Qs) or Board (10-Ks)
    - Continued compliance with internal controls over financial reporting reported on by Grant Thornton annually
  - Press Releases and Investor Conferences
    - Leverage off day-to-day internal controls in place for SEC reporting
    - Detailed review of press release or investor presentation content performed by Finance/Clinical Development
    - General review of press releases or investor presentation performed by Disclosure Committee, and outside auditors/counsel when appropriate

620

PHARMASSET
WHERE INNOVATION IS VIRAL

Business Proprietary Information – Confidential Treatment Requested

Risk Management – Financial

- Critical Reporting Risk Management Practices
  - Review comments received are aggregated and then reviewed at face-to-face Disclosure Committee meeting.
  - Maintenance of the right "tone at the top" is routinely demonstrated by all Disclosure Committee members.

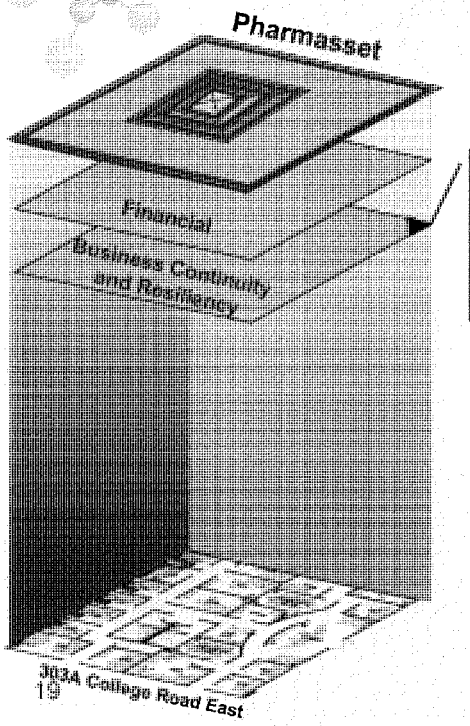
- Market Risk Management
  - Protecting against liquidity risks
    - Maintenance of appropriate levels of cash to fund operations
      - Semi-annual development of comprehensive operating plan and financing plan that is approved by the Board
      - Maintenance of longer term (3 to 5 year) financial projection model
      - Maintenance of multi-year model (25 years) accessing financial risk and reward contemplated actions
  - Minimize dilution to existing stockholders
    - Close monitoring of capital markets
      - Determining when, how much, with whom, and the form of each financing (debt vs. equity)

621

PHARMASSET
WHERE INNOVATION IS VIRAL

Business Proprietary Information – Confidential Treatment Requested

Board-Level Risk Management Program Elements



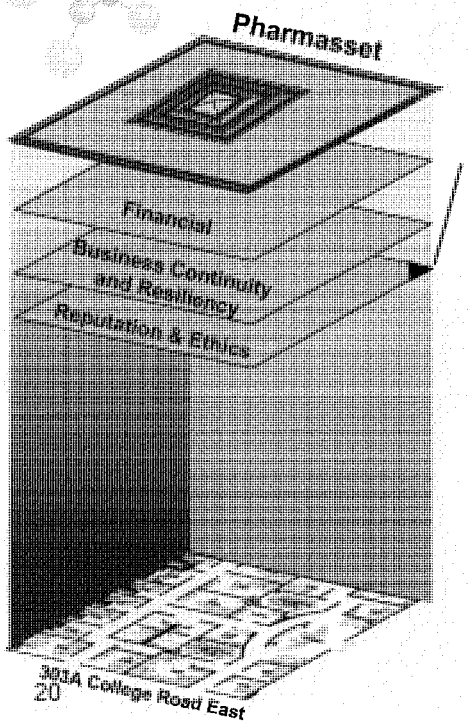
- R&D and Mfg.
- Logistics
- Environment/Safety
- Business Continuity
- Outsourcing
- Branding

- Information safeguards
- Intellectual property protection
- Disruption detection
- Mitigation management
- Emergency response
- Disaster recovery plans

PHARMASSET
WHERE INNOVATION IS VIRAL

Business Proprietary Information – Confidential Treatment Requested

Board-Level Risk Management Program Elements

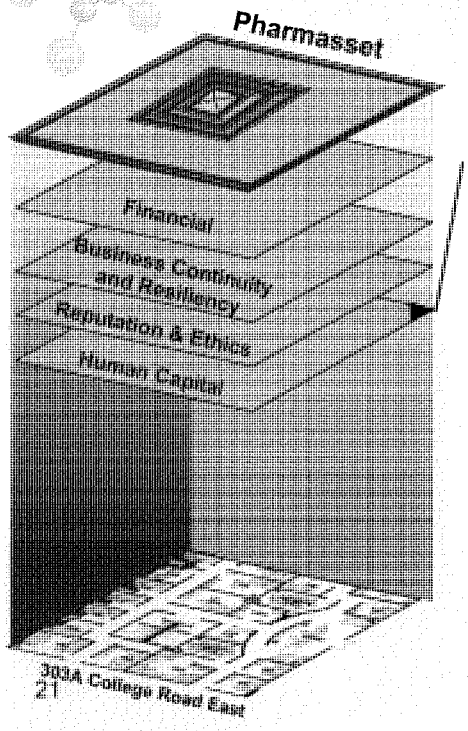


- Customer Relationships Data
- Community Relations
- Corporate Governance

- Privacy policies and compliance
- Law enforcement and liaison
- Regulatory security adherence
- Allegation response

PHARMASSET
WHERE INNOVATION IS VITAL

Board-Level Risk Management Program Elements

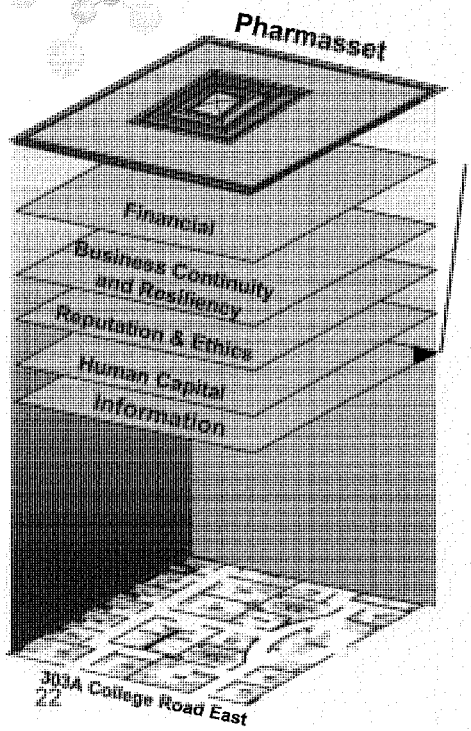


- Misconduct
- Environment Hazards
- Turnover
- Employee Skills & Performance
- Compensation & Benefits
- Services

- Background checks
- Awareness & training
- Code of conduct
- Benefits loss prevention
- Intellectual property protection

PHARMASSET
WHERE INNOVATION IS VIRAL

Board-Level Risk Management Program Elements



- Intellectual Property
- Information & Privacy
- Networks
- Applications
- Hardware
- New Technologies

- Data classification
- Intrusion detection
- Authentication and access control
- Physical access controls
- Digital ID management

PHARMASSET
WHERE INNOVATION IS VIRAL

Business Proprietary Information – Confidential Treatment Requested

Intellectual Property

- Risks
  - Disclosure of Pharmasset ideas and information
  - Failure to obtain sufficient patent protection
  - Prior invention by third party
  - Dominate third party IP
  - Intervening or interfering third party IP

- Management of Risks
  - Utilize external IP counsel/expertise
  - Protect Pharmasset IP
  - Survey third party IP and take action when necessary

626

Business Proprietary Information – Confidential Treatment Requested

Intellectual Property

- Pharmasset IP
  - Maintain strict confidentiality
  - Record-keeping
    - Laboratory Notebook
    - Invention Disclosure
    - Invention Record
  - Employee/Vendor invention assignments
  - File for patent protection
    - Provisional Patent Application
    - Non-Provisional, PCT and Non-PCT patent applications
  - Claim types and timing
  - Implement strategies through divisionals, continuations and new patent filings

PHARMASSET
WHERE INNOVATION IS VITAL

Business Proprietary Information – Confidential Treatment Requested

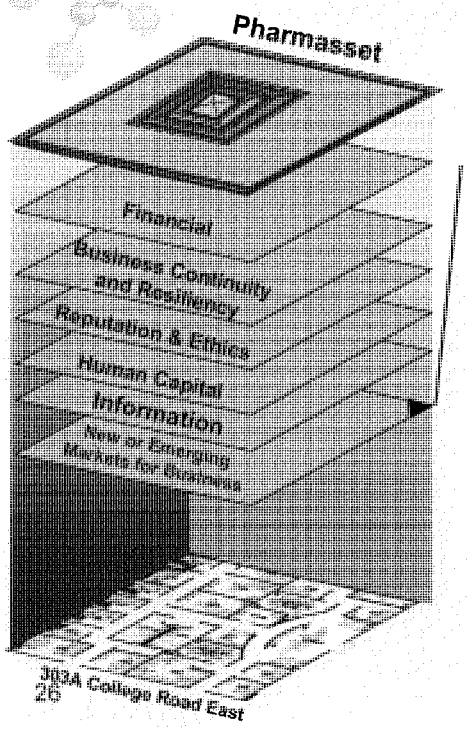
Intellectual Property

- Third Party IP
  - Surveillance
    - Patent publications
    - Scientific publications
  - Evaluation
    - Priority date
    - Overlap of subject matter
    - Patentability/validity (novelty, non-obviousness, enablement, written description)
  - Offensive Actions
    - Interference
    - Re-exam
    - Opposition (ex-US)
    - Challenge validity in district court
  - Defensive Actions
    - Licensing

PHARMASSET
WHERE INNOVATION IS VIRAL

Business Proprietary Information – Confidential Treatment Requested

Board-Level Risk Management Program Elements

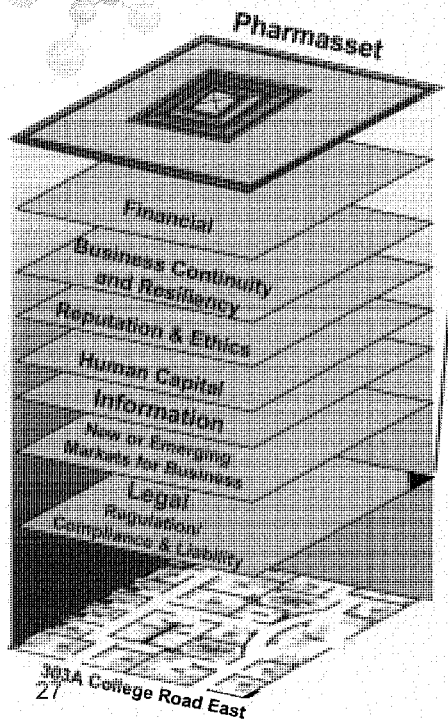


- Global/International
- Mergers & Acquisitions
- Compensation

- Intelligence analysis and mitigation
- Country business risk assessment
- Due diligence investigations
- Business intelligence gathering
- Information safeguards

PHARMASSET
WHERE INNOVATION IS VIRAL

Board-Level Risk Management Program Elements



- Liability
- Litigation
- Procurement
- Partnerships & Service Providers
- Sales & Marketing
- Procurement
- Antitrust Violation
- Noncompliance
- Audits
- Accreditation
- Third-party Vendors
- Supply Chain

- Regulatory Controls
- Risk assessment
- Security programs certification
- Partner due diligence
- Records retention policy
- Investigations
- Program integrity
- Regulatory compliance
- Vendor contracts/code of ethics

PHARMASSET
WHERE INNOVATION IS VIRAL

Business Proprietary Information – Confidential Treatment Requested

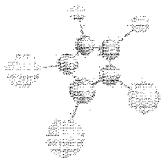
Risk Management – Legal and Compliance

- **Corporate – State Law**
  - Delaware corporate law
    - Board of Directors fiduciary duties
    - Officer fiduciary and legal duties
  - Compliance under state and local laws
- **Federal Securities Law**
  - Disclosure obligations
    - Materiality judgments
    - Periodic filings
    - Current disclosures
    - Proxy materials
    - Investor presentations
  - Regulation FD
  - Section 16
  - NASDAQ
  - Insider trading policy and process

631

PHARMASSET
WHERE INNOVATION IS VIRAL

Business Proprietary Information – Confidential Treatment Requested



Risk Management – Legal and Compliance

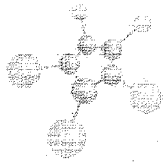
- **FDA compliance**
  - R&D including clinical
  - Product supply
- **HR matters**
  - EEOC and other antidiscrimination laws
  - Healthcare reform
  - Hiring and firing
  - Privacy
- **Transactions**
  - Draft and review contracts with awareness of compliance and other legal issues (FDA and other regulatory requirements; IP; confidentiality and disclosure obligations; nondiscrimination; antitrust; etc)

Risk Management – Legal and Compliance

- **Policies and procedures**
  - Draft, review, and assess compliance
    - Employee policies and procedures
    - SOPs
    - Board governance policies
    - Board committee charters
- **IP**
  - Assignment of invention and confidentiality agreements
    - Employees
    - Contractors
    - Consultants

PHARMASSET
WHERE INNOVATION IS VIRAL

Business Proprietary Information – Confidential Treatment Requested

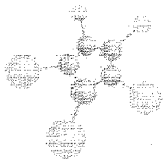


Risk Management – Legal and Compliance

- **IP (continued)**
  - NDAs
    - Vendors
    - Contractors
    - Consultants
    - Partners
  - Licenses
  - Tradenames and trademarks
  - Patents
  - Trade secrets

PHARMASSET
WHERE INNOVATION IS VIRAL

Business Proprietary Information – Confidential Treatment Requested

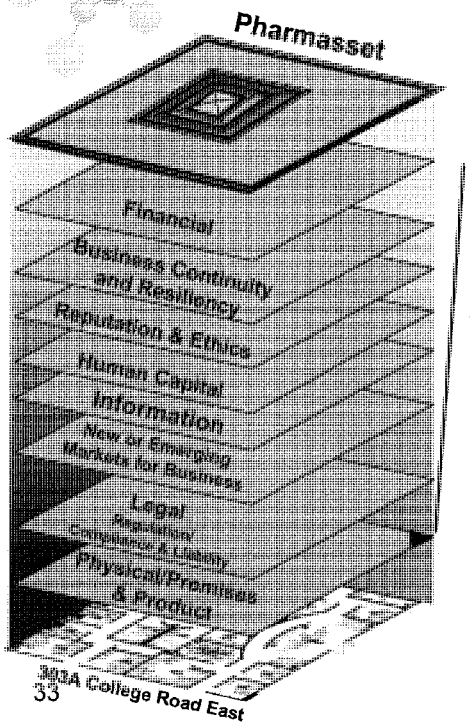


Risk Management – Legal and Compliance

- **Future compliance programs**
  - Product Liability (other than clinical trial liability)
  - Compliance related to manufacturing, importation, exportation, sales, marketing, packaging and labeling, transporting and distribution of API and final drug product
  - Compliance with federal, state, and foreign statutes regulating drug pricing and sales including extensive reporting and disclosure requirements
  - Sales force training and compliance
  - Foreign corrupt practices and anti-bribery laws
  - Foreign drug regulatory compliance

635

Board-Level Risk Management Program Elements



- Partnerships
- Inventory & Products
- Unauthorized Access

- Facility protection
- Product protection program
- Property protection program
- Facility access policy

PHARMASSET
WHERE INNOVATION IS VIRAL

Business Proprietary Information – Confidential Treatment Requested

PHARMASSET

WHERE INNOVATION IS VIRAL

303-A College Road East
Princeton NJ 08540 USA
Office 609 613 4100
Fax 609 613 4150
www.pharmasset.com

MEMORANDUM

TO: Board of Directors

FROM: Abel De La Rosa, Ph.D., Mike McElhaugh, Kurt Leutzinger, Michelle Berrey MD

DATE: July 15, 2010

RE: **Business Development Update**

This memo is intended to update the Board on the status of business development activities and strategies for value creation of Pharmasset programs by leveraging PSI-7977.

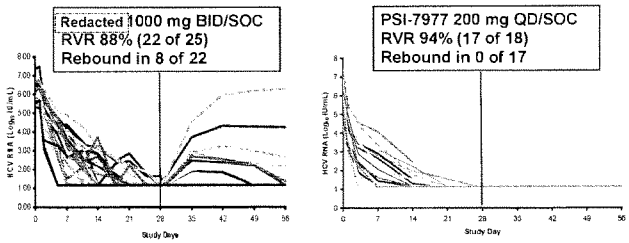
PSI-7977 Clinical Update

In early May, we reported the preliminary antiviral, safety, and PK from the 28 day study of PSI-7977 in combination with pegylated interferon (peg-IFN) and ribavirin (RBV), the current standard of care (SOC). Three doses of PSI-7977 (100, 200 or 400 mg QD) and placebo were assessed in combination with Peg-IFN/RBV in this randomized, blinded study at seven sites in the US. The very high Rapid Virologic Response rates of 88%, 94%, and 93%, respectively were some of the highest reported to date in a blinded direct acting antiviral (DAA) study. Significantly, no resistance related viral breakthrough was observed, differentiating the nucleoside analogs [Redacted] and now PSI-7977 from the first generation protease inhibitors and non-nucleoside polymerase inhibitors which continue to be hampered by emergence of resistance in early treatment – and which may limit future utility of other compounds in the same antiviral classes.

Significant and consistent antiviral activity was observed during the 28 days of PSI-7977/SOC administration with no on-treatment viral breakthrough. Sixteen patients receiving PSI-7977 100 mg QD/SOC achieved 88% (14/16) Rapid Virologic Response (RVR). Eighteen patients receiving PSI-7977 200 mg QD/SOC achieved 94% (17/18) RVR. Fifteen patients receiving PSI-7977 400 mg QD/SOC achieved 93% (14/15) RVR. Fourteen patients received placebo/SOC and 21% (3/14) achieved RVR. There were no differences in response rates for patients with HCV GT 1a versus 1b. After discontinuation of PSI-7977, no rebound in HCV RNA was detected in any patient who received PSI-7977 200 mg QD/SOC through week 12. Of the 14 patients who received PSI-7977 400 mg QD/SOC and achieved RVR, 12 of 14 maintained HCV RNA "undetectable" through week 12. The lack of rebound after the 4 weeks of "triple" therapy is supportive of potentially shorter total durations of treatment, and demonstrates significant antiviral activity of the active uridine triphosphate, dosed once daily due to the long intracellular

half-life of the uridine, and efficiently delivered to the liver via our phosphoramidate prodrug technology.

Three patients elected to discontinue the pegylated interferon and ribavirin on or after day 28 due to tolerability issues, confirming the continued difficulties of interferon-containing regimens even for shorter time periods. Remarkably, none of the three patients who discontinued the interferon and ribavirin prematurely experienced a rebound in their HCV RNA. We are continuing to follow these patients closely, but at this point, it appears two patients have been cured of their HCV with only four weeks of PSI-7977 together with the current standard of care, pegylated interferon and ribavirin, traditionally administered for 48 weeks. The potency demonstrated to date through very high RVRs, lack of virologic rebound, and the cure of 2 or 3 patients with only 28 days of PSI-7977 will serve to differentiate the low-dose QD PSI-7977 from the first-in-class nucleoside Redacted. Although high RVR rates were also seen in the 28 day studies of Redacted many patients had a rebound in HCV RNA after discontinuation of the Redacted, despite continuing with SOC treatment (See figure below).



*Rodriguez-Torres AASLD LB#1899 2008

In the ongoing Phase 2b studies being conducted by Redacted preliminary data from the cohort of patients who have received 8 weeks of Redacted 1000 mg BID followed by 16 weeks of continued IFN/RBV has shown the same phenomenon of on-therapy "rebound" in HCV RNA after discontinuation of the Redacted component of the triple combination. It remains to be determined if 12 weeks of Redacted will be adequate to maximize SVR, or if the ongoing 24-week triple combination study will be necessary. If a majority of treatment-naïve patients can obtain SVR with a 24 week regimen (either "24+0" or "12+12"), Redacted will still have advantages over the first generation protease inhibitors in total dosing duration, resistance, and safety.

In addition to the improvement in efficacy over our first generation nucleoside Redacted PSI-7977 offers a significant improvement in overall drug exposure, regimen and "pill burden." Aside from convenience to the patient, the low dose of PSI-7977 creates an opportunity for a fixed dose combination with another DAA.

Preliminary safety and tolerability in the PSI-7977 2a study for the 28 day treatment period were similar for PSI-7977/SOC and placebo/SOC. There were no serious adverse events (SAEs) reported, and no adverse events (AEs) led to treatment discontinuation. A majority of AEs reported were mild intensity. AEs reported were similar to clinical experience with SOC. There were no dose-related changes in safety laboratory assessments, vital signs or ECGs. A dose-dependent decrease in serum ALT was observed coincident with HCV RNA decline.

PSI-7977 continues to progress in preclinical toxicology studies, with successful completion of 90-day studies in rat, dog, and mouse to support up to 12 weeks' dosing in the clinic. Plans for the 12-week dose-ranging study in the US are progressing well, with an Advisory Board Meeting and Investigators Meeting to take place in early August. Duke Clinical Research Institute will serve as our CRO, and site selection and initiation are underway. First patient dosed should occur in September, 2010. In addition to the HCV GT1 dose-ranging study, an open-label HCV GT2/3 study in 25 patients will be running in parallel, with an intended duration of 12 weeks of triple therapy. Success with this regimen in non-1 HCV genotypes is vital to our continued differentiation as a pan-genotype DAA class, versus the GT-1 only first generation protease inhibitors and non-nucleoside polymerase inhibitors. In addition to the dose-finding study in the US, we are also planning to initiate an exploratory study in 40 patients with HCV GT2/3 in New Zealand, which will be the first study to shorten the interferon component of DAA combination therapy to either 4 or 8 weeks, while the DAA continues dosing through week 12.

Business Development Update

We have been in discussions with multiple companies with regards to licensing PSI-7977 and

Redacted

At this time, we believe we could complete negotiations for a partnership on fairly good terms for PSI-7977, given its stage of development. Alternatively, we could initiate and complete the phase 2b dose-finding study, reevaluate the licensing opportunity at that time, and partner with enhanced economics. The biggest change in value from partnering now versus partnering later is the ability to better judge the product attributes of our future partner's combination molecule. If we guess wrong today, it will have a negative impact on the value of PSI-7977.

The current terms being negotiated

Business Proprietary Information – Confidential Treatment Requested GS-0015033

The current term sheet is a slight improvement upon that previously presented to the board, when the PSI-7977 program had 3 day monotherapy data. Now that the program has 28 day triple combination data, the economics have improved. At high level, the current terms being sought are:

Up-front:	$150 million
Development milestones:	$525 Million (as follows)
- Phase 2b initiation:	$50M
- Phase 3 initiation:	$75M
- Filing NDA:	$50M
- Filing MAA:	$50M
- US Approval:	$150M
- EU Approval:	$150M
Commercial Milestones:	$150 million
Royalty on Partner Net Sales:	22.5%

As in the past, our partner would fund 100% of the development expenses. The Pharmasset territory includes North, Central and South America and the Caribbean, where we maintain the commercial rights to sell monotherapy (not a co-formulated or co-packaged product). Our partner will be allowed to commercialize a combination product (co-formulated or co-packaged) in our territory, for which we are to receive 100% of the PSI-7977 component of any combination product as if it were a monotherapy sale.

Since Pharmasset is to derive significant long-term value from our partner's combination product sales, it is important to Pharmasset that the best combination product is achieved in a partnership.

Consistent with our hepatitis C development strategy, we retain all rights to combine 7977 with any drug owned and controlled by Pharmasset on a global basis. This allows us the right to make a nuc-nuc combination and retain global commercial rights to it. It would also allow us to-in-license or acquire another drug candidate and commercialize that in combination with 7977.

PSI-7977 is less risky than other drugs at this stage of development

The two biggest risks in drug development are clinical efficacy and safety. The efficacy of PSI-7977 is likely not an issue as we have seen robust antiviral effects in human studies to date. Safety, on the other hand, is generally viewed differently and until the compound is shown to be safe at the projected therapeutic dose and duration, the assumption is that the candidate will likely fail. This is the reason why analysts and investors typically apply a probability of success of around 30% to pre-phase 3 compounds.

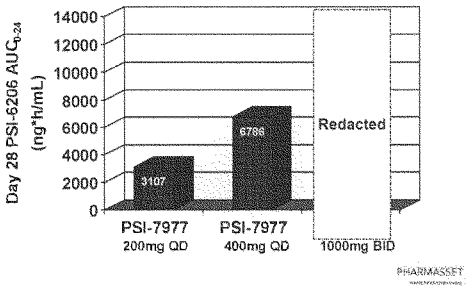
Fortunately, some characteristics of Pharmasset's cytidine nucleotide analog, RG7128, may predict that development of PSI-7977 may not be as risky as typical novel drug development candidates. PSI-6130 is delivered via the Redacted prodrug. When dosed in humans, a percentage of PSI-6130 is deaminated to yield PSI-6206, the inactive uridine nucleoside, which is the metabolite most likely to cause off-target safety issues and is delivered as a

Business Proprietary Information – Confidential Treatment Requested

monophosphate via PSI-7977. In the four week Redacted plus SOC combination study, the steady state mean AUC in plasma for PSI-6206 from a 1000mg BID Redacted dose was 12626 ng*h/ml. In contrast, the steady state AUC in plasma of PSI-6206 in the phase 2a study of PSI-7977 from a 400mg QD dose was 6786 ng*h/ml. In that same study, the 200mg QD dose yielded a steady state mean AUC of 3107 ng*h/ml (See graph below). One of these two doses of PSI-7977 is the likely commercial dose for PSI-7977. Given this, PSI-6206 has a steady state plasma concentration that is 1.86 – 4.06 fold higher when dosed as Redacted than when dosed as PSI-7977 when given at clinically and commercially relevant doses. As Redacted has already been dosed for 12 weeks and exhibited placebo-like safety, the risk due to safety of PSI-7977 should be considerably reduced. Based on its relationship to Redacted, we have more comfort than we might normally have with the safety of PSI-7977.

More 6206 Metabolite is Produced by Redacted than PSI-7977

6206 is the most likely metabolite to cause off-target safety issues



Partner now or partner later?

With 12 week human safety, PSI-7977 could be viewed as an approvable drug. We anticipate having 12 week safety from the phase 2b study in April 2011. Given this, there is additional upside value in licensing discussions. The upfront payment would increase to $200 million to include the current milestone payment for the initiation of phase 2b. The milestones would likely remain relatively unchanged as they are already at the high end of the potential range. Royalty payments for the licensee territory could also probably increase to 25% from 22.5%. The biggest change would likely come from an expansion of the Pharmasset territory. In addition to the Americas, we would also seek to retain select countries in Western Europe, where

Business Proprietary Information – Confidential Treatment Requested GS-0015035

we would retain 100% of the monotherapy sales and 100% of the PSI-7977 portion of any combination sales.

If one assumes a partnership could be established on 30 Sept 2010 (a hypothetical and not likely) but Pharmasset chooses to defer such partnership until after the 12 week safety is available from the PSI-7977 phase 2b study, Pharmasset would spend an additional $52 million from September 30, 2010 to March 31, 2011. Our cash balance at end of March would be $65 million. If we choose to delay a partnership, it would be wise to undertake an additional financing to raise the $52 million spent during the wait for safety data.

Licensing the compound after obtaining 12 weeks of human safety also allows additional time for the hepatitis C treatment market to further evolve. An important aspect of licensing PSI-7977 is ensuring that the licensee has a compound or preferably, compounds, in the pipeline that will provide the best fit from an efficacy and compound attribute perspective. Ideal attributes of a drug for a combination with PSI-7977 are low milligram dose, once daily and pan-genotype activity. Such attributes are believed to be possessed by the early-phase 2 programs including Redacted and the protease inhibitors from Redacted Redacted

Within the next year, substantial new data will be available on second generation protease inhibitors and Redacted that will better inform our licensing decision. Of course, there is the downside risk that companies gain additional comfort with the potential of their pipeline candidates thereby tempering their interest in licensing PSI-7977. As an example of how quickly the potential landscape for best combination partner changes, Redacted from Redacted was not seen as a favorable combination molecule due to potential toxicity. On Monday July 12, a press release indicating very good antiviral activity and safety up to 24 weeks moved this compound to the top of potential combination options for PSI-7977. The hepatitis C development landscape is dynamic and what may look like a potential best in class combination option for PSI-7977 today might not be the best combination in the future.

The ability to more accurately predict the antiviral profile and safety of potential combination products prior to entering into a collaboration agreement is also critical from the perspective of investors and Wall Street, as evident in the effects of negative news from the Redacted protease inhibitor program on Pharmasset's stock price. A clause in the Redacted agreement with Intermune provides exclusivity with respect to Redacted access to protease inhibitors, making Intermune the sole provider. In November 2009, InterMune announced that they were discontinuing the highest dose in their ongoing 12 week study due to elevations of ALT and the potential for hepatotoxicity. This press release resulted in a ~15% decline in our stock price as investors grew concerned about the likelihood of success for a combination of Redacted and danoprevir. Our stock declined another ~15% when the INFORM-2 study, a four week direct acting antiviral (DAA) combination of Redacted and danoprevir was put on indefinite hold. This provides a concrete example of the risk associated with choosing incorrectly in regards to a companion molecule.

Business Proprietary Information – Confidential Treatment Requested GS-0015036

Delaying a partnership until next summer could also generate interest from additional parties. For example, recent discussions with Novartis were positive and they showed interest, but indicated they could not complete the process prior to initiation of the phase 2b study. Redacted is another partner possibility since they have shown some interest, although presently on a non-exclusive basis. Although Gilead has not shown recent interest, they just hired Dr. John McHutchison as their new head of Liver Disease Therapeutics. John had been our advisor for several years and is believed to be a strong advocate for nucleosides.

Current Status

Redacted

Business Proprietary Information – Confidential Treatment Requested

Redacted

Financial Analysis

We do not believe that the first generation of DAAs (telaprevir, boceprevir, danoprevir, Redacted have the combination of safety, efficacy and dosing characteristics to become market leading co-formulated combination drugs. However, we believe desirable drug candidates will emerge from the second generation DAAs, and that PSI-7977 will be one of them. Our goal is to ensure that the first market leading HCV combination is built with PSI-7977 before the emergence of another nucleoside or an Redacted that could take its place.

On the other hand, we don't want PSI-7977 to be locked into a fixed dose combination (FDC) until we are sure that the other DAA has the necessary characteristics to insure that their FDC satisfies the unmet medical need sufficiently to maintain a dominant market share and discourage the development of competing FDCs. To date, only Redacted has emerged as a candidate companion to PSI-7977, based on results announced on July 12, but our collaboration discussions with Redacted are very early. Other candidates may yet emerge and Redacted may fade as more data becomes available at AASLD this October. Timing is everything.

Longer-term we believe a nuc-nuc combo is presently the only likely means of accomplishing a once daily co-formulated product that will possess activity across all HCV genotypes. If this vision is realized, then this partnership decision is lessened in importance. However, we have to recognize that if it takes too long to commercialize our nuc-nuc combo, it may be difficult to dislodge a well established genotype 1 co-formulated product, relegating the nuc-nuc combo to genotypes outside of 1.

The analysis below quantifies the importance of choosing the right partner for PSI-7977 by showing the NPV of PSI-7977 in an FDC with a 10% share of the interferon-free portion of the market versus its NPV in an FDC with a 60% market share. It also compares both the "good deal" and "bad deal" cases with a "no deal" case to show what the terms of a "good deal" have to

Business Proprietary Information – Confidential Treatment Requested GS-0015038

be to beat the NPV of developing PSI-7977 without a collaborator. These cases are limited to the US market, and deal terms have been simplified from those of our current term sheets, for ease of calculation so as to show relative values and are not to be taken as our estimate of the absolute value of PSI-7977.

The NPVs are as follows:

No Deal: $2.3 billion
Good Deal: $2.7 billion
Bad Deal: $1.0 billion

In the No Deal case, we receive all future revenues and pay all costs of developing, marketing and selling PSI-7977. Future development costs will be about $240 million. The No Deal case does not preclude putting PSI-7977 into an FDC, but it does assume that the FDC is built after we have enough information to pick the best available partner compound, and we pay all costs and receive all revenues of the PSI-7977 portion of the FDC.

In both of the deal cases, we receive a 22.5% royalty on PSI-7977 sales in combination with interferon, and all of PSI-7977's portion of sales in an interferon-free fixed dose combination. In the Good Deal, this combination takes 60% of the combination market, where the Bad Deal takes 10%. In both deals, the partner pays all costs of developing, marketing and selling PSI-7977 and pays us the milestones in the present term sheet listed above.

Even with the generous deal terms assumed, the Good Deal's NPV is not much greater than the No Deal case, whereas the Bad Deal is less than half the value of the No Deal case. So a premature deal is more likely to destroy value than add value.

It is also important to understand that at this point in time, the likelihood of choosing wrong is significantly higher than the likelihood of choosing the right combination partner for PSI-7977. As an example, assume that a protease inhibitor is the correct combination partner. The most promising protease inhibitors are currently in phase 2, each with a probability of success around 30%. There are five protease inhibitors to choose from. Based on what we currently know about these programs, we can probably eliminate three of the molecules from consideration, leaving us with a 50% chance that the chosen protease inhibitor will have the best attributes and thus the combination will dominate in the market. Given this, there is only about a 15% overall probability of choosing the correct compound for combination with PSI-7977 and achieving the Good Deal scenario. This example is artificially low as most of the potential big pharma partners have more than one molecule in their pipelines that could also be combined with PSI-7977, but even factoring that in the likelihood of choosing wrong substantially exceeds the likelihood of choosing right, given the currently available information.

Business Proprietary Information – Confidential Treatment Requested

PHARMASSET

WHERE INNOVATION IS VIRAL

MEMORANDUM

To: Board of Directors

From: Executive Team

Date: 15 July 2010

Subject: **Review of Pharmasset Corporate Strategy**

Recommendation

Pharmasset has been fortunate to experience a continued flow of good data in its HCV program. This is in stark contrast to earlier disappointments in its HBV and HIV programs. The setback of the HBV and HIV programs did not significantly hurt Pharmasset shareholders due to Pharmasset's possession of a pipeline of drug candidates balanced across indication, stage of development and financial exposure. Pharmasset no longer possesses such a well balanced pipeline. Presently, Pharmasset's pipeline is entirely focused on nucleoside analogs for treating HCV. This pipeline is balanced across stage of development and across financial exposure (Redacted) but is not balanced across indication.

The executive team at Pharmasset has undertaken efforts over the past 9 months to assess this product concentration and attempt to identify additional research efforts and product opportunities that could be added to our R&D efforts in order to further balance our pipeline by therapeutic indication. These efforts have not identified any current opportunity that is of greater benefit and less risk than is presently inherent in our own pipeline.

However, over time, we have identified opportunities that with a little investment in research could result in success in several years. In addition, there are a couple of programs in clinical development that we are watching that may result in opportunities that would be considered for in-licensing at the appropriate time.

This memo serves to provide the board with an update on things we are considering to diversify our pipeline. At this point no specific action is sought. Rather, should management desire to invest in one of these opportunities, we would prepare a more detailed assessment of specific opportunities for the board's consideration. This would be presented in the context of a budget request for the more tactical items (transplant label claim or starting a new research project) or as a special board agenda item as a proposal to in-license a program or to acquire a company.

Background

Pharmasset has seen significant success in its efforts thus far to discover, develop and ultimately commercialize new drugs for treating hepatitis C virus. In order to understand the value of this statement, one needs to understand the HCV market opportunity and the product attributes of nucleosides which appear to possess competitive advantages in this market.

HCV Market Opportunity

An estimated 170 million people worldwide are chronically infected with HCV. Approximately 6.8 million of these are in the U.S. and Western Europe. The current standard of care is suboptimal with low cure rates in genotypes 1 and 4. In addition, the regimen is not well tolerated. It is estimated that the average treatment duration for treating genotype 1 is 26 weeks, significantly shorter than the prescribed 48 weeks currently in the AASLD treatment guidelines. The vast majority of infections were through blood transfusions prior to the virus being identified and the initiation of appropriate screening parameters (1992 in the U.S.). Although HCV has a slow progressing pathology to fibrosis, cirrhosis and eventually hepatocellular carcinoma, there is an increasing number of individuals infected 20-30+ years ago. This will lead to increased diagnostic rates and an increased need for better therapy.

In contrast to this burgeoning need for a better therapy, the incidence has fallen off dramatically to approximately 17,000 acute cases per year in the U.S., largely a result of IV drug use. It is projected that with advancing age and safer and more efficacious therapies, a bolus of HCV-infected patients will move through the healthcare system. This increase in therapy may last a decade or two as more patients are treated, cured and removed from the pool of treatable patients.

There are differing reports about the treatable population in the U.S. Most think approximately 10% of the roughly three million American chronic carriers are presently treated. However, Abbott estimates that 20% are currently eligible for therapy and an additional 20% may become eligible for therapy with the addition of a direct acting antiviral to increase the efficacy rate of therapy. Of those presently eligible for therapy but not treated, 43% prefer to defer therapy and 40% are concerned about the side effects and the ability to comply with therapy. With the advent of an interferon free therapy it is estimated that the treatable population could grow by approximately five to ten-fold over the current treatable population.

Roche's Pegasys is the current market leader with an approximate 80% market share of long-acting interferons. While its ~$1.5 billion in global sales in 2009 is good, it fails to keep pace with the other market leading specialty drugs. Five specialty drugs placed amongst the top 15 largest drugs by sales in 2009. These blockbuster drugs each had approximately $5.0 billion in sales in 2009.

Business Proprietary Information – Confidential Treatment Requested

Leading Specialty Drugs

Drug	2009 Sales	Indication	Marketer
Enbrel	$5.8 B	Rheumatoid Arthritis	Amgen
Remicade	$5.4 B	Rheumatoid Arthritis	JNJ
Humira	$5.0 B	Rheumatoid Arthritis	Abbott
Avastin	$5.0 B	Cancer	Genentech/Roche
Mabthera/Rituxan	$4.7 B	Cancer/RA	Genentech/Roche

In 2009, the antiviral segment also saw robust sales, but not on the level of Enbrel and Avastin. The leading antiviral product in 2009 was Truvada from Gilead, reaching $2.5 billion in sales (this ignores the pandemic preparation sales of tamiflu). In total, Gilead's antiviral franchise had 2009 sales of $5.8 billion ($6.5 including pulmonary and cardiovascular sales).

Leading Antivirals

Drug	2009 Sales	Indication	Marketer
Tamiflu^	$2.9 B	Influenza	Roche (GILD)
Truvada	$2.5 B	HIV	Gilead
Atripla§	$2.4 B	HIV	Gilead
Valtrex	$2.0 B	Herpes (I/II and zoster)	GSK
Pegasys	$1.5 B	HCV, HBV	Roche
Reyataz	$1.4 B	HIV	BMS
Kaletra	$1.4 B	HIV	Abbott
Sustiva	$1.3 B	HIV	BMS

^ Roche stated 59% (or $1.7 B) from pandemic planning – GILD received $392 million in Royalties from Roche
§ Represents only the Truvada portion of Atripla

As HCV drugs are antivirals, one would expect them to have sales comparable to other antiviral drugs with comparable treatment rates. However, our estimates of product sales and those of most investment banking analysts expect HCV sales to approach those of blockbuster specialty drugs.

Global Revenue Forecasts for Redacted and PSI-7977

Bank	Redacted	PSI-7977
Bank of America	$4.5B (2014)	$4.5B (2015)
Cannacord	$1.8B (2014)	$1.5B (2015)
JP Morgan	$1.3B (2014)	$2.4B (2018)
JMP	$4.0B (2014)	$2.0B (2015)
Citigroup	$3.0B (2018)	$3.9B (2019)

As expected, most big pharmaceutical companies with antiviral franchises are expecting HCV to be the next big antiviral market and are placing a strong emphasis on quickly establishing market leadership through the use of direct acting antivirals to improve the efficacy of current therapy with the hope of decreasing the duration of interferon therapy. This will be quickly followed by combinations of direct acting antivirals in hopes of eliminating interferon therapy. If this can be accomplished in a well tolerated, once daily fixed dose combination, the antiviral companies will have accomplished in approximately 5 years what it took almost 20 years to do in HIV. With

Business Proprietary Information – Confidential Treatment Requested

this compression of product life cycle, there is intense competition and incredible attention on time to market.

Competition

Merck and Vertex are currently obtaining results from their phase 3 clinical studies and are expected to receive market authorizations for the HCV protease inhibitors in mid-2011. Vertex's telaprevir was the first to demonstrate SVR data in a registration study. Its 75% SVR in a naïve genotype 1 population was heralded as a breakthrough in contrast to the ~ 40% SVR typically obtained with pegylated-interferon and ribavirin in genotype 1 patients. However, this efficacy comes with a toxicity burden. Both telaprevir and Merck's boceprevir have significant toxicities associated with their use. For this reason, most antiviral companies also have second generation protease inhibitors in development which they hope to will be non-inferior to the first generation protease inhibitors in regards to efficacy, but will have better tolerability and a superior dosing regimen of BID or QD instead of q8hours for telaprevir and boceprevir.

Redacted

HCV antivirals select for drug resistant mutations, as antivirals do in all other indications. The current research and clinical data suggest that nucleosides have a unique advantage in that the mutants that they select for are very unfit and do not replicate effectively. This means that even with a virus that is constantly mutating, it is rare to find a nucleoside resistant virus before therapy. This is in stark contrast to recent data suggesting that 70% of untreated HCV infected individuals have 1-3% of their virus containing some drug resistance to protease inhibitors and 80% of subjects having 1-5% of their virus with drug resistance to non-nucleosides. This has translated into very rapid selection for drug resistant variants while on protease inhibitor or non-nucleoside based therapy. Early data suggest that telaprevir and boceprevir have greater than 10% drug resistant variants that break through on therapy or lead to relapse after concluding therapy. Because of this, nucleosides may have an ability to demonstrate superiority on an SVR endpoint to these early protease inhibitors.

Redacted

Redacted

The non-nucs and cyclophilin inhibitors are viewed in the industry as companion molecules to other direct acting antivirals. This view is based on the belief that these molecules will be inferior to first generation protease inhibitors due to their limited efficacy. In addition, the non-nucleosides suffer from limited genotype coverage (effective against genotype 1b but not genotype 1a (33% of GT1), and ineffective against non-1 genotypes) as well as from a poor resistance profile. While cyclophilins do not have problems with resistance and are also likely to possess pan-genotype activity, their safety is questionable since they target human factors involved in viral assembly. This same family of targets was also investigated for anti-HIV and HBV activity without success.

Redacted

Should Pharmasset diversify its risk?

Experience in an industry fraught with clinical failures has demonstrated repeatedly that companies which possess well balanced and diversified product pipelines more easily survive clinical failures. This has been Pharmasset's experience as well. Clevudine provided risk mitigation for Reverset's HIV failure and Redacted Redacted Now Pharmasset possesses a pipeline of nucleosides for HCV which is well balanced by stage of development and financial commitment (partnered) but is not diversified by indication.

Over the past five years, we have kept watch for antiviral research and clinical programs that appear clinically and commercially attractive for in-licensing or acquisition to achieve diversification within our pipeline. With the exception of Clevudine, we have not been

Business Proprietary Information – Confidential Treatment Requested

persuaded to bring anything else into our pipeline. Significant thought has been given to acquiring other HCV mechanisms of action. While this would diversify our pipeline from being solely nucleoside focused, it would still have us positioned exclusively in HCV. It was this diversification goal that led us to enter into a relationship with the Genomic Research Institute of the University of Cincinnati. We screened an entire proprietary library to identify new molecules with novel mechanisms of action for suppressing replication of HIV and HCV.

We have been asked to consider whether we should diversify from the risk of solely developing nucleosides for HCV. There are several methods of achieving diversification which will be explored in the pages to follow:

- Achieving financial diversification through partnership,
- Adding additional development programs in new indications,
- Leveraging our research platform into new areas of research, and

We did not include an analysis of acquiring commercial assets as a pre-commercialization strategy for Redacted and PSI-7977. We have undertaken efforts in this regard in the past and have not had success. These include approaches to:

- Redacted

In the future, at the appropriate time, we will once again analyze the opportunity to build out or buy an existing commercial operation. One other possible access to a commercial product is the possibility of obtaining a co-promote from our PSI-7977 partner as a quid in that transaction.

Achieving financial diversification through partnership

Establishing a partnership in HCV centered on PSI-7977 would both decrease our remaining financial exposure to the program and also provide us with access to our partner's pipeline of HCV drug candidates for the purpose of creating combinations. The only current perceived weakness of nucleosides is that their potency may be slower than that of the protease inhibitor and non-nucleoside classes. While this observation may be true for Redacted it is not necessarily the same, or as significant, for PSI-7977. In addition, it is not known, even if slightly slower, whether this will have any impact on the SVR end point.

Potential external candidates should complement the product profile of our HCV nucleosides, possessing both fast acting potency and pan-genotype coverage. Only two classes of molecules presently fit this description, Redacted and pan-genotype protease inhibitors. The pan-genotype protease inhibitor is elusive and yet to be seen in human clinical trials. Nonetheless, Abbott and Merck believe they have just such molecules. These programs are in phase 1 or 2. In addition, only Redacted As none of these pharmaceutical companies will out-license them to us, we can only access them through

Business Proprietary Information – Confidential Treatment Requested

partnerships where we provide them access to our nucleoside for combination with their molecules.

A few biotech companies, namely Idenix and Achillion, believe they have also discovered pan-genotype protease inhibitors. However, these are still in preclinical studies and it is too early to conclude that these molecules will possess enough differentiation from the competing programs at Abbott and Merck to sufficiently overcome their disadvantage in time to market. In addition, protease inhibitors are typically associated with some safety liability due to their interaction with human proteases. As such, we decided a couple of years ago not to consider in-licensing any early-stage protease inhibitors until they had at least 28 days of human safety, or ideally 12 weeks.

Presidio Pharmaceuticals has an NS5a inhibitor they believe is promising and is about to enter human clinical trials. There will be robust competition between NS5a programs as several companies began efforts to discover NS5a inhibitors some time ago and have either lead compounds or programs approaching clinical development. Pharmasset had a similar discovery effort in NS5a, but unfortunately the chemical template overlapped with Redacted Redacted

At present, we are comfortable that our pipeline offers significant return for our continued investment in HCV nucleosides. Our biggest concern is the time Redacted has wasted in developing Redacted. As more time progresses, the market will become satisfied with protease inhibitors and it will become more difficult to displace them. However, should the market become driven by drug combinations in an interferon-free regimen, the impact may be lessened.

As we consider strategic alliances for PSI-7977 with pharmaceutical partners, we have significant concern regarding timing. It is possible that promising molecules or classes today will not be the ideal combination companion for PSI-7977 as more data become available in this rapidly changing market. We are presently punished by our shareholders because Redacted Redacted Redacted We do not want to make the same mistake of placing PSI-7977 in the hands of a partner with an inferior combination product.

However, having the financial commitment from a partner assures the program will be well funded. The single largest strategic decision faced by the company today is whether to partner PSI-7977 now, or continue to invest in the program until we are certain that a potential partner's molecule will not impair a future PSI-7977 drug combination. For more on this topic, please see the business development memo in this board book.

Business Proprietary Information – Confidential Treatment Requested GS-0015046

Development Diversification

There are very few indications in the antiviral area that are being explored. We have analyzed most of these and come to the following observations:

- Influenza is a fairly well served market and there is limited time for therapeutic intervention;
- RSV is not well served, but is complicated by a very limited window for therapeutic intervention that would require an infected person to have ready access to a home diagnostic and readily available drug supply;
- HBV is not well served and the market is growing, however, until combinations become the standard of care, thus allowing for new mechanisms of action to enter the market, it is too difficult to find a better nucleoside than those currently available;
- EBV is not well served but the lack of understanding of the basic biology and pathogenic mechanisms associated with EBV-related diseases makes drug discovery and development problematic;
- CMV for transplantation has generics in the market place. In order to meet an unmet need in this market, one needs to discover a very safe drug that can be used for prophylaxis in bone marrow transplants (see Research Diversification); and
- Herpes is a very well satisfied market for type 1 and 2, however, an opportunity may exist for varicella zoster (see below and in Research Diversification).

When one considers the possibility of finding a new indication for a drug already in our pipeline, one must recognize the very high specificity designed into our pipeline drugs. In discovery, our series of nucleosides do not show activity in other flaviviruses, as some other HCV nucleosides do. However, there is a very large unmet need in preventing HCV re-infection in a person undergoing a liver transplant. At question is whether this is a new indication or an element of an indication for use in treating chronic HCV. This question will be considered below.

In addition, we are also in the process of assessing an opportunity to in-license a late-stage compound under development for shingles (varicella zoster). The market for this indication is significant and increasing because of the aging of the US and European populations but development risk is high because of the efficacy of Valtrex and the unknown link between viral suppression and the emergence of post herpetic neuralgia which is a significant driver of the potential of this market.

Treatment of HCV in Patients Undergoing Liver Transplantation

There is increasing interest in the use of Direct Acting Antivirals (DAAs) in the setting of liver transplantation in patients with HCV infection. The FDA has publically appealed to industry to consider addressing this unmet medical need. Potentially, this could be in the form of treatment pre-transplantation, prophylaxis peri-transplantation, and/or chronic suppression post-transplantation. An indication, or evidence of efficacy in this population, could be of strategic value to Pharmasset due to the medical need, interest in the regulatory communities and

Business Proprietary Information – Confidential Treatment Requested GS-0015047

relationships with key opinion leaders and advocacy groups. The nucleoside class of DAAs could be the best option for these patients relative to other classes due to their safety profile, relative lack of drug interactions and high barrier to drug resistance. Pharmasset is in the unique position of having numerous candidate compounds in the nucleoside/tide class. In particular, one of the compounds from our purine program could be positioned to exploit the transplantation opportunity.

Purine Program Update

PSI-938 and PSI-661 are both purine nucleotide analogs which share a common guanosine nucleoside, but differ in the prodrug approaches employed. PSI-938 has a unique cyclic prodrug moiety, while PSI-661 shares a similar prodrug moiety with PSI-7977. Both compounds have the same resistance profile (both purines retain activity against the mutation S282T) which differs from that of PSI-7977 and Redacted and have the potential for once-daily administration. PSI-938 is currently being studied in a Single Ascending Dose study and appears to be safe and well-tolerated to date. This study will be followed by a short-term monotherapy study in HCV-infected GT1 patients this summer. This monotherapy study will then enable a study of the dual nucleotide combination of PSI-938 with PSI-7977 in the fall of 2010 to demonstrate 'proof-of-concept' for this approach.

PSI-661 is approximately 3 quarters behind PSI-938, but has recently had positive developments in the chemistry/manufacturing area which may allow this program to be accelerated to lead to an IND filing in the fall of 2010 with FTIH dosing shortly thereafter. PSI-661 is currently in GLP toxicology studies, thus any potential toxicological risk is unknown. An investment has been made in the 6 month toxicity studies for both compounds to allow either molecule to be dosed in 6 month human studies as early as next summer. So although PSI-938 has a clinical head start, whichever one is selected for late-stage development for HCV will have the same NDA filing timing.

Medical Need

Up to 40% of all orthotopic liver transplants (OLT) performed in the US are for patients with HCV-induced cirrhosis, making it the leading indication for liver transplantation. An estimated 170 million people are infected with HCV worldwide, with an estimated 4 million in the United States alone. Of these people up to 20% are expected to develop cirrhosis within 20-30 years of infection and 1-4% will develop hepatocellular carcinoma per year. The only treatment for the majority of these is either a living related or deceased donor liver transplant. Given the scarcity of donor organs, many of the patients will die while on the transplant wait list, so there is a dire need for new medical treatments with potent antiviral efficacy, in addition to an excellent safety profile.

To get a sense of the need in this patient population, as of July 25, 2010, there were 16,785 people awaiting a liver transplant in the U.S., 4,781 of whom had HCV-induced cirrhosis. The median waiting time for a liver transplant, for all causes of liver disease, ranges from 459, 351, 231 and 76 days for patients with blood types O, A, B and AB, respectively. Wait times vary from region to region. In the Northeast, for example, and at larger transplant centers, the wait

Business Proprietary Information – Confidential Treatment Requested

time for an 'O' liver can be as long as 2 years. Many patients with advanced decompensated cirrhosis have, at most, 6 months of life expectancy, similar to that seen in patients with metastatic cancers. As a result, of the 16,000 on the transplant list approximately 6,000 will get a transplant. Of the remaining patients ~ 1,500 (15%) patients will die while on the waiting list each year.

Current medical treatment of HCV in well-compensated cirrhotics is limited to pegylated interferon and ribavirin, the standard-of-care (SOC). Sustained viral response (SVR), or cure rates, in cirrhotics is low because of advanced fibrosis and because of the inability of patients to tolerate the medications' side effects necessitating dose reductions. Adding a DAA to SOC, or combining two DAAs in an SOC-sparing regimen, may increase SVR rates in this patient population, through greater antiviral potency and, if using a DAA-SOC combination, fewer dose reductions of SOC and/or shorter treatment durations. Furthermore, early cirrhosis can be reversed if SVR is attained and the liver can regenerate obviating the need for a liver transplant.

Decompensated HCV cirrhotics have no realistic treatment options, other than transplantation, since pegylated interferon treatment is associated with worsening hepatic decompensation and death. Therefore, the decompensated cirrhotic would be a good candidate for an interferon-free treatment regimen with DAA either as monotherapy or in combination with a second DAA with or without ribavirin.

Furthermore, viral eradication pre-transplant greatly benefits patient and graft survival post-transplant. Reinfection of the graft with HCV is universal post-OLT if the recipient is HCV RNA positive at the time of transplantation. 70-90% and 90-95% of patients have evidence of chronic HCV infection 1- and 5-years post-OLT. Once recurrent HCV has been established, disease progression and decompensation are greatly accelerated compared to the pre-transplant setting. Cirrhosis occurs in 10-30% of post-OLT patients within 5 years, compared to 20-30 years in the pre-OLT setting. The rate of hepatic decompensation once patients are cirrhotic is also accelerated post-transplant: > 40% at 1 year & >70% at 3 years. 5-year survival is also decreased compared to the non-cirrhotic post-OLT patient: 30% versus 70%, respectively. The only treatment for these patients is SOC, before they have decompensated. SVR rates are <30% in this setting. Often, patients need to be retransplanted, but mortality rate can be as high as 50%, so many centers are less likely to retransplant these patients.

The aim of treatment should be to cure chronic HCV infection pre-OLT in order to obviate the need for transplantation or to prevent recurrence in the post-OLT setting. This would not only save the lives of patients with HCV, but would also impact the number of donor organs which are available for transplantation for all of the other liver disorders.

Regulatory Background

In the global regulatory context, HCV infection is considered a serious and life threatening disease. Furthermore, drugs which successfully treat the infection are considered by Health Authorities, including FDA, to address an unmet medical need. These concepts were codified in the US drug regulations based on the experience gained from the HIV/AIDS epidemic. An additional beneficial regulatory construct is that of special populations wherein FDA recognizes

Business Proprietary Information – Confidential Treatment Requested GS-0015049

that subgroups of the larger patient population may derive significant benefit from treatment and therefore merit separate, special regulatory consideration. As a result, the FDA now has in place sufficient authority to help expedite HCV drug development, providing Pharmasset the opportunity to begin a creative discussion with FDA's Division of Antiviral Products Division (DAVP).

On April 30, 2010, the DAVP Division Deputy Director, Dr. Jeffrey Murray stated the existing regulations are perfectly suited to address any foreseeable HCV drug development scenario. The citations include the IND regulations for serious and life threatening diseases, the NDA "accelerated approval" regulations and statutory incentives such as Fast Track Designation. Furthermore, at this meeting and at other presentations, FDA has clearly identified the treatment of HCV in liver transplantation patients as an important special population and one which they are extremely interested in discussing with industry.

Development Strategies

Option 1: Develop PSI-661 solely for treatment of HCV in the transplantation setting
Rather than choosing to develop only one purine compound, Pharmasset could decide to develop PSI-661 where the sole indication is treatment of HCV in liver transplantation patients and continue to develop PSI-938 for treatment of chronic HCV infection. This approach would clearly differentiate between the two purine molecules, PSI-938 (indicated for treatment of chronic HCV infection) and PSI-661 (indicated for treatment of HCV in patients undergoing transplantation), and would create incremental value for the overall portfolio. It may be of strategic value for Pharmasset to have a drug with an indication in the transplant setting because it could create an opportunity for a transplant franchise or an out-license option. Because of the high unmet medical need, the dataset required for marketing approval would be relatively small. The exact size of the safety database would be a point of negotiation with the FDA but clearly would be measured in hundreds of patients rather than a thousand as required for an indication in chronic HCV. Also, as mentioned above, it might be possible to obtain an "accelerated approval" which allows rapid access to the market and is then followed by submission of a more robust safety dataset and "traditional" approval.

Cost of Program: We estimate the incremental costs after phase 1 for the sole indication of treatment of HCV in patients requiring transplantation to be ~$100 million.

Pros: Rapid development path, satisfy medical need, create goodwill among KOLs and advocacy groups, potential for creating a transplant franchise

Cons: Cost and regulatory risk

Market Opportunity: Ability to market the indication with estimated annual sales of ~50 million in U.S.

Option 2: Develop drug for transplantation first to accelerate time to market and follow with a conventional indication of treatment of chronic HCV as a secondary indication

Business Proprietary Information – Confidential Treatment Requested

Another approach could be the development of one of the guanosines for two indications. Pharmasset could propose to FDA a dual path HCV development program which leverages the existing preclinical and clinical database to support a rapid market entry for the first indication of HCV treatment for liver transplantation patients. That is, in addition to the ongoing clinical development program, we could propose an additional HCV liver transplant program consisting of two small and adequate pivotal studies supported by data from the core HCV clinical program. This strategy satisfies the regulatory expectation for a robust safety database in a large patient population at the time of submission for the transplantation indication. Additionally, this provides the FDA with assurance that Pharmasset is committed to making promising therapies available to all patients who might benefit from the drug.

Cost of Program: The total cost of developing a guanosine from IND filing to launch for the "conventional" indication of treatment of chronic HCV is estimated to be ~$234 million. We expect an indication for transplantation would add an incremental $40-50 million depending on the patient numbers required by FDA for an NDA.

Pros: Lowest risk path to transplantation indication, development efficiencies gained by pursuing multiple indications

Cons: Could "tarnish" our guanosine drug if safety and efficacy problems occur in transplant population, no incremental value created with the other guanosine

Market Opportunity: As we currently stand, the HCV label will have minimal side effects and may not differentiate from standard of care. Leading with a transplant indication increases the chances of a side effect appearing in the label thereby starting promotion at a disadvantage to other marketed products. Transplant label may not give you access to certain formularies who would restrict use according to indication.

Option 3: Conduct little or no development in liver transplantation
Development of one of the guanosine compounds could proceed on its current conventional path and the project team could assess the need for a small study in transplantation as the field evolves. If, for example, telaprevir, boceprevir or RG7128 are rapidly adopted for this indication, there may be no medical need at the time of the launch of our guanosine. A small study for the purpose of awareness and a publication could be conducted with minimal resource use.

Cost of Program: A small published study of ~20-30 patients would drive use and could be conducted for $3-5 million

Pros: No incremental cost or regulatory risk

Cons: No indication for transplant population

Business Proprietary Information – Confidential Treatment Requested

Market Opportunity: No indication for transplantation, but could get a label that references transplant. Publication plan might result in a reference in the label to transplant which could be included in promotional pieces.

Variations to these scenarios would be provocative, perhaps more viable and of equal interest to the FDA, such as DAA combination therapy with Pharmasset nucleosides/tides and displacing the need for existing standard of care (SOC). Any HCV therapy(ies) which meet or exceed the SOC SVR or match that profile but allow for safer therapy/therapy for previously contraindicated patient populations (SOC is currently contraindicated for liver transplantation patients) will generate great interest at FDA.

Adding additional complexity to this decision is the future licensing environment surrounding our purine program. Based on our experience with licensing discussions for PSI-7977, two relevant areas of contention that apply to the current discussion are the definition of the field and the scope of the license grant. The field has been described as the treatment of hepatitis C infected humans. This was inserted to limit the scope of the opportunity and allow us to retain our rights in the unlikely event that the compounds show activity in other indications. Hepatitis C transplant, however, would be covered in the current definition of the field and would be difficult to restrict given that it's the same indication.

In addition, interested parties have been very specific in including all related compounds in the license definition. Initial iterations of term sheets that we provided listed specific compounds as backups, but interested parties quickly modified the terms to include all compounds delivering the same active tripbosphate, regardless of which prodrug moiety is utilized, to maintain exclusivity to the active component of the drug. In this case, all of the pro-drugs were phosphoramidates. However, given this experience, it is highly unlikely that we would be successful in convincing any potential partner that our cyclic phosphate and phosphoramidate guanine nucleotides are sufficiently differentiated that they would be comfortable licensing one without including the other as there is substantial risk to their future franchise if both drugs are marketed by different corporations.

The size of the liver transplant market is small and is constrained by the availability of donors. The hepatitis C transplant market is a subset of the overall liver transplant market. To be attractive to companies with transplant franchises, the cost of therapy must be sufficiently high to provide a reasonable return on investment. This is an unlikely scenario as any drug with an acceptable safety profile that is approved for the treatment of hepatitis C is a potential competitor and will exert downward pricing pressure. Although there is significant risk of competition from other drugs approved for hepatitis C, the biggest competitive threat to a stand-alone HCV drug in transplant is Pharmasset's retained guanine nucleotide. Given that PSI-938 and PSI-661 are both converted to the same active triphosphate, and would likely require the same dosing duration as they are both treating chronic hepatitis C, there is nothing to stop these two drugs from being used interchangeably in the market. Thus, the retained Pharmasset guanosine must be priced competitively with other chronic hepatitis C drugs which would be priced significantly lower than a transplant-specific compound.

Business Proprietary Information – Confidential Treatment Requested

In-license Late Stage Compound for Herpes Zoster (Shingles)

Pharmasset's analysis shows that treatment of shingles is potentially a large and increasing market with an unmet medical need – reduction in postherpetic neuralgia. Although current therapy is extremely safe and effective at healing of skin lesions and shortening the duration of pain, zoster patients still suffer extreme pain for weeks or months despite antiviral therapy. There are three marketed drugs for zoster – acyclovir, valacyclovir and famciclovir. Clinical studies of these drugs suggest that impact on pain duration is roughly correlated with greater potency/exposure; thus creating an opportunity for a new agent with similar safety and greater potency. Internal discovery of a compound for herpes zoster is a viable option since Pharmasset does have expertise in the area, but there could be no assurances of successful discovery efforts on a timely basis. There are several good candidates already in late-stage development by small companies. FV-100 (Inhibitex) is probably the best compound and is currently completing Phase 2. FV-100 appears to be safe with much greater intrinsic potency than currently marketed drugs.

Epidemiology and Natural History

Varicella–zoster virus causes two distinct syndromes. Primary infection presents as varicella (or chickenpox), a contagious and usually benign illness that occurs in epidemics among susceptible children. Subsequent reactivation of latent varicella–zoster virus in dorsal-root ganglia results in a localized cutaneous eruption termed "herpes zoster" (or "shingles"). Declining virus-specific cell-mediated immune responses, which occur naturally as a result of aging or are induced by immunosuppressive illness or medical treatments, increase the risk of shingles.

Over 90 percent of adults in the United States have serologic evidence of varicella–zoster virus infection and are at risk for herpes zoster. The annualized incidence of herpes zoster is about 1.5 to 3.0 cases per 1000 persons. An incidence of 2.0 cases per 1000 persons would translate into more than 500,000 cases annually in the United States. Increasing age is a key risk factor for the development of herpes zoster; the incidence of shingles among persons older than 75 years of age exceeds 10 cases per 1000 person-years. The lifetime risk of herpes zoster is estimated to be 10 to 20 percent.

The other well-defined risk factor for herpes zoster is altered cell-mediated immunity. Patients with neoplastic diseases (especially lymphoproliferative cancers), those receiving immunosuppressive drugs (including corticosteroids), and organ-transplant recipients are at increased risk for shingles.

Herpes zoster occurs with higher frequency among persons who are seropositive for HIV than among those who are seronegative. A longitudinal study demonstrated an incidence of 29.4 cases of herpes zoster per 1000 person-years among HIV-seropositive persons, as compared with 2.0 cases per 1000 person-years among HIV-seronegative controls.

The disease begins with localized abnormal skin sensations, ranging from itching or tingling to severe pain, which precede the skin lesions by one to five days. Pain of variable severity occurs in virtually all patients with acute herpes zoster. An erythematous maculopapular rash progresses to clusters of clear vesicles, which continue to form for three to five days and evolve through

Business Proprietary Information – Confidential Treatment Requested

stages of pustulation, ulceration, and crusting. Healing occurs over a period of two to four weeks, and often results in scarring and permanent changes in pigmentation.

Postherpetic neuralgia and other complications

Postherpetic neuralgia (defined as pain that persists more than 30 days after the onset of rash or after cutaneous healing) is the most serious complication in immunocompetent patients. Both the incidence and the duration of postherpetic neuralgia are directly correlated with the patient's age. The reported incidence of postherpetic neuralgia ranges from 8 to 70 percent and increases with advancing age. Each one-year increment in age is associated with 9 and 12 percent increases in the prevalence of postherpetic neuralgia at 30 and 60 days, respectively. Pain can persist for months and occasionally years.

Complications of herpes zoster in immunocompetent patients include encephalitis, myelitis, cranial- and peripheral-nerve palsies, and a syndrome of delayed contralateral hemiparesis. Before antiviral drugs, cutaneous dissemination of varicella–zoster virus was reported in 6 to 26 percent of immunocompromised patients. In most patients, disseminated disease was limited to the skin; however, 10 to 50 percent of these patients also had evidence of visceral involvement (such as pneumonitis, encephalitis, or hepatitis). Even with intravenous acyclovir therapy, the mortality rate from herpes zoster with visceral dissemination is 5 to 15 percent, with most deaths caused by pneumonitis.

Acute retinal necrosis caused by varicella–zoster virus occasionally occurs in immunocompetent patients, although more recent reports have focused on ocular disease in HIV-infected patients. Visual changes begin weeks or months after the resolution of herpes zoster. In HIV-infected patients, the lesions rapidly extend and coalesce, respond poorly to antiviral therapy, and almost inevitably cause blindness in the involved eye.

Antiviral therapy

Current therapy for herpes zoster accelerates healing, has variable impact on the severity and duration of acute and chronic pain, and reduces complications. In immunocompromised patients, an additional therapeutic objective is to reduce the risk of dissemination of varicella–zoster virus. Thus, assessment of a new drug should be based on its potential to impact duration of pain.

Three drugs are currently approved in the United States for the treatment of herpes zoster: acyclovir (Zovirax), valacyclovir (Valtrex), and famciclovir (Famvir). In placebo-controlled trials, acyclovir (800 mg five times daily) shortened the duration of viral shedding, halted the formation of new lesions more quickly, accelerated the rate of healing, and reduced the severity of acute pain. Variable benefit was reported with respect to a reduction in the frequency and duration of postherpetic neuralgia. A meta-analysis of these data showed that acyclovir was significantly superior to placebo for reducing the duration of pain, defined as the continuum of pain measured from onset until final resolution. Among patients who were at least 50 years of age, the median time to the resolution of pain was 41 days, as compared with 101 days in the placebo group, and the proportion with persistent pain at 6 months was 15 percent, as compared with 35 percent in the placebo group.

Business Proprietary Information – Confidential Treatment Requested GS-0015054

Famciclovir (500 mg every eight hours), a prodrug of penciclovir, was significantly superior to placebo in reducing the duration of viral shedding, limiting the duration of new lesion formation, and accelerating healing in a placebo-controlled trial. In a subgroup analysis of subjects who were at least 50 years of age and who had persistent pain after skin healing, the median duration of postherpetic neuralgia was 163 days in the placebo group and 63 days in the famciclovir group.

Valacyclovir, a prodrug of acyclovir, produces serum acyclovir levels that are three to five times as high as those achieved with oral acyclovir therapy. In a trial of patients who were at least 50 years of age, valacyclovir (1000 mg every eight hours) and acyclovir resulted in equivalent rates of cutaneous healing. Valacyclovir significantly shortened the median time to the resolution of zoster-associated pain (38 days vs. 51 days). The proportion of patients experiencing pain at six months was 25.7 percent in the acyclovir group and 19.3 percent in the valacyclovir group (P=0.02).

Valacyclovir and famciclovir have been compared for the treatment of herpes zoster in immunocompetent patients and were shown to be therapeutically equivalent, in terms of both the rate of cutaneous healing and pain resolution. At six months, 19 percent of patients in each treatment group still reported pain. Because of their superior pharmacokinetic profiles and simpler dosing regimens, valacyclovir and famciclovir are preferred to acyclovir for the treatment of herpes zoster. All three drugs are exceptionally safe and well tolerated.

Overall, results of meta-analyses and most, but not all, randomized trials have demonstrated that antiviral therapy for shingles significantly reduces the duration or incidence of prolonged pain if initiated early. The impact of therapy on duration of chronic pain varies significantly depending on age and choice of therapy. In general, there is a trend of greater impact on chronic pain with drug potency, ie valacyclovir>famciclovir>acyclovir. This suggests that a new drug with greater potency could be more effective than valacyclovir in reducing the duration of postherpectic pain.

Commercial Opportunity

Global estimates for shingles cases are around 2.5 million cases annually. Since shingles is a disease that increases with age and the incidence of shingles among persons older than 75 years of age exceed 10 cases per 1000-person years. Thus the opportunity in shingles mirrors hepatitis C as the epidemiology will likely rise as the population ages. In 2003–2005, an annual average of 1.1 million persons in the US had shingles or its complications, and 0.9 million sought medical treatment. There was an annual average of 2.1 million ambulatory care visits for the treatment of shingles.

From 2003–2005, an average of $566 million per year (in 2005 dollars) was spent on health care for shingles and its complications. Since 900K patients in the US sought medical care and the cost was $157 per patient, the prescription sales in 2005 would have been about $140M. Doubling this to make it a global number (since US is about 1/2) gives us $280M in 2005. Adjusted for price increases this market would be approximately $350 million. However, earlier this year Valtrex became generically available, so the future market would decline without innovation in care. Despite the generic, with a marketed improvement in pain associated with

Business Proprietary Information – Confidential Treatment Requested GS-0015055

shingles, the market would be willing to accept brand pricing and show growth. This could be accomplished in several ways: a reduction of patient ambulatory visits (Note: a 25% reduction in visits removes ~ $150 million in costs from the healthcare system); and increased pricing for the patient preference of reduction in duration of pain, plus QD vs. TID dosing. A successful treatment for shingles also combines with our long-term strategy of gravitating hepatitis C treatment into the primary care setting with simpler treatment regimens. Shingles treatment is primary handled by primary care physicians.

Potential Licensing Opportunity: FV-100 (Inhibitex)

FV-100 is a bicyclic pyrimidine nucleoside analog with activity specific to VZV. It is not active against other herpes viruses. FV-100 is a prodrug of CF1743 which has an EC_{50} of 170 pg/mL. Thus, CF1743 is 4000X more potent than acyclovir *in vitro*. It is also extremely safe in preclinical models with a selectivity index >100,000. *In vitro* studies show that CF1743 rapidly enters VZV infected cells and can completely stop replication within 5 minutes of exposure.

Once daily dosing of 100 – 800 mg x 7 days of FV-100 delivered plasma concentrations well above the EC_{50} for the entire dosing interval. No trends for type, severity or frequency of adverse events were observed across all dose levels.

FV-100 is currently completing a phase 2 trials. The trial is a double-blind study comparing two arms of FV-100 to an active control (valacyclovir). Inhibitex plans to enroll and randomize approximately 350 shingles patients, aged 50 years and older, equally to one of three treatment arms: 200 mg FV-100 administered once daily; 400 mg FV-100 administered once daily; and 1,000 mg valacyclovir administered three times per day. In addition to further evaluating its safety, the objectives of the trial are to evaluate the potential therapeutic benefit of FV-100 in reducing the severity and duration of shingles-associated pain, the incidence of post herpetic neuralgia (PHN), and the time to lesion healing. In April, 2010, Inhibitex announced that the phase 2 study would continue after a DSMB review of 50% of the enrolled patients. The DSMB review included an analysis of safety and the primary endpoint, which is the reduction in a composite of the severity and duration of shingles-associated pain over the first thirty (30) days of follow-up. Final study data is expected in fourth quarter, 2010.

Business Proprietary Information – Confidential Treatment Requested GS-0015056

Research Diversification

Leveraging Pharmasset's HCV nucleoside/tide expertise: Expanding Research

Our primary research focus has been on nucleosides/tides for the treatment of HCV. In order to minimize the risk of having all our research narrowly focused, we have sought ways to leverage our strengths in chemistry and biology by expanding the research targets. To this end we licensed the compounds from GRI in hopes of identifying inhibitors of HCV that are not nucleosides. We successfully identified compounds with intriguing activity. From these studies we have identified a series of compounds that appear to inhibit HCV NS4b, another viral protein critical for replication, and are progressing those compound forward in research.

We also undertook an evaluation of other viral diseases where our nucleoside expertise could be applied. These included herpes viruses, respiratory viruses, human papilloma viruses, xenotropic murine leukemia-like virus (XMRV), flaviviruses and exotic viruses in the developing world. We looked at the feasibility of these viruses from both the technical and clinical perspectives and determined whether or not research tools were available or would need to be developed. We also evaluated the ease or difficulty of clinical trials as well as the treatability of the diseases. As a result of our evaluation, we found:

- human papilloma viruses are complicated by using host proteins to replicate and no research reagents are available to assist discovery efforts;
- respiratory viruses possess limited windows for therapeutic intervention;
- exotic viruses have regions of high endemicity but generally lack markets in developed countries; and
- XMRV, while interesting from a research perspective, was eliminated due to the lack of convincing data showing a causal relationship to a specific disease.

In addition, we also considered the opportunity to leverage our nucleoside library by initiating programs in cancer and inflammation. However, there is a significant amount of preclinical and clinical work in these areas being conducted by big pharma and biotech companies, making these areas very competitive. In addition, most of these efforts are focused on biological programs, primarily antibodies, to achieve greater therapeutic effect while minimizing off target toxicities.

Overall the more attractive opportunities were viral targets for certain emerging viruses belonging to the flaviviruses as well as the human herpes viruses, in particular human cytomegalovirus and varicella zoster virus.

Emerging Viruses

A number of flaviviruses such as Dengue Virus or Yellow Fever Virus which belong to the same genus as Hepatitis C Virus cause clinically significant disease. Most of these viruses are mosquito borne and found in tropical and subtropical regions. Testing of Pharmasset's library against these viruses would be a relatively straight forward and cost effective method for diversifying our portfolio. The most efficient approach to identifying candidate compounds

Business Proprietary Information – Confidential Treatment Requested

would be through collaborations with researchers in the endemic regions. These researchers are experts with respect to the target viruses, have testing methods in place, and are currently funded by local government agencies. Pharmasset would not need to establish either the in-house expertise or the test systems. Our investment would be limited to providing small amounts of compounds for *in vitro* testing and later larger amounts to support follow up testing in animals. Due to the high unmet medical need for treatment in these endemic regions the cost for preclinical safety assessments as well as clinical development could be covered by the government funding in exchange for providing the compound. To this end, we have already been contacted by scientists in Brazil interested in testing Pharmasset compounds for activity against Dengue Virus. Should a lead compound be discovered, Pharmasset could enter into a relationship with a governmental agency to secure development funding in exchange for the government retaining local commercialization rights. Pharmasset could retain commercial rights in other territories for use by the military and travelers to the endemic region.

Herpes Viruses

Herpes viruses which include human cytomegalovirus (HCMV) and varicella zoster virus (VZV) are attractive targets for drug development. HCMV is a significant problem in organ transplant recipients and an effective prophylactic antiviral would be very beneficial. VZV infection usually occurs in childhood (chicken pox) but can also be acquired in immune-suppressed individuals from the live vaccine. The primary clinical syndrome in adults is shingles (as mentioned above).

Pharmasset's library of compounds contains a significant number of deoxynucleosides/tides which have never been tested for activity against HCMV or VZV. In addition, our cyclicphosphate technology may provide a unique tool for efficient delivery of inhibitors to the sites of infection. Initially we would not need to devote significant chemistry resources but as active compounds were identified additional chemistry resources would be required. While we have some internal experience in the biology group in herpesvirus drug discovery, we would need to set up and validate new assays. We would need to acquire the required reagents and train new personnel and possibly realign some existing personnel. Setting up a new research project such as this will require a significant investment in time and effort, but we believe that initial assays could be in place (given the necessary resources) in approximately nine months. However, based on previous experience, industry standards and a bit of luck, identifying and progressing a candidate compound to the IND stage could take 2 - 4 years. Efforts such as this can not be initiated until we have resources available from our HCV efforts or additional personnel are hired.

Business Proprietary Information – Confidential Treatment Requested GS-0015058

Historical Diversification of Large Cap Biotech Companies

To learn from the success of others, we analyzed the strategic decisions of Gilead to assess how long they remained committed to their core area of expertise before diversifying their business and what if anything could be learned from the timing of the diversifications and decisions to partner or retain commercialization rights.

Gilead

Gilead is obviouosly thought of as a very successful biotechnology company. It has a market capitalization comparable to many pharmaceutical companies and it possesses a dominant leadership position in the antiviral specialty market where its HIV and HBV drugs enjoy significant leadership positions. But Gilead has taken many strategic missteps along its path to arrive at this success.

Gilead was founded as "Oligogen, Inc." an antisense (oligonucleotide) company in 1987. It used this antisense platform to entice Glaxo into a strategic alliance three years later in 1990. Early research efforts were focused on oligonucleotides. These efforts did not meet with success and Glaxo terminated its collaboration in 1996 and the entire IP estate for antisense was sold to Isis for $6 million.

Fortunately, Gilead recruited John Martin from BMS as the new CEO in 1992. John subsequently in-licensed some early-stage nucleoside drug candidates from the Rega Institute. These were programs he knew well as he worked on them while he ran BMS's virology research efforts. These in-licensed compounds would eventually become commercialized as Hepsera and Viread.

Tbese early antiviral efforts provided the core focus which catapulted Gilead to its current prominence as a specialty pharmaceutical company. First came the product launch of Vistide in1996, marketed by development partner Pharmacia and Upjohn (now Pfizer). In this partnership, Gilead retained the US commercialization rights. Also in 1996, Gilead entered into a development partnership with Roche to develop and commercial a neurominidase inhibitor for treating influenza. As part of this transaction, Gilead was successful in obtaining the rights to co-promote Roferon for HCV in the U.S. At the time, John Martin stated that this was an important element of the partnership since HCV was "an area of strategic importance to Gilead". Later, in 2005, Gilead would sue Roche for lack of diligence in commercializing Tamiflu.

Potential lesson: Focus on building a commercial entity very early in the development of the company.

After the product launches of Vistide in 1996 and Tamiflu in 1999, Gilead attempted its first strategic diversification by acquiring NeXstar Pharmaceuticals. Its acquisition in 1999 brought Gilead the products Ambisome (fungal infections) and DaunoXome (for AIDS-related Kaposi's sarcoma) as well a European commercial organization of 135 sales reps focusing in infectious diseases.

Business Proprietary Information – Confidential Treatment Requested

Gilead paid $550 million in stock for NeXstar. Also acquired in the acquisition was a pipeline of cancer compounds and a liposomal formulation expertise. With this capability, Gilead then in-licensed an early-stage thymidylate synthase inhibitor from Glaxo Wellcome and a nucleoside analog from SRI, both in 2000. That same year, Gilead would out-license a NeXstar aptomer to EyeTech pharmaceuticals for $32 million and a royalty. The aptomer was being developed for macular degeneration and was later to be successfully developed and branded as Macugen. One year later, they would sell the NeXstar pipeline, its personnel and facility and cancer programs to OSI Pharmaceuticals for $200 million.

Gilead sought NeXstar in preparation for launching PREVEON, adefovir for use in treating HIV patients, then in phase 3. In December of 1999, five months after acquiring NeXstar, Gilead terminated the adefovir HIV program after an unfavorable outcome at a FDA advisory meeting. Luckily, two years earlier, activity against HBV was seen at lower doses and adefovir was eventually approved for treating chronic HBV and marketed as Hepsera.

Potential lessons: Make sure you will have long-term strategic advantage to ensure longevity in a strategic diversification and an advanced commercialization strategy only works if your drug is ultimately approved.

2001 thru 2005 was probably the pinnacle of development success for Gilead. This period would produce antiviral products that would propel Gilead to the success that it is to this day. In 2001, Viread was approved for HIV. One year later, Hepsera was approved for HBV. In January of 2003, Gilead acquired Triangle Pharmaceuticals to gain access to Emtriva for HIV. Six months later, Emtriva was approved, setting the stage for making the fixed dose combination of Emtriva and Viread, Truvada. Truvada was approved in 2005. One and a half years later, Atripla (Truvada + Sustiva, a NNRTI) would be approved, providing a new standard of care for first-line therapy that is still the standard of care.

Starting in 2006, Gilead lost focus on its core strategy and completed several acquisitions to diversify its business.

In April of 2006, Gilead purchased a $25 million equity position in Corus Pharmaceuticals, with an option to acquire the company in the future which it did a few months later for $365 million. Corus' lead product candidate, then in phase 3 was Cayston(TM) (aztreonam lysine for inhalation), an inhaled antibiotic with activity against gram-negative bacteria including Pseudomonas aeruginosa, which can cause lung infections in patients with cystic fibrosis (CF). In Feb 2010, Cayston received marketing approval from the U.S. FDA.

In October 2006, Gilead purchases Myogen for $2.5 billion. At the time of acquisition, Myogen had completed two pivotal studies for ambrisentan, Myogen's lead product candidate, for the potential treatment of pulmonary arterial hypertension (PAH). Ambrisentan is an orally available endothelin receptor antagonist. "Myogen represents a unique scientific and strategic fit with our company, bringing to Gilead a late-stage product candidate that addresses an area of significant unmet medical need and further enhances our growing focus on pulmonology, as initially established through our recent acquisition of Corus Pharma," said John C. Martin, PhD,

Business Proprietary Information – Confidential Treatment Requested GS-0015060

President and Chief Executive Officer about the acquisition. Letairis (ambrisnetan) received US marketing approval in June of 2007. In Feb 2010, Letairis had global sales of $184 million.

In March of 2009 CV Therapeutics was purchased for $1.4 billion or almost 10-fold the 2008 sales of its two marketed products RanexaÂ® (ranolazine extended-release tablets), indicated for the treatment of chronic angina, and LexiscanÂ® (regadenoson) injection for use as a pharmacologic stress agent for perfusion imaging in patients unable to undergo adequate exercise stress. In 2009, sales of Ranexa and Lexiscan had global sales of approximately $147 million.

Without exception, Wall Street analysts presently see these acquisitions as failures and distractions from Gilead's core strategy of antivirals. Most analysts are perplexed why Gilead is not making a greater strategic commitment to HCV. Gilead's discovery efforts are working towards five HCV targets. Their protease inhibitor in phase 2 is not very potent and has a resistance problem. Their non-nuc, also in phase 2, is only active in genotype 1b and has a QTc signal at the more efficacious dose levels.

Gilead did enter into two partnerships for access to HCV drug condidates. One relationship was with Achillion to discover an NS4a inhibitor, but this program was terminated due to kidney toxicities seen in phase 1. Another relationship was entered into with Genelabs to discover novel nucleosides. This effort was also unsuccessful.

Today, Gilead is left wondering what to do in HCV. As a result of their lack of success in HCV, they hired John McHutchison to head their Hepatitis development efforts in June 2010. The very clear signals from Gilead and Jobn are that they will be making some strategic moves in HCV.

Potential lesson learned: Even great companies can make strategic mistakes.

Business Proprietary Information – Confidential Treatment Requested GS-0015061

Exhibit – Gilead History (source Wikipedia)

Gilead Sciences was originally formed under the name of "Oligogen, Inc." in August 1987 by Michael L. Riordan, a medical doctor who was 29 years old at the time. Riordan graduated from the Johns Hopkins University School of Medicine, spent a year as a consultant and then joined the venture capital firm from which he founded the company. The name of the company was changed to "Gilead Sciences" in 1988. Riordan looked to Donald Rumsfeld as a mentor in the business world and to navigate the political waters. Under the technical leadership of scientist Mark Matteucci, the company focused on discovery research, making small strands of DNA (oligomers) to assess the potential of genetic code blockers (gene therapy). Its development of small molecule antiviral therapeutics was ushered in by John Martin in 1992 with the licensing of nucleotide compounds discovered in two European academic labs.

In 1990, Gilead entered into a collaborative research agreement with Glaxo for the research and development of genetic code blockers, also known as antisense. This collaboration was terminated in 1998, and Gilead's antisense intellectual property portfolio was sold to Isis Pharmaceuticals.

Gilead debuted on the NASDAQ in January 1992. Its IPO raised $86.25 million in proceeds.

In June 1996, Gilead launched its first commercial product, Vistide (cidofovir injection) for the treatment of cytomegalovirus (CMV) retinitis in patients with AIDS. The company cooperated with Pharmacia & Upjohn to market the product outside the United States.

In March 1999, Gilead acquired NeXstar Pharmaceuticals of Boulder, Colorado following two years of negotiations with the company. At the time, NeXstar's annual sales of $130 million was three times Gilead's sales. NeXstar's two revenue-generating drugs were AmBisome, an injectable fungal treatment, and DaunoXome, an oncology drug taken by HIV patients.

Also in 1999, Roche announced first approval of Tamiflu (oseltamivir) for the treatment of influenza. Tamiflu was originally discovered by Gilead and licensed to Roche for late-phase development and marketing.

Viread (tenofovir) achieved first approval in 2001 for the treatment of HIV.

In January 2003, Gilead completed its acquisition of Triangle Pharmaceuticals. The company also announced its first full year of profitability. Later that year Hepsera (adefovir) was approved for the treatment of chronic hepatitis B, and Emtriva (emtricitabine) for the treatment of HIV.

In 2004, Gilead launched Truvada, a fixed-dose combination of tenofovir and emtricitabine.

In January 1997, Donald Rumsfeld, a Board member since 1988, was appointed Chairman of the company.[2] He stood down from the Board in January 2001 when appointed Secretary of Defense at the start of George W. Bush's first term as President. Federal disclosure forms indicate that Rumsfeld owns between USD$5 million and USD$25 million in Gilead stock. The

Business Proprietary Information – Confidential Treatment Requested

rise in Gilead's share prices from USD$35 to USD$57 per share will have added between USD$2.5 million to USD$15.5 million to Rumsfeld's net worth.[3]

In November 2005, George W. Bush urged Congress to pass $7.1 billion in emergency funding to prepare for the possible bird flu pandemic, of which one billion is solely dedicated to the purchase, and distribution of Tamiflu.

In July 2006, the U.S Food and Drug Administration (FDA) approved Atripla, a once a day single tablet regimen for HIV, combining Sustiva (efavirenz), a Bristol-Myers Squibb product, and Truvada (emtricitabine and tenofovir disoproxil fumarate), a Gilead product.[4][5]

Gilead purchased Raylo Chemicals, Inc. in November 2006 for a price of $133.3 million.[6] Raylo Chemical, based in Edmonton, Alberta, was a wholly-owned subsidiary of Degussa AG, a German company. Raylo Chemical was a custom manufacturer of active pharmaceutical ingredients and advanced intermediates for the pharmaceutical and biopharmaceutical industries.

Entry in the cardiovascular and respiratory therapeutic areas

In 2006, Gilead completed two acquisitions that allowed the company to branch out from its historical antiviral franchise into the cardiovascular and respiratory therapeutic arenas.

Myogen[7], based in Boulder, Colorado, was completing Phase 3 studies of ambrisentan--now marketed as "Letairis"--an orally available endothelin receptor antagonist. The U.S. FDA subsequently approved ambrisentan for the treatment of pulmonary arterial hypertension in June 2007.[8][9][10]

Under an agreement with GlaxoSmithKline, Myogen marketed Flolan (epoprostenol sodium) in the United States for the treatment of primary pulmonary hypertension. Additionally, Myogen was developing (in Phase 3 studies) darusentan[11], also an endothelin receptor antagonist, for the potential treatment of resistant hypertension.

The other acquisition was Corus Pharma. Corus' lead product candidate, aztreonam lysine for inhalation, is an antibiotic with activity against gram-negative bacteria including Pseudomonas aeruginosa, which can cause lung infections in patients with cystic fibrosis. The product is in Phase 3 studies.[12] Gilead also obtained an inbalation formulation of two antibiotics for treatment of respiratory infections.[13]

Gilead expanded its move into respiratory therapeutics in 2007 by entering into a licensing agreement with Parion for an epithelial sodium channel inhibitor for the treatment of pulmonary diseases, including cystic fibrosis, chronic obstructive pulmonary disease and bronchiectasis.[14]

In 2009, Gilead acquired CV Therapeutics. This acquisition brought Ranexa and Lexiscan as commercial products. Ranexa is a cardiovascular drug used to treat chronic angina (chest pain related to coronary artery disease).

Timetable of Licensing and M&A

Business Proprietary Information – Confidential Treatment Requested

Timetable of Corporate Activities			
Year	**Company**	**Price**	**Notes**
1987			Founding date of "Oligogen Inc., Now known as Gilead
1990	Out-license to Glaxo		Entered into a broad collaboration to discover antisense molecules
1996	Out-license to Pharmacia & Upjohn	$20 million	Vistide ex US marketing rights
1996	Out-license to Roche		Tamiflu
1996	Co-Promote with Roche		Roferon for HCV
1998	Sold Antisense IP to Isis	$6 million	After terminating the Glaxo Wellcome anti-sense partnership, all IP assets were sold
1999	Acquired Nexstar Pharmaceuticals	$550 million	Nexstar had two drugs (AmBisome and DaunoXome) of which only AmBisome is still in Gilead's portfolio, although it is not a major source of income for the company. DaunoXome was sold to Diatos in 2006. As important as the products, Nexstar also provided Gilead with a much-needed sales force and commercialization team in Europe and Australia, in preparation for the launch of Adefovir for HIV.
April 2000	Out-license to Eyetech	$32 million	Sold off aptamer technology (NX-1838) for macular degeneration - originally acquired in Nexstar transaction
Dec 2000	In-license from Glaxo	ND	Gilead obtains exclusive, worldwide rights to GW1843U89, Glaxo Wellcome's investigational thymidylate synthase (TS) inhibitor for the potential treatment of cancer
Dec 2000	In-license from SRI	ND	Gilead obtains exclusive, worldwide development and marketing rights to 4'-thio-araC (GS 7836), a nucleoside analogue for the potential treatment of cancer
Jan 2001	In-license from Cubist	$44 million	exclusive rights to commercialize Cubist's investigational antibacterial drug Cidecin™ (daptomycin for injection) and an oral formulation of daptomycin in 16 European countries following regulatory approval
Nov 2001	Out-license to OSI Pharamceuticals	$200 million	Sold off cancer assets acquired in Nexstar acquisition including IP, facility and personnel in Boulder CO.
2003	Acquired Triangle Pharmaceuticals	$464 million	Triangle owned the development and commercialization rights to emtricitabine, which although marketed as a stand-alone product (Emtriva), is also a component of the more profitable combination products Atripla and Truvada.[17]
2006	Corus Pharma, Inc.	$365 million	The acquisition of Corus signaled Gilead's entry into the respiratory arena. Corus was developing aztreonam lysine

Business Proprietary Information – Confidential Treatment Requested GS-0015064

			for the treatment of patients with cystic fibrosis who are infected with *Pseudomonas aeruginosa*
2006	Myogen, Inc.	$2.5 billion	With two drugs in development (ambrisentan and darusentan), and one marketed product (Flolan) for pulmonary diseases, the acquisition of Myogen has solidified Gilead's position in this therapeutic arena.
2009	CV Therapeutics, Inc.	$1.4 billion	This acquisition brings Ranexa and Lexiscan as commercial products. Ranexa is a cardiovascular drug used to treat chest pain related to coronary artery disease. These products and pipeline build out Gilead's cardiovascular franchise.

Business Proprietary Information – Confidential Treatment Requested GS-0015065

Exhibit 7

WHERE INNOVATION IS VIRAL

303-A College Road East
Princeton NJ 08540 USA
Office 609 613 4100
Fax 609 613 4150
www.pharmasset.com

MEMORANDUM

To: Board of Directors

From: Mike Rogers and Kurt Leutzinger

Date: September 16, 2011

Subject: Approval of P7977-0523 Part 3 of Electron

Recommendation

Management recommends the approval of the incremental budget for Part 3 of the Electron Study for PSI-7977 in the amount of $847 thousand.

Background

We are adding 2 additional arms to the Electron Study to further explore the clinical utility of 7977. The first arm will assess 7977 monotherapy in 25 genotype 1 patients. This is a robust assessment and will enable phase 3 studies of 7977 monotherapy in the patient population most relevant to the US market. The second arm will assess 7977 + ribavirin in 25 genotype 2/3 patients who have failed previous therapy. This is an area of high unmet medical need and, if the data are positive, will be of great interest to health agencies and the medical community in general. Your authorization is required for this work to proceed due to the timing of budgeted amounts and the total amounts quoted in the proposals. We note that the board approved the start of the PSI-7977 Electron Study with the prior budget submission in March 2011 and the additional memo dated July 14, 2011. In order to stay Sarbanes Oxley (SOX) compliant, we need your formal approval of the total expense that will occur during the duration of the studies in order to proceed. Unanimous written approval will be required in lieu of a meeting. The work to be performed is detailed below:

New Zealand CNS: Site Management, Investigator Expense Passthroughs, and Regulatory support ($165 thousand)

Cenetron: Central lab work and sample analysis ($528 thousand)

IDDI: Data Management ($104 thousand)

QPS: Bioanalysis ($22 thousand)

Other: Statistics, IRB, and Medical Writing ($28 thousand)

Exhibit 8

Global Commercialization Strategy Update to Pharmasset Board of Directors

It was requested at the March 23, 2011 Board of Director's meeting that management provide a plan of action and update on our Global commercialization strategy at the upcoming Board meeting in July. This document provides an update on our intended course of action for preparing our deliverable. Please note we expect that our recommendations at the July 21, 2011 Board Meeting will be the first step in a multi-phase three-year rollout with additional detail and updates at future board meetings.

The key issue to be addressed through this process is to determine the strategic path forward for Pharmasset in each of the world markets focusing on whether we commercialize independently (either through organic growth or acquisition), seek and develop partnerships, or leverage distribution arrangements.

To assist with the analysis and strategy development in countries outside our current expertise in the US and Big 5 countries in Europe (France, Germany, Italy, Spain and UK), management is considering the use of an outside consultant. We anticipate working with this consultant to gain additional insight into:

- Alignment on preliminary screening criteria to evaluate strategic options for commercialization
- Characterization of addressable patient populations by country
- Development of key market and investment assumptions for PSI-7977 in each country
- In-depth understanding of distribution value chain and landscape of key HCV players in each country
- Identification of key risks and key commercial success factors for each strategic option
- Prioritization by country of strategic options for Pharmasset consideration.

For the upcoming board meeting in July, the team will provide the members with the following:

1. A detailed view of the US HCV commercial requirements and strategy serving as a base template for other markets.
2. A high level view of the big 5 European markets with some NPV
3. A review of several case studies of other biotech companies who faced similar commercialization decisions. Particular attention will be given to Alexion, Biogen-Idec, Celgene, Genzyme, Gilead, and Human Genome Sciences on how they approached growth beyond the US market.
4. A description of the selection criteria that will be used in prioritizing countries for commercialization. (Note: our initial view of the key data we are accumulating is available below)

The HCV market is a tremendous global opportunity with high rates of prevalence, with estimates of 170 million people infected worldwide. While this opportunity is substantial, there are several factors that must be considered to appropriately address how to best capture the value. The economic, social and political environments of each country coupled with the regulatory approval process and each country's ability to deliver HCV care must be examined to provide the most appropriate commercialization strategy in any given country.

In establishing criteria, we will collect data from most countries and evaluate how this may evolve over time. For example, in looking at who delivers HCV healthcare in the US today, the specialist tends to be the provider of care. If interferon-free regimens can deliver an SVR, the burden of care may switch to a more primary care-centric model.

The following chart summarizes our initial list of selection criteria and when we expect to use each item in our on-going evaluation process:

US Commercial Requirements

Current Target Audience:

The current HCV prescribing base is a small specialized group of physicians. There are ~14,000 physicians who treat at least one patient for HCV, but ~3,600 treat 80% of the patients and even fewer ~1,500 physicians write 60% of the presciptions. The majority of these physicians are gastroenterologists (GE), hepatologists (HEP) and internists (IM). The internists treating HCV are usually physicians who did not specialize in hepatology or gastroenterology, but act much like a GE/HEP in practice.). While there are a large number of GE's in the US, the majority spend their time doing lucrative proceedures such as endoscopy and coloscopy and rarely treated the HCV patient. These patients are time consuming, need more patient care and instruction, and with reimbursement low relative to procedures, most care is turfed to academic centers, practices who specialize and carve out a business in Hepatology, or to a single specialist in a group practice. In a typical group gastoenterology practice, there could be ~10 GE's, yet only one GE handles HCV, most likely not even 100% of his/her time. Offices that can afford a PA or NP will manage these patients trying to squeeze out a small profit based on the traditionally low reimbursement for HCV by PA or NP. Some of the reasons offices treat HCV is either based on their concern for the endemic proportion of patients or their recognition that HCV patients also have to other GE or liver related disorders that require referral to other parts of their practice.

infectious disease (ID), and some primary care (GP,FP, DO

The ID's have traditionally been more involved in treatment and care of HIV patients. However, since the advent of simple and effective chronic care using Truvada and Atripla for HIV, the ID specialists have been considered a possible new target audience to handle HCV patients when the bolous of new patients are expected into the marketplace. While ID's do treat HCV/HIV coinfection, the number of currently treated coinfected patients is small (>5%) compared to mono-infection. Many ID's, however, have practices with patients mono-infected with just HCV. The ID's understanding of viral resistance, their knowledge of anti-viral therapy, and if interferon can be eliminated, Pharmasset's product portfolio makes them very atrractive target audience and prescriber base. Likewise, if treatment regimens can be simplified with the elimination of interferon and/or ribavirin coupled with a safe toxcitity profile there could be a shift in treaters toward Primary Care.

One of the significant drivers to this theory is that physician capacity has been an issue in this market in the past. At the peak of pegylated interferon use in 2002-2004, there was a limited number of treaters of HCV resulting in only ~100,000 patients treated annually without significant lead-times between first diagnosis and intitating care. As screening and diagnosis increases it is expected that capacity will again be a major issue necessitating new treaters to handle the influx.

Competitive Sales Forces in HCV:

Based on the limited number of treaters currently handling HCV patients, the sales force sizes of Roche/Genentech, Merck And Vertex are comparable. Genentech sales force numbers 120 specialists, Merck 110 specialists and Vertex 96 specialists. These are the requirements to call on the target audiences of prescribing physicans. The expected calls per day to targeted physicians is 5 per rep. These targets are considerable less than Primary Care sales forces (~7-8/day) due to these specialists have many expanded roles with the numerous allied health professionals and caregivers in the office, including: physician assistants; nurse practitioners; nurses; clinical coordinators; education corrdinators and pharmacists in teaching institutions. It is often that the HCV specialist will spend up to ½ day in one office. Furthermore, the productivity of the high rescribers means the specialists will often see an office once/week or twice month. In addtion to the sales specialists, the supporting functions to the sales force bring the total number of commercial operations to ~200 people.

The following is a definition of some of these support functions, their roles and responsibilities:

Nurse Educators:

In Hepatitis C, the nurse plays a critical role in achieving patient outcomes through education on side effect management, assisting in compliance, and in determining brand selection that meets these objectives. Unfortunately, due to lack of physicians who treat HCV, they also have a corresponding lack of nursing staff to provide these services. Consequently, Roche, Merck, and Vertex have put in place ~ 20-25 nurse educators who go into physician offices to assist the office staff with this education. They are welcome additions to the delivery of care by the HCV treated because of the amount of time required to deal with a patient on injection training, the numerous side effects associated with interferon and ribavirin; coupled with the increase in side effects reported with the first generation DAA's (rash, anal puritis, and increased anemia). Assuming that Pharmasset is successful in delivering an interferon-free regimen, as part either a combo or monotherapy, the demand for patient training will less. The shift of our education will be toward the improved safety profile and decreased costs associated with a nuc-based care model. Therefore, Pharmasset will shift resources away from nurse education into increasing payer awareness and using Specialty Pharmacies who can provide nurse education if required.

Management:

Unlike Primary Care, the role of manager is also unique. In addition to their hiring, coaching, and leadership roles they also get more involved in key opinion

leader/regional thought leader development and handling local organized customers, such as prisons, managed care, specialty pharmacies. They play one of the most critical roles in the success of HCV franchise and will come with considerable experience and relationships. Since their role is expanded and the sixe of their geographies are large the rep to manager ratio is ~ 6 to 1.

Role of Specialty Pharmacy:

The lead times necessitated their role in helping take burden away from offices.

Payer Strategies:

Timing:

The initial timing and size of the US commercial organization is tied to several very critical factors that will become clearer as we progress in to 2012. Included below are the critical data points confirming efficacy and safety of PSI-7977 and the expected timing for making decision.

- August 2011 - Positive data coming from the Proton trial showing that there is a low level relapse associated with PSI-7977 and standard of care (Peg/RBV)
- August 2011 - Agreement with the FDA at the end of Phase 2 meeting on a Phase 3 design and path to approval with PSI-7977 in genotype 2/3 patients naïve to treatment.
- October 2011- Initiation of Phase 3 program in patients
- December 2011 – Satisfactory 12-week safety from 475 patients treated to date with PSI-7977
- May 2012 – Positive SVR12 results from the first wave of 50 patients in the Atomic study
- July 2012 – Positive SVR12 results from all 275 patients in the Atomic study
- February 2013 – Positive SVR12 results from the Phase 3 study giving us confidence that PSI-7977 can possibly be approved.

There are additional data points that will be released over the next two years which will increase our level of confidence in the approvability of PSI-7977, as well as, how PSI-7977 will be positioned and perform in the market. All of this data will be available prior to either the initial hiring of sales specialists in October 2012 or being fully functional mid-year 2013. These include:

- Fall-2011 – Positive results from any of the Electron arms showing that interferon can be spared or eliminated for the treatment of HCV
- June 2012 - Positive SVR12 results from the 12-week arms of Quantum, further demonstrating interferon-free is possible.
- Mid-year 2012 – SVR 12 data from the BMS combo trial, and 12-week arms of the J&J and Merck trials (assuming hoth initiate in October 2011)

- October 2012 – Positive SVR12 results from the 24-week arms of Quantum, further demonstrating interferon-free is possible with longer duration.

Exhibit 9

"Extraordinary claims require extraordinary evidence."
– Carl Sagan

HIGHLY CONFIDENTIAL VRUS_00005262

Business Proprietary Information – Confidential Treatment Requested GS-0011638

PSI-7977 Phase 3 Program Starting November 2011

- Study 1: GT2/3 Treatment Naïve – IFN free
- Study 2: GT2/3 IFN ineligible/intolerant
- Study 3: GT1 IFN ineligible/intolerant
- Study 4: Pre-transplant Study

- Target NDA Submission: October 2013
  - Interferon-Free
  - Pan-genotype

HIGHLY CONFIDENTIAL VRUS_00005263

Business Proprietary Information – Confidential Treatment Requested GS-0011639

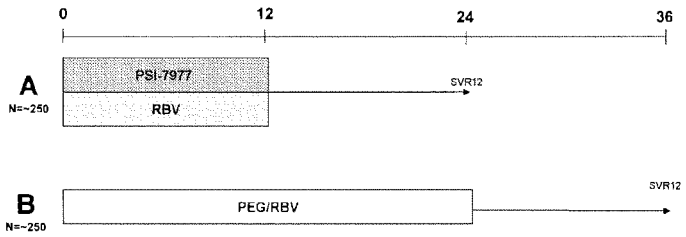
End-of-Phase 2 Meeting with FDA
August 18, 2011

- Pharmasset presented rationale for initial registrational program of 12 week regimen in HCV GT2/3
  - **PROTON** GT2/3 96% SVR24 (24/25)
    - One patient lost to f/u after day 1
  - **ELECTRON** GT2/3 100% SVR8 (40/40)
    - 34/34 to date with SVR12
- FDA response: **PSI-7977 could enable rapid transition away from interferon AND ribavirin**
- FDA suggested ***all interferon-free*** investigational regimens for our registrational studies. They were supportive of a ***rapid move to monotherapy*** in order to eliminate both interferon and ribavirin.

HIGHLY CONFIDENTIAL VRUS_00005264

Business Proprietary Information – Confidential Treatment Requested GS-0011640

Phase 3 Study 1 (P7977-1231): PSI-7977/RBV
HCV Genotype 2/3 Treatment-Naïve

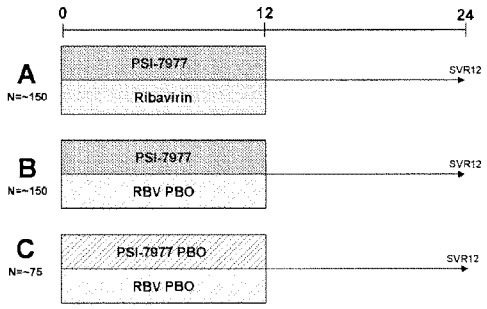


- 12-wk PSI-7977/RBV vs 24-wk PEG/RBV control
- Superiority: assumes 15% Δ Arms A (90%), B (75%); 90% power
- Over-enrolling GT3 (3:1)
- Protocol finalized, submitted to FDA & Ethics Committees
- FPFD ~November 2011

HIGHLY CONFIDENTIAL VRUS_00005265

Business Proprietary Information – Confidential Treatment Requested GS-0011641

Ph 3 Study #2 (P7977-1533) : PSI-7977 +/- RBV
HCV GT 2/3 Interferon Intolerant / Ineligible



- 12-wk PSI-7977/RBV vs PSI-7977 mono vs PBO
- Superiority Assessment A v C, B v C
- Non-inferiority of A v B, assume 15% Δ, 90% power
- Over-enrolling GT3 (3:1)
- Protocol drafted, FPFD 1Q2012

HIGHLY CONFIDENTIAL VRUS_00005266

Business Proprietary Information – Confidential Treatment Requested GS-0011842

End-of-Phase 2 Meeting
Is RBV necessary?

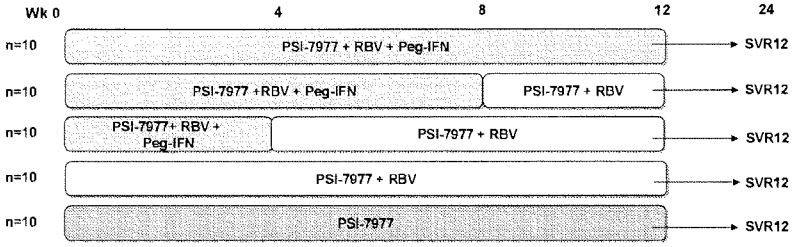
Redacted

FDA Meeting Minutes, ref #3016391

HIGHLY CONFIDENTIAL **VRUS_00005267**

Business Proprietary Information – Confidential Treatment Requested GS-0011643

ELECTRON



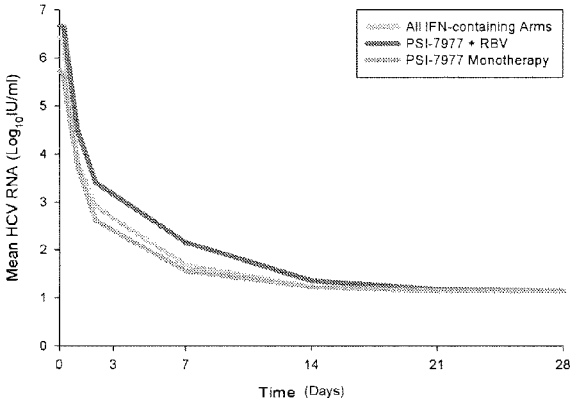
- Abbreviated (4-8-12 wk) IFN and IFN-free PSI-7977 in HCV GT2 and GT3 demonstrate no difference in early viral kinetics, no post-IFN breakthrough,
- 40/40 achieved SVR8 (34/34 SVR12 as of 01 Oct 2011)
- Monotherapy arm PSI-7977 added to ELECTRON

HIGHLY CONFIDENTIAL
VRUS_00005268
Business Proprietary Information – Confidential Treatment Requested
GS-0011644

ELECTRON

PSI-7977 monotherapy

rapid viral suppression, no breakthrough @ Wk 12



8 CONFIDENTIAL PHARMASSET

ELECTRON:

PSI-7977 monotherapy achieves 100% EOT

Time (Weeks)	PSI-7977 RBV 12 weeks PEG		PSI-7977 RBV 8 weeks PEG		PSI-7977 RBV 4 weeks PEG		PSI-7977 RBV NO PEG		PSI-7977 NO PEG NO RBV	
	n	%<LOD	n	%<LOD	n	%<LOD	n	%<LOD	n	%<LOD
0	11	0	10	0	9	0	10	0	10	0
1	2/11	27	4/10	40	1/9	22	2/10	20	6/10	60
2	8/11	82	8/9	89	7/8	88	8/10	80	8/10	80
3	9/11	82	9/9	100	7/7	100	9/10	90	10/10	100
4	11/11	100	10/10	100	9/9	100	10/10	100	10/10	100
8	11/11	100	10/10	100	9/9	100	10/10	100	10/10	100
12	11/11	100	10/10	100	9/9	100	10/10	100	10/10	100
SVR4	11/11	100	10/10	100	9/9	100	10/10	100	-	-
SVR8	11/11	100	10/10	100	9/9	100	10/10	100	-	-
SVR12	8/8	100	7/7	100	9/9	100	10/10	100	-	-

SVR4 Nov 1st

ELECTRON Demographics

- **Treatment naive patients: 18/50 GT2 & 32/50 GT3**
- **Non-cirrhotic on bx/Fibroscan, HCV RNA >50,000 IU/mL**
- **Stratified by HCV and IL28B (CC vs any T allele)**

	Cohort 4 PSI-7977 RBV 12 wk PEG N=11	Cohort 3 PSI-7977 RBV 8 wk PEG N=10	Cohort 2 PSI-7977 RBV 4 wk PEG N=9	Cohort 1 PSI-7977 RBV n=10	PSI-7977 Mono n=10
Median HCV RNA	**6.4 (5.2-7.1)**	**6.4 (5.1-7.0)**	**6.6 (5.8-7.3)**	**6.7 (6.6-7.3)**	**5.7 (4.6-7.3)**
GT2/GT3	**4/7**	**4/6**	**3/6**	**4/6**	**3/7**
IL28B CC/CT/TT	**4/5/2**	**4/4/2**	**4/4/1**	**5/4/1**	**2/6/2**

HIGHLY CONFIDENTIAL VRUS_00005271

Business Proprietary Information – Confidential Treatment Requested GS-0011647

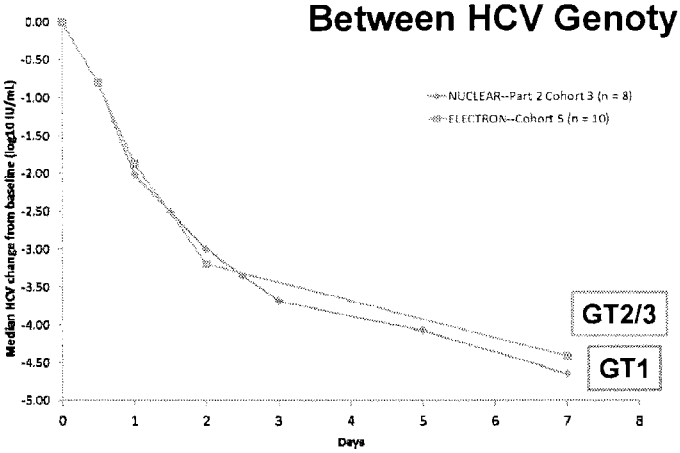
End-of-Phase 2 Meeting with FDA
August 18, 2011

- Verbally, Pharmasset presented a rationale for additional IFN-free PSI-7977 registrational study in HCV GT1, supported by IFN-free data in patients with HCV GT1:
  - **ELECTRON** GT1 (n=25)
  - BMS NS5a+PSI-7977 (n=42)
  - NIH PSI-7977 monotherapy (n=60)
  - **QUANTUM** PSI-7977/RBV (n=100)
  - **ATOMIC** 12-wk PSI-7977/PEG/RBV
- **Redacted**

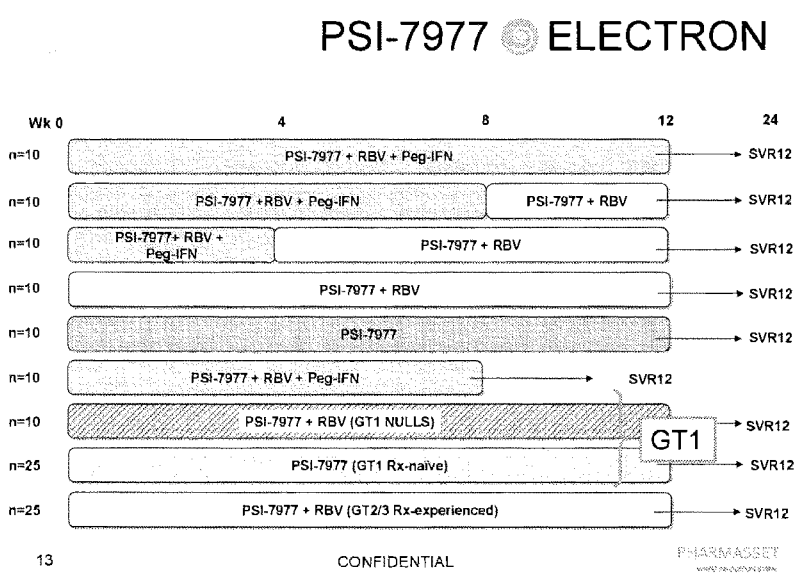
FDA Meeting Minutes, ref #3016391

11 CONFIDENTIAL PHARMASSET

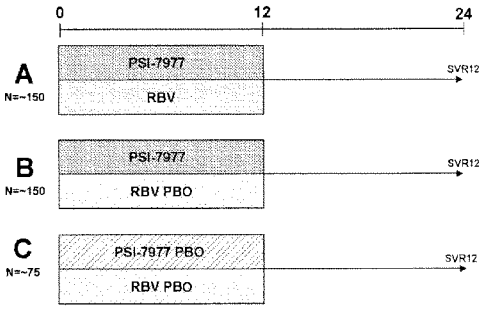
PSI-7977 Monotherapy: No Differences in Viral Kinetics Between HCV Genotypes



12 CONFIDENTIAL PHARMASSET


PSI-7977 ELECTRON
Wk 0
4
8
12
24
n=10
PSI-7977 + RBV + Peg-IFN
SVR12
n=10
PSI-7977 +RBV + Peg-IFN
PSI-7977 + RBV
SVR12
n=10
PSI-7977+ RBV + Peg-IFN
PSI-7977 + RBV
SVR12
n=10
PSI-7977 + RBV
SVR12
n=10
PSI-7977
SVR12
n=10
PSI-7977 + RBV + Peg-IFN
SVR12
n=10
PSI-7977 + RBV (GT1 NULLS)
GT1
SVR12
n=25
PSI-7977 (GT1 Rx-naive)
SVR12
n=25
PSI-7977 + RBV (GT2/3 Rx-experienced)
SVR12
13
CONFIDENTIAL
PHARMASSET

Phase 3 Study 3: PSI-7977 +/- RBV
HCV GT1 Interferon Intolerant / Ineligible

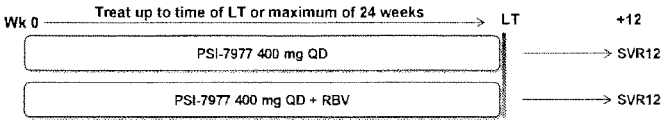


- Final study design will be based on emerging data in HCV GT1
- 12-wk PSI-7977/RBV vs PSI-7977 mono vs PBO
- Superiority Assessment A v C, B v C
- Non-inferiority of A v B, assume 15% Δ, 90% power
- Protocol drafted, FPFD mid-2012

HIGHLY CONFIDENTIAL VRUS_00005275

Business Proprietary Information – Confidential Treatment Requested GS-0011651

PSI-7977 Pre-Transplant POC



- 60 HCV Patients on LT list due to HCC (HCC MELD ≥21)
  - 30 subjects per arm
  - Treat pre-transplant to clear circulating HCV prior to LT
  - Expected transplant within 3-12 months
  - Opportunity to explore intrahepatic HCV RNA and triphosphate concentrations in explant liver
- Primary efficacy endpoint : SVR12 post-LT
- Status: Protocol under development

15 CONFIDENTIAL PHARMASSET

Target Indication for PSI-7977

- PSI-7977 is indicated for the treatment of chronic HCV infection

HIGHLY CONFIDENTIAL VRUS_00005277

Business Proprietary Information – Confidential Treatment Requested GS-0011653

Strategic Questions

- Can HCV therapy be **simplified** to reach ALL patient populations?
- What characteristics enable a regimen to be IFN-free?
- IF antiviral potency + lack of clinical resistance = SVR, is monotherapy for HCV a possibility?
- Would the FDA consider an interferon-free regimen in a registrational program?
- How can PSI-7977 most rapidly achieve a first approval, and with the broadest potential indication?

HIGHLY CONFIDENTIAL **VRUS_00005278**

Business Proprietary Information – Confidential Treatment Requested GS-0011654

Goals of optimal HCV DAA

1. **Potency** to suppress HCV replication
2. **Safety** profile to dose long enough to clear HCV in the liver
3. **No clinically relevant resistance**

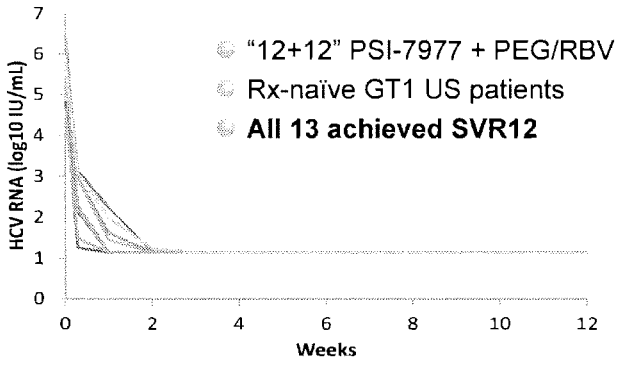
- Nucleotide analogs accomplish these critical objectives with the potential to treat all potential patient populations
  - All HCV genotypes
  - No dependence on a second agent - IFN or another DAA - to "cover" resistant variants
  - Potential for one pill, once a day
  - Minimal drug interactions

HIGHLY CONFIDENTIAL VRUS_00005279

Business Proprietary Information – Confidential Treatment Requested GS-0011655

PROTON: HCV GT1 viral kinetics

13 patients with genetic predictor of non-response to IFN (IL28B T/T)

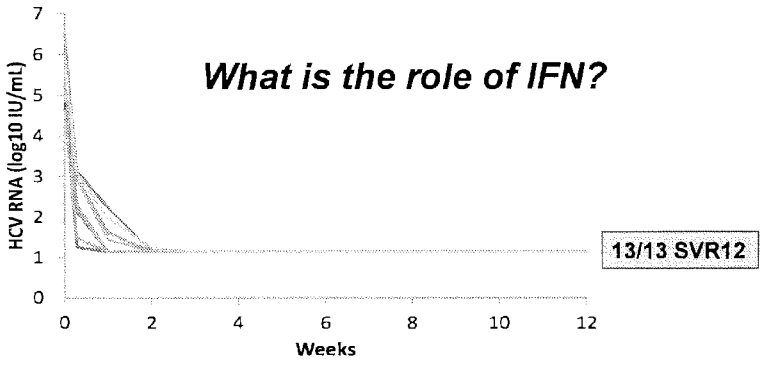


HIGHLY CONFIDENTIAL **VRUS_00005280**

Business Proprietary Information – Confidential Treatment Requested GS-0011656

PROTON: HCV GT1 viral kinetics

13 patients with genetic predictor of non-response to IFN (IL28B T/T)

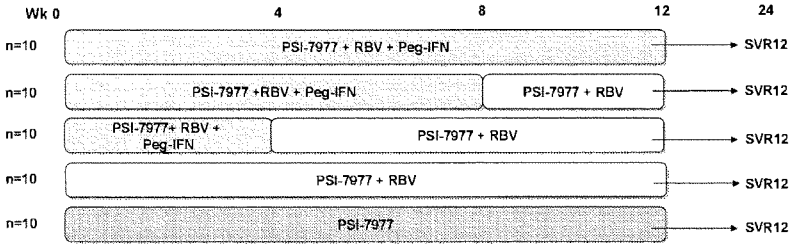


What is the role of IFN?

HIGHLY CONFIDENTIAL **VRUS_00005281**

Business Proprietary Information – Confidential Treatment Requested GS-0011657

ELECTRON



AASLD: Sunday, Nov 6 @ 3:45PM – ELECTRON

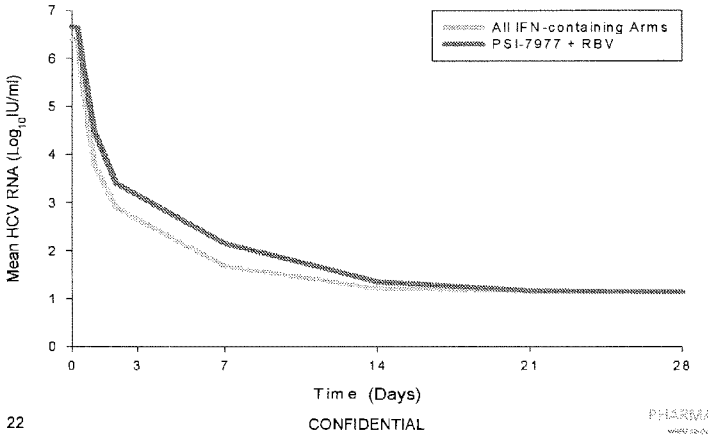
 # 34. Once Daily PSI-7977 plus RBV: Peg-IFN not required for RVR/SVR in Treatment-naïve Patients with HCV GT2 or GT3

EJ Gane, CA Stedman, RH Hyland, RD Sorensen, WT Symonds, R Hindes, MM Berrey

21 CONFIDENTIAL PHARMASSET

ELECTRON

Early viral suppression with PSI-7977 is independent of IFN



22 CONFIDENTIAL PHARMASSET

ELECTRON

IFN-free PSI-7977 achieves 100% SVR12

Time (Weeks)	PSI-7977 RBV 12 weeks PEG		PSI-7977 RBV 8 weeks PEG		PSI-7977 RBV 4 weeks PEG		PSI-7977 RBV NO PEG	
	N	%<LOD	N	%<LOD	N	%<LOD	N	%<LOD
0	11	0	10	0	9	0	10	0
1	2/11	27	4/10	40	1/9	22	2/10	20
2	8/11	82	8/9	89	7/8	88	8/10	80
3	9/11	82	9/9	100	7/7	100	9/10	90
4	11/11	100	10/10	100	9/9	100	10/10	100
8	11/11	100	10/10	100	9/9	100	10/10	100
12	11/11	100	10/10	100	9/9	100	10/10	100
SVR4	11/11	100	10/10	100	9/9	100	10/10	100
SVR8	11/11	100	10/10	100	9/9	100	10/10	100
SVR12	8/8	100	7/7	100	9/9	100	10/10	100

23 CONFIDENTIAL

US Epidemiology: 5.2-7.1 million persons living with HCV

Population	Reported prevalence range	Estimated number in US population	Estimated range of HCV cases
Homeless	22.2–52.5%	643 067 (14)	142 761–337 610
Incarcerated	23.1–41.2%	1 613 656 (96)	372 754–664 826
Veteran	5.4–10.7%	22 915 943 (97)	1 237 461–2 452 006
Active military duty	0.48%	1 417 747 (98)	6805
Healthcare workers	0.9–3.6%	7 200 950 (99)	64 809–259 234
Nursing home residents	4.5%	1 413 540 (85)	63 609
Chronic haemodialysis	7.8%	263 820 (80)	20 578
Haemophiliacs with transfusions before 1992	76.8–100%	17 000 (92)	12 971–17 000
		Unaccounted number of HCV positive NHANES*	1 921 748–3 821 668
			3 220 000
		Total	5 191 748–7 091 668

"Our most conservative estimates suggest that there are at least 5.2 million persons living with HCV in USA today, approximately 1.9 million of whom were unaccounted for in the NHANES survey."

S Saab, et al *Liver International* 2011

HIGHLY CONFIDENTIAL **VRUS_00005285**

Business Proprietary Information – Confidential Treatment Requested GS-0011661

Special populations
"We encourage development in these populations prior to NDA submission."

1. **Adequate representation of females & minorities**
2. **HIV/HCV co-infected**
3. **Transplant**
4. **Bleeding disorders**
5. **Substance abuse**
6. **Pediatrics**
7. **Decompensated liver disease**

FDA EOPh2 Meeting Minutes, ref #3016391

CONFIDENTIAL

PHARMASSET

HIGHLY CONFIDENTIAL

VRUS_00005286

Business Proprietary Information – Confidential Treatment Requested

GS-0011662

Special populations
"We encourage development in these populations prior to NDA submission."

1. **Adequate representation of females & minorities –** clinical sites with appropriate minority and female patient populations demonstrated in Phase 2
2. **HIV/HCV co-infected** – drug interaction study protocol finalized with PSI-7977 tenofovir/emtricitabine; results will support clinical trial in co-infected patients
3. **Transplant** – pre-transplant protocol in development; anticipate FPFD 1Q2012
4. **Bleeding disorders** – not excluded from current trials
5. **Substance abuse** – not excluded from current trials; methadone interaction study completed
6. **Pediatrics** – Pediatric assessment underway; plan to be submitted to FDA/EMA; includes development of oral solution
7. **Decompensated liver disease** – CP B and C will be included in Ph3 studies; Hepatic Impairment in HCV+ CP B complete; CP C enrolling.

PHARMASSET

HIGHLY CONFIDENTIAL VRUS_00005287

Business Proprietary Information – Confidential Treatment Requested GS-0011663

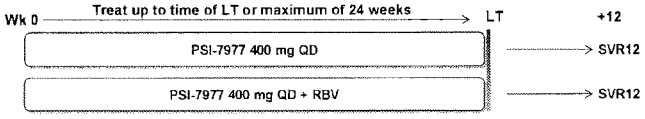
Demographics: Non-Caucasians and Females represented in Phase 2 Trials

	P7977-0422 PROTON (n=146)	P7977-0523 ELECTRON (n=40)	P7977-0724 ATOMIC (n=127)	Total (N=313)
Female, n (%)	57 (39.0)	13 (32.5)	40 (31.5)	110 (35%)
Hispanic or Latino, n (%)	20 (13.7)	0	30 (23.6)	50 (16%)
Black or African American, n (%)	22 (15.1)	0	15 (11.8)	37 (12%)

HIGHLY CONFIDENTIAL VRUS_00005288

Business Proprietary Information – Confidential Treatment Requested GS-0011664

PSI-7977 Pre-Transplant POC



- 60 HCV Patients on LT list due to HCC (HCC MELD ≥21)
  - 30 subjects per arm
  - Treat pre-transplant to clear circulating HCV prior to LT
  - Expected transplant within 3-12 months
  - Opportunity to explore intrahepatic HCV RNA and triphosphate concentrations in explant liver
- Primary efficacy endpoint : SVR12 post-LT
- Status: Protocol under development

HIGHLY CONFIDENTIAL VRUS_00005289

Business Proprietary Information – Confidential Treatment Requested GS-0011665

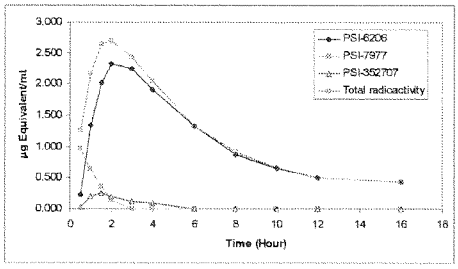
PSI-7977 Clinical Pharmacology

- Clinical Pharmacology Objectives:
  - Support potential for accelerated NDA with required Clinical Pharmacology Data
  - Rapidly generate sufficient data to support enrollment of relevant patient populations with HCV
    - Renal impairment
    - Hepatic insufficiency
    - Methadone
    - QT
    - Population PK for age>65, ethnic/racial groups, expanded BMI

HIGHLY CONFIDENTIAL VRUS_00005290

Business Proprietary Information – Confidential Treatment Requested GS-0011666

PSI-7977 Mass Balance Study

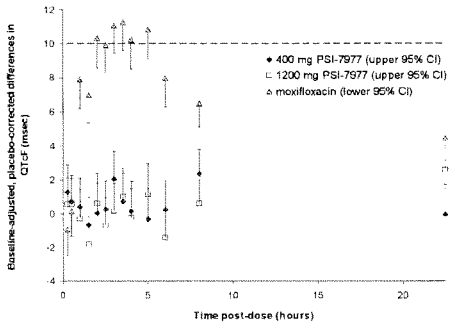


- Plasma radioactivity exposure shown above for 7 healthy subjects
- 92.6% of 400 mg/100 µCi PSI-7977 dose was recovered in 168 hours
  - 76.1% in urine
  - 14.0% in feces
  - 2.5% in expired air

HIGHLY CONFIDENTIAL VRUS_00005291

Business Proprietary Information – Confidential Treatment Requested GS-0011667

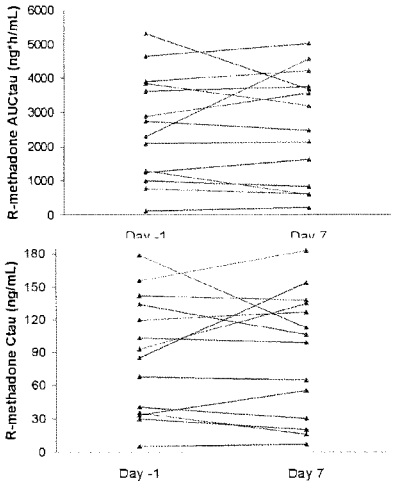
Thorough QT Study: PSI-7977 Has No Effect on QTc Interval



- No upper ΔΔQTc 95% CI ≥ 10 msec
- 1200 mg provided 2.5x > GLSM ratio versus 400 mg dose
- 400 mg single dose exposure similar to steady state in HCV subjects
- No correlation between concentration and ΔΔQTc
- 53 AEs reported in 26 of 60 (43%) subjects; no SAEs
  - 11 AEs in 8 subjects were considered possibly related to study drug

31 CONFIDENTIAL PHARMASSET

Methadone Interaction Study: No Effect of PSI-7977 on Methadone



- D7: D-1 GLSM ratio confidence intervals for R- and S- methadone AUC_{tau}, C_{max}, and C_{tau} were all within the 70-143% no-effect range
- With methadone, PSI-6206 Cmax modestly reduced but no change in AUC
- No changes in Short Opiate Withdrawal Scale, Desires for Drugs Questionnaire, pupillometry, or methadone toxicity

PHARMASSET

HIGHLY CONFIDENTIAL VRUS_00005293

Business Proprietary Information – Confidential Treatment Requested GS-0011669

PSI-7977: Renal Impairment Study Preliminary Results

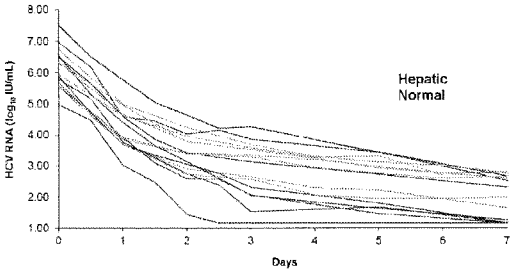
- As renal function decreased, single-dose exposure to PSI-7977 and PSI-6206 increased
- Dialysis reduced arterial concentrations by ~10% for PSI-7977 and ~50% of PSI-6206, supported by differences in pre- and post-dialysis AUC
- **Dosing recommendations will be necessary for dosing patients with eGFR < 30 mL/min and those on dialysis**
  - **May also be necessary for patients with eGFR 30-50 mL/min depending on steady-state simulation estimates**

HIGHLY CONFIDENTIAL VRUS_00005294

Business Proprietary Information – Confidential Treatment Requested GS-0011670

PSI-7977: Hepatic Impairment Study Preliminary Data

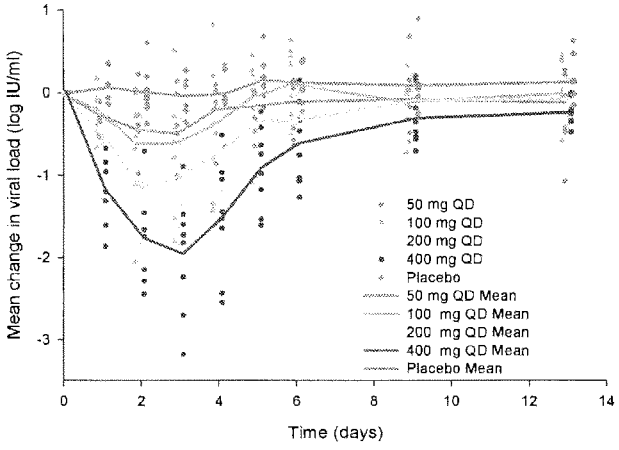
- Open-label PSI-7977 400 mg QD x 7 days in HCV-infected, Child-Pugh B & Child-Pugh C
- [PSI-6206] similar to HCV patients with normal hepatic function
- Safety: 2 AEs reported, no significant laboratory changes
- Day 7 HCV RNA change from baseline (n = 8): -3.7 log10 IU/mL



34

PHARMASSET

Dose Rationale: PSI-7851 3-Day Monotherapy

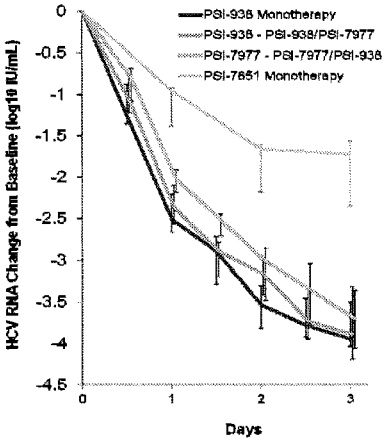


PHARMASSET

HIGHLY CONFIDENTIAL VRUS_00005296

Business Proprietary Information – Confidential Treatment Requested GS-0011672

PSI-7977 More Potent than Expected

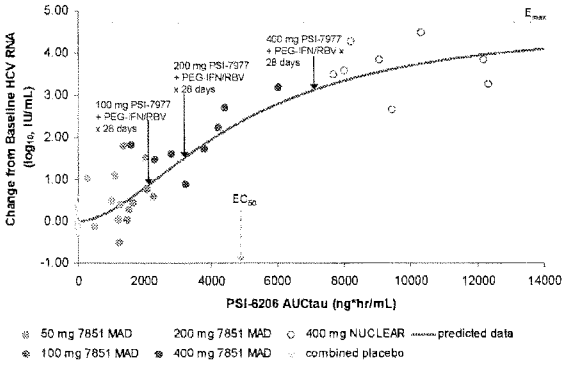


- PSI-7977 is a single isomer found in PSI-7851, a mixture of 2 isomers
- PSI-7977 monotherapy resulted in greater viral suppression at Day 3 than PSI-7851 at Day 3
- Monotherapy with either PSI-938 300 mg QD or PSI-7977 400 mg QD resulted in 3.7 to 3.9 $\log_{10}$ IU/mL declines in HCV RNA after 3 days

HIGHLY CONFIDENTIAL VRUS_00005297

Business Proprietary Information – Confidential Treatment Requested GS-0011673

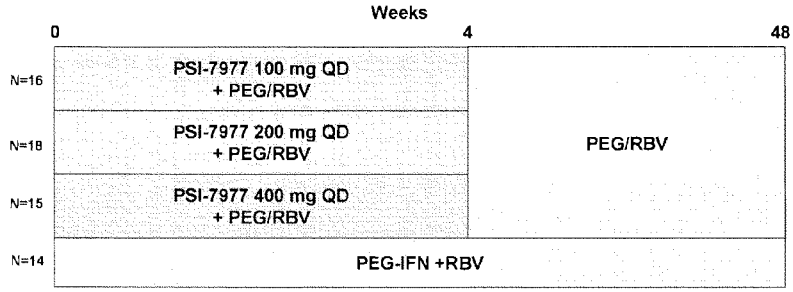
Exposure/Day 3 HCV RNA Modeling



- PK data support better systemic delivery of PSI-7977 with new formulation as measured by PSI-6206, which mediates the interstudy differences in HCV RNA declines with PSI-7977
- Early PD data support 400 mg dose as superior to lower doses

37 CONFIDENTIAL PHARMASSET

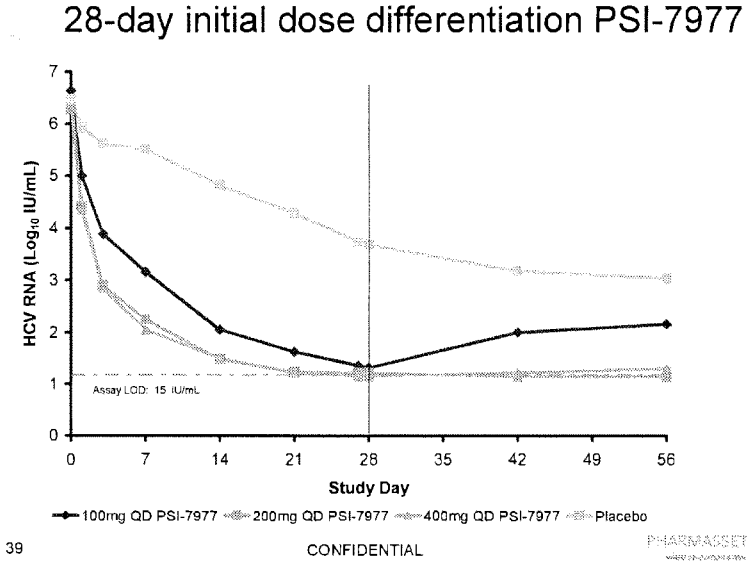
PSI-7977 : Dose-ranging Phase 2a Study



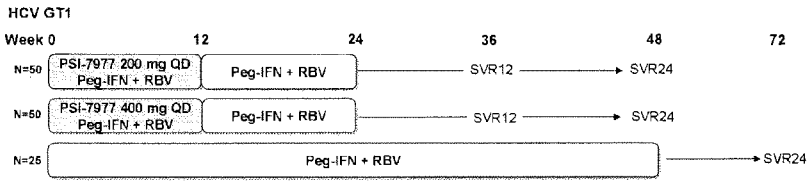
- N=63; GT1 treatment-naïve subjects
- Primary efficacy endpoint : RVR: 93-94%
- Stratified by IL28B
- No dose-limiting toxicity identified to date in up to 4-weeks' dosing
- No viral breakthrough at any dose

HIGHLY CONFIDENTIAL VRUS_00005299

Business Proprietary Information – Confidential Treatment Requested GS-0011675


28-day initial dose differentiation PSI-7977
HCV RNA (Log10 IU/mL)
7
6
5
4
3
2
1
0
Assay LOD: 15 IU/mL
0
7
14
21
28
35
42
49
56
Study Day
100mg QD PSI-7977
200mg QD PSI-7977
400mg QD PSI-7977
Placebo
39
CONFIDENTIAL
PHARMASSET

PROTON: Confirm Dose in 12-week regimen



- 125 treatment-naïve patients with HCV GT1
- Dose finding study

- 25 treatment-naïve patients with HCV GT2/3

HIGHLY CONFIDENTIAL VRUS_00005301

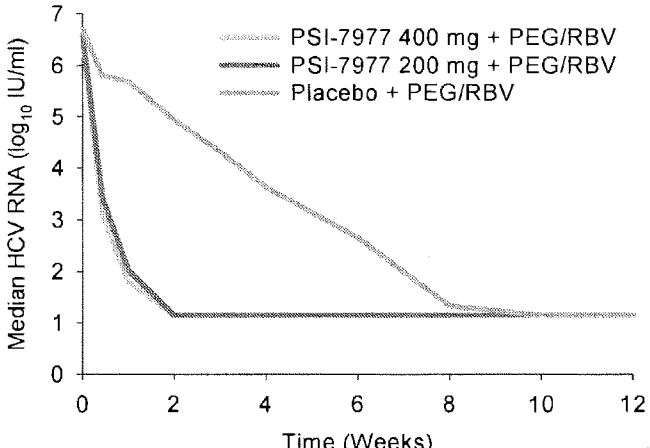
Business Proprietary Information – Confidential Treatment Requested GS-0011677

PROTON HCV GT1
Demographics and Baseline Characteristics

	GT1 200 mg PEG/RBV n=48	GT1 400 mg PEG/RBV n=47	GT1 PBO PEG/RBV n=26
Median HCV RNA (log_{10} IU/mL)	**6.6**	**6.6**	**6.5**
Gender M(%)	**33 (69%)**	**21 (45%)**	**19 (73%)**
Median Age	**51**	**53**	**48**
Mean BMI	**29**	**27**	**29**
IL28B C/C (%)	**21(44%)**	**18 (38%)**	**11 (42%)**

41 CONFIDENTIAL PHARMASSET

PROTON: Rapid viral suppression with PSI-7977 200mg or 400mg QD + PEG/RBV



42

CONFIDENTIAL

PHARMASSET

PSI-7977 Phase 2b PROTON: Treatment-naïve HCV GT1[1]

- 95 patients with HCV GT1 enrolled in active PSI-7977 arms
  - 90/95 randomized eligible to stop all therapy at wk 24
    - **4/95 d/c during 1st 12 weeks with IFN/RBV-attributable AEs/SAEs**
    - **1/95 did not obtain RVR on 200mg QD (<LOD at wk6) – SVR12**
- No "non-responders"
- No correlation of any baseline predictors with time to HCV RNA <LOD (gender, BMI, BL HCV RNA, IL28B, platelets)
  - 13/95 patients with IL28B T/T – all achieved SVR12
- Viral kinetics were independent of IL28B genotype
- No viral breakthrough observed

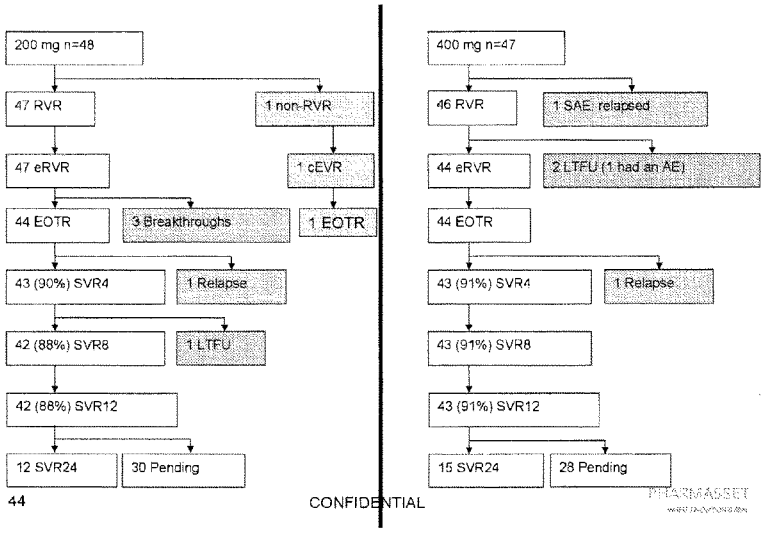
- **SVR12 of 91% (ITT) achieved with 400mg QD[2]**

[1] Nelson D. *et al.* EASL 2011 LB poster 1372
[2] Pharmasset press release (date 9/6/2011)

HIGHLY CONFIDENTIAL VRUS_00005304

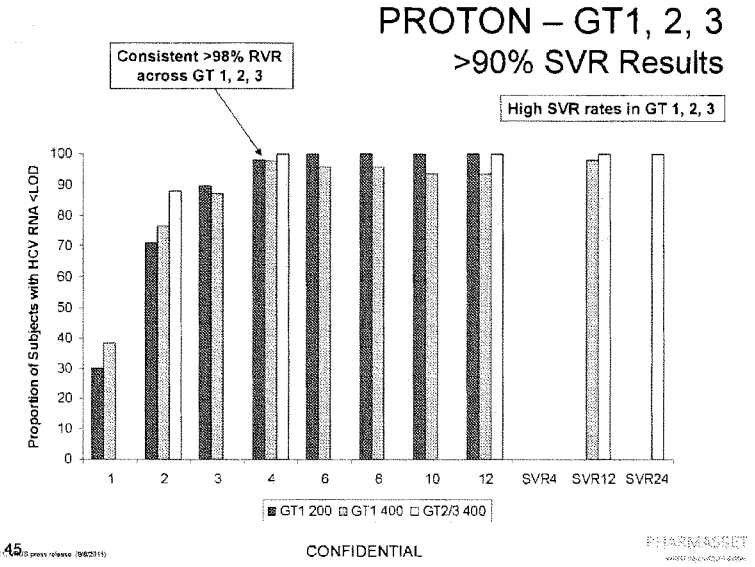
Business Proprietary Information – Confidential Treatment Requested GS-0011680

PROTON Subject Disposition



44

CONFIDENTIAL


PROTON – GT1, 2, 3
>90% SVR Results
Consistent >98% RVR across GT 1, 2, 3
High SVR rates in GT 1, 2, 3
Proportion of Subjects with HCV RNA <LOD
100
90
80
70
60
50
40
30
20
10
0
1
2
3
4
6
8
10
12
SVR4
SVR12
SVR24
GT1 200
GT1 400
GT2/3 400
45
CONFIDENTIAL
PHARMASSET

Current Therapy for HCV GT2 and GT3 is Complex and Suboptimal for Many Patients

- **IFN-based regimens**
  - 24 wks PEG/RBV is current standard of care for HCV GT2/3
    - remains suboptimal treatment regimen
  - ACCELERATE Trial: attempting to shorten duration

	16 week	24 week
SVR	66%	70%
Relapse	31%	18%

- **Few promising DAA options in development**
  - Protease inhibitors (PIs) and non-nucleoside polymerase inhibitors (NNI) have limited genotype coverage

References: Shiffman *NEJM* 2007; Mangia *NEJM* 2005; de Leuw *Liver Intl* 2011; Shiffman AASLD 2009

HIGHLY CONFIDENTIAL VRUS_00005307

Business Proprietary Information – Confidential Treatment Requested GS-0011683

PROTON : HCV GT2/GT3

- Open label, 25 treatment naïve patients with GT2 or 3
- 24/25 enrolled subjects completed therapy
  - One subject lost to follow-up after day 1
- Consistent HCV RNA reduction: 24/24 RVR & cEVR/EOT
  - **No difference in viral kinetics: GT 2 v GT 3; IL28B CC v T allele**
- No virologic breakthrough
- No relapse through 24 weeks post-therapy

	Week 2	Week 4 *RVR*	Week 12 cEVR/EOT	*SVR12*	SVR24
n (evaluable)	24	24	24	24	**24**
HCV RNA < LOD	21	24	24	24	**24**
% Response	88%	100%	100%	100%	**100%**
Lost to follow-up	1	1	1	1	**1**
% Response (ITT)	84%	96%	96%	96%	**96%**

47 CONFIDENTIAL PHARMASSET

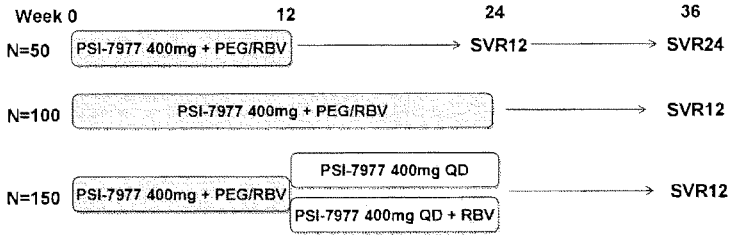
PROTON HCV GT2/3: Demographics and Baseline Characteristics

	GT2 n=15	GT3 n=10	**Overall n=25**
Median HCV RNA (log_{10} IU/mL)	6.4	5.6	**6.1**
Gender (M/F)	8/7	8/2	**16/9**
Median Age (yrs)	51	41	**47**
Mean BMI	29.8	26.2	**28.3**
IL28B (**CC** v T allele)	**4** / 11	**3** / 7	**7 / 18 (28%)**

48 CONFIDENTIAL PHARMASSET

ATOMIC : Establish Optimal Duration

Fully Enrolled

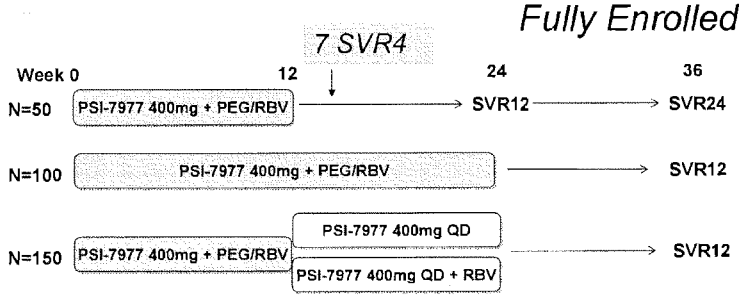


- Explore 12-wk duration across more heterogenous GT1 population
- Confirm safety of 24-week duration PSI-7977
- Enrolled 315 treatment naïve patients with HCV GT-1
  - HCV GT4 (n=10), GT 6 (n=5) enrolled in 24wk arm
  - Stratified by IL28B and baseline HCV RNA

49 CONFIDENTIAL PHARMASSET

ATOMIC : Establish Optimal Duration

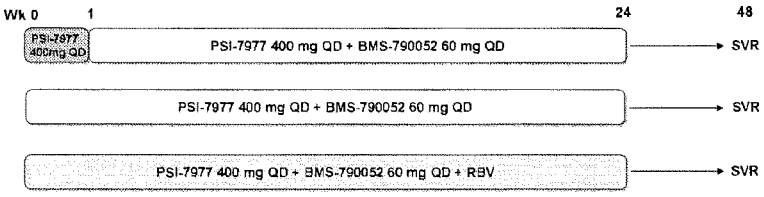
Fully Enrolled



- Explore 12-wk duration across more heterogenous GT1 population
- Confirm safety of 24-week duration PSI-7977
- Enrolled 315 treatment naïve patients with HCV GT-1
  - HCV GT4 (n=10), GT 6 (n=5) enrolled in 24wk arm
  - Stratified by IL28B and baseline HCV RNA

50 CONFIDENTIAL PHARMASSET

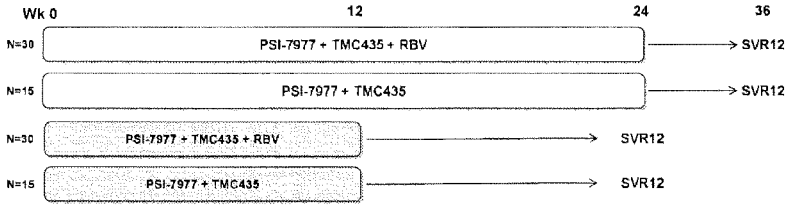
PSI-7977+BMS-790052



- PSI-7977 + BMS-790052 (NS5a Inhibitor)
- 84 Treatment-naïve patients with HCV GT1, GT2/GT3
  - 42 GT1; 42 GT2/3
- Primary efficacy endpoint : SVR
- Status: Enrollment complete

51 CONFIDENTIAL PHARMASSET

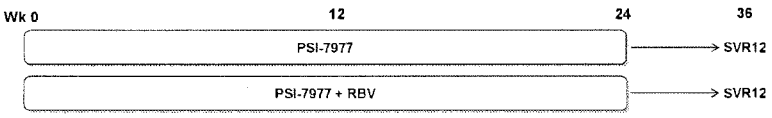
PSI-7977 + TMC435



- N=180 patients with HCV GT1, prior null responders
  - 30 subjects per arm in RBV arms, 15 in non-RBV
  - 1st cohort of 90 subjects with Metavir ≤F2
  - 2nd cohort of 90 subjects with Metavir F3/4
- Primary efficacy endpoint : SVR
- Status: Final Protocol

52 CONFIDENTIAL PHARMASSET

NIH: PSI-7977 Monotherapy

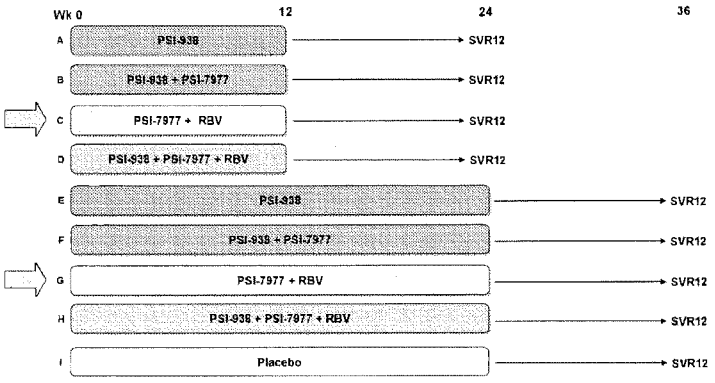


- 60 Treatment-naïve patients* with HCV GT1
  - N=30 / arm
  - Metavir ≤ F2
- Primary efficacy endpoint : SVR
- Status: Screening

* Predominantly African American/Black

53 CONFIDENTIAL PHARMASSET

PSI-7977 & PSI-938 QUANTUM



- International, interferon-free combination trial
- All HCV genotypes (N=450)
  - Cirrhotic and non-cirrhotic patients
- Primary endpoint : SVR

54 CONFIDENTIAL PHARMASSET

PSI-7977: Safety Database

- Exposure as of 30 September 2011:

7977 exposure	<4 wks	4-8 wks	8-12 wks	12+ weeks
ELECTRON no IFN			20	
ELECTRON w IFN	4	5	30	
PROTON	3	1	68	
ATOMIC	92	60	55	72
BMS STUDY	38	38	5	
TOTAL	**137**	**104**	**178**	**72**

PHARMASSET

HIGHLY CONFIDENTIAL VRUS_00005316

Business Proprietary Information – Confidential Treatment Requested GS-0011692

	Number of subjects (study)	Total Subjects Exposed to Date	Total Subjects Exposed at Start of Phase 3
Any dose / duration of PSI-7977	Phase 1: 33 (P7851-1101) 32 (P7851-1102) 24 (P7977-0111) 7 (P7977-0312) 60 (P7977-0613) 24 (P2938-0212) 4 (P2938-0515) 15 (P7977-0814) 30 (P7977-0915) Phase 2: 49 (P7977-0221) 119 (P7977-0422) 55 (P7977-0523) 176 (P7977-0724)	**628**	
PSI-7977 400 mg any duration	Phase 2: 15 (P7977-0221) 71 (P7977-0422) 176 (P7977-0724) 55 (P7977-0523)	**317**	
PSI-7977 200 mg 12w	47 (P7977-0422)	47	
PSI-7977 400 mg 12w	**67 (P7977-0422)** **40 (P7977-0523)** **27 (P7977-0724)**	**134**	**307**

PHARMASSET

HIGHLY CONFIDENTIAL VRUS_00005317

Business Proprietary Information – Confidential Treatment Requested GS-0011693

Safety database for NDA Submission

- "1000-1500 patients at the dose and duration"
- Assuming PSI-7977 400 mg x 12 weeks:
  - **307** at start of Phase 3
  - **P7977-1231 (Rx-naïve GT2/3) = 250**
  - **P7977-1533 (IFN ineligible/intol) = 300**
  - **GT1 Ph3 study = 300**
  - **NIH – 60 HCV GT1 predom African American/Black**
  - **QUANTUM – 100**
  - **BMS Study – 84**
  - **Tibotec Study – 180**

  - **Total Safety Database >1500 patients PSI-7977 400mg x 12 weeks**

HIGHLY CONFIDENTIAL VRUS_00005318

Business Proprietary Information – Confidential Treatment Requested GS-0011694

PSI-7977: Total Program Safety

- To date, no identifiable safety signal for PSI-7977
- No discontinuations due to PSI-7977
- No SAEs attributable to PSI-7977
- Single doses up to 1200mg tolerated without identifiable toxicity (n=60 in QT Study)
- No lab changes different from placebo with PEG/RBV

- Monotherapy arms (ELECTRON, NUCLEAR) have not demonstrated drug-related lab changes

HIGHLY CONFIDENTIAL VRUS_00005319

Business Proprietary Information – Confidential Treatment Requested GS-0011695

PSI-7977 Total Program SAEs

- 15 SAEs have been reported to date
  - 354 exposed ≥4 weeks
- All "unrelated" to PSI-7977
  - **RLE Ischemia**
  - **Anemia**
  - **Abdominal Pain**
  - **Retinal Vein Occlusion**
  - **Depression x 3**
  - **Chest Pain**
  - **Ischemic colitis**
  - **Acute Pancreatitis,**
  - **Atypical CP**
  - **Acute MI**
  - **Lymphangitis**
  - **Pulmonary Embolism**
  - **Autoimmune hepatitis**
- 5 of 15 occurred during treatment with PSI-7977
  - **Major depression**
  - **Acute MI**
  - **Autoimmune hepatitis**
  - **Ischemic colitis**
  - **Atypical chest pain**

HIGHLY CONFIDENTIAL **VRUS_00005320**

Business Proprietary Information – Confidential Treatment Requested GS-0011696

PSI-7977: Hematologic Safety
Preclinical and Clinical Data

- Safety Pharm – *in vitro* Bone Marrow Toxicity Study
  - Slight (26%) inhibition of erythroid cell proliferation at 26.5 µg/mL (50µM) but not at ≤5.3 µg/mL
- Toxicology
  - Rats: no hematology findings in 6 Month Study
  - Dogs: 10% ↓ in erythron mass and minimal BM erythroid precursor alterations in 28 days, modest effect on hgb in higher doses of 90-day study with similar changes in erythroid mass; no hematologic effects at 500 mkd in 6 month study
- Clinically, no dose-related changes have been noted in hematology parameters to date in subjects treated with PSI-7977 with or without PEG/RBV

HIGHLY CONFIDENTIAL VRUS_00005321

Business Proprietary Information – Confidential Treatment Requested GS-0011697

PSI-7977 Liver Safety
Preclinical and Clinical Data

- Liver:Plasma 7-23x in rat, dog, monkey
- Toxicology Studies
  - Rat: No liver-related findings in 90-Day Study
  - Dog: Reversible liver findings in 7-Day at 1500 mkd. Slight increase in liver weight in 90-day study, considered non-adverse; no liver changes in 500 mkd in 6 month study
- Data to date suggests that PSI-7977 does not result in increased ALT
- > 90% of subjects with baseline ALT elevation who received PSI-7977 400mg with IFN x 12 weeks experienced ALT normalization; ALL patients receiving PSI-7977 without IFN have rapid normalization of ALT

HIGHLY CONFIDENTIAL VRUS_00005322

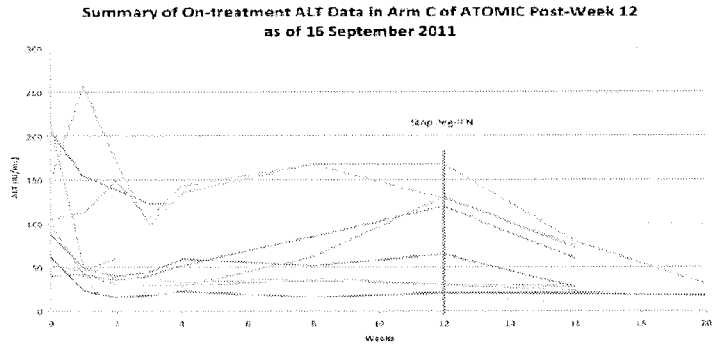
Business Proprietary Information – Confidential Treatment Requested GS-0011698

Subjects with Abnormal ALT at Baseline have rapid ALT Normalization

	GT1 P7977-0422 PSI-7977 200mg PEG/RBV n=22	GT1 P7977-0422 PSI-7977 400mg PEG/RBV n=19	GT2/3 P7977-0422 PSI-7977 400mg PEG/RBV n=10	P7977-0523 PSI-7977 400mg/ +/- PEG/RBV n=21
Subjects with ALT normalization n (%)	19 (86.4)	18 (94.7)	10 (100.0)	21 (100.0)

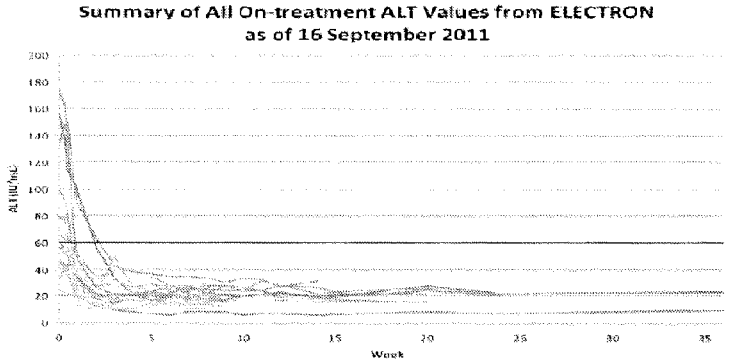
62 CONFIDENTIAL PHARMASSET

ATOMIC ALT Normalization



- 12 weeks PSI-7977/PEG/RBV followed by 12 weeks PSI-7977

ELECTRON: ALT



- All subjects in ELECTRON have ALT WNL by week 3

HIGHLY CONFIDENTIAL VRUS_00005325

Business Proprietary Information – Confidential Treatment Requested GS-0011701

Grade 3/4 Treatment-Emergent Chemistry Lab Abnormalities During 12 weeks PSI-7977 + PEG/RBV

	P7977-0422 PSI-7977 400mg PEG/RBV X 12 weeks n=72	P7977-0523 PSI-7977 400mg PEG/RBV x 12weeks n=40	P7977-0724 PSI-7977 400mg PEG/RBV x 12 weeks n=127	Total PSI-7977 400mg PEG/RBV X 12 weeks n=239	P7977-0724 PSI-7977 200mg PEG/RBV x 12 weeks n=48	Placebo P7977-0221 & P7977-0442 PEG/RBV x 12 weeks n=40
Grade 3						
AST	1 (1.4)	0	2 (1.6)	3 (1.4)	0	0
Total Bilirubin	0	0	0	0	1 (2.1)	0
Glucose	2 (2.8)	0	1 (0.8)	3 (1.3)	0	1 (2.5)
Lipase	0	0	0	0	1 (2.1)	1 (2.5)
Phosphate	2 (2.8)	0	0	2 (0.8)	1 (2.1)	4 (10.0)
Grade 4	0	0	0	0	0	0

PHARMASSET

Grade 3/4 Treatment-Emergent Hematology Lab Abnormalities During 12 wks of PSI-7977/PEG/RBV

Grade 3						
Anemia	12(16.7)	1(2.5)	10(7.9)	**23 (9.6)**	15(31.3)	**4 (10.0)**
Elevated INR	0	0	0	**0**	1(2.1)	**0**
Lymphopenia	2(2.8)	3(7.5)	0	**5 (2.1)**	2(4.2)	**1 (2.5)**
Neutropenia	20(27.8)	13(32.5)	8(6.3)	**41 (17.2)**	11(22.9)	**7 (17.5)**
Leucopenia	4(5.6)	9(22.5)	2(1.6)	**15 (6.3)**	3(6.3)	**1 (2.5)**
Elevated PT	0	0	0	**0**	1(2.1)	**0**
Elevated PTT	0	0	0	**0**	0	**1 (2.5)**
Grade 4						
Neutropenia	1(1.4)	4(10.0)	1(0.8)	**6 (2.5)**	2(4.2)	**0**
Lymphopenia	1(1.4)	0	1(0.8)	**2 (0.8)**	2(4.2)	**0**
Elevated PTT	0	0	0	**0**	0	**1(2.5)**

Treatment-Emergent AEs in ≥10% of Subjects During 12 wks of PSI-7977/PEG/RBV

AE	P7977-0422 PSI-7977 400mg PEG/RBV X 12 weeks (n=72)	P7977-0423 PSI-7977 400mg PEG/RBV x 12 weeks (n=40)	P7977-0724 PSI-7977 400mg PEG/RBV x 12 weeks (n=127)	Total PSI-7977 400mg PEG/RBV X 12 weeks (n=239)	P7977-0774 PSI-7977 200mg PEG/RBV x 12 weeks (n=78)	Placebo PEG/RBV x 12 weeks (n=40)
No. subjects with ≥ one AE	70(97.2)	40(100)	95(74.8)	**276 (85.8)**	47(97.9)	**39 (97.5)**
Fatigue	41(56.9)	12(30.0)	35(27.6)	**88 (36.8)**	32(66.7)	**22 (55.0)**
Headache	30(41.7)	26(65.0)	29(22.8)	**85 (35.6)**	17(35.4)	**17 (42.5)**
Nausea	33(45.8)	9(22.5)	24(18.9)	**66 (27.6)**	16(33.3)	**15 (37.5)**
Chills	28(38.9)	2(5.0)	25(19.7)	**55 (23.0)**	18(37.5)	**12 (30.0)**
Insomnia	18(25.0)	19(47.5)	9(7.1)	**46 (19.2)**	9(18.8)	**10 (25.0)**
Pain	17(23.6)	2(5.0)	14(11.0)	**33 (13.8)**	14(29.2)	**11 (27.5)**
Pyrexia	14(19.4)	2(5.0)	15(11.8)	**31 (13.0)**	12(25.0)	**3 (7.5)**
Rash	15(20.8)	10(25.0)	6(4.7)	**31 (13.0)**	13(27.1)	**4 (10.0)**
Neutropenia	20(27.8)	4(10.0)	6(4.7)	**31 (13.0)**	8(16.7)	**6 (15.0)**
Diarrhea	12(16.7)	5(12.5)	11(8.7)	**30 (12.6)**	7(14.6)	**3 (7.5)**
Dizziness	10(13.9)	12(30.0)	6(4.7)	**28 (11.7)**	5(10.4)	**5 (12.5)**
Myalgia	16(22.2)	4(10.0)	8(6.3)	**28 (11.7)**	5(10.4)	**7 (17.5)**
Arthralgia	13(18.1)	5(12.5)	7(5.5)	**25 (10.5)**	5(10.4)	**5 (12.5)**
Decreased appetite	9(12.5)	5(12.5)	11(8.7)	**25 (10.5)**	5(10.4)	**4 (10.0)**
Irritability	10(13.9)	7(17.5)	7(5.5)	**24 (10.0)**	8(16.7)	**7 (17.5)**

Preliminary P7977-0724 ATOMIC Safety Summary

- ATOMIC study is ongoing
- First study of >12 weeks PSI-7977
  - One SAE: "Atypical chest pain" (onset Day 55 in Arm B: PSI-7977/PEG/RBV x 24 wks), unrelated to PSI-7977
  - Majority of AEs to date grade 1 or 2
    - only 3 subjects had grade 3/4 events
    - Most commonly reported AEs: fatigue, headache, chills & nausea
  - No significant issues or potential trends noted in safety labs

HIGHLY CONFIDENTIAL VRUS_00005329

Business Proprietary Information – Confidential Treatment Requested GS-0011705

Preliminary P7977-0523 ELECTRON Safety: AEs >10% Incidence

	PSI-7977 RBV PEG 12 wk N=11	PSI-7977 RBV PEG 8 wk N=10	PSI-7977 RBV PEG 4 wk N=9	PSI-7977 RBV N=10	PSI-7977 N=10
Headache	7 (64)	8 (80)	7 (78)	4 (40)	8 (80)
Insomnia	5 (46)	5 (50)	6 (67)	3 (30)	2 (20)
Fatigue	5 (46)	3 (30)	3 (33)	1 (10)	2 (20)
Dizziness	3 (27)	2 (20)	4 (44)	3 (30)	0
Nausea	2(18)	4(40)	3 (33)	0	3 (30)
Rash	2(18)	2(20)	3 (33)	3 (30)	0
Pruritus	2(18)	3(30)	3 (33)	1 (10)	0
Flu-like illness	2 (18)	3(30)	1 (11)	2 (20)	0
Irritability	4 (36)	1 (10)	0	2 (20)	1 (10)
Arthralgia	1 (9)	3 (30)	1 (11)	1 (10)	0
Anemia	2 (18)	0	2 (22)	1 (10)	0
Decreased appetite	3 (27)	0	2 (22)	0	0
Depression	2 (18)	0	1 (11)	2 (20)	0
Diarrhea	2 (18)	1 (10)	0	2 (20)	0
Dry skin	0	4 (40)	1 (11)	0	0
Dyspnea	4 (36)	1 (10)	0	0	0
Hemolytic anemia	1 (9)	1 (10)	2 (22)	1 (10)	0

ELECTRON: Treatment-Emergent Laboratory Abnormalities: Hematology

	PSI-7977 RBV PEG 12 wk N=11	PSI-7977 RBV PEG 8 wk N=10	PSI-7977 RBV PEG 4 wk N=9	PSI-7977 RBV N=10	PSI-7977 N=10
Gr 3 Anemia	0	0	1 (11.1)	0	0
Gr 3 Lymphopenia	0	2 (20.0)	1 (11.1)	0	0
Gr 3 Neutropenia	7 (63.6)	4 (40.0)	2 (22.2)	0	0
Gr 3 Leucopenia	4 (36.4)	3 (30.0)	2 (22.0)	0	0
Gr 4 Neutropenia	1 (9.1)	1 (10.0)	2 (22.2)	0	0

HIGHLY CONFIDENTIAL VRUS_00005331

Business Proprietary Information – Confidential Treatment Requested GS-0011707

PSI-7977: Virology
Sequence Changes Observed to Date

Subject	Dose QD	HCV Subtype	Virologic Failure Category	Amino Acid Change at Tested Time Point
1057	200 mg	1b	Breakthrough on SOC at wk16	R/S113R, V116V/I
1170	200 mg	1a	Breakthrough on SOC at wk20	F/S39S, N/S62N, H63Y, K/Q206K, Q/E327E, P/Q330Q
1184	200 mg	1b	Relapse at wk4 post EOT	K/R90K, N/S110S, A189S, K/R212R, I/L434L
1193	400 mg	1b	Relapse at wk4 post EOT	R/K50R
1204	200 mg	1b	Breakthrough on SOC at wk16	D549D/G, D/N559D

- To date, no amino acid change has been observed in more than one subject
- The S282T has not been seen in Pharmasset's clinical development program

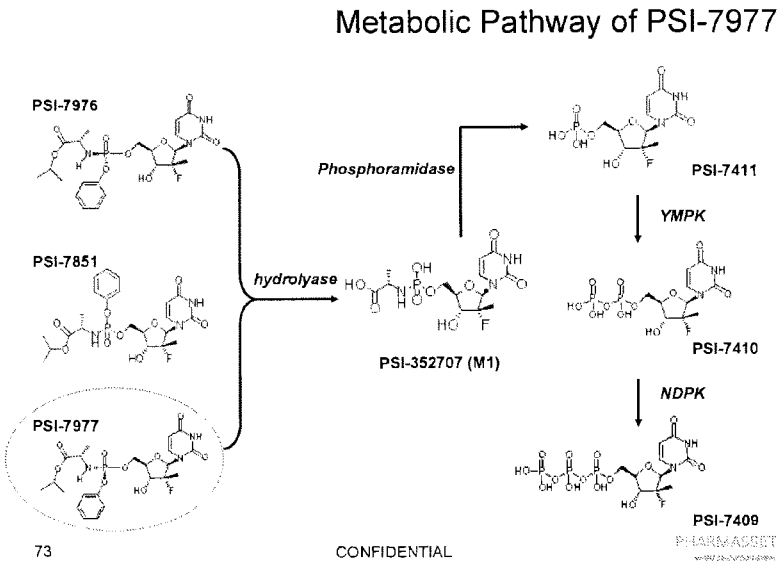
HIGHLY CONFIDENTIAL VRUS_00005332

Business Proprietary Information – Confidential Treatment Requested GS-0011708

PSI-7977 Preclinical Data

HIGHLY CONFIDENTIAL **VRUS_00005333**

Business Proprietary Information – Confidential Treatment Requested GS-0011709


Metabolic Pathway of PSI-7977
PSI-7976
PSI-7851
PSI-7977
hydrolyase
PSI-352707 (M1)
Phosphoramidase
PSI-7411
YMPK
PSI-7410
NDPK
PSI-7409
73
CONFIDENTIAL

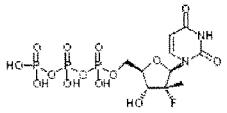
Production of the active substrate in Clone A cells: PSI-7409

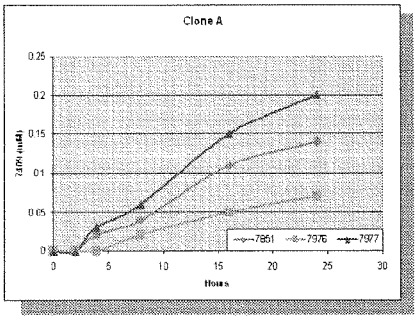
Clone A cells

↓ 100 µM of PSI-7851, PSI-7976, or PSI-7977

↓ Lysed cells at appropriate time points

HPLC chromatography to determine PSI-7409 concentration





Clone A cells: PSI-7977 > PSI-7851 > PSI-7976

PHARMASSET

Preclinical Assessment

- hERG – no effect
- Ames – no effect
- Chromosomal Aberration – no effect
- Mouse Micronucleus – no effect
- Bone Marrow toxicity – CC_{50} > 50μM
- Ligand binding assays – no effect
- CYP inhibition – no effect
- Irwin (neurobehavorial) study – no effect
- Rat respiratory study – no effect
- Dog cardiovascular study – no effect

75 CONFIDENTIAL PHARMASSET

DMPK Program

Study	Status	Results
Rat ADME	Complete	• Extent of absorption >70% • Total recovery >95% with >70% in urine • PSI-6206 is major metabolite, PSI-7977 not detected
Rat QWBA	Complete	• Highest radioactivity in alimentary canal, lymphatic system, and excretory system • Lowest in CNS, bone, eye lens, and white adipose • No evidence of binding with melanin
Dog ADME	Complete	• Total recovery >96% with >80% in urine • PSI-6206 is major metabolite, PSI-7977 detected in plasma/urine
PGP substrate /inhibition	Complete	• PSI-7977 & PSI-352707 are substrates, not inhibitors • PSI-6206 is neither substrate or inhibitor
Human hepatocyte induction	Complete	• Little or no induction in CYP1A2 or CYP3A4/5 activity or CYP1A2 mRNA expression levels • Slight increases in CYP2B6 activity and CYP2B6/3A4 mRNA levels

76

Chronic Toxicology Program

Study Type and Duration	Test Article	PSI-7977 Daily Dose (mg/kg)	Status
Rats			
7-day, with 14-day recovery	PSI-7851	0, 15, 125, 1000	Complete
14-day bridging	PSI-7851 PSI-7977	PSI-7851 = 250 PSI-7977 = 500	Complete
28-day, with 14-day recovery	PSI-7851	0, 20, 100, 500	Complete
90-day, with 4-week recovery	PSI-7977	0, 20, 100, 500	Complete
6-month, with 4-week recovery	PSI-7977	0, 20, 100, 500	Complete
2-year carcinogenicity	PSI-7977	0, 75, 250, 750	Ongoing
Dogs			
7-day, with 14-day recovery	PSI-7851	0, 15, 75, 750	Complete
14-day bridging	PSI-7851 PSI-7977	PSI-7851 = 250 PSI-7977 = 500	Complete
28-day, with 14-day recovery	PSI-7851	0, 20, 100, 500	Complete
90-day, with 4-week recovery	PSI-7977	0, 20, 100, 500	Complete
6/9-month, with 4-week recovery	PSI-7977	0, 20, 100, 500	Complete
Mice			
14-day	PSI-7977	0, 50, 150, 500, 1500	Complete
90-day	PSI-7977	0, 100, 300, 1000	Complete
2-year carcinogenicity	PSI-7977	Males: 0,20,60,200 Females: 0, 60, 200, 600	Ongoing

CONFIDENTIAL

PSI-7977 Toxicology Summary

- In rats, the only AEs were an increase in vehicle-related clinical signs, which included soft feces and watery diarrhea; study NOAELs reflect differences in whether vehicle-related clinical signs were considered to be adverse; all reversible.
  - 28-day NOAEL was 20 mg/kg
  - 90-day NOAEL not identified
  - 180-day NOAEL was 500 mg/kg
- In dogs, the only AEs were increased GI-related clinical signs (soft feces and emesis) and a slight (10%) decrease in mean erythron mass; all reversible.
  - 28-day NOAEL 100 mg/kg
  - 90-day NOAEL 20 mg/kg
  - 180-day NOAEL 100 mg/kg

HIGHLY CONFIDENTIAL VRUS_00005339

Business Proprietary Information – Confidential Treatment Requested GS-0011715

Comparison of Preclinical NOAEL and Clinical Systemic Exposures

	Dose (mg/kg)	PSI-7977	PSI-352707	PSI-6206	PSI-7411
Mice					
90-day study	1000	ND	48.1 (M) 67.1 (F)	81.5 (M) 161.1 (F)	NE
Rats					
7-day study	250	NE	30.3 (M) 17.1 (F)	41.4 (M) 20.9 (F)	4.6 (M) 3.9 (F)
28-day study	500	7.1 (M)[b] 68.1 (F)[b]	42.5 (M) 43.2 (F)	55.0 (M) 59.3 (F)	0.8 (M) 0.3 (F)
90-day study	500	NE	37.6 (M) 18.2 (M)	74.1 (M) 62.0 (F)	NE
6-month study	500	NE	NE	66.5 (M) 65.5 (F)	NE
Dogs					
7-day study	150	5.5[b]	7.4	93.9	1.3
28-day study	100	8.0[b]	7.4	52.1	0.3
90-day study	20	1.1	1.2	19.6	NE
6-month study	100	NE	NE	89.4	NE
Humans					
P2938-0721	6.7[c]	0.50[d]	0.78[d]	9.5[d]	NE

[a]For repeat-dose studies, the mean AUC values are from a dose near the end of the study.
[b]These PSI-7977 AUCs are estimated from the AUCs for PSI-7851 by assuming that PSI-7977 accounted for approximately half of the PSI-7851 AUC and are therefore approximate.
[c]Based on a 60-kg human subject and a 400-mg dose.
[d]Data are geometric mean steady-state AUC_{tau} observed on Day 7 for PSI-7977 and metabolites after PSI-7977 monotherapy in Cohort 3 of Part 2 of the NUCLEAR Study (P2938-0212).

ND = not detected NE = not evaluated

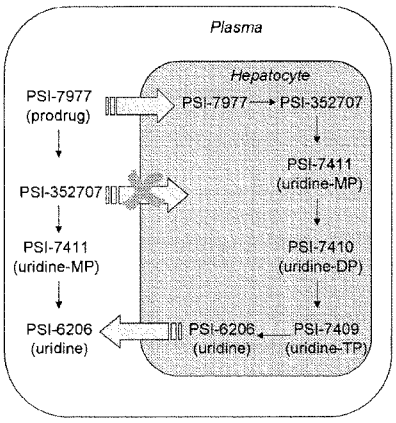
CONFIDENTIAL

PHARMASSET

79

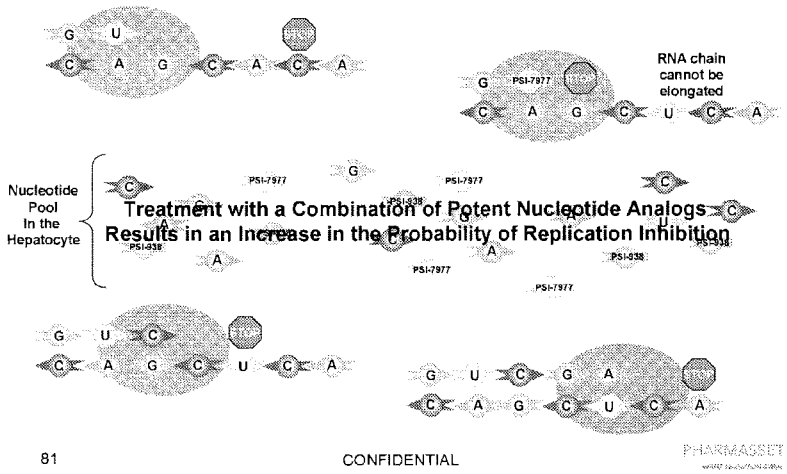
PSI-7851 to PSI-7977

- Initially dosed as PSI-7851 (mixture of PSI-7977 and PSI-7976) in SAD, 3-day monotherapy studies
- relative bioavailability study
- two PSI-7977 formulations employed in patient clinical studies
- importance of measuring 6206 given short-lived prodrug

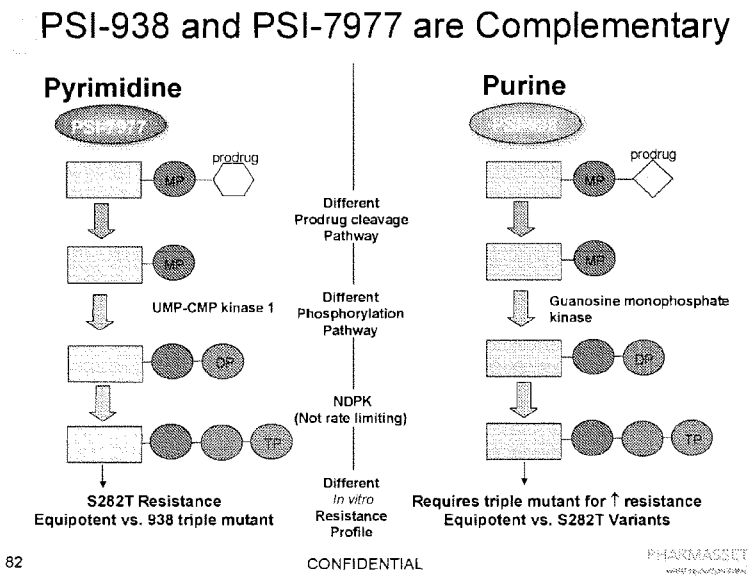


80 CONFIDENTIAL PHARMASSET

Combination of Two Nucleotides Increases the Likelihood of Chain Termination

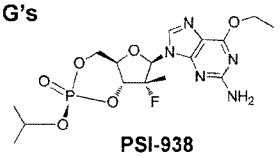


81 CONFIDENTIAL PHARMASSET


PSI-938 and PSI-7977 are Complementary
Pyrimidine
Purine
prodrug
MP
UMP-CMP kinase 1
Guanosine monophosphate kinase
DP
TP
Different Prodrug cleavage Pathway
Different Phosphorylation Pathway
NDPK (Not rate limiting)
Different In vitro Resistance Profile
S282T Resistance
Equipotent vs. 938 triple mutant
Requires triple mutant for ↑ resistance
Equipotent vs. S282T Variants
82
CONFIDENTIAL

PSI-938 is a Guanosine Nucleotide Analog Polymerase Inhibitor of HCV

- **Potent *in vitro* activity with broad genotype coverage**
- **Complementary phosphorylation**
- **RBV, PI, Non-nuc pol inh. and Nuc analogs**
- **Equipotent *in vitro* against wild type and S282T resistant variant – unique among G's**
- **NUCLEAR: 14d combo study complete**
  - Generally safe and well tolerated
  - Potent antiviral activity observed
  - No virologic breakthrough



PSI-938

- **QUANTUM: POC for use in combination with PSI-7977 and potentially other DAA classes**
  - Complementary resistance profile
  - Complementary phosphorylation

CONFIDENTIAL

PHARMASSET

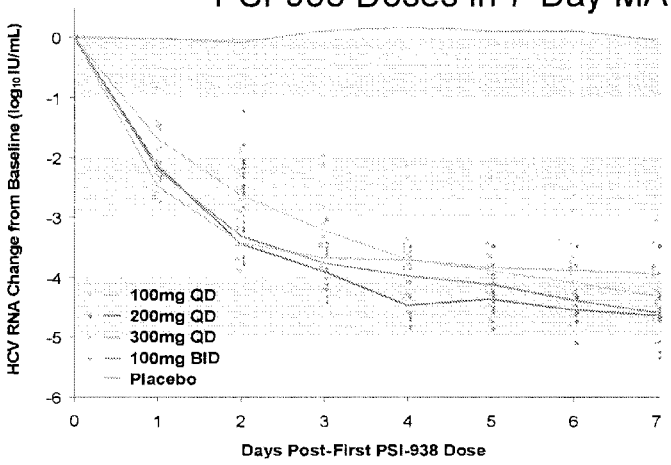
HIGHLY CONFIDENTIAL

VRUS_00005344

Business Proprietary Information – Confidential Treatment Requested

GS-0011720

Robust Antiviral Response At All PSI-938 Doses in 7-Day MAD



84 CONFIDENTIAL PHARMASSET

Significant Antiviral Activity Observed Following 7 Days of PSI-938 Monotherapy

PSI-938 Dose	# Subjects	Median HCV RNA Reduction after 7 days (log_{10} IU/mL)	Range (log_{10} IU/mL)	Number of Subjects with HCV RNA <LOD	Number of Subjects with HCV RNA <LOQ
100mg QD	8	-4.31	-2.66 to -5.12	1	3
200mg QD	8	-4.64	-3.49 to -5.35	5	7
300mg QD	8	-3.94	-3.43 to -5.29	4	4
100mg BID	8	-4.59	-3.94 to -5.08	2	3
Placebo	8	-0.05	+0.17 to -0.29	0	0

LOQ – Limit of Quantification (43 IU/mL)
LOD – Limit of Detection (15 IU/mL)

CONFIDENTIAL

PHARMASSET

HIGHLY CONFIDENTIAL

Business Proprietary Information – Confidential Treatment Requested

PSI-938 7-Day MAD Summary

Pharmacokinetics

- Drug concentrations were similar in healthy subjects and HCV+
- Support once-daily administration

Safety and Tolerability

- PSI-938 was generally safe and well tolerated in all cohorts
- No SAEs; no study drug discontinuations
- AEs were not more frequent or more severe through dose escalations
- No clinically significant changes in hematology or chemistry lab values

Antiviral Response

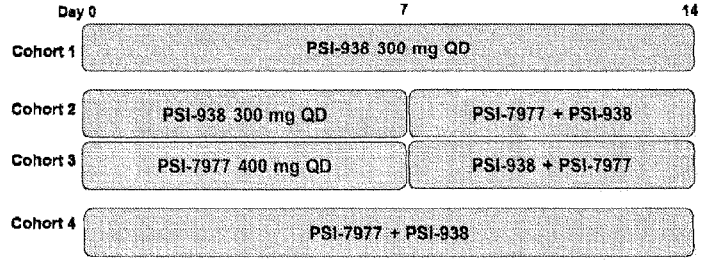
- PSI-938 200 mg and 300 mg QD were similar, but early time points support higher potency with 300 mg
- Based upon these data, 300 mg will be studied in future studies
  - BID offers no additional antiviral activity

HIGHLY CONFIDENTIAL VRUS_00005347

Business Proprietary Information – Confidential Treatment Requested GS-0011723

NUCLEAR: PSI-7977 + PSI-938 Combo

First Purine/Pyrimidine Combination Study



- 40 HCV GT 1, treatment-naïve subjects
  - 8 active and 2 placebo per cohort
- HCV RNA >50,000 IU/mL, no evidence of cirrhosis
- All subjects offered full course of peg-interferon (Peg-IFN) and ribavirin (RBV) on study day 15

CONFIDENTIAL
PHARMASSET

HIGHLY CONFIDENTIAL VRUS_00005348

Business Proprietary Information – Confidential Treatment Requested GS-0011724

NUCLEAR

PSI-7977 + PSI-938 Combination Results

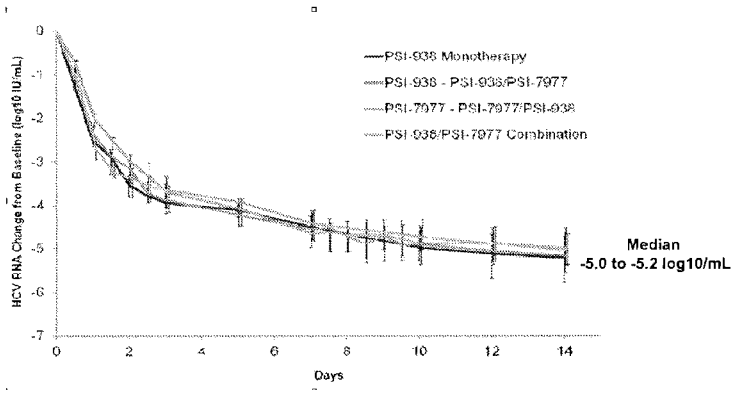
- Both compounds and the combination were generally safe and well-tolerated
  - No discontinuations or serious adverse events
  - AEs were mild in intensity
    - Five AEs considered possibly related to active study drug
    - Headache (2), fatigue, non-cardiac chest pain, dizziness
    - No dose- or duration-related toxicities
- No clinically significant treatment-emergent changes in laboratory parameters, vital signs or ECGs
- No treatment-emergent grade 4 laboratory abnormalities
- 47% subjects had elevated ALT at baseline, all normalized during study

HIGHLY CONFIDENTIAL VRUS_00005349

Business Proprietary Information – Confidential Treatment Requested GS-0011725

NUCLEAR : Dual-Nuc Represents Potent DAA Combination

NUCLEAR



89

CONFIDENTIAL

Includes 2 subjects who did not begin PEG/RBV & HCV RNA <...OD at day 15

PHARMASSET

NUCLEAR: Consistent Antiviral Activity Observed in All Subjects

Median (Q1,Q3) HCV RNA Change from Baseline and Number of Subjects with HCV RNA <15 IU/mL (LOD) by Cohort

	Day 7		Day 14			Total[1]
	# < LOD	Median [Q1,Q3]	# < LOQ	# < LOD	Median [Q1,Q3]	# < LOD
Cohort 1	2	-4.5 (-4.3,-4.7)	5	4	-5.2 (-4.8,-5.8)	4/8 (50%)
Cohort 2	2	-4.6 (-4.2,-5.0)	8	8	-5.2 (-4.8,-5.5)	8/8 (100%)
Cohort 3	4	-4.7 (-4.3,-4.8)	8	7	-5.0 (-4.6,-5.4)	7/8 (88%)
Cohort 4	1	-4.4 (-4.2,-4.8)	8	5	-5.0 (-4.7,-5.3)	7/8 (88%)[2]

94%

92%

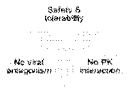
1. Cumulative total of individuals whose HCV RNA reached < LOD as a result of the study treatment
2. Includes 2 additional subjects whose HCV RNA reached < LOD on Day 16

HIGHLY CONFIDENTIAL VRUS_00005351

Business Proprietary Information – Confidential Treatment Requested GS-0011727

NUCLEAR : PSI-7977 + PSI-938 Combo

First Purine + Pyrimidine Combination Study



Proof-of Concept achieved

- ✓ Generally safe and well-tolerated as single nucleotides and in combination for 7-14 days
- ✓ No significant PK interactions were observed
- ✓ No antiviral antagonism with rapid HCV RNA reductions in all subjects

HIGHLY CONFIDENTIAL VRUS_00005352

Business Proprietary Information – Confidential Treatment Requested GS-0011728

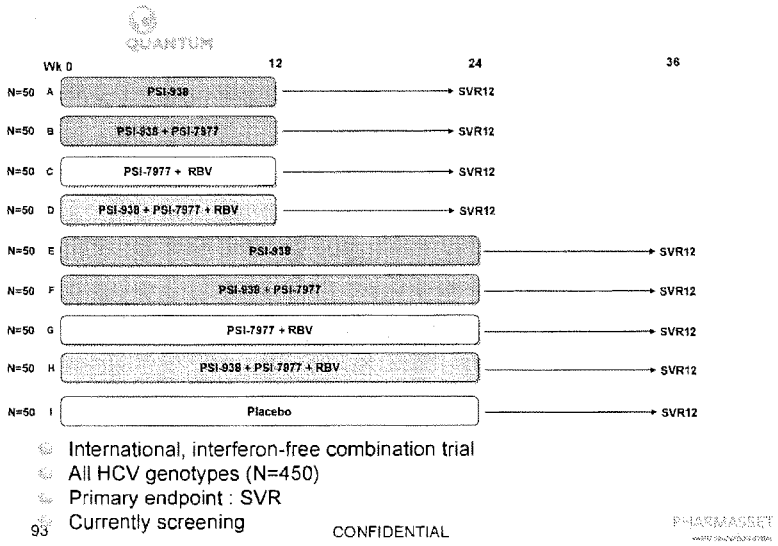
PSI-938 Chronic Toxicology Program

Study Duration	Test Article	Purine Dose mg/kg/day	Status
Rats			
14 Day	PSI-352938	0, 100, 300, 1000	Complete
6 Month	PSI-352938	0, 10, 30, 75, 200	Complete
Dogs			
14 Day	PSI-352938	0, 30, 90, 300	Complete
6/9 Month	PSI-352938	0, 30, 90, 300/200	Complete

HIGHLY CONFIDENTIAL VRUS_00005353

Business Proprietary Information – Confidential Treatment Requested GS-0011729

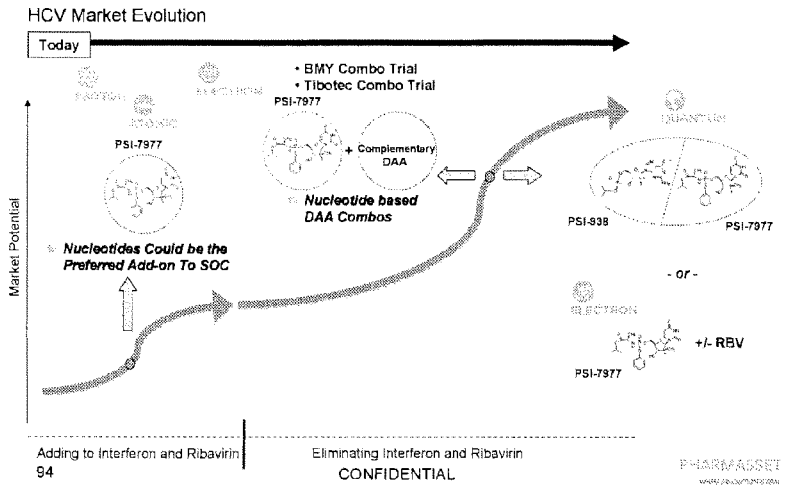
PSI-7977 & PSI-938 QUANTUM Trial



- International, interferon-free combination trial
- All HCV genotypes (N=450)
- Primary endpoint : SVR
- Currently screening

93 CONFIDENTIAL PHARMASSET

Potential Paradigm Shift(s) in HCV



PHARMASSET

Treatment-Emergent Rashes
PSI-7977/PEG/RBV

AE	P7977-0482 PSI-7977 400mg PEG/RBV x 12 weeks (n=72)	P7977-0523 PSI-7977 400mg PEG/RBV x 12weeks (n=40)	P7977-0724 PSI-7977 400mg PEG/RBV x 12 weeks (n=127)	Total PSI-7977 400mg PEG/RBV x 12 weeks (n=239)	P7977-0724 PSI-7977 200mg PEG/RBV x 12 weeks (n=48)	Placebo PEG/RBV x 12 weeks (n=40)
No. subjects with at least one AE n,%	19 (26.5)	17 (42.5)	6 (4.7)	42 (17.6)	17 (35.4)	6 (15.0)
Skin & subcutaneous tissue disorders	19 (26.4)	17 (42.5)	6 (4.7)	42 (17.6)	17 (35.4)	6 (15.0)
Dermatitits	2 (2.8)	0	0	2 (0.8)	1 (2.1)	2 (5.0)
Derms, psoria.	0	0	0	0	0	1 (2.5)
Drug eruption	1 (1.4)	0	0	1 (0.4)	0	0
Rosacea	0	1 (2.5)	0	1 (0.4)	2 (4.2)	0
Rash	15 (20.8)	10 (25.0)	6 (4.7)	31 (13.0)	13 (27.1)	4 (10.0)
Rash, macular	1 (1.4)	2 (5.0)	0	3 (1.3)	0	0
Rash, m-p.	1 (1.4)	0	0	1 (0.4)	0	0
Rash, papular	0	3(7.5)	0	3 (1.3)	0	0
Rash pruritic	1 (1.4)	1 (2.5)	0	2 (0.8)	2 (4.2)	0
Urticaria	0	1 (2.5)	0	1 (0.4)	0	0

HIGHLY CONFIDENTIAL VRUS_00005357

Business Proprietary Information – Confidential Treatment Requested GS-0011733

Regimens exploring PSI-7977 In different HCV Populations

HCV GT	PSI-7977	PSI-7977 + RBV	PSI-7977 + PEG +RBV	PSI-7977 + PSI-352938	PSI-7977 + PSI-938 + RBV	PSI-7977 + NS5a +/- RBV	PSI-7977 200 mg + RBV
GT 1	**25 ELECTRON** 25 NIH 150 Ph3	**75 ATOMIC** **10 ELECTRON** 150 Ph3 25 NIH	**47 PROTON** 314 ATOMIC	75 QUANTUM	75 QUANTUM	42	**48 PROTON**
GT2/3	150 Ph3 **10 ELECTRON**	250 Ph3 150 Ph3 **25 ELECTRON** **10 ELECTRON** 25 QUANTUM	**24 PROTON** **40 ELECTRON** 25 QUANTUM	25 QUANTUM	25 QUANTUM	42	
GT 4/5/6			10 GT4 5 GT6 ATOMIC	allowed	allowed		
Ind			1 ATOMIC				

HIGHLY CONFIDENTIAL **VRUS_00005358**

Business Proprietary Information – Confidential Treatment Requested GS-0011734

Exhibit 10

Introduction to Project Harry

John Milligan
President and COO

Board Meeting
July 21, 2011

Gilead HCV Program

- Good progress made in Gilead's portfolio
  - GS9451 (PI) + GS5885 (NS5A) + GS9190 (NNPI) + ribavirin now dosing in a PII Study
- GS6620 (nucleotide) will not advance due to low activity
  - Backup molecules are 18 to 24 months behind
- Based on clinical data from other companies, it seems that the nucleotide class will be the backbone for future treatments

781

Business Proprietary Information – Confidential Treatment Requested

Accelerating access to an HCV nucleotide

- Harry is the best, and most timely, way to bring a nucleotide to Gilead's portfolio
  - Most advanced clinically
    - > Good antiviral activity
    - > Best safety profile
  - IP picture is now clearer
  - No partnerships for the two best assets
  - Compatible with Gilead's existing portfolio

- Many investors and Pharma companies also see the value in Harry

Business Proprietary Information – Confidential Treatment Requested

Additional considerations

- Potential breakthrough products in HCV treatment will soon be in Phase III trials
  - Response rates will likely be high across a wider range of genotypes and patient groups
  - Harry would help ensure Gilead's portfolio is competitive

- Potential to offer cures to 130 million people worldwide
  - Would rival or surpass Gilead's HIV franchise for revenues and profitability

- Harry is unlikely to be available a year from now
  - Attractive acquisition for several companies

783

Business Proprietary Information – Confidential Treatment Requested

BARCLAYS CAPITAL

Project Harry – Board of Directors Meeting

Investment Banking Division

Global Healthcare Group

July 21, 2011

Confidential Presentation

Business Proprietary Information – Confidential Treatment Requested

Harry

Summary

* **CEO**: Schaefer Price
* **Location**: Princeton, NJ
* **Employees**: 62 total (42 in R&D)
* **Stock Price**: $124.95 (As of July 11, 2011, 92% of 52-wk high and all-time high)
* **Enterprise Value**: $4.8 billion[1]

The Opportunity

* Enhance Gryffindor's HCV portfolio thrcugh an acquisition of Harry's compounds
* Accelerate time to market for both companies
* Increase POS via combined portfolios
* Combined portfolio of Harry and Gryffindor leads to potential for substantial increase in value

Key Programs

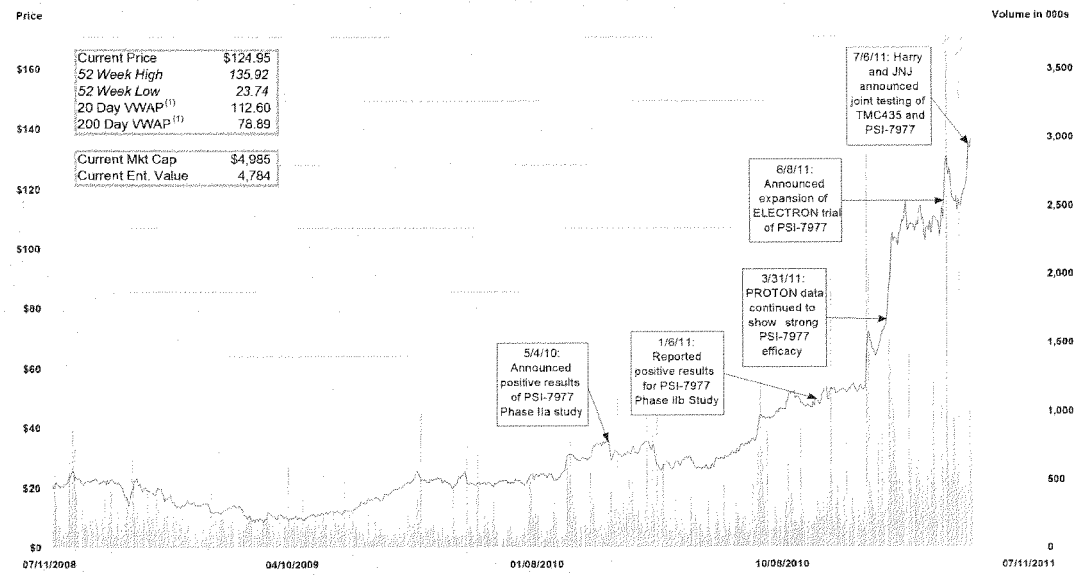
Product	Phase	MOA	Comments
PSI-7977	Phase IIb	Uracil Nucleotide	Largest driver of value today; WW rights
PSI-938	Phase Ib	Guanine Nucleoside	Very good early data; significant second source of value alone and particularly in combination; WW rights
RG7128	Phase IIb	Cytidine Nucleoside	Royalty under 2004 Roche collaboration; limited value

* Exploring combination of 7977 and 938 in combination for GT2/3 and interferon sparing
* Exploring 7977 with BMY's NS5A and JNJ's PI

1. *39.9 million fully diluted shares outstanding and $201 million net cash.*

Harry Stock Performance

3 Year Stock Price / Volume Performance



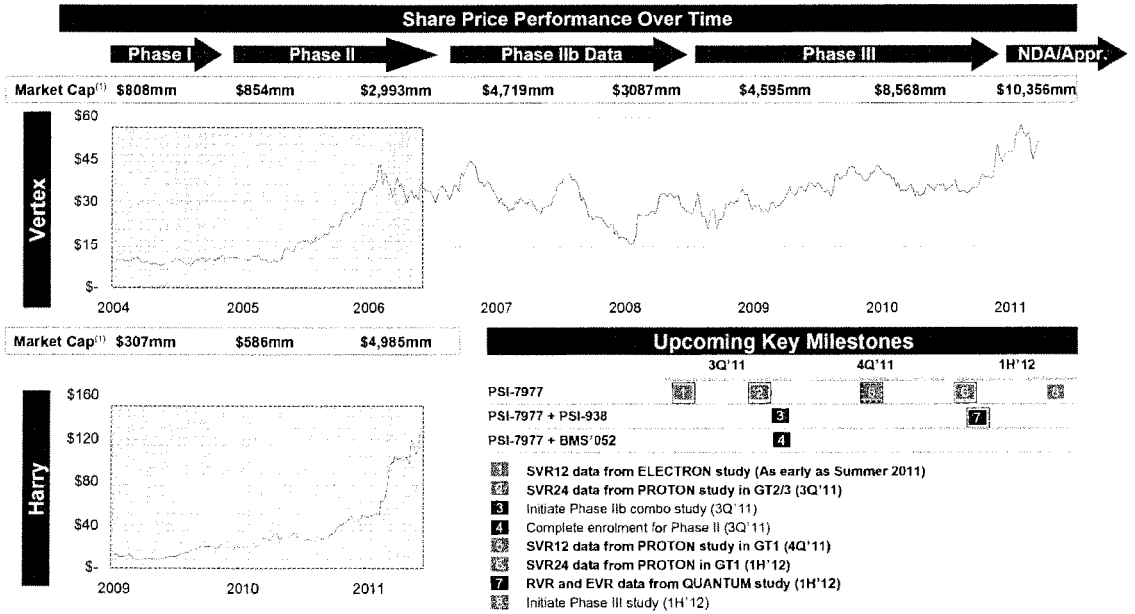
1. VWAP: Volume weighted average price.

BARCLAYS CAPITAL

Business Proprietary Information – Confidential Treatment Requested

Harry Value Progression

Harry looks similar to Vertex 5 years ago, but the Street sees more and faster upside



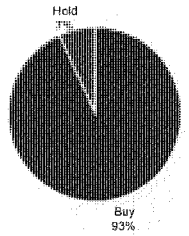
Source: Company information, Wall Street research and FactSet.
1. *Market value of equity as of the first day of each year and 7/11/11.*

BARCLAYS CAPITAL

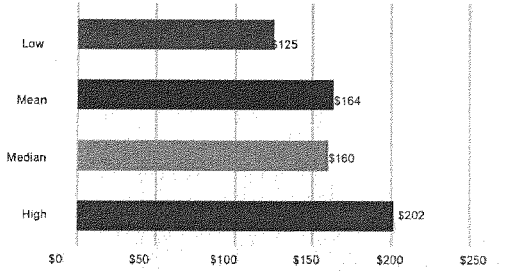
Business Proprietary Information – Confidential Treatment Requested

Wall Street Perspective on Harry

Rating Summary



Price Target Summary



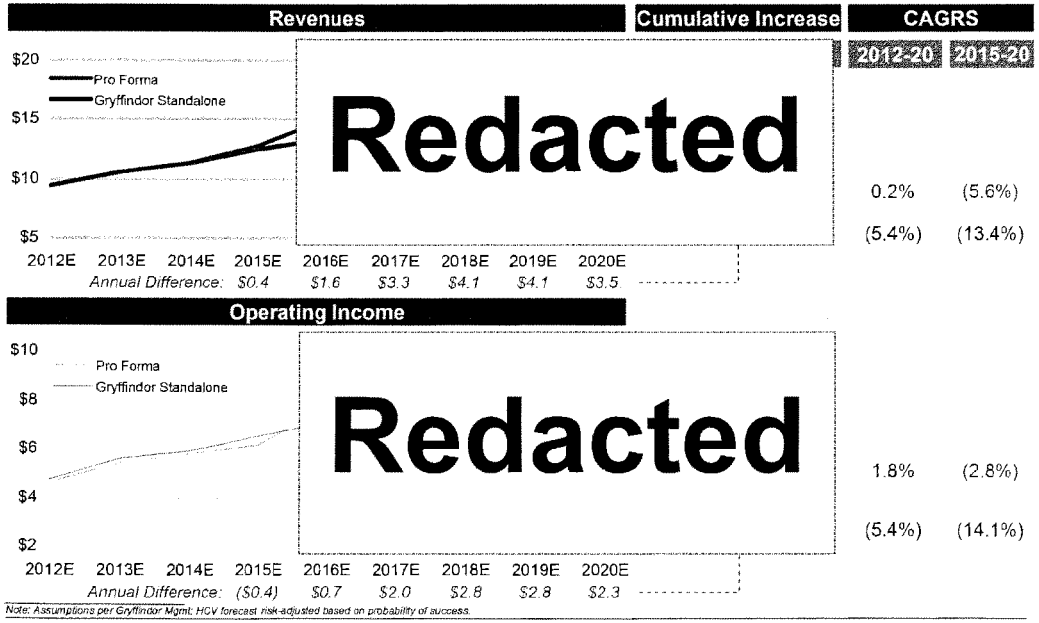
Analyst Commentary

Based on our growing optimism for the box office and significant upside to EPS 2012 should we see a positive [illegible] PT of $[illegible] The [illegible] value of these [illegible] should [illegible] [illegible] [illegible]

Pro Forma Revenue and Operating Income

($ in billions)

By 2020 Harry is expected to generate incremental annual revenues and operating income of $3.5 billion and $2.3 billion respectively (probability adjusted)



Note: Assumptions per Gryffindor Mgmt; HCV forecast risk-adjusted based on probability of success.

BARCLAYS CAPITAL

Business Proprietary Information – Confidential Treatment Requested

Key Valuation Assumptions

Combined portfolio of Harry and Gryffindor leads to potential for substantial increase in value

Harry Standalone

Product	POS	U.S. Launch Year	Weighted Average U.S. Peak Penetration	WW Peak Sales ($bn)	NPV ($bn)
Redacted	50.0%	2014	10.0%	$0.6	$0.1
Harry nuc + IFN/RBV	65.0%	2015	22.5%	1.9	1.1
Harry nuc + nuc	15.0%	2016	27.5%	4.4	1.1
Harry nuc + other	35.0%	2016	30.0%	4.7	2.1
				Net Cash	0.2
				TOTAL	**$4.5**

Gryffindor Standalone

Product	POS	U.S. Launch Year	Weighted Average U.S. Peak Penetration	WW Peak Sales ($bn)	NPV ($bn)
Gryffindor PI/NS5A + IFN/RBV	43.0%	2016	11.0%	$1.0	$0.1
Gryffindor All Oral Regimen	26.0%	2017	23.0%	3.6	1.4
				TOTAL	**$1.5**

Gryffindor Pro Forma

Product	POS	U.S. Launch Year	Weighted Average U.S. Peak Penetration	WW Peak Sales ($bn)	NPV ($bn)
Redacted	50.0%	2014	10.0%	$0.6	$0.1
Gryffindor OAV + IFN/RBV	80.0%	2015	25.0%	2.1	1.5
Gryffindor All Oral Regimen	55.0%	2016	50.0%	7.7	8.5
				NOL	0.1
				Net Cash	0.2
				TOTAL	**$10.3**

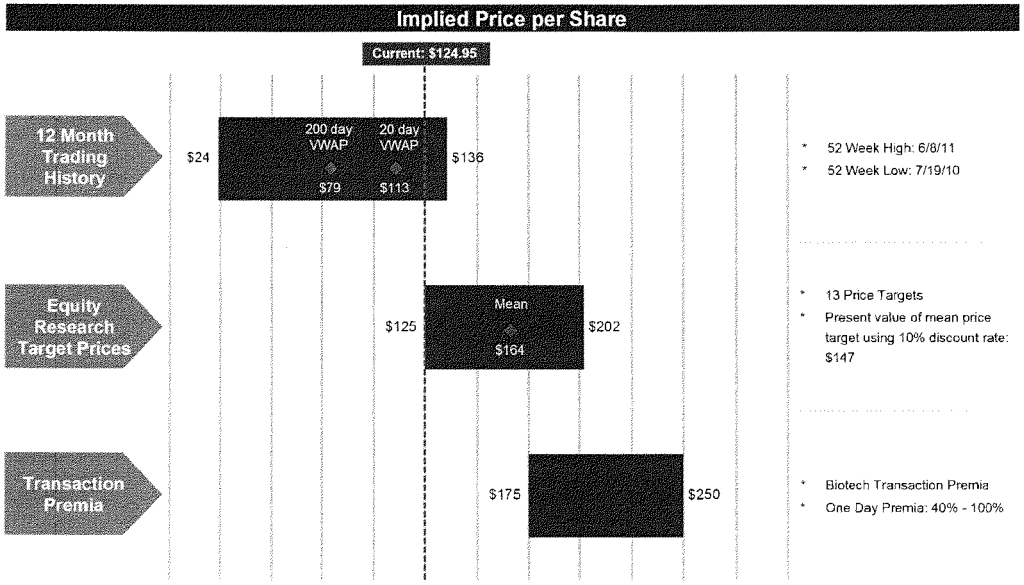
Note: Assumptions per Gryffindor; 10% discount rate assumed.

BARCLAYS CAPITAL

Business Proprietary Information – Confidential Treatment Requested

Valuation Range

($ in billions, except per share value)



Per Share	$0	$25	$50	$75	$100	$125	$150	$175	$200	$225	$250	$275	$300
Equity Value	$0.0	$1.0	$2.0	$3.0	$4.0	$5.0	$6.0	$7.0	$8.0	$9.0	$10.0	$11.0	$12.0
% Premium						*0%*	*20%*	*40%*	*60%*	*80%*	*100%*	*120%*	*140%*

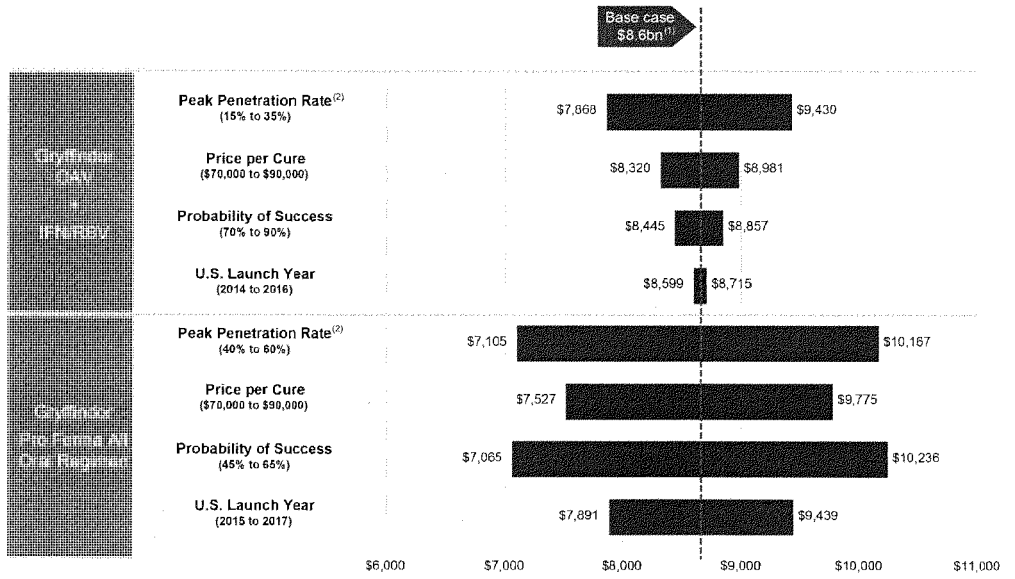
BARCLAYS CAPITAL

Business Proprietary Information – Confidential Treatment Requested

Harry Value to Gryffindor – NPV Sensitivities

($ in millions except Base case and price per cure)

Gryffindor Pro Forma NPV – Gryffindor Standalone NPV – Net Cash = Harry Value to Gryffindor



Note: Assumptions per Gryffindor; 10% discount rate assumed.

1. *Represents the difference between Gryffindor Pro Forma NPV of $10.3bn and Gryffindor Standalone NPV of $1.5bn less $0.2bn of Harry net cash.*
2. *Based on weighted average peak penetrations.*

BARCLAYS CAPITAL

Business Proprietary Information – Confidential Treatment Requested

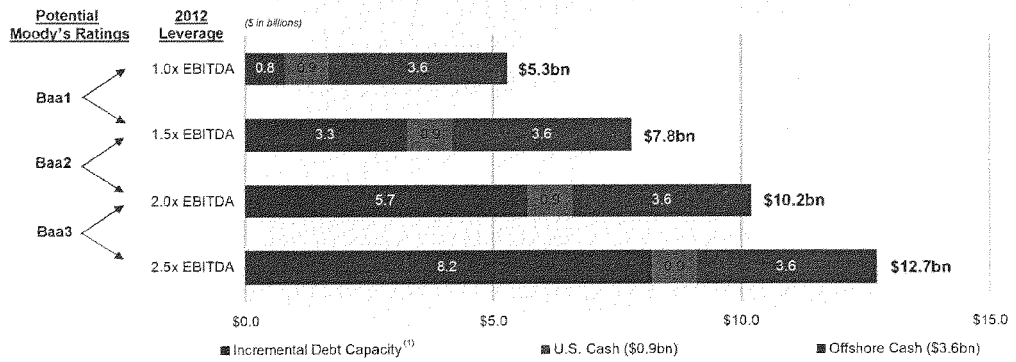
Risks, Mitigants and Upsides

Risks	Commentary
Clinical Development	* Highly predictive nature of early-stage HCV data and translation to late-stage success * Highest SVR rates observed to date * Clear safety profile observed in a large patient population
Competition	* Other nucs in development are several years behind * Potential first to market with all-oral HCV therapy across genotypes
Intellectual Property	* Worldwide rights to major value drivers PSI-7977 and PSI-938
Debt	* Current cash flow more than adequate to support incremental debt burden with IG credit rating * Large transaction size would require significantly more debt, perhaps approaching our capacity
Dilution / Shareholder Reaction	* Near-term dilution due to increased R&D expenses and lowered share buyback program * Incremental revenues and earnings after 2015 will likely improve P/E
Upsides	
Geographies	* Valuation and pro forma model ignores large geographies outside of the U.S., EU and Japan, which may have significant sales potential
GT 2/3	* Opportunities for earlier approval in GT2/3 population through nuc-nuc combination or increased POS through partnership alternative (if required)

Debt Capacity

- **Preliminary analysis of financial capacity takes into account key objectives**
  - Retain capacity within Investment Grade ratings for future opportunities
  - Balance providing enough liquidity for current M&A strategy v. ratings downgrade ramifications
  - Maximize use of existing liquidity to optimize execution on external financing
  - Provide for at least a share-neutral repurchase strategy
- **Based on initial analysis, Gryffindor has ratings capacity as follows**

Acquisition Capacity at Various Debt / EBITDA Ratios (assuming no equity issuance)



1. Incremental debt capacity: Gryffindor 2012 Pro Forma EBITDA ($4,948mm) multiplied by leverage minus Gryffindor Standalone total debt ($4,150mm).

BARCLAYS CAPITAL

Business Proprietary Information – Confidential Treatment Requested

Gryffindor Stock Price Considerations

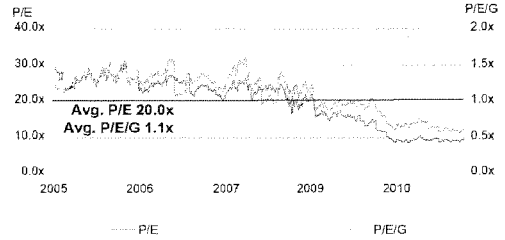
Illustrative Pro Forma Stock Prices

2013 EPS Dilution[1]	Implied 2013 EPS[2]
5.0%	$5.02
7.5%	4.89
10.0%	4.75
12.5%	4.62

	2013 P/E			
Current 7.8x[2]	9.0x	10.0x	Comps Average 12.4x[3]
$39.21	$45.16	$50.18	$62.43
38.17	43.97	48.86	60.79
37.14	42.78	47.54	59.15
36.11	41.60	46.22	57.50

Stock Price as of July 11, 2011: $41.27

Gryffindor Historical – P/E and P/E/G since 2005



Comparable Valuation Metrics [3]

	2013 P/E	2013 P/E/G
Allergan	17.2x	1.1x
Amgen	9.3x	1.3x
Biogen Idec	15.5x	1.7x
Bristol-Myers	14.4x	NM
Celgene	12.3x	0.6x
Genzyme	10.7x	0.5x
Shire	7.8x	0.3x
Average	12.4x	0.9x

Note: Gryffindor's consensus long-term growth rate is 14% (SQ) and Pro Forma long-term growth rate is 19%.
1. *EPS dilution is a function of purchase price, financing structure and magnitude of share repurchase suspension.*
2. *2013 Consensus EPS of $5.28 used to calculate implied 2013 EPS with dilution.*
3. *Based on Wall Street consensus estimates. Genzyme P/E and P/E/G ratios are for 2012. P/E/G equals ratio of P/E to long-term EPS growth.*

BARCLAYS CAPITAL

Business Proprietary Information – Confidential Treatment Requested

Tactical Approaches and Considerations

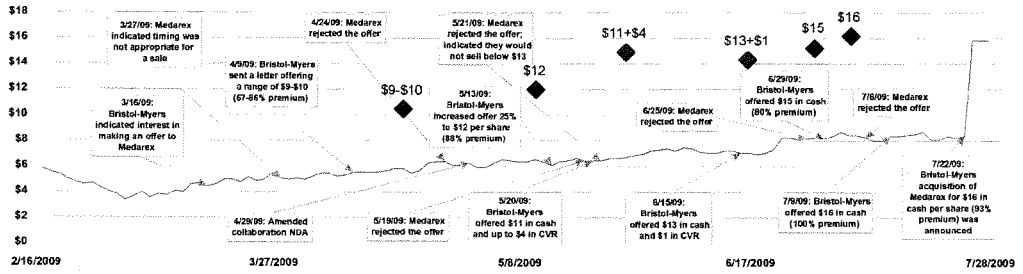
- The challenge for Gryffindor will be to not only convince Harry to engage in a strategic dialogue but also to control the timetable and process as much as possible – this will be a functio n of many factors including:
  - Offered value vs. Harry's view of intrinsic value
    - Potential for widely varying perspectives given financial and clinical profile of target
    - Stock price volatility and relatively near term milestones
  - Offered value vs. Harry's view of Gryffindor's abilty to increase value (or walk.)
  - Non-economic factors
    - Ability to consummate transaction
    - Ability to address other key aspects, such as development and exploitation, social issues, etc.
  - History of previous expressions of interest to Harry and board view on value associated with a process vs. risks associated with a process

The approach stages listed below are viewed in a continuum and pursued as a step-wise progression. The goal of the approach should be to engage in the negotiation of a "friendly" transaction, applying increasing degrees of pressure, as necessary, to Harry's management and board to achieve that result.

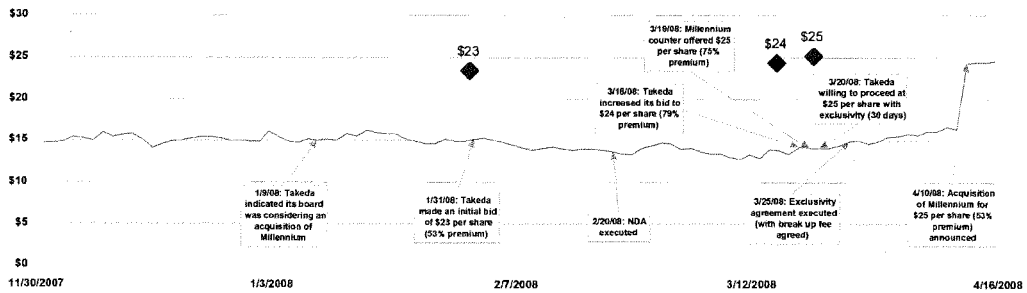
CEO	Board	Shareholders
* Most straight forward and accepted approach * Allows personal relationship to develop; possibility to present "social issues" * Less publicity risk if no deal * Approach CEO with verbal offer followed by (or concurrent with) letter (not intended to be disclosed)	* Viewed more aggressively as a starting point and more often used to follow CEO discussion if belief that CEO is not in synch with board * May create management negativity towards our offer	* Utilized often as last resort * Forces response from Harry and creates turnover in its shareholder base * Broadest possible auction process * Potentially lengthy process given Harry's board structure * Perception of Gryffindor

Successful Pre-Emptive Approaches

Medarex / Bristol-Myers ($2.4bn; 93% premium)



Millennium / Takeda ($8.8bn; 53% premium)



1. *Premium based on the average 60 day trailing closing price.*

BARCLAYS CAPITAL

Business Proprietary Information – Confidential Treatment Requested

Potential Interested Parties

($ in billions)

Tier 1

Company	Financials	Comments
Redacted		
Redacted		
MERCK	Market Cap $110.1 Cash $13.0 Debt $17.8	• Victrelis on market will benefit by co-promotion with Roche in U.S. • Potential inferiority to Incivek may create pressure to acquire • Pan genotypic PI in MK-5172 but no nuc • Looking for smaller acquisitions to complement internal R&D efforts in infectious disease as well as other TAs • 3Q'11: Potential boceprevir EU approval
Redacted		

Other Potential Interested Parties

NOVARTIS | Abbott A Promise for Life | VERTEX | Boehringer Ingelheim

Source: Company information, FactSet and EvaluatePharma.
Note: Market data as of 7/11/11. PI: protease inhibitor, Nuc: nucleoside polymerase inhibitor, Non-Nuc: non-nucleoside polymerase inhibitor.

BARCLAYS CAPITAL

Business Proprietary Information – Confidential Treatment Requested

Appendix

Business Proprietary Information -- Confidential Treatment Requested

Management and Stakeholders

Management

Name / Title (Age)	Background	Harry % Ownership
P. Schaefer Price *CEO, President and Director (48)*	Joined Harry in June 2004 Former Exec. in Residence at Bay City Capital	1.03%
Kurt Leutzinger *CFO, Exec. VP (59)*	Joined Harry in January 2005 CFO of Abgenix from 1997 to 2004	0.50%
M. Michelle Berrey, M.D. *Chief Medical Officer (44)*	Joined Harry in January 2007 Former VP at GlaxoSmithKline	0.01%
Michael J. Otto, Ph.D. *Chief Scientific Officer (62)*	Joined Harry in November 1999 Former Associate Director at Rhone-Poulenc	0.02%
Michael D. Rogers, Ph.D. *Chief Dev. Officer (57)*	Joined Harry in October 2007 Former VP at GlaxoSmithKline	0.00%
Patrick T. Higgins *Exec. VP, Mktg/Sales (53)*	Joined Harry in November 2007 Former VP at Hoffmann-LaRoche	0.00%
Abel De La Rosa, Ph.D. *Senior VP, Business Dev./ Scientific Affairs (NA)*	Joined Harry in December 2002 Previously held positions at Visible Genetics, Innogenetics, Boston Biomedica, and Digene	0.00%

Non-Executive Board of Directors

Name (Age)	Background	Harry % Ownership
Herbert J. Conrad, Ph.D. *Chairman (78)*	Former President, Roche Pharmaceuticals Division	0.02%
William J. Carney *(73)*	Professor at Emory University	0.20%
Elliot F. Hahn, Ph.D. *(66)*	President of ACCU-BREAK Pharmaceuticals	0.32%
Michael K. Inouye *(55)*	Former Senior VP at Pharmacyclics	0.03%
Robert F. Williamson III *(45)*	Former Chief Executive Officer of Arriva Pharmaceuticals	0.01%

Top Gryffindor Institutional Shareholders

Top 20 Shareholders	Mkt. Val.	% O/S	Investment Style
[redacted]	[redacted]	[redacted]	[redacted]
Capital Research Global Investors	532	1.6%	GARP
Thornburg Investment Management, Inc.	518	1.6%	GARP
Walter Scott & Partners Ltd.	518	1.5%	GARP
T. Rowe Price Associates, Inc.	430	1.1%	Growth
Invesco PowerShares Capital Management LLC	407	1.2%	Growth
Northern Trust Investments	390	1.2%	Index
Invesco Advisers, Inc.	351	1.0%	GARP
GE Asset Management, Inc.	348	1.0%	GARP
Columbia Management Investment Advisers LLC	327	1.0%	GARP
American Century Investment Management, Inc.	317	1.0%	GARP
Goldman Sachs Asset Management LP (United States)	316	0.9%	GARP

Top Harry Institutional Shareholders

Top 20 Shareholders	Mkt. Val.	% O/S	Investment Style
Fidelity Management & Research Co.	$617	13.0%	Growth
T. Rowe Price Associates, Inc.	331	7.0%	Growth
BlackRock Fund Advisors	280	5.9%	Index
Capital World Investors	242	5.1%	Growth
Baker Bros. Advisors LLC	224	4.7%	GARP
The Vanguard Group, Inc.	213	4.5%	Index
Capital Guardian Trust Co.	202	4.3%	GARP
QVT Financial LP	187	3.9%	GARP
Wellington Management Co. LLP	173	3.6%	GARP
Ridgeback Capital Management LLC	142	3.0%	GARP
State Street Global Advisors	103	2.2%	Index
Visium Asset Management LLC	92	1.9%	Growth
Pyramis Global Advisors LLC	85	1.8%	Value
Adage Capital Advisors LLC	77	1.6%	GARP
AllianceBernstein LP	66	1.4%	GARP
OrbiMed Advisors, Inc.	62	1.3%	GARP
Wells Capital Management, Inc.	62	1.3%	Growth
Capital International Research & Management	61	1.3%	GARP
Turner Investment Partners, Inc.	60	1.3%	Growth
TIAA-CREF Asset Management LLC	59	1.3%	GARP

Source: Company information and FactSet. Shareholder data as of March 31, 2011.
Note: Highlighting represents common shareholders between Gryffindor and Harry. Investment styles sometimes vary within the same institution as different funds within the larger entity are represented.

Precedent Hostile Transactions in Healthcare

($ in millions)

Healthcare Hostile Transactions

Date	Suitor	Target	Deal Size	% Cash	Initial Bid 1-Day Premium	Final Offer 1-Day Premium	Bumps % above Offer	Days to Resolution / Completion	Outcome
3/29/11	Valeant Pharmaceuticals	Cephalon	$5,410	100%	24.0%	24.0%	0%	34	White Knight (Teva at $81.50 per share, or 12% above Valeant offer)
12/9/10	Community Health Systems	Tenet Healthcare	7,180	83%	40.0%	69%	21%	151	Withdrawn
8/29/10	Sanofi-Aventis	Genzyme	20,740	100%	38.0%	48%	7%	222	Announced Deal
3/1/10	Astellas Pharma	OSI Pharmaceuticals	3,730	100%	40.5%	55%	11%	100	Announced Deal
9/4/09	Biogen Idec	Facet Biotech	380	100%	64.0%	98%	21%	104	Withdrawn (Acquired by Abbott in March at $27, 54% above Biogen offer)
1/27/09	Astellas Pharma	CV Therapeutics	1,180	100%	41.0%	41.0%	0%	48	White Knight (Gilead at $20 per share, or 25% above Astellas offer)
8/22/08	King Pharmaceuticals	Alpharma	1,240	100%	37.0%	54%	12%	130	Announced Deal
7/31/08	Bristol-Myers Squibb	ImClone Systems	5,070	100%	29.0%	33%	3%	67	White Knight (Eli Lilly at $70 per share, or 13% above BMS bid)
6/25/07	Roche	Ventana Medical	3,080	100%	44.0%	72%	19%	210	Announced Deal

4 of 9 hostiles were "successful"

Business Proprietary Information – Confidential Treatment Requested

Disclaimer

This document has been prepared by Barclays Capital, the investment banking division of Barclays Bank PLC ("Barclays"), for information purposes only. This document is an indicative summary of the terms and conditions of the securities/transaction described herein and may be amended, superseded or replaced by subsequent summaries. The final terms and conditions of the securities/transaction will be set out in full in the applicable offering document(s) or binding transaction document(s).

This document shall not constitute an underwriting commitment, an offer of financing, an offer to sell, or the solicitation of an offer to buy any securities described herein, which shall be subject to Barclays' internal approvals. No transaction or services related thereto is contemplated without Barclays' subsequent formal agreement. Barclays is acting solely as principal and not as advisor or fiduciary. Accordingly you must independently determine, with your own advisors, the appropriateness for you of the securities/transaction before investing or transacting. Barclays accepts no liability whatsoever for any consequential losses arising from the use of this document or reliance on the information contained herein.

Barclays does not guarantee the accuracy or completeness of information which is contained in this document and which is stated to have been obtained from or is based upon trade and statistical services or other third party sources. Any data on past performance, modelling or back-testing contained herein is no indication as to future performance. No representation is made as to the reasonableness of the assumptions made within or the accuracy or completeness of any modelling or back-testing. All opinions and estimates are given as of the date hereof and are subject to change. The value of any investment may fluctuate as a result of market changes. The information in this document is not intended to predict actual results and no assurances are given with respect thereto.

Barclays, its affiliates and the individuals associated therewith may (in various capacities) have positions or deal in transactions or securities (or related derivatives) identical or similar to those described herein.

IRS Circular 230 Disclosure: Barclays Capital and its affiliates do not provide tax advice. Please note that (i) any discussion of U.S. tax matters contained in this communication (including any attachments) cannot be used by you for the purpose of avoiding tax penalties; (ii) this communication was written to support the promotion or marketing of the matters addressed herein; and (iii) you should seek advice based on your particular circumstances from an independent tax advisor.

BARCLAYS CAPITAL INC., THE UNITED STATES AFFILIATE OF BARCLAYS CAPITAL, THE INVESTMENT BANKING DIVISION OF BARCLAYS BANK PLC, ACCEPTS RESPONSIBILITY FOR THE DISTRIBUTION OF THIS DOCUMENT IN THE UNITED STATES. ANY TRANSACTIONS BY U.S. PERSONS IN ANY SECURITY DISCUSSED HEREIN MUST ONLY BE CARRIED OUT THROUGH BARCLAYS CAPITAL INC., 200 PARK AVENUE, NEW YORK, NY 10166.

NO ACTION HAS BEEN MADE OR WILL BE TAKEN THAT WOULD PERMIT A PUBLIC OFFERING OF THE SECURITIES DESCRIBED HEREIN IN ANY JURISDICTION IN WHICH ACTION FOR THAT PURPOSE IS REQUIRED. NO OFFERS, SALES, RESALES OR DELIVERY OF THE SECURITIES DESCRIBED HEREIN OR DISTRIBUTION OF ANY OFFERING MATERIAL RELATING TO SUCH SECURITIES MAY BE MADE IN OR FROM ANY JURISDICTION EXCEPT IN CIRCUMSTANCES WHICH WILL RESULT IN COMPLIANCE WITH ANY APPLICABLE LAWS AND REGULATIONS AND WHICH WILL NOT IMPOSE ANY OBLIGATION ON BARCLAYS OR ANY OF ITS AFFILIATES.

THIS DOCUMENT DOES NOT DISCLOSE ALL THE RISKS AND OTHER SIGNIFICANT ISSUES RELATED TO AN INVESTMENT IN THE SECURITIES/TRANSACTION. PRIOR TO TRANSACTING, POTENTIAL INVESTORS SHOULD ENSURE THAT THEY FULLY UNDERSTAND THE TERMS OF THE SECURITIES/TRANSACTION AND ANY APPLICABLE RISKS.

Barclays Bank PLC is registered in England No. 1026167. Registered Office: 1 Churchill Place, London E14 5HP. Copyright Barclays Bank PLC, 2009 (all rights reserved). This document is confidential, and no part of it may be reproduced, distributed or transmitted without the prior written permission of Barclays.

Exhibit 11

BARCLAYS CAPITAL

Description of Fairness Opinion:
Project Harry

Investment Banking Division

Global Healthcare Group

November 13, 2011

804

Confidential Presentation

Table of Contents

Agenda

1. Transaction Overview
2. Valuation
3. Pro Forma Analysis

Appendix: Supplemental Materials

BARCLAYS CAPITAL

Business Proprietary Information – Confidential Treatment Requested

Transaction Overview

Executive Summary

Background & Process

- Initially approached Harry with $100 per share; increased value to $125 per share after receipt of non-public information subject to NDA
- Morgan Stanley conducting a one-step auction process with binding proposals due on Thursday, November 17 (requested contract submission November 15)
  - Competition likely includes companies such as Roche, JNJ, Merck and Bristol-Myers

Strategic Rationale

- Diversifies Gryffindor's business outside of HIV while leveraging Gryffindor's area of expertise
- Harry acquisition accelerates Gryffindor's development program in the treatment of HCV
- Harry's nucleotide analog PSI-7977 and portfolio of nucs have demonstrated potency and effectiveness in 700+ patients without safety or resistance concerns
- Gryffindor's expertise in anti-viral therapies positions it as the company uniquely capable of maximizing Harry's HCV commercial opportunity

Proposed Transaction

- Final purchase price yet to be determined
- Transaction to announce as early as November 21
  - Expected close in late December or early January [1]
  - Gryffindor intends to fund the acquisition with cash on hand and debt financing supported by bridge loans, if necessary

1. *Assumes 90% of the shares achieved in the tender process.*

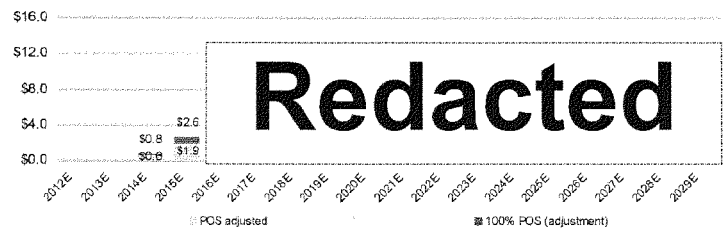
BARCLAYS CAPITAL

Business Proprietary Information – Confidential Treatment Requested

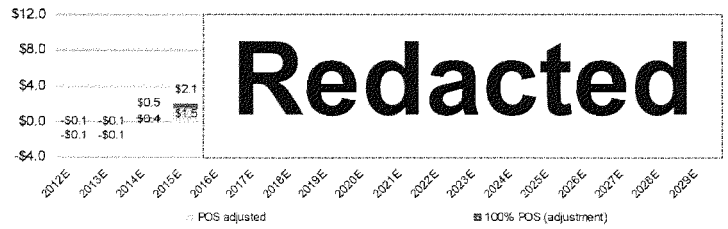
Summary of Projections

($ in billions)

Incremental Revenues



Incremental Operating Income [3]



Key Assumptions

- Assumes all oral pan genotypic regimen [1] will be the key HCV product post transaction
  - Redacted
- Launch Year:
  - U.S.: 2014
  - EU-5: 2015
  - ROG [2] : 2015
  - Japan: 2016
- Overall peak penetration of 50% in each market and globally
  - GT1: 54%, GTnon-1: 38%
- Assumes ~$55k gross price per patient per year in U.S.
  - 18%-25% gross to net discount in U.S.
  - 25% discount to U.S. gross price in EU
  - 40% discount to U.S. gross price in ROG
  - 43% discount to U.S. gross price in Japan
- SG&A and R&D expenses are in line with industry standard
- Patents expire in 2026-2029

Note: Assumptions per Gryffindor management. POS adjusted case assumes Redacted and 75% for Gryffindor PF All Oral Pan Genotypic Regimen.

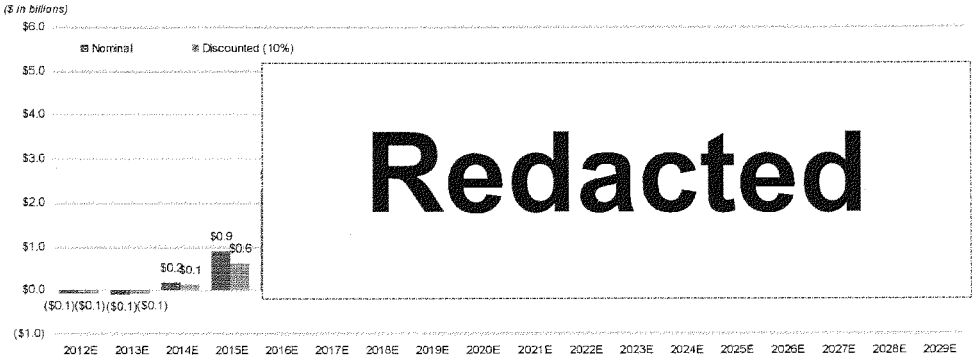
1. *Representative of initial regimen of 7977 + RBV for GT2/3 and IFN-intolerant and follow-on regimen of 7977 + Gryffindor DAV Pan Genotypic.*
2. *ROG territories include developed EU countries (Austria, Denmark, Finland, Greece, Ireland, Norway, Poland, Portugal, Sweden and Switzerland), Turkey, Australia, Canada and Brazil. Note only in Brazil does Gryffindor not have a presence today.*
3. *Operating income is non-GAAP and excludes amortization of intangibles.*

BARCLAYS CAPITAL

Business Proprietary Information -- Confidential Treatment Requested

Value of Incremental Cash Flow

Probabilized Incremental Cash Flows



($ in millions, except per share values)	Adjusted for POS				100% POS			
Discount Rate	**Nominal**	**9%**	**10%**	**11%**	**Nominal**	**9%**	**10%**	**11%**
Sum of FCF '12E-'29E	$44,209	$19,807	$18,272	$16,882	$61,848	$27,683	$25,535	$23,590
Plus: PV of NOL		77	77	77		77	77	77
Less: Debt		(4)	(4)	(4)		(4)	(4)	(4)
Plus: Cash		188	188	188		188	188	188
Equity Value		$20,067	$18,532	$17,143		$27,943	$25,795	$23,851
Implied Equity Value/Share		$250	$231	$213		$347	$321	$297

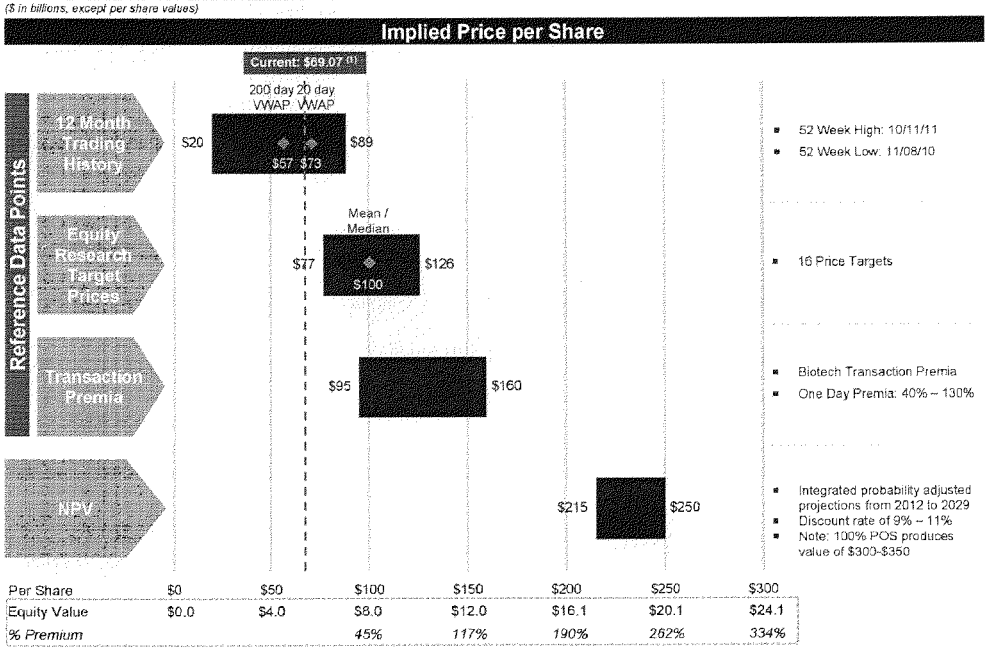
Note: Assumptions per Gryffindor management.

BARCLAYS CAPITAL

Business Proprietary Information – Confidential Treatment Requested

Valuation Summary

($ in billions, except per share values)



1. *Current stock price as of 11/08/11.*

BARCLAYS CAPITAL

Business Proprietary Information – Confidential Treatment Requested

Pro Forma Analysis

Business Proprietary Information – Confidential Treatment Requested

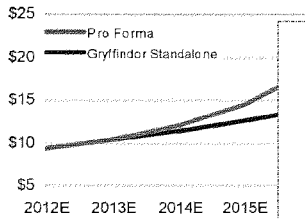
Pro Forma Revenue and Operating Income

($ in billions)

Redacted

Revenues

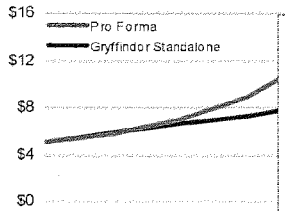
	Cumulative Increase	CAGRS	
	2014-2020	2012-20	2014-20
Pro Forma	Redacted	6.4%	4.2%
Gryffindor Standalone		(1.3%)	(5.0%)



Annual Difference: $0.6 $1.9

Operating Income

	Cumulative Increase	CAGRS	
	2014-2020	2012-20	2014-20
Pro Forma	Redacted	8.6%	5.3%
Gryffindor Standalone		(3.9%)	(9.5%)



Annual Difference: $0.4 $1.5

Note: Assumptions per Gryffindor Mgmt; HCV forecast risk-adjusted based on probability of success. Operating income is non-GAAP and excludes amortization of intangibles.

BARCLAYS CAPITAL

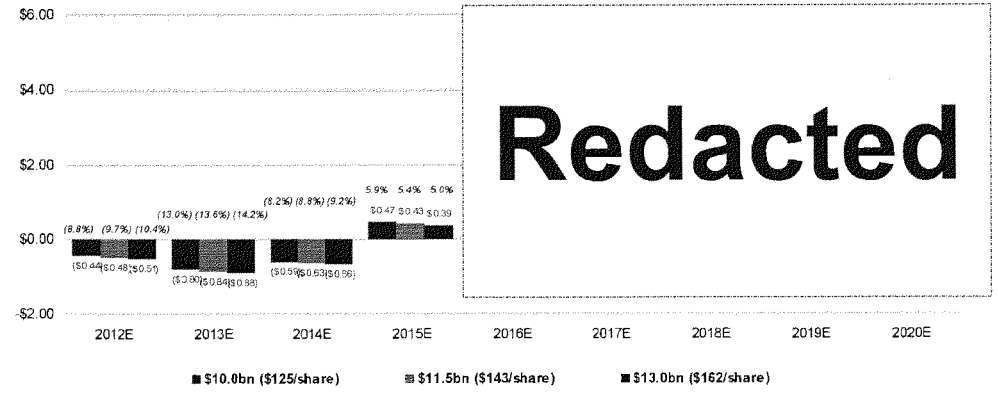
Business Proprietary Information – Confidential Treatment Requested

Pro Forma EPS Impact

Equity purchase prices of $10.0bn ($125 per share), $11.5bn ($143 per share) and $13.0bn ($162 per share)

- ~$5bn use of cash on hand at a cost of 1.0%
- Pro Forma buyback case assumes "dilution only" share repurchases
  - Standalone assumes $5bn share repurchase program through 2013 and dilution-only share repurchases through 2020

Pro Forma Cash EPS Impact



Redacted

Note: Assumptions per Gryffindor Mgmt.

BARCLAYS CAPITAL

Business Proprietary Information – Confidential Treatment Requested

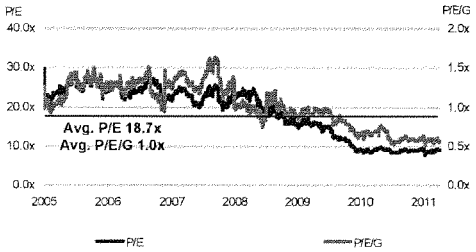
Gryffindor Stock Price Considerations

Illustrative Pro Forma Stock Prices

2013 EPS Dilution [1]	Implied 2013 EPS [2]	2013 P/E Current 7.9x [2]	9.0x	10.0x	Comps Average 12.9x [3]
6.0%	$4.88	$38.75	$43.96	$48.84	$63.13
8.0%	4.78	37.92	43.02	47.80	61.78
10.0%	4.67	37.10	42.09	46.76	60.44
12.0%	4.57	36.27	41.15	45.72	59.10
14.0%	4.47	35.45	40.22	44.69	57.75

Stock Price as of November 8, 2011: $41.22

Gryffindor Historical – P/E and P/E/G since 2005



Comparable Valuation Metrics [3]

	2013 P/E	2013 P/E/G	LTG
Allergan	17.7x	1.2x	14.5%
Amgen	9.2x	1.1x	8.0%
Biogen Idec	16.0x	1.6x	9.8%
Bristol-Myers	15.8x	NM	1.0%
Celgene	12.3x	0.5x	23.9%
Shire	8.9x	0.5x	17.5%
Average	**12.9x**	**0.9x**	**13.5%**
Gryffindor SQ	7.9x	0.5x	16.5%
Gryffindor PF	11.0x	0.5x	22.9%
	Implied		

1. *EPS dilution is a function of purchase price, financing structure and magnitude of share repurchase suspension.*
2. *2013 Consensus EPS of $5.20 used to calculate implied 2013 EPS with dilution.*
3. *Based on Wall Street consensus estimates. P/E/G equals ratio of P/E to long-term EPS growth. Gryffindor LTG calculated as 5-year CAGR of operating income.*

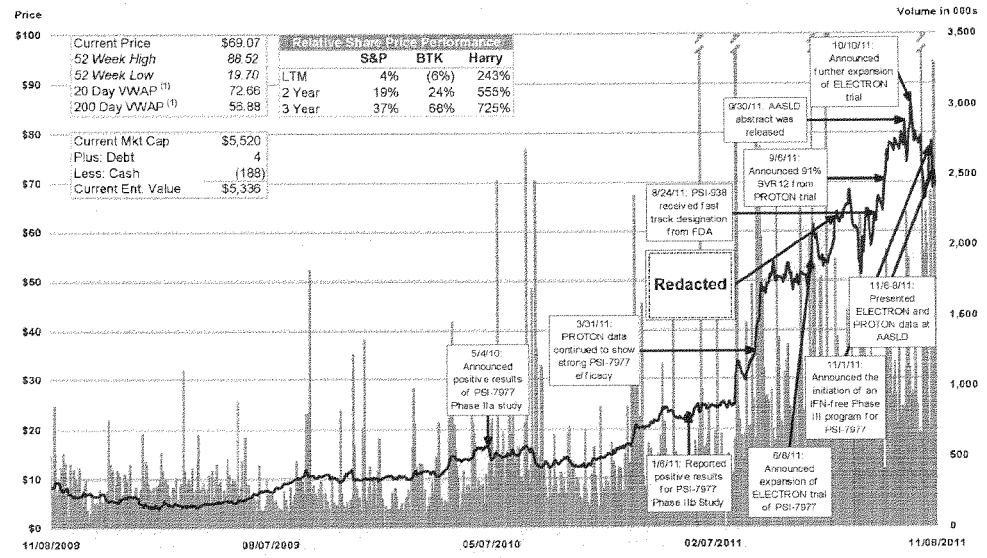
BARCLAYS CAPITAL

Business Proprietary Information -- Confidential Treatment Requested

Appendix: Supplemental Materials

Harry Stock Performance

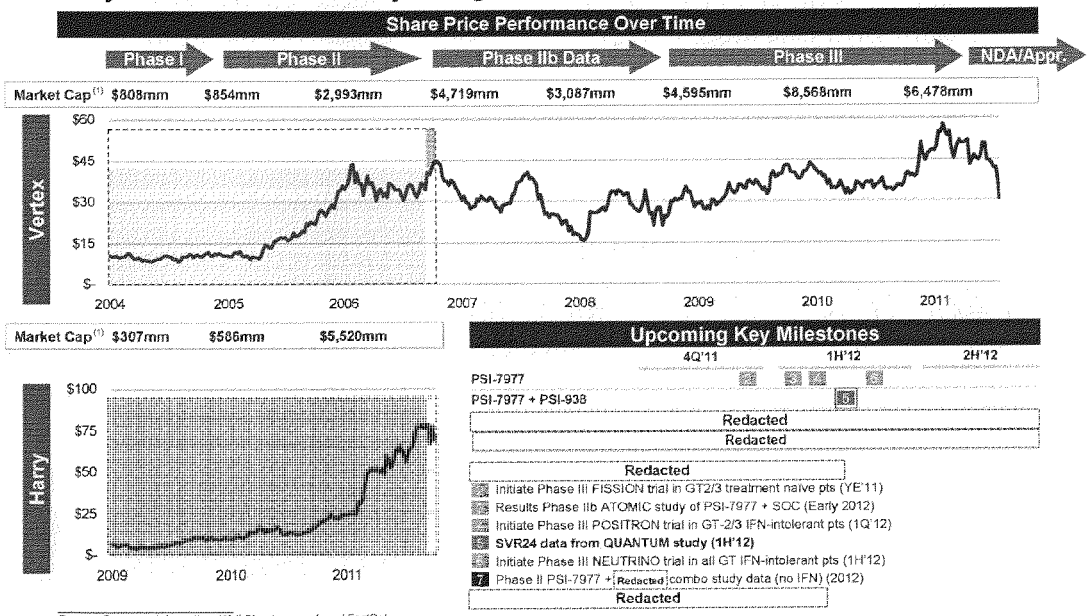
3 Year Stock Price / Volume Performance



Note: Market data as of 11/08/11.
1. VWAP: Volume weighted average price.

Harry Value Progression

Harry looks similar to Vertex 5 years ago, but the Street sees more and faster upside



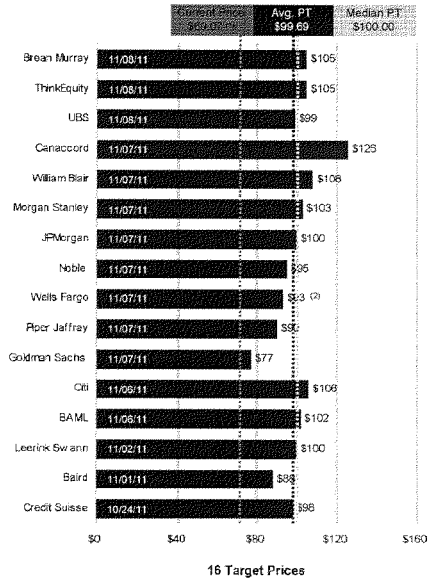
Source: Company information, Wall Street research and FactSet.
1. Market value of equity as of the first day of each year and 11/08/11

BARCLAYS CAPITAL

Business Proprietary Information – Confidential Treatment Requested

Wall Street Perspectives on Harry

Wall Street Target Prices



Selected Analyst Commentary

[redacted]

JPMorgan, November 7, 2011

"Our overall takeaway from these data, in conjunction with existing '7977 data, is that Harry's 2nd gen nuke retains its potential best in disease profile on the important metrics to us and physicians: efficacy, safety, tolerability, resistance, and pan-genotype activity…We believe that it can consistently post ~90+% SVR rates, effectively raising the bar high for competitor regimens."

Morgan Stanley, November 7, 2011

[redacted]

UBS, November 7, 2011

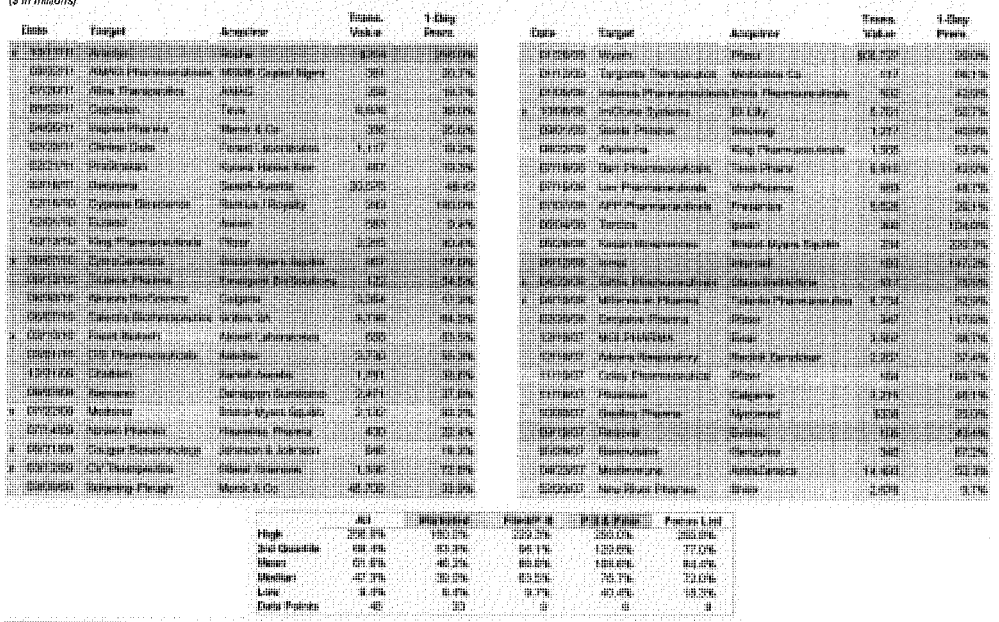
[redacted]

Citi, November 6, 2011

1. *Current stock price as of 11/08/11.*
2. *Represents average of $91-$95 valuation range.*

Pharma and Biopharma Precedent Transactions Premiums Paid

($ in millions)



Source: SDC, FactSet, Wall Street research and Company information.
Note: Includes selected transactions since 2007 with U.S. targets and transaction values of $100 million or greater. Excludes partial acquisitions and acquisitions of subsidiaries. "x" denotes transactions on "Focus List".

BARCLAYS CAPITAL

Business Proprietary Information – Confidential Treatment Requested

GS-0011893

Selected Biotech Premiums Paid – Focus List

($ in millions)

Premiums Paid Analysis

Date	Target	Acquiror	Equity Value	Trans. Value	Premiums 1-Day	30-Day Avg.	60 Day Avg.	52-Wk High	Lead Product	Phase
10/17/11	Anadys Pharmaceuticals	Roche	$230	$204	255.8%	289.1%	343.3%	111.4%	Setrobuvir	Phase II
09/07/10	ZymoGenetics	Bristol-Myers Squibb	838	907	77.0%	101.0%	117.2%	33.9%	Peg-inteferon lambda[1]	Phase IIb
03/12/09	CV Therapeutics	Gilead Sciences	1,318	1,330	72.0%	101.3%	111.8%	69.6%	Ranexa	Marketed
10/06/08	ImClone Systems	Eli Lilly	5,978	5,761	50.7%	62.6%	69.8%	43.6%	Erbitux	Marketed
04/10/08	Millennium Pharmaceuticals	Takeda Pharmaceutical	8,779	8,734	52.9%	68.2%	74.1%	50.4%	Velcade	Marketed
03/10/10	Facet Biotech	Abbott Laboratories	678	668	63.5%	62.8%	64.7%	49.6%	Volociximab	Phase III
07/22/09	Medarex	Bristol-Myers Squibb	2,019	2,132	93.2%	92.4%	106.4%	58.6%	Ipilimumab	Phase III
05/21/09	Cougar Biotechnology	Johnson & Johnson	894	846	18.3%	24.0%	26.3%	12.3%	CB7630	Phase III
04/22/08	Sirtris Pharmaceuticals	GlaxoSmithKline	636	617	76.5%	76.8%	88.4%	12.5%	SIRT1 activators	Pre-Clinical
					Mean	**84.4%**	**97.6%**	**111.3%**	**49.1%**	
					Median	**72.0%**	**76.8%**	**88.4%**	**49.6%**	

Source: FactSet, Wall Street research and Company information.
1. ZymoGenetics' marketed product, Recothrom, was not considered the key "lead" product.

Weighted Average Cost of Capital

WACC	
Cost of Equity	
Unlevered Beta	1.00
Target Debt to Equity	8.6%
Assumed Tax Rate	26.0%
Levered Beta	1.07
Risk Free Rate	3.1%
Market Risk Premium	6.7%
Cost of Equity	**10.3%**
Cost of Debt	
Risk Free Rate	3.1%
Credit Spread	8.9%
Marginal Cost of Debt	12.0%
Assumed Tax Rate	26.0%
After-Tax Cost of Debt	**8.9%**
Cost of Capital	
After Tax Cost of Debt	8.9%
Target Debt / (Debt + Equity)	7.9%
Cost of Equity	10.3%
Target Equity / (Debt + Equity)	92.1%
Weighted Average Cost of Capital	**10.1%**

Bloomberg Betas		
Company	**Levered**	**Unlevered**
Celgene Corp.	0.76	0.72
Biogen Idec Inc.	0.85	0.83
Alexion Pharmaceuticals Inc.	0.88	0.88
Vertex Pharmaceuticals Inc.	0.88	0.83
Regeneron Pharmaceuticals Inc.	0.85	0.83
BioMarin Pharmaceutical Inc.	1.03	1.03
Seattle Genetics Inc.	0.92	0.92
Onyx Pharmaceuticals Inc.	1.13	1.07
Incyte Corp.	1.20	1.20
Amylin Pharmaceuticals Inc.	1.23	0.85
InterMune Inc.	2.07	1.91
Pharmacyclics Inc.	1.22	1.22
Exelixis Inc.	1.36	0.99
Medivation Inc.	0.77	0.77
Average	**1.08**	**1.00**

Source: Barra, Bloomberg, and Wall Street Research.
Note: Risk free rate calculated as 3 year average for 10-Year Treasury Bond; levered beta based on Bloomberg beta.

Business Proprietary Information – Confidential Treatment Requested

Selected Comparable Companies

($ in millions)

Selected Comparable Companies

Name	Equity Value	% 52-wk High	Enterprise Value	EV / Sales 2012E	EV / Sales 2013E	EV / Sales 2014E	P / E 2012E	P / E 2013E	P / E 2014E	Lead Product	Phase	Launch Year
Celgene	$29,725	95.5%	$28,650	5.33x	4.67x	4.01x	14.6x	12.3x	10.0x	Revlimid	Marketed	2006
Biogen Idec	28,591	94.4%	26,791	6.10x	4.69x	4.22x	17.9x	16.0x	13.8x	Avonex	Marketed	1996
Alexion Pharmaceuticals	12,286	92.1%	11,842	11.59x	9.25x	7.58x	37.3x	27.8x	22.1x	Soliris	Marketed	2007
Vertex Pharmaceuticals	6,478	81.7%	6,433	2.50x	1.97x	1.87x	6.7x	5.1x	5.4x	Incivek	Marketed	2011
Regeneron Pharmaceuticals	5,598	68.6%	5,594	9.37x	6.34x	4.81x	NM	NM	46.9x	Arcalyst / VEGF Trap-Eye	Marketed / Filed	2008 / 2012
BioMarin Pharmaceutical	4,452	89.6%	4,227	8.19x	7.30x	5.66x	NM	155.4x	46.2x	Naglazyme	Marketed	2005
Onyx Pharmaceuticals	2,558	86.1%	2,078	6.48x	4.91x	3.41x	NM	216.9x	27.1x	Nexavar (sorafenib)	Marketed	2005
Incyte	2,455	63.7%	2,138	10.47x	6.69x	4.10x	NM	NM	16.4x	Ruxolitinib	Filed & Phase III	2012 / 2014
Seattle Genetics	2,061	76.4%	1,686	8.86x	6.71x	5.03x	NM	NM	856.0x	Adcetris	Marketed & Phase III	2011 / 2014
InterMune	1,672	44.3%	1,359	15.49x	6.43x	3.61x	NM	NM	17.1x	Pirfenidone	Marketed (EU) Phase III (U.S.)	2011 / 2014
Medivation	1,608	94.1%	1,426	20.80x	15.02x	10.47x	NM	NM	100.6x	MDV3100	Phase III	2013
Amylin Pharmaceuticals	1,436	59.4%	1,644	2.32x	2.09x	1.63x	NM	NM	121.6x	Byetta (exenatide)	Marketed	2005
Pharmacyclics	928	93.5%	823	76.21x	33.81x	6.43x	NM	NM	NM	PCI-32765	Phase II	2014-2015
Exelixis	562	33.2%	463	5.78x	6.10x	4.42x	NM	NM	NM	Cabozantinib (XL184)	Phases II & III	2012 / 2015
				High	**76.21x**	**33.81x**	**10.47x**	**37.3x**	**216.9x**	**856.0x**		
				Mean	**13.45x**	**6.26x**	**4.80x**	**19.1x**	**72.3x**	**108.5x**		
				Median	**6.53x**	**6.38x**	**4.32x**	**16.2x**	**21.9x**	**24.6x**		
				Low	**2.32x**	**1.97x**	**1.63x**	**6.7x**	**5.1x**	**5.4x**		
Valuation												
Harry @ Current Stock Price	$5,520	79.0%	$5,336	NM	NM	9.41x	NM	NM	20.4x	PSI-7977	Phase IIb [1]	2014
Harry @ $125/share	10,025	141.2%	9,841	NM	NM	17.36x	NM	NM	37.0x	PSI-7977	Phase IIb [1]	2014
Harry @ $143/share	11,509	162.0%	11,325	NM	NM	19.97x	NM	NM	42.5x	PSI-7977	Phase IIb [1]	2014
Harry @ $162/share	13,000	182.9%	12,817	NM	NM	22.61x	NM	NM	48.0x	PSI-7977	Phase IIb [1]	2014
Street Estimates												
Harry @ Current Stock Price	$5,520	79.0%	$5,336	NM	NM	194.04x	NM	NM	NM	PSI-7977	Phase IIb [1]	2014
Harry @ $125/share	10,025	141.2%	9,841	NM	NM	357.86x	NM	NM	NM	PSI-7977	Phase IIb [1]	2014
Harry @ $143/share	11,509	162.0%	11,325	NM	NM	411.81x	NM	NM	NM	PSI-7977	Phase IIb [1]	2014
Harry @ $162/share	13,000	182.9%	12,817	NM	NM	466.06x	NM	NM	NM	PSI-7977	Phase IIb [1]	2014

Source: Company information and FactSet (I/B/E/S Global Consensus Estimates).
Note: Market data as of 11/08/11. Harry valuation multiples based on probability adjusted figures.
1. Announced the initiation of an IFN-free Phase III program for PSI-7977 on November 1, 2011.

Key Valuation Assumptions for NPV

Gryffindor Standalone

Product	POS	U.S. Launch Year	Weighted Average U.S. Peak Penetration	WW Peak Sales ($bn)	NPV ($bn)
Gryffindor PI/NS5A + IFN/RBV	43%	2016	11%	$1.4	$0.4
Gryffindor All Oral Regimen	26%	2017	23%	5.2	2.2
				TOTAL	**$2.6**

$18.3bn incremental value less net cash

Gryffindor Pro Forma

Product	POS	U.S. Launch Year	Weighted Average U.S. Peak Penetration	WW Peak Sales ($bn)	NPV ($bn)
Redacted					
Gryffindor PF Pan Genotypic (1)	75%	2014	50%	11.9	21.2
				Other R&D	(0.6)
				NOL	0.1
				Net Cash (2)	0.2
				TOTAL	**$21.0**

Note: Assumptions per Gryffindor; 10% discount rate assumed.
1. *Representative of initial regimen of 7977 + RBV for GT2/3 and IFN-intolerant and follow-on regimen of 7977 + Gryffindor OAV Pan Genotypic.*
2. *Net cash includes cash and cash equivalents of $188.2mm and debt of $4.4mm.*

Business Proprietary Information – Confidential Treatment Requested

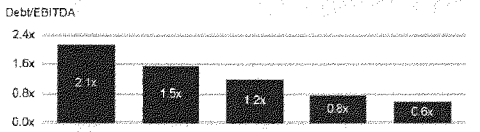
Financing Overview – Illustrative $10.0bn Purchase Price

($ in millions)

Sources & Uses [1]

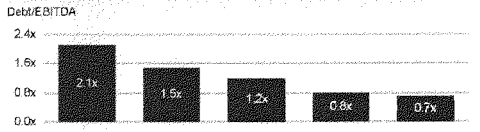
	Sources:	$	%	Uses:	$	%
$4 billion "cash" bridge	Domestic Cash	$1,008	10.0%	Equity Purchase Price	$10,025	99.2%
	Offshore Cash	4,000	39.6%	Financing Fees (est.)	33	0.3%
	Revolver / CP	1,500	14.8%	Transaction Fees (est.)	50	0.5%
~$5 billion "debt" bridge	Term Loan	0	0.0%			
	New 1 Year Convert	0	0.0%			
	New 3 Year Notes	500	4.9%			
	New 5 Year Notes	1,200	11.9%			
	New 10 Year Notes	1,400	13.9%			
	New 30 Year Notes	500	4.9%			
	Total Sources	**$10,108**	**100.0%**	**Total Uses of Funds**	**$10,108**	**100.0%**

Pro Forma Leverage – Management Case



	2011E	2012E	2013E	2014E	2015E
Debt	$9.3bn	$7.8bn	$7.1bn	$5.4bn	$5.4bn
Cash	$1.3bn	$2.9bn	$5.6bn	$8.4bn	$13.9bn
EBITDA	$4.4bn	$5.0bn	$5.9bn	$7.1bn	$9.0bn

Pro Forma Leverage – No Harry Contribution



	2011E	2012E	2013E	2014E	2015E
Debt	$9.3bn	$7.8bn	$7.1bn	$5.4bn	$5.4bn
Cash	$1.3bn	$2.9bn	$5.6bn	$8.2bn	$13.0bn
EBITDA	$4.4bn	$5.0bn	$5.9bn	$6.8bn	$7.5bn

Source: Estimates based on Gryffindor management, Wall Street research and Barclays Capital estimates.
Note: Assumes equity purchase price of $10.0bn ($125.00 per share) based on a 81% premium to stock price of $69.07 on 11/08/11 using ~$5.0bn cash on hand and ~$5.1bn of new debt at a cost of cash of 1.0% and blended cost of debt of 2.8%.
1. Sources subject to change based on market conditions.

BARCLAYS CAPITAL

Business Proprietary Information – Confidential Treatment Requested

Financing Overview – Illustrative $13.0bn Purchase Price

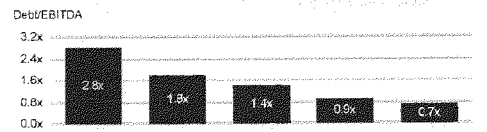
($ in millions)

Sources & Uses [1]

	Sources:	$	%
$4 billion "cash" bridge	Domestic Cash	$1,003	7.7%
	Offshore Cash	4,000	30.5%
~$8 billion "debt" bridge	Revolver / CP	1,750	13.4%
	Term Loan	750	5.7%
	New 1 Year Convert	1,000	7.6%
	New 3 Year Notes	500	3.8%
	New 5 Year Notes	1,250	9.5%
	New 10 Year Notes	1,500	11.4%
	New 30 Year Notes	1,350	10.3%
	Total Sources	**$13,103**	**100.0%**

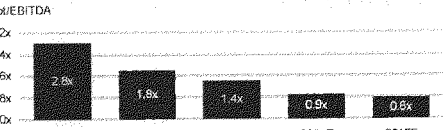
Uses:	$	%
Equity Purchase Price	$13,000	99.2%
Financing Fees (est.)	53	0.4%
Transaction Fees (est.)	50	0.4%
Total Uses of Funds	**$13,103**	**100.0%**

Pro Forma Leverage – Management Case



	2011E	2012E	2013E	2014E	2015E
Debt	$12.3bn	$8.9bn	$8.1bn	$6.4bn	$6.4bn
Cash	$1.3bn	$1.0bn	$3.7bn	$6.2bn	$11.7bn
EBITDA	$4.4bn	$5.0bn	$5.9bn	$7.1bn	$9.0bn

Pro Forma Leverage – No Harry Contribution



	2011E	2012E	2013E	2014E	2015E
Debt	$12.3bn	$8.9bn	$8.1bn	$6.4bn	$6.4bn
Cash	$1.3bn	$1.0bn	$3.7bn	$6.1bn	$10.8bn
EBITDA	$4.4bn	$5.0bn	$5.9bn	$6.8bn	$7.5bn

Source: Estimates based on Gryffindor management, Wall Street research and Barclays Capital estimates.
Note: Assumes equity purchase price of $13.0bn ($161.94 per share) based on a 134% premium to stock price of $69.07 on 11/08/11 using ~$5.0bn cash on hand and ~$8.1bn of new debt at a cost of cash of 1.0% and blended cost of debt of 2.7%.
1. Sources subject to change based on market conditions.

BARCLAYS CAPITAL

Business Proprietary Information – Confidential Treatment Requested

Disclaimer

The proceeding pages contain material that was provided to the Board of Directors (the "Board") of Gryffindor (the "Company") by Barclays Capital Inc. ("Barclays Capital"), the United States affiliate of Barclays Capital, the investment banking division of Barclays Bank PLC. The accompanying material was compiled or prepared on a confidential basis solely for consideration by the Board and no part of it may be reproduced, distributed or transmitted without the prior consent of Barclays Capital. The information contained in this material was obtained from the Company and publicly available sources, and Barclays Capital has relied upon such information without independent verification thereof. These materials are being provided in connection with an actual engagement and may not be used or relied upon for any purpose other than as specifically contemplated by a written agreement with Barclays Capital. Nothing herein shall constitute an offer to sell or the solicitation of an offer to buy any securities described herein.

Any estimates and projections for the Company contained herein have been prepared by management of the Company, were obtained from publicly available sources or are based upon such estimates and projections. The projections contained herein may or may not be achieved and differences between projected results and those actually achieved may be material. No representation or warranty, expressed or implied, is made as to the accuracy or completeness of such information and nothing contained herein is, or shall be relied upon as, a promise or representation, whether as to the past or the future. The analysis contained herein is based on current market conditions which are subject to change and Barclays Capital assumes no obligation to update or otherwise revise these materials.

Because these materials were prepared for use in the context of a presentation to the Board, these materials are incomplete without reference to, and should be viewed in conjunction with, the oral briefing provided by Barclays Capital. These materials was not prepared to comply with the disclosure standards under state and federal securities laws and, to the extent these material may be considered by readers not as familiar with the business and affairs of the Company as the Board, neither the Company nor Barclays Capital nor any of their respective legal or financial advisors or accountants takes any responsibility for the accuracy or completeness of any of the material if used by persons other than the Board. These materials are not intended to provide the sole basis for evaluation of the proposed transaction and do not purport to contain all information that may be required and should not be considered a recommendation with respect to the proposed transaction.

Barclays Capital, its affiliates and the individuals associated therewith may (in various capacities) have positions or deal in transactions or securities (or related derivatives) of the Company or any counterparty to the transaction contemplated herein.

IRS Circular 230 Disclosure: Barclays Capital and its affiliates do not provide tax advice. Please note that (i) any discussion of U.S. tax matters contained in this communication (including any attachments) cannot be used by the Company for the purpose of avoiding tax penalties; (ii) this communication was written to support the promotion or marketing of the matters addressed herein; and (iii) the Board should seek advice based on its particular circumstances from an independent tax advisor.

Exhibit 12

Gilead Liver Disease Franchise

John McHutchison
Senior Vice President
Liver Disease Therapeutic Area

BOD Strategic Review

October 2011

Business Proprietary Information – Confidential Treatment Requested

Liver Disease Franchise Strategic Focus

Requirements for Success

- Organizational focus on the Global prevalence of HCV and HBV
  - Greatest burden of disease from HBV and HCV are in the emerging markets

- Preparation for rapid evolution of chronic HCV therapies
  - Highly competitive landscape with many HCV treatments
  - Consolidation to few leading regimens over time

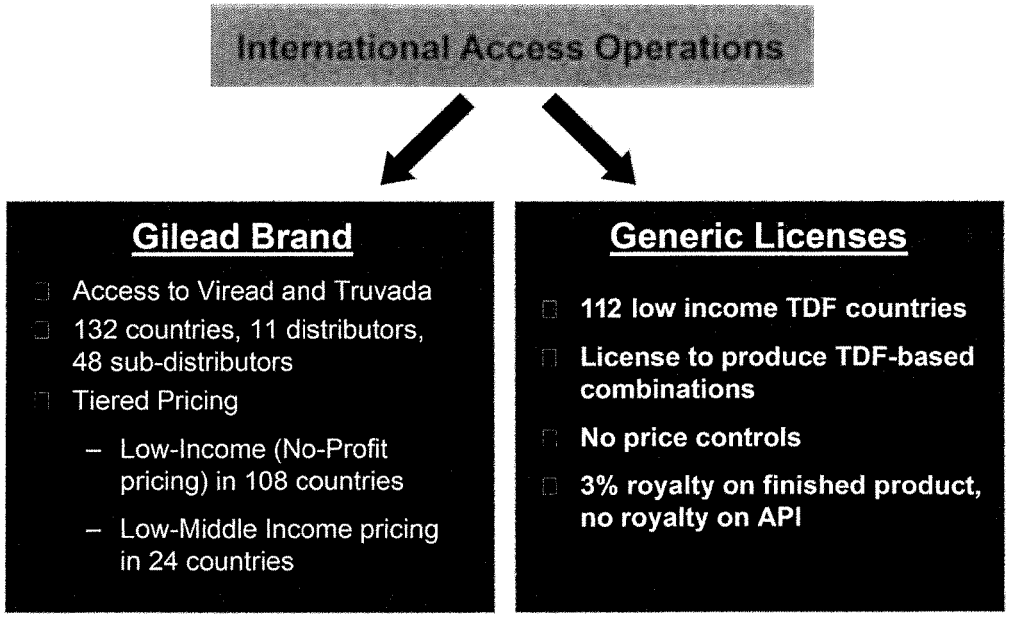
Liver Disease Therapeutic Area Franchise Vision

- HBV: change paradigm from chronic to cure
- HCV: remove IFN from HCV regimens, develop a single regimen for all genotypes
- Liver Fibrosis: develop a treatment that reverses the course of disease in the highest unmet need population

Confidential

Business Proprietary Information – Confidential Treatment Requested

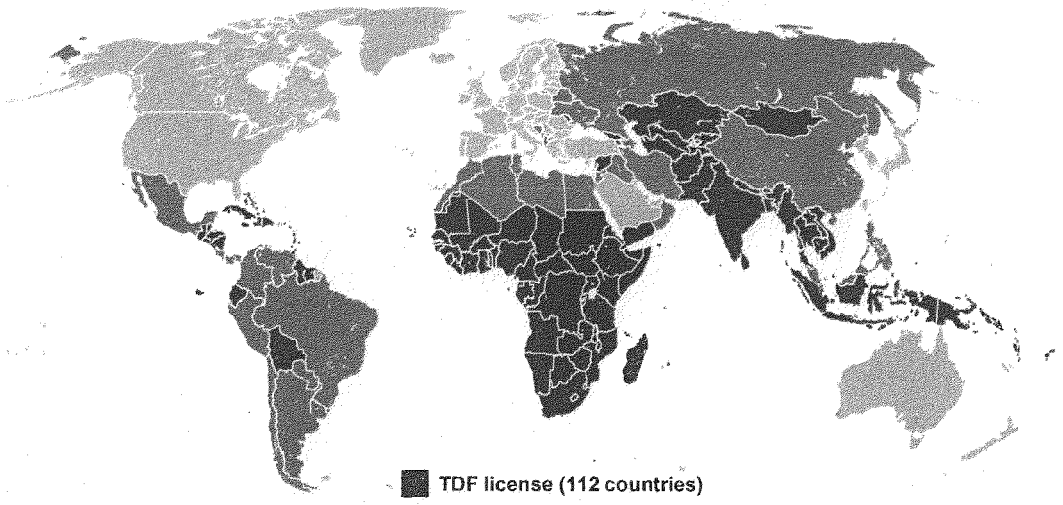
What We Know: Gilead Access Program Model
A Global Approach for a Global Epidemic



Confidential

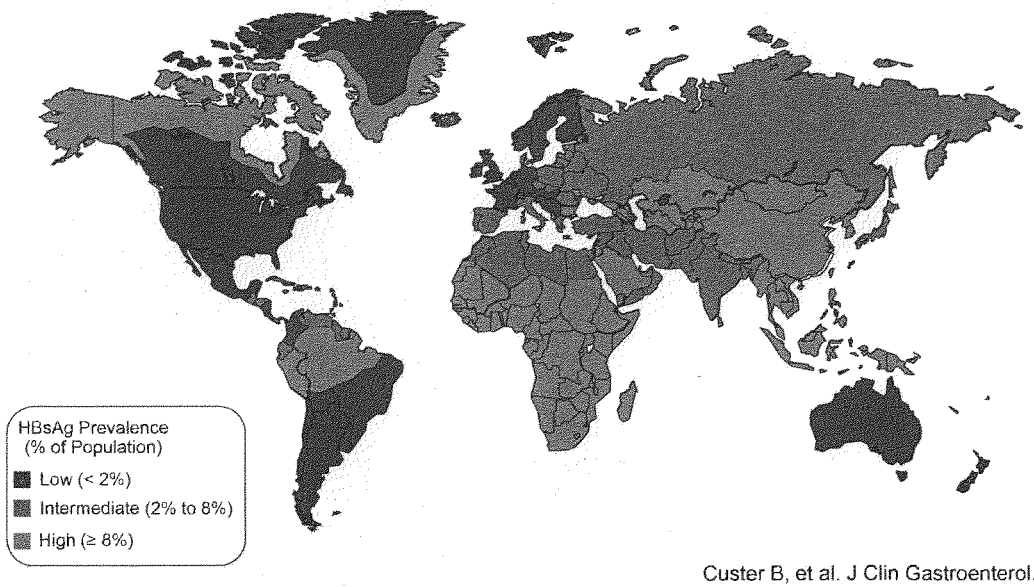
Business Proprietary Information – Confidential Treatment Requested

What We Know: Tenofovir Licensed Territories & Distributor Network



Existing Network of 11 Distributors and 48 distributors in 132 countries that support Registrations, Distribution, Medical Education and Training and Safety Reporting

Global Prevalence of Chronic HBV Infection is Estimated to be 350 Million Individuals



Custer B, et al. J Clin Gastroenterol. 2004;38(10 suppl):S158-S168.

Rapid Global Development Requires Significant Resources in Asia

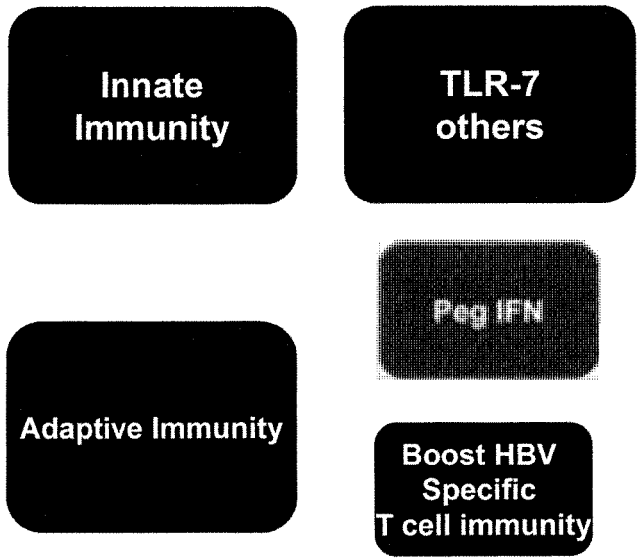
HBV Therapy	First Study in HBV	US Approval	Lag Time to Approval in Asia	
			China	Japan
Baraclude	~2000[1]	2005	+6 months	+9 months
Pegasys	~2001[2]	2005	0 months	+6 years
Viread	~2002[3]	2008	Not approved	Not approved

1. De Man, et al. Hepatol. 2001, 34, 3, 578-582.
2. Cooksley, et al. J Virol Hepatitis. 2003, 10, 298-305.
3. Van Bommel, et al. AASLD 2003.

Confidential

Business Proprietary Information – Confidential Treatment Requested

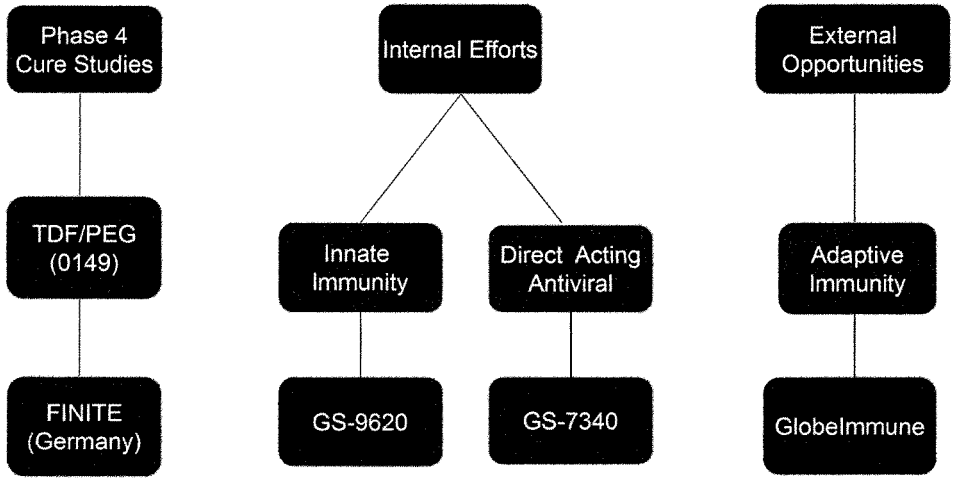
Immunologically Driven HBV Finite Therapy Strategies Will Cure More HBV Patients



Confidential

Business Proprietary Information – Confidential Treatment Requested

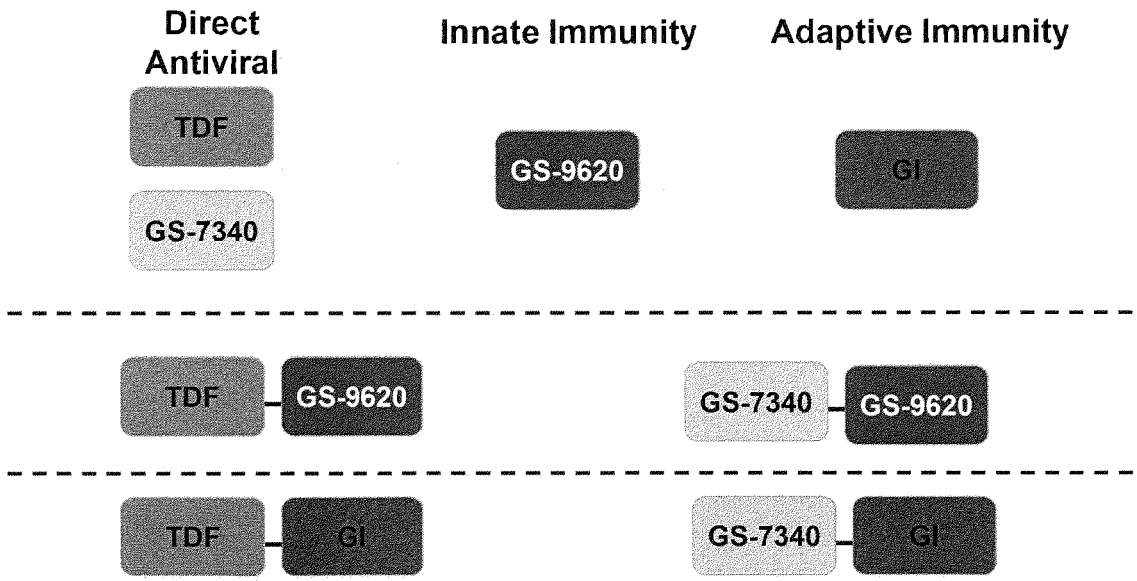
HBV: Global Strategy to Achieve the Vision of Moving from Chronic to Cure



Confidential

Business Proprietary Information – Confidential Treatment Requested

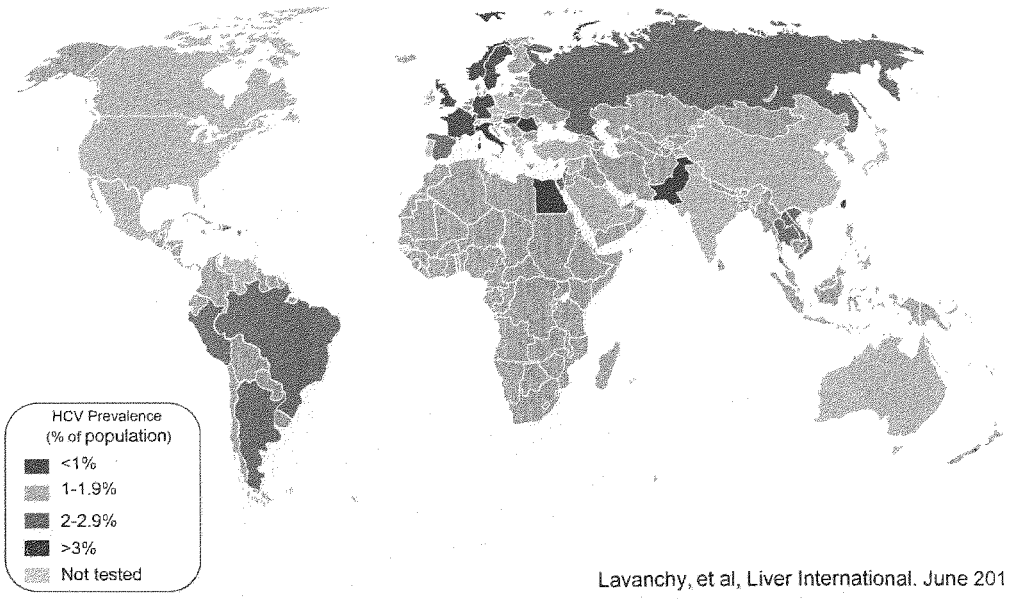
HBV Combination Approaches



Confidential

Business Proprietary Information – Confidential Treatment Requested

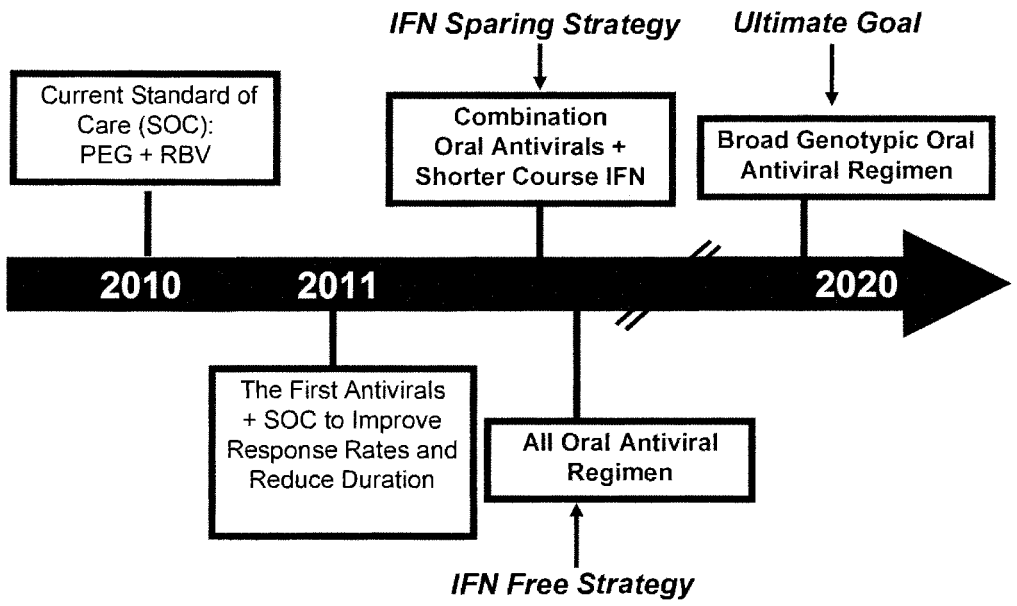
Global Prevalence of HCV is Estimated to be 160 Million Individuals



Lavanchy, et al, Liver International. June 2011.

Business Proprietary Information – Confidential Treatment Requested

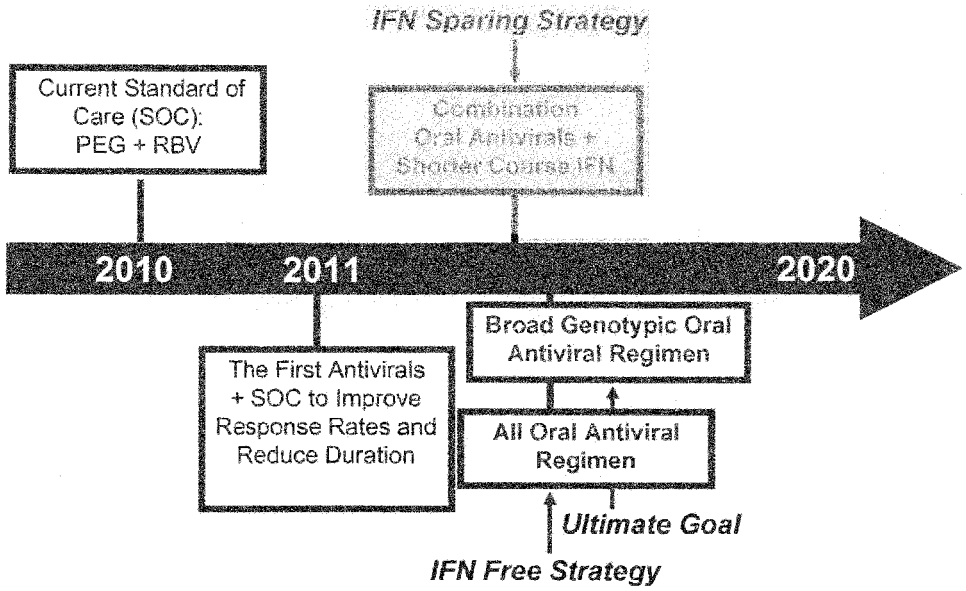
Gilead's HCV Therapy Strategies: 2010



Confidential

Business Proprietary Information – Confidential Treatment Requested

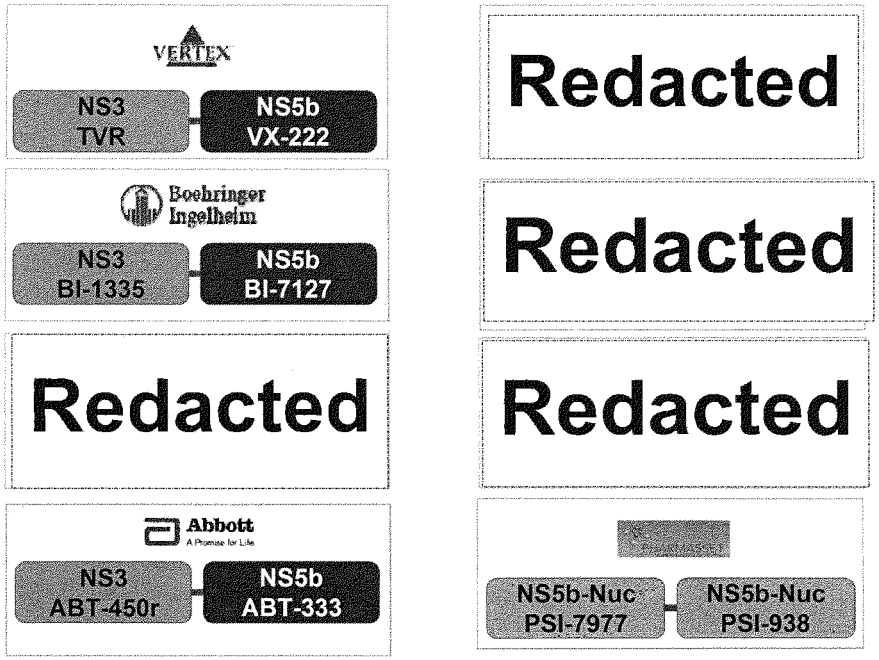
The Competitive Nature of the Field and Speed of Development has Now Compacted the Timelines



Slide 12

Confidential

Companies Evaluating All Oral HCV Regimens



Slide 13

Confidential

841

Companies Evaluating All Oral HCV Regimens

36% SVR GT 1

(EASL 2011)

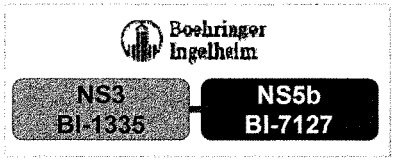
Redacted

90% SVR GT 1b

(AASLD 2011)

842

Companies Evaluating All Oral HCV Regimens



88% week 4 response

70% week 12 response

13% breakthrough

12% stopped Rx: side effects

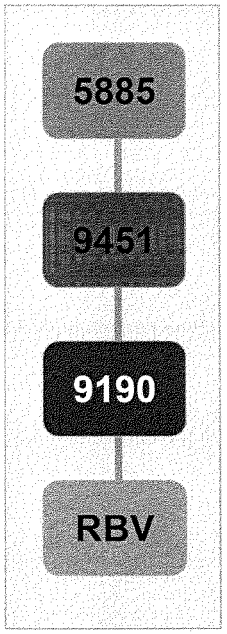
SVR pending

(AASLD 2011)

Confidential

Business Proprietary Information – Confidential Treatment Requested

Gilead's 1st IFN-free Regimen



81% week 2 response

97% week 4 response

5% breakthrough

0% stopped Rx: side effects

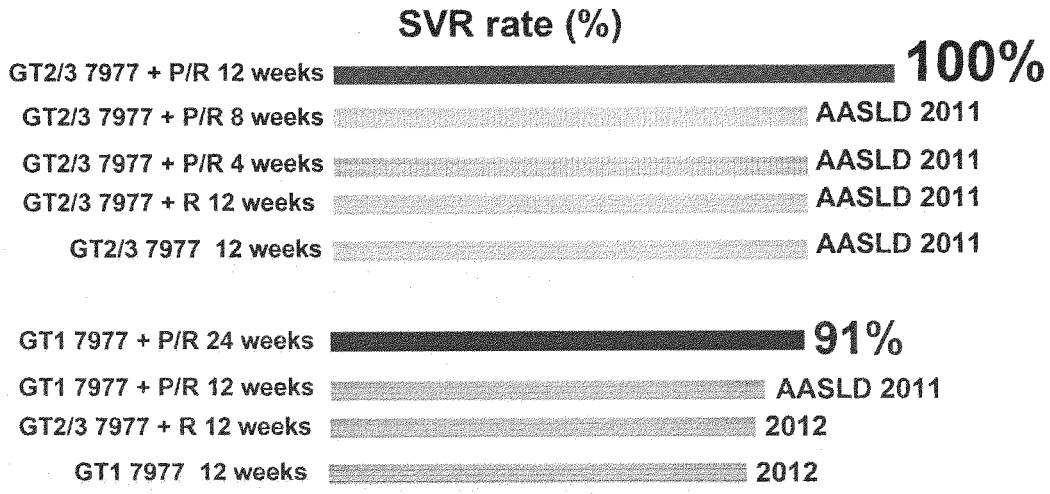
SVR pending

(to be submitted to EASL 2012)

Confidential

Business Proprietary Information – Confidential Treatment Requested

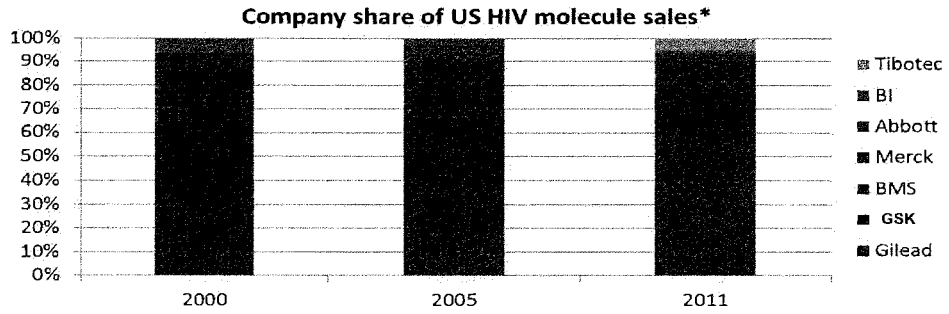
Pharmasset: Upcoming Data at AASLD 2011



Confidential

Business Proprietary Information – Confidential Treatment Requested

What We Know: Consolidation of The HIV Market Will Likely Occur in HCV also



HIV dynamics

Nascent market

- Few options with tolerable SE's

Market diversification

- Multiple options with 'similar' efficacy and tolerable SE's
- Minimal long-term safety data

Maturing market consolidation

- Long-term safety/efficacy data drives consolidated opinion of 'best in class' agents
- Inclusion of best-in-class agents in FDCs & STRs

- Like HIV, HCV will be driven by Successful, Safe, Short, Simple Regimens Rather than Single Agents

Slide 18

* Excludes RTV, Atripla fully attributed to Gilead

Confidential

LOXL2 is A Core Pathway in Fibrosis:

Volume 17 | Number 5 | May 2011 Nature Medicine

BETWEEN BEDSIDE AND BENCH

Scraping fibrosis

Animal experiments using single organs as models of fibrosis spur therapeutic development toward promising targets, but testing of these therapies in human fibrosis yielded disappointing results and limited efficacy. Finding core pathways relevant in different organs that can become fibrotic will uncover molecules that will prove useful as therapeutic targets in many species, including humans. In 'Bench to Bedside', Scott Friedman, Wajahat Mehal and John Iredale discuss this new paradigm in fibrosis research and its potential as a new drug development approach. In 'Bedside to Bench', Alison Eddy peruses how the protein encoded by *UMOD*, a gene linked to variable risk for chronic kidney disease and hypertension in humans, may have a role in fibrosis and kidney disease. Uncovering the normal function of UMOD and its gene variants will shed light on the pathogenesis of chronic kidney disease and aid in the discovery of new targets for kidney fibrosis and hypertension.

■ BENCH TO BEDSIDE

Expressway to the core of fibrosis

Wajahat Z Mehal, John Iredale & Scott L Friedman

Studies of organ fibrosis have flourished over the last decade, identifying a growing number of molecules that regulate the development of fibrosis in experimental models. Fibrotic diseases account for up to 45% of deaths in the developed world, yet there are no approved antifibrotic therapies[1]. Translating advances in experimental fibrosis to clinical management has been challenging, in part, because there are now many candidate antifibrotic targets, and most are tested in highly controlled experimental settings, usually only in a single organ type and species. The therapeutic implications of these animal studies are therefore only relevant to that specific rodent strain and within the constraints of the experimental design. Moreover, the field is driven by a bias toward publishing the most novel findings and away from confirmation of fibrosis, regulatory pathways are those that can influence the core pathway but do not directly convert the initial stimulus into the basic component of fibrosis. Therefore, cells and molecules along the core pathway are essential to fibrosis, and their targeting may be sufficient to limit progression. The regulatory pathways may have substantial effects on fibrosis but will also have greater variability between organs, species and individuals, challenging the value of these targets. For this core-versus-regulatory pathway approach to have utility in fibrosis, criteria should be established for identifying components of these pathways, and, unfortunately, the reductionist approach used in animal models rarely makes this distinction.

Evidence of evolutionary pathway conservation can help identify core pathways, assuming ited to the liver, as they are present in very low numbers in other organs. NK cells could be potential targets to limit fibrosis in individuals with hepatitis C without compromising wound repair at other sites.

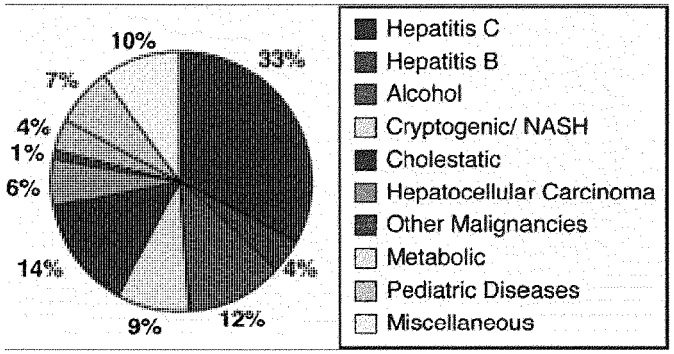
A recent study by Barry-Hamilton *et al.*[5] exploring the role of the enzyme lysyl oxidase-2 (LOXL2) in fibrosis represents a comprehensive approach in which they have probably identified a core pathway. It showed a vital role for LOXL2 in mouse experimental models of liver and lung fibrosis, as well as in subcutaneous tissue fibrosis in response to tumor implants. LOXL2 expression also correlated with fibrosis in human tissues, including chronic hepatitis C and idiopathic pulmonary fibrosis. These findings, therefore, meet the above criteria for placing LOXL2 in a core pathway. Although the role

847

Confidential

Business Proprietary Information – Confidential Treatment Requested

Most Frequent Reasons for Liver Transplantation are Non-viral Fibrotic Liver Diseases



All USA Transplants 1992-2007

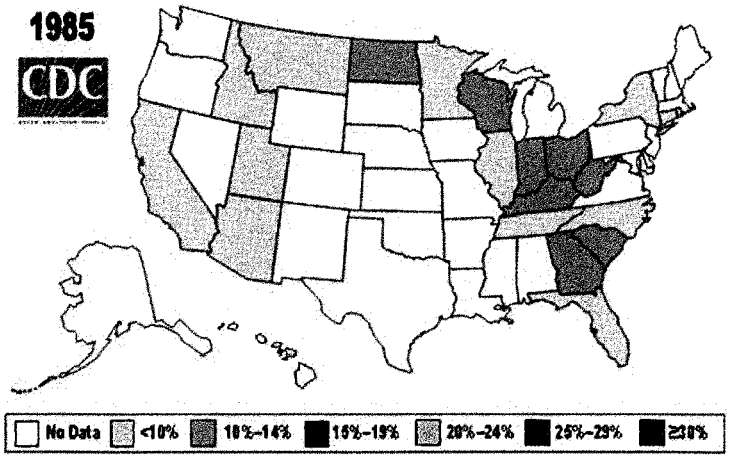
NASH is currently the 3rd leading cause of liver transplantation, but it is expected to surpass alcohol and HCV in the decade ahead

Gastroenterology 2008;134:1764

Confidential

Business Proprietary Information – Confidential Treatment Requested

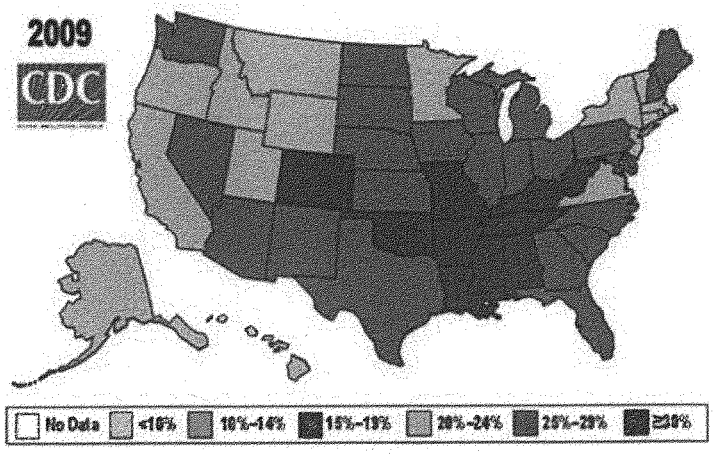
CDC Statistics – Obesity in USA 1985



Confidential

Business Proprietary Information – Confidential Treatment Requested

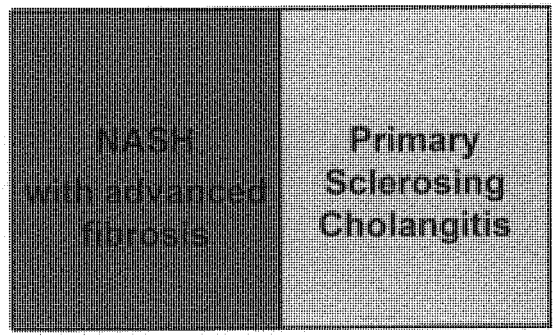
CDC Statistics Obesity in USA 2009



Confidential

Business Proprietary Information – Confidential Treatment Requested

Liver Fibrosis: Target High Unmet Need Populations To Demonstrate The Effect

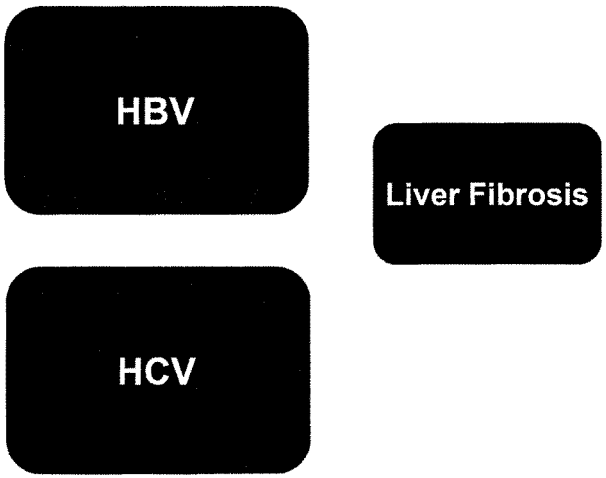


- High unmet need and rapid progression of liver fibrosis
- Efficacy demonstrable in 1-2 years

Confidential

Business Proprietary Information – Confidential Treatment Requested

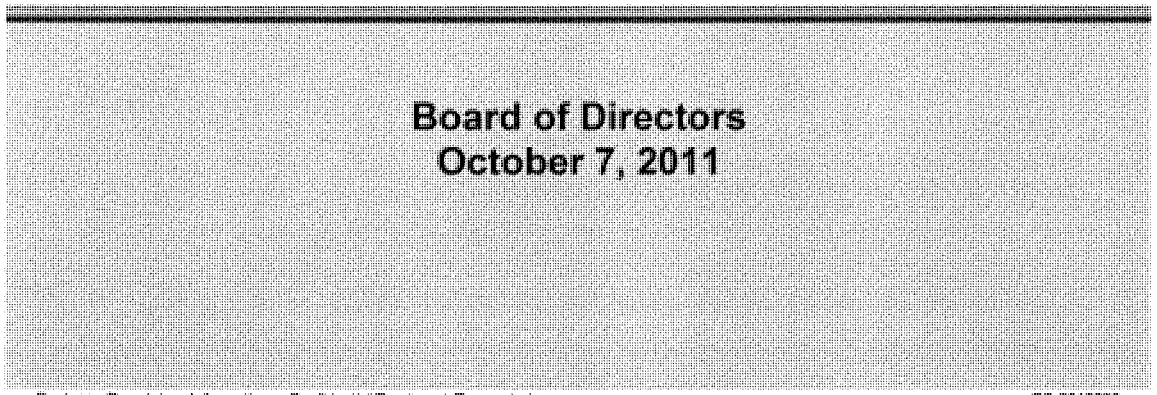
Liver Diseases R & D Programs



Business Proprietary Information – Confidential Treatment Requested

Exhibit 13

Harry Update



Business Proprietary Information – Confidential Treatment Requested

Agenda

- Opening comments - John Martin and John Milligan
- Update on information received during meeting with Harry - John McHutchison
- Updated revenue model - Kevin Young
- Updated valuation model - Robin Washington
- Discussion and approval of revised offer for Harry - John Milligan
- Adjourn

Update on Information Received During Meeting With Harry

John McHutchison, M.D.
SVP,Liver Disease Therapeutics

Business Proprietary Information – Confidential Treatment Requested

Gilead Global Advisory Board

- Last weekend we had the Gilead Global Liver Disease Advisory Board. Takeaways:
  - Significant negatives (side effects and complexity) with the two PIs approved earlier this year.
  - Doctors are delaying therapy for patients in the hope of better options in the future.
  - Advisors see that all oral therapy is coming very soon and **"safety and simplicity"** will drive use. Timelines are shrinking rapidly.
  - Field is moving very fast; faster than anyone anticipated.
  - Harry trials are recruiting fastest of all on going trials.
  - FDA have stated that SVR 12 will be acceptable as a registrational endpoint for clinical approval.
  - Increasing comfort that an interim four week readout (SVR4) is a very good indicator for likely SVR 12 endpoint.

857

Harry Senior Management Meeting

- Most of the data focused on PSI 7977, Harry's lead pyrimidine nucleotide analogue
  - Excellent safety profile (no measurable side effects in any patients to date); 250 patients at 8 weeks or more already; 1500 patients by May 2014.
  - Harry (based on new FDA guidelines) are predicting an approval in May 2014. This is 18-24 months faster than anticipated earlier.
  - High rates of cure without IFN (100% in GT2/3). Very good monotherapy data without IFN or Ribavirin.
  - High on Rx response in GT1 without IFN (cure data early 2012).
  - High Early Cure rates in GT1 with 12 weeks of IFN/Ribavirin.
  - Multiple expanding data sets spanning different populations.

Business Proprietary Information – Confidential Treatment Requested

ELECTRON: Results to be Presented AASLD (Nov 2011). Genotype 2/3

Time (Weeks)	PSI-7977 RBV 12 weeks PEG		PSI-7977 RBV 8 weeks PEG		PSI-7977 RBV 4 weeks PEG		PSI-7977 RBV NO PEG		PSI-7977 NO PEG NO RBV	
	n	%<LOD	n	%<LOD	n	%<LOD	n	%<LOD	n	%<LOD
0	11	0	10	0	9	0	10	0	10	0
1	2/11	27	4/10	40	1/9	22	2/10	20	6/10	60
2	8/11	82	8/9	89	7/8	88	8/10	80	8/10	80
3	9/11	82	9/9	100	7/7	100	9/10	90	10/10	100
4	11/11	100	10/10	100	9/9	100	10/10	100	10/10	100
8	11/11	100	10/10	100	9/9	100	10/10	100	10/10	100
12	11/11	100	10/10	100	9/9	100	10/10	100	10/10	100
SVR4	11/11	100	10/10	100	9/9	100	10/10	100	-	-
SVR8	11/11	100	10/10	100	9/9	100	10/10	100		
SVR12	8/8	100	7/7	100	9/9	100	10/10	100	-	-

SVR4 Nov 1st

Business Proprietary Information – Confidential Treatment Requested

Harry Senior Management Meeting

- Favorable End of phase 2 meetings with FDA
  - Phase 3 protocols defined
  - All genotypes
  - IFN Free (RBV sparing approach included)
  - 12 week treatment duration
  - All patient populations
    - IFN naïve, IFN ineligible and IFN-failures
  - Approval Date May 2014
- No meetings held with European authorities

Business Proprietary Information – Confidential Treatment Requested

Planned Phase 3 Programs

- Target NDA submission October 2013
  - Approval March 2014
  - Gilead will augment and accelerate the programs
- 3 registrational studies with 1250 patients
  - Genotype 2,3 treatment naïve (start 4Q 2011)
    - 500 patients (active SOC control)
  - Genotype 2,3 IFN intolerant, ineligible (start 1Q 2012)
    - 375 patients (placebo control)
  - Genotype 1 IFN intolerant, ineligible (start 1Q 2012)
    - 375 patients (placebo control)
- Indication: treatment of chronic hepatitis C
  - All genotypes, all patient populations
  - Single tablet once a day; or with RBV

Business Proprietary Information – Confidential Treatment Requested

The Net Effect with Success in Phase 3

- Simple once daily oral regimen : ***simple, short and safe***
- The approvals will be applicable to ALL genotypes including those that are difficult to or cannot currently be treated
- IFN sparing strategy is less relevant
- The timelines for the second "wave" of HCV therapies we expected (all oral and then pan genotypic regimens) have now been collapsed
- The POS increases alongside the truncated timelines to approval
- Based on current information, the all oral combination programs from Abbott, BI, BMS, Gilead, Roche, Tibotec, and Vertex will not be best in class

Business Proprietary Information – Confidential Treatment Requested

Risks

- Limited data with monotherapy
  - Genotype 2,3 is less of a risk
  - Higher risk of relapse or breakthrough in Genotype 1
    - Viral breakthrough observed with lower doses
- Limited current data for Genotype 1, available by year end
  - Need for additional Gilead OAV in genotype 1 is unknown
  - Need for RBV also not known
- The Data set is Expanding but still limited
  - 137 patients < 4 weeks exposure
  - 354 patients > 4 weeks exposure
  - (250 of which have > 8 weeks exposure)

Business Proprietary Information – Confidential Treatment Requested

Summary

- Accelerated registration path discussed with FDA with NDA filing in October 2013, approval in May 2014
- Phase 3 program to be initiated in 2011
  - Broad genotypic, IFN-free regimen
  - Single tablet monotherapy regimen (± RBV)
  - 3 studies to provide adequate safety database
- Harry needs to refine the approach to mitigate operational risk and shorten timelines
- Harry feel that 938 (purine nucleotide) can provide either back-up for monotherapy or second compound should they need a second molecule.
- Harry has established the fastest pathway forward with the simplest regimen that is furthest along

Business Proprietary Information – Confidential Treatment Requested

Updated Revenue and Valuation Model

Kevin Young
EVP, Commercial Operations

Robin Washington
SVP and Chief Financial Officer

Discussion and Approval of Revised Offer for Harry

John F. Milligan, Ph.D.
EVP and Chief Operating Officer

Appendix

Confidentiality and Standstill Agreement

- Confidentiality Obligations: Gilead and Harry are both prohibited from using or disclosing any confidential information of the other party except solely for evaluating a potential acquisition.
- Standstill Covenant: For six months, Gilead is prohibited from:
  - acquiring any Harry stock or assets;
  - launching a hostile tender or exchange offer to acquire Harry;
  - attempting to control or influence Harry's board or management (including by soliciting proxies or launching a proxy contest); and
  - making any public disclosure or doing anything that could require Harry to make a public disclosure of a potential acquisition.
- Standstill Exceptions and Termination:
  - Gilead is permitted to submit private, non-public acquisition proposals to Harry's CEO or board of directors.
  - The standstill terminates if: (i) a third party acquires 20% or more of Harry's stock or launches a tender offer to acquire Harry (which is not rejected by Harry); (ii) Harry enters into a merger agreement; or (iii) Harry announces it is conducting a sale process.
- Non-Solicitation Covenant: Neither party can hire or solicit any director-level or higher employees of the other for 12 months.

Confidential

Business Proprietary Information – Confidential Treatment Requested

GS-0019250

Exhibit 14

From:	Schaefer Price
To:	Conrad, Herb; Elliot Hahn (e.hahn@accubreak.com); lawwjc@law.emory.edu; Michael Inouye (mki919@earthlink.net); Schaefer Price (sprice@pharmasset.com); Williamson, Rob (RFWilliamson3@gmail.com)
CC:	Bryce Roberts; Kurt Leutzinger
Sent:	11/18/2011 4:26:05 PM
Subject:	FW: Forecast Assumptions
Attachments:	Forecast Assumptions for Morgan Stanely 111611.ppt

Gents,

For today's call, attached please find Pat's forecast assumptions based upon recent changes in the HCV arena.

Speak with you soon.

Schaefer

From: Patrick Higgins [mailto:patrickthiggins@comcast.net]
Sent: Friday, November 18, 2011 11:16 AM
To: Schaefer Price
Subject: Forecast Assumptions

Here is what we provided for Morgan Stanley.

PTH

Exhibit 15

Adjustments to Forecast Assumptions, Based on Learnings from AASLD

- Upside case no longer appropriate for PSI-7977 based on Electron results showing monotherapy in G 2 and 3 is less effective than 7977 + RBV
  - Monotherapy with PSI-938 still option and is reflected in revised forecast parameters
- Downside case no longer appropriate based on data from Idenix and Roche suggesting that one DAA + any NUC is not sufficient to achieve SVR
- Two-drug regimens (PSI-7977 +RBV) sufficient vs. 3-drug and 4-drug regimens by Abbott, Gilead, Vertex, BMS and others.
- RBV proven to be valuable component of combination when combined with drug with high barrier to resistance
- Any 2-drug regimen must include a NUC except G1b (~25% of US)
- 12-week of treatment is sufficient based on Abbott data and Electron data
- Electron data release resulted in MD suggestion that warehousing to begin immediately
- Quantum enrollment in five weeks suggests potential improvement in approval timing.
- Data from Chak, et. al. showed potential market in US underestimated by 1-3 million additional patients not reported in original NHANEs survey

Business Proprietary Information – Confidential Treatment Requested

Forecast Assumptions with Ranges

	Base	Range
Dx Rate	+10% Annually (2014+)	+10% to +15% Annually (2014-2016), +10% Annually (2017+)
Tx Rate	Lower rate 2012-2013 due to warehousing; 2x 2011 rate 2014+	Lower rate 2012-2013 due to warehousing; 2x 2011 rate 2014+
US Launch Date	GT2/3: 3Q14, GT1: 3Q14	(All Genotypes), 4Q13 to 2Q15
EU Revenue Recognition	US + 6 months	US + 1 year to same timing as US
US Price	$36,000	$36,000 to $72,000
US Gross/Net	7.5% growing to 20% w/ competition	7.5% growing to 30% w/competition in 2017
EU Price	67% of US price	60% to 70% of US price
G1 Nuc Share	90% at Peak	90% at Peak
G1 VRUS Share	60% at Peak	60 to 70% at Peak
GT 2/3 VRUS Share	80%	80%

Adjustments to assumptions:

- Launch date improves to 4Q13 based on Neutrino start 2Q11, 3-month enrollment, SVR12 in 1Q13, NDA Filed 2Q13
- Potential six-month on approval due to manufacturing delay to meet increased demand
- Current cost to Tx PI + SOC ranges from $65K to $74K based on length of Tx (RGT)
- Price for 7977 + RBV ranges from $36,000 (Victrelis only) to $72K (Incivek +SOC). This does not reflect any price premium or cost savings to payers.
- Price increases not inlcuded in forecast model

Redacted

Japan Assumptions:

Launch in 2018
Revenue determined based on IMS Consulting projections through 2025 for base case
For other cases, the percentage of base case Japan sales to US+EU sales was applied through 2020, then the base case year over year percentage was applied for 2021-2025 (because these years are outside of the model revenue forecast period)

BRICE Assumptions:

Launch in 2017
Growth over 4 years to 20% of total market (5% year 1, 10% year 2, 15% year 3, 20% year 4)
Beyond the model forecast period (2020), 10% year over year growth for two years, then flatline
Time to peak based on IMS Consulting

Business Proprietary Information – Confidential Treatment Requested

Exhibit 16

Project Royal

Discussion Materials

18 November 2011

Table of Contents

Section 1	Process Update
Section 2	Review of King Valuation
Appendix A	Appendix

876

Disclaimer

We have prepared this document and the analyses contained in it based, in part, on certain assumptions and information obtained by us from the recipient, its directors, officers, employees, agents, affiliates and/or from other sources. Our use of such assumptions and information does not imply that we have independently verified or necessarily agree with any of such assumptions or information, and we have assumed and relied upon the accuracy and completeness of such assumptions and information for purposes of this document. Neither we nor any of our affiliates, or our or their respective officers, employees or agents, make any representation or warranty, express or implied, in relation to the accuracy or completeness of the information contained in this document or any oral information provided in connection herewith, or any data it generates and accept no responsibility, obligation or liability (whether direct or indirect, in contract, tort or otherwise) in relation to any of such information. We and our affiliates and our and their respective officers, employees and agents expressly disclaim any and all liability which may be based on this document and any errors therein or omissions therefrom. Neither we nor any of our affiliates, or our or their respective officers, employees or agents, make any representation or warranty, express or implied, that any transaction has been or may be effected on the terms or in the manner stated in this document, or as to the achievement or reasonableness of future projections, management targets, estimates, prospects or returns, if any. Any views or terms contained herein are preliminary only, and are based on financial, economic, market and other conditions prevailing as of the date of this document and are therefore subject to change. We undertake no obligation or responsibility to update any of the information contained in this document. Past performance does not guarantee or predict future performance.

We have (i) assumed that any forecasted financial information contained herein reflects the best available estimates of future financial performance, and (ii) not made any independent valuation or appraisal of the assets or liabilities of any company involved in any proposed transaction, nor have we been furnished with any such appraisals, upon which we have relied without independent verification

This document and the information contained herein do not constitute an offer to sell or the solicitation of an offer to buy any security, commodity or instrument or related derivative, nor do they constitute an offer or commitment to lend, syndicate or arrange a financing, underwrite or purchase or act as an agent or advisor or in any other capacity with respect to any transaction, or commit capital, or to participate in any trading strategies, and do not constitute legal, regulatory, accounting or tax advice to the recipient. We recommend that the recipient seek independent third party legal, regulatory, accounting and tax advice regarding the contents of this document. This document does not constitute and should not be considered as any form of financial opinion or recommendation by us or any of our affiliates. This document is not a research report and was not prepared by the research department of Morgan Stanley or any of its affiliates.

Notwithstanding anything herein to the contrary, each recipient hereof (and their employees, representatives, and other agents) may disclose to any and all persons, without limitation of any kind from the commencement of discussions, the U.S. federal and state income tax treatment and tax structure of the proposed transaction and all materials of any kind (including opinions or other tax analyses) that are provided relating to the tax treatment and tax structure. For this purpose, "tax structure" is limited to facts relevant to the U.S. federal and state income tax treatment of the proposed transaction and does not include information relating to the identity of the parties, their affiliates, agents or advisors.

This document is provided by Morgan Stanley & Co. Incorporated and/or certain of its affiliates, which may include Morgan Stanley Realty Incorporated, Morgan Stanley Senior Funding, Inc., Morgan Stanley Bank, Morgan Stanley & Co. International Limited, Morgan Stanley Securities Limited, Morgan Stanley Bank AG, Morgan Stanley MUFG Securities Co., Ltd, Mitsubishi UFJ Morgan Stanley Securities Co., Ltd, Morgan Stanley Dean Witter Asia Limited, Morgan Stanley Dean Witter Australia Securities Limited, Morgan Stanley Dean Witter Australia Limited, Morgan Stanley Dean Witter Asia (Singapore) Pte., Morgan Stanley Services Limited, Morgan Stanley & Co. International Limited Seoul Branch, Morgan Stanley Canada Limited and/or Morgan Stanley, S.V., S.A. Unless governing law permits otherwise, you must contact an authorized Morgan Stanley entity in your jurisdiction regarding this document or any of the information contained herein.

© Morgan Stanley and/or certain of its affiliates. All rights reserved.

Section 1

Process Update

Project Royal

PROCESS UPDATE

Situation Update

- On September 2nd, King received an unsolicited acquisition proposal from Knight for $100 per share in cash
  - Following preliminary discussions, Knight raised proposal on October 7th to $125 per share in cash

- Following the Board Meeting on October 11th, 2011 to review Knight's revised proposal, commenced a process to explore a potential sale of Royal by contacting selected parties
  - Knight was notified of decision to pursue a process
  - Earl, Prince and Count were contacted during the week of October 10th
  - Duke was contacted in late October
- Of the parties contacted, Earl and Prince expressed interest in pursuing a transaction and executed confidentiality agreements with standstill provisions
  - Count was unable to agree to terms of the confidentiality agreement and Duke was not interested in participating in the process
  - Earl and Prince each attended full day management presentations the week of October 24th
  - Additionally, Earl and Prince, along with Knight, received access to the virtual data room on October 23rd
- On November 14th, Earl notified Morgan Stanley that it would not be submitting a proposal, citing conflicting priorities at this time
- On November 17th, Knight submitted a final bid, consistent with procedures outlined by Morgan Stanley
  - Prince informed King it was dropping from the process

Morgan Stanley

Business Proprietary Information – Confidential Treatment Requested

Project Royal

PROCESS UPDATE

Review of Knight Proposal

- Current proposal of $135 per share represents a 85% premium to the closing stock price on 17-Nov-11

Knight Proposal Statistics [1]
$ / Share

Offer Price		$135.00
Metrics:		
Equity Value ($MM)		10,879
Aggregate Value ($MM)		10,715
Premiums to:		
– Current	$72.83	85%
– 1 Week Average	$70.51	91%
– 2 Week Average	$69.43	94%
– 1 Month Average	$71.40	89%
– 3 Month Average	$72.82	85%
– 6 Month Average	$65.33	107%
– LTM Average	$48.54	178%
– LTM High	$86.00	57%

Summary of Key Terms & Conditions
$MM

Price per Share	– $135.00 / Share
Consideration	– 100% Cash – Employee options / RSU's to be cashed out
Transaction Structure	– Tender offer with back end merger – Minimum tender condition of 50.1% and 'top-up' option
Financing	– Purchase price backed by financing commitments from BAML and Barclays and Knight cash on hand
Conditions to Announcement	– Negotiation of mutually satisfactory merger agreement – Diligence complete – Board approval obtained
Merger Agreement	– To be addressed by Sullivan & Cromwell
Timing	– None specified

Note
1. Diluted shares outstanding based on 75.7MM in basic shares outstanding plus dilutive effect of options as of Oct-11; cash of $166.5MM and debt & minority interest of $2.8MM as of 30-Sep-11

Morgan Stanley

Business Proprietary Information – Confidential Treatment Requested

881

Section 2

Review of King Valuation

Project Royal

REVIEW OF KING VALUATION

King Historical Share Price Performance

Last Twelve Months

- Recent data has been positively received by Street
  - King share price has decreased by 8% in the last month and increased 13% since receipt of the first offer
  - Competitive data from Abbott and Inhibitex somewhat dampened the upward trajectory of the share price over the last two weeks
- Macroeconomic environment has also caused share price volatility

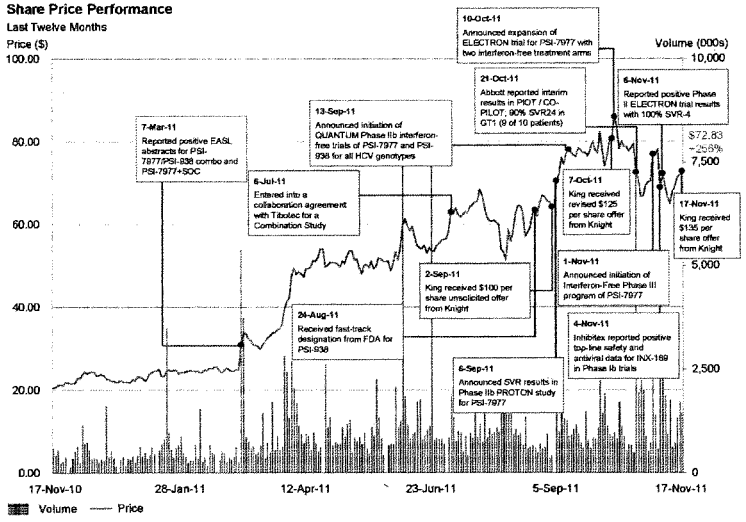
Market Statistics (1)

$MM, except per share data

Current Price (17-Nov-11)	$72.83
1-Month Spot Price (18-Oct-11)	$79.40
3-Month Spot Price (17-Aug-11)	$57.11
1-Month Average Price	$71.06
3-Month Average Price	$72.82
52 Week Closing Low (17-Nov-10)	$20.48
52 Week Closing High (10-Oct-11)	$86.00
All Time Closing High (10-Oct-11)	$86.00
All Time Trading High (11-Oct-11)	$88.52
Common Shares Outstanding	75.7
Fully Diluted Shares Outstanding	79.9
Fully Diluted Market Value	**5,819**
Cash & Cash Equivalents	166
Debt	3
Fully Diluted Aggregate Value	**5,655**

Share Price Performance

Last Twelve Months



Source CapIQ

Note
1. Market data as of 17-Nov-11; balance sheet data as of latest filing

Morgan Stanley

Inhibitex Update

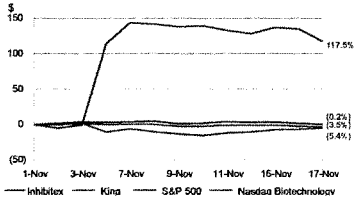
- On November 4th, 2011, Inhibitex announced 4.25 log reduction in viral load over 7 days of monotherapy
  - Further validates NUCs as the backbone of Hepatitis C therapy
  - Positive outlook, however, long term safety and efficacy profile remain key
- According to sellside analysts, King's 7977 remains standard to beat in all oral treatment regimen, though stock might have come under pressure following Inhibitex announcement as investors rotate into Inhibitex with expectation of greater near-term upside

Key Recent Developments

- 11-4-2011: Announced antiviral data for HCV nuc, INX189, in the 200mg cohort of a Phase 1b study
  - Demonstrated a 4.25 log reduction over a seven day monotherapy 200mg daily dose in Genotype 1 treatment-naive patients
- Key Near-Term Events:
  - 12-week safety data for doses up to 100mg QD; expected Q2 2012
  - 12-week safety data for 200mg QD dose; expected 2H 2012

Recent Share Price Performance

Since 1-Nov-11



Selected Analyst Commentary

- "This activity appears as good as [King] nucs PSI-7977 and PSI-938, and also builds on prior data for IHX189 showing a nice dose response… Pending 12-week safety data on INX189 (2Q/3Q12 at lower doses), INHX could follow [King] clinical footsteps, but is at least 2 years behind." *(BAML, 11-4-2011)*
- "We note that at least in GT2/3, if PSI-7977+R already could achieve near 100% SVR, there will be no room to improve with INX-189+R. However, if PSI-7977+R leaves some room for improvement in other populations, INX-189+R may potentially make a difference." *(William Blair, 11-4-2011)*
- "Potency 4.25 logs at 7-days puts '189 in elite company, and lack of safety issues is equally important… As relates to [King], our views are unchanged. [King] continues to set the bar/pace for the field, competition is a given, and data for its more-advanced '7977 is the reason for high conviction in the "nuc" class." *(Baird, 11-4-2011)*
- "With data (while early) now showing strong potency, the drug's pangenotypic coverage, once daily dosing and apparent clean safety profile, we believe INX-189 represents possibly the most attractive partnerable nucleotide in clinical stage development (we do not believe [King] will partner PSI-7977." *(Wedbush, 11-4-2011)*
- "Nucs are scarce assets and the success of [King's] nucs has drawn a significant amount of attention to this class. [King] is further ahead and appears to be going it alone. Any company looking to build an important HCV franchise could likely benefit from having a nuc, in our view. We believe that INX189 could be at or near the top of larger companies' wish lists." *(Credit Suisse, 11-7-2011)*
- "However, we are stepping to the sidelines on [King], as we believe the company is highly valued and that there is more competition coming next year from other nucleotide inhibitors (nucs) as well as other combination regimens, which will benefit from the advances made by [King] in the development interferon-free regimens." *(JMP Securities, 11-4-2011)*

Project Royal

REVIEW OF KING VALUATION

HCV Landscape

- Continued positive momentum in HCV post-AASLD
- PSI-7977's profile continues to be reinforced as the backbone of HCV therapy and potential for interferon free HCV regimen

HCV Competitive Landscape Changes since October 2011

Product	Company	Partner	Comment
INX-189			- Announced antiviral data showing a 4.25 log reduction over a seven day monotherapy 200mg daily dose in GT1 patients
ABT-450 / ABT-333	Abbott		- Disclosed interim PILOT and CO-PILOT results indicating 90% SVR24 in GT1, interferon free (9 out of 10 patients). Formal readout expected in Q1 2012 for full 41 study participants
IDX184	Idenix		- Delayed interim safety and rapid virologic response (RVR) data release for Ph IIb study to Q1 2012 due to slower than expected enrollment
TMC649128	Mediivir	*JNJ*	- Discontinued development of TMC649128 (nucleoside)
Redacted			

Source: Press Releases and Street Research

Morgan Stanley

Business Proprietary Information – Confidential Treatment Requested

Project Royal

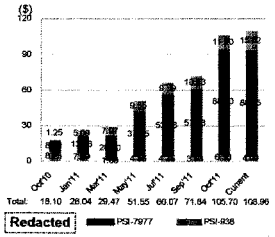
REVIEW OF KING VALUATION

Summary of Sellside Analyst Perspectives

- Analyst value expectations have continued to increase post AASLD
  - More value being ascribed to PSI-7977 and PSI-938
- Consensus probability estimates for PSI-7977 are 60%+
- Investors view PSI-7977 as backbone of Hepatitis C therapy with best-in-class profile and significant efficacy
- POS estimates are very similar to Company POS estimates (key difference now driven by peak sales from market penetration and operating infrastructure)

Evolution of DCF Value / Share[4]

By Drug Candidate



Selected Analyst Summary

Firm	Date	Rating	Price Target ($)	Premium to Current (%)	Valuation Methodology	Value Per Share PSI-7977	Value Per Share PSI-938	Est. Probability of Success PSI-7977	Est. Probability of Success PSI-938
JMP	11/15/11	Buy	-	NA	-	-	-	-	-
ThinkEquity	11/15/11	Buy	105.00	54.9%	SOTP	$88.00	$16.00	-	-
UBS	11/15/11	Buy	99.00	46.0%	DCF SOTP	-	-	60%	-
Robert Baird	11/15/11	Buy	88.00	29.8%	15.0x P/E & 6.5x PS (17E), SOTP DCF	-	-	-	-
Cowen	11/15/11	Buy	-	NA	-	-	-	-	-
Robert Baird	11/15/11	Buy	88.00	29.8%	15.0x P/E & 6.5x PS (17E), SOTP DCF	-	-	-	-
Canaccord	11/15/11	Buy	126.00 (1)	85.6%	DCF / M&A	-	-	-	-
Piper Jaffray	11/15/11	Buy	90.00	32.7%	Blended multiples / DCF analyses	$90.00		-	-
Citi	11/14/11	Buy	106.00	56.3%	DCF	-	-	-	-
Wells Fargo	11/14/11	Buy	91.00	34.2%	Blended multiples / DCF analyses	-	-	58%	-
JPMorgan	11/14/11	Buy	100.00	47.5%	Probability adjusted SOTP / NPV	-	-	75%	60%
BoAML	11/8/11	Buy	102.00	50.4%	Probability adjusted SOTP (by scenario)[2]	$99.64	$2.36	90%	15%
Brean Murray	11/8/11	Buy	105.00	54.9%	-	-	-	-	-
Leerink	11/8/11	Buy	92.00	35.7%	18x forward-year 2017 EPS of $10.70	-	-	-	-
Morgan Stanley	11/7/11	Buy	103.00	51.9%	DCF	-	-	-	-
Noble	11/7/11	Buy	95.00	40.1%	NPV DCF	$79.24	$15.61	65%	40%
Goldman Sachs	11/7/11	Hold	77.00	13.6%	SOTP / M&A (65% / 15% Split)	-	-	80%	-
William Blair	11/7/11	Buy	108.00	59.3%	NPV DCF	$88.69	$15.62	88%	54%
Credit Suisse	10/24/11	Buy	96.00	44.5%	DCF	-	-	-	-
Gleacher	8/16/11	Buy	101.00	49.0%	Probability adjusted NPV [3]	$92.00		81%	81%
Low			**$77.00**	**13.6%**		**$79.24**	**$2.36**	**60%**	**15%**
High			**$126.00**	**85.6%**		**$99.64**	**$16.00**	**90%**	**81%**
Mean			**$98.56**	**45.4%**		**$86.64**	**$12.40**	**76%**	**50%**
Median			**$99.50**	**46.8%**		**$88.35**	**$15.62**	**78%**	**54%**

Redacted

Source Wall Street Research

Notes

1. Represents an M&A value; based on DCF assuming 7977 sales only and an exit via acquisition
2. Values per share roughly broken out based on probability weighted proportion of peak sales estimated by Bank of America Merrill Lynch analyst; 90% POS for 7977 in G1 ($2.5B in peak sales in 2018); 95% POS of 80%+ cure rates for 7977 in G2/3 ($1.2B in incr. peak sales in 2018); 15% POS for 7977 + 938 dual program ($0.6B in incr. peak sales in 2021); 35% POS for 7977 + Redacted ($0.9B in incr. peak sales in 2021)
3. Includes value of cash and other pipeline; $92.00 represents combined per share value of 7977 and 938
4. "Current", October, September, July, and May include reports issued post EASL; DCF value per share includes only selected reports that provide values by compound

Redacted

Morgan Stanley

Business Proprietary Information – Confidential Treatment Requested

Project Royal

REVIEW OF KING VALUATION

Review of Management Projections (1)

Management Case (As of November 2011)

Management POS (Cumulative) (2):

Redacted

- PSI-7977 – 77%
- PSI-938 – 34%

- Management Case (previously Scenario A) represents management's view of the most probable scenario in light of recent developments in the Hepatitis C landscape

Overview of Assumptions

Scenario	Management Case	Management Illustrative Downside Case	Management Illustrative Upside Case
Redacted			
PSI-7977			
Launch	2014	2015	2013
Peak Sales	$6.5Bn	$4.8Bn	$6.5Bn
Status	Wholly Owned	Wholly Owned	Wholly Owned
Royalty	Japan & BRICE Sales: 30%	Japan & BRICE Sales: 30%	Japan & BRICE Sales: 30%
PSI-938			
Launch	2015	2015	2014
Peak Sales	$3.1Bn	$2.2Bn	$4.2Bn
Status	Wholly Owned	Wholly Owned	Wholly Owned
Royalty	NA	NA	NA
Diagnosis (Dx) Rate	+10% Annually (2014+)	+10% Annually (2014+)	+15% Annually (2014-2016), +10% Annually (2017+)
Treatment (Tx) Rate	Lower rate 2012-2013 (warehouse), 2x 2011 Rate 2014+	Lower rate 2012-2013 (warehouse), 2x 2011 Rate 2014+	Lower rate 2012-2013 (warehouse), 2x 2011 Rate 2014+
US Launch Date	GT2/3: 3Q14, GT1: 3Q14	GT2/3: 2Q15, GT1: 2Q15	GT2/3: 4Q13, GT1: 4Q13
EU Revenue Recognition	US + 6 months	US + 1 Year	same as US
US Price	$36,000	$36,000	$36,000
US Gross/Net	7.5% growing to 20% w/ competition	7.5% growing to 30% w/ competition	7.5% growing to 20% w/ competition
EU Price	67% of US price	60% of US price	70% of US price
Single Pill	Yes	Yes	Yes
G1 Nuc Share	90% at Peak	90% at Peak	90% at Peak
G1 King Share	60% at Peak	60% at Peak	70% at Peak
GT 2/3 King Share	80% (based on current data)	80% (based on current data)	80% (based on current data)

Downside Sensitivities to Management Case Upside Sensitivities to Management Case

Notes
1. Based on King Management forecasts as of November 2011
2. POS assumptions applied to all Management cases

Morgan Stanley

Business Proprietary Information – Confidential Treatment Requested

Project Royal

REVIEW OF KING VALUATION

Summary of Management Case

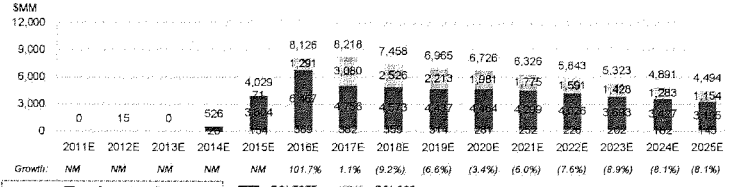
Unweighted; As of November 2011

- Management Case forecasts peak sales of $8.2Bn in 2017

Revenue by Product

2011E-2025E

$MM

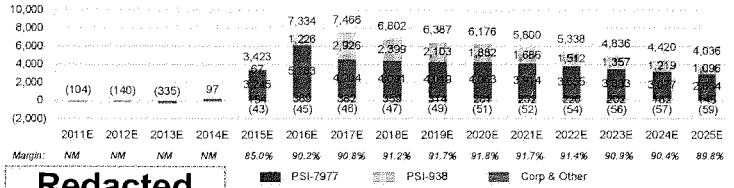


Redacted

EBIT by Product [1]

2011E-2025E

$MM



Redacted

Note

1. Corporate & Other includes Corporate R&D, G&A and S&M, 561 Developmental Costs, D&A and CapEx

Morgan Stanley

Business Proprietary Information – Confidential Treatment Requested

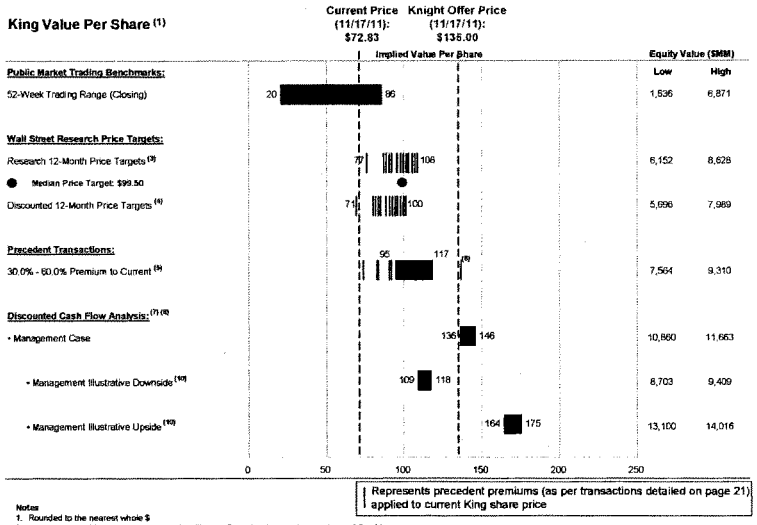
Project Royal

REVIEW OF KING VALUATION

Preliminary Summary of Indicative Analyses

As of 17-Nov-11

- Using current spot Treasury rates as a proxy for the risk free rate and assuming an equity risk premium of 4-6%, CAPM yields a theoretical WACC of 6.5% - 8.5% for King [9]
  - With a focus on the higher end of the risk premium range in light of the current market volatility, indicative analysis assumes a discount rate of 7.5% – 8.5%
  - Discount rate has declined ~100bps since September 15th Board meeting (value impact of ~$10 per share (post-dilution)



Notes
1. Rounded to the nearest whole $
2. Assumes 75.7MM shares outstanding plus dilutive effect of options and warrants as of Oct-11
3. Reflects research updated post AASLD and excludes M&A price target – takeover target at $126 per share from Canaccord excluded from analysis
4. Discounted to present at discount rate of 8.0%
5. Based on precedent transaction analysis as summarized on Pg. 21
6. Based on premium paid in Bristol-Myers Squibb acquisition of Medarex (60.5% = upper limit of precedents)
7. Twenty-year DCF valuation based on probability weighted Management Case (as outlined on Pg. 12); discount rate of 7.5%-8.5%; discounted to 12/31/2011
8. Diluted shares outstanding assumes dilution from future equity financings at cost of equity of 8.0%. Management Case - $360MM offering in 2012 at $72.83 / share; $100MM in 2013 at $78.66 / share; total equity financings equal $460MM
9. WACC calculation as of 17-Nov-11; Risk based on interpolation of 10-yr (2.01%) and 30-yr (3.05%) treasuries over 19 year forecast period and predicted Barra Beta as of 17-Nov-11
10. Illustrative downside and upside cases reflect the cumulative impact of the sensitivities highlighted on page 12

Morgan Stanley

Business Proprietary Information – Confidential Treatment Requested

Project Royal

REVIEW OF KING VALUATION

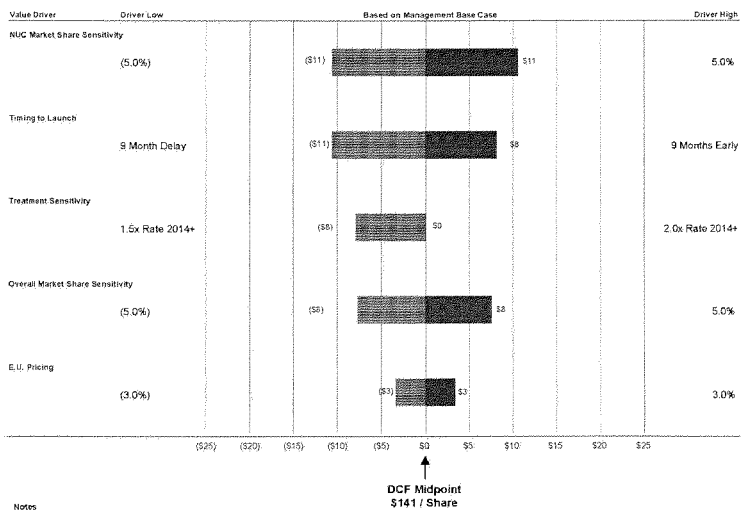
Illustrative DCF Sensitivity Analysis

As of 17-Nov-11

- King DCF valuation is highly sensitive to underlying market share, pricing and other key inputs

King Intrinsic Value Sensitivity (1)(2)(3)(4)(5)(6)

Implied King Share Price Increase or (Decrease) / Absolute Value Increase or (Decrease)



Pricing Sensitivity - Mgmt. Case

$ / Share

Price per Unit	Price per Share
$36,000	$141
$50,000	$199
$72,000	$290

Notes
1. Rounded to the nearest whole $
2. Assumes 75.7MM shares outstanding plus dilutive effect of options and warrants as of Oct-11
3. Twenty-year DCF valuation based on probability weighted Management Case (as outlined on Pg. 12), discount rate of 7.5%-8.5%; discounted to 12/31/2011
4. Diluted shares outstanding assumes dilution from future equity financings at cost of equity of 8.0%. Management Case - $360MM offering in 2012 at $72.83 / share; $100MM in 2013 at $78.66 / share; total equity financings equal $460MM
5. WACC calculation as of 17-Nov-11. Risk based on interpolation of 10-yr (2.01%) and 30-yr (3.05%) treasuries over 19 year forecast period and predicted Barra Beta as of 17-Nov-11
6. Changes in King share price relative to Management Case due to specified change in value driver while holding all other variables constant (equal to Management Case)

Morgan Stanley

Project Royal

REVIEW OF KING VALUATION

Illustrative Analytical Matrix

King

Selected Precedent Transactions

Target / Acquiror	Date	Size ($Bn)	Premium to: 1-day	30-day	52-wk High
Consensus					
Mitsubishi / Tekeda	4/10/2008	$8.2	65%	54%	45%
Imclone / Eli Lilly	10/6/2008	$6.4	51%	75%	42%
Pre-Consensus					
New River / Shire	2/23/2007	$2.7	10%	15%	8%
Myogen / Gilead	10/2/2006	$2.2	50%	51%	24%
Mentarix / BMS	7/23/2008	$2.1	90%	95%	56%

King Analytical Matrix (1)(2)(3)

FYE 9/30

Purchase Price ($)	Current 17-Nov-11	Initial Offer Date 2-Sep-11	Second Offer Date 7-Oct-11	Final Offer Date 17-Nov-11	Premium: 1 Week	VWAP: 1 Month	VWAP: 3 Month	All Time High: Trading	All Time High: Closing	Price Target: Median	Price Target: High	Equity Value	Aggregate Value
Statistic	$72.83	$84.20	$80.37	$71.77	$71.13	$71.00	$73.08	$88.52	$86.00	$94.50	$106.00	5,819	5,655
$72.83	0%	13%	(9%)	1%	2%	3%	(0%)	(18%)	(15%)	(27%)	(32%)	5,819	5,655
$100.00	37%	56%	24%	39%	41%	41%	37%	13%	16%	1%	(7%)	8,023	7,860
$125.00	72%	95%	56%	74%	76%	76%	71%	41%	45%	26%	16%	10,063	9,899
$135.00	85%	110%	68%	88%	90%	90%	85%	53%	57%	36%	25%	10,879	10,715
$145.00	99%	126%	80%	102%	104%	104%	98%	64%	69%	46%	34%	11,695	11,531

Notes
1. Market data as of 17-Nov-11
2. Assumes 75.7MM shares outstanding plus the dilutive effect of in-the-money options and warrants as of Oct-11, and ($163.9MM) net debt, as of 30-Sep-11
3. Second offer and final offer presented to King on 7-Oct-11 and 17-Nov-11 respectively; trading price as of 6-Oct-11 and 16-Nov-11 respectively as offer received during trading hours

Morgan Stanley

Business Proprietary Information – Confidential Treatment Requested

Appendix A

Appendix

891

Project Royal

APPENDIX

Selected Precedent BioPharma Transactions

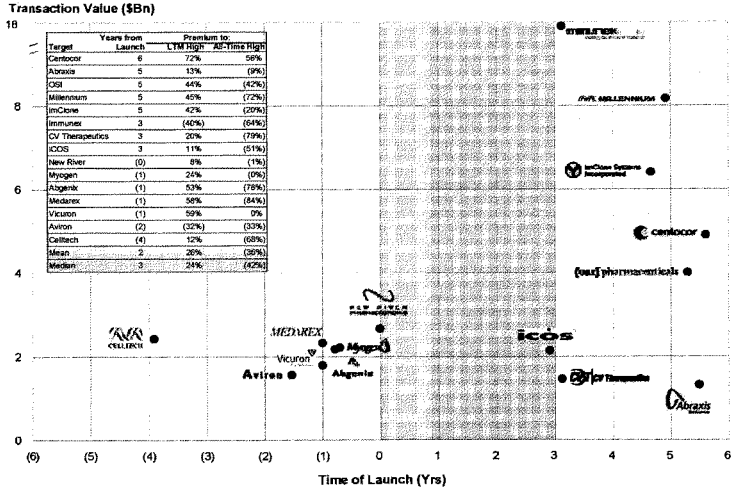
Transaction Value > $1 Bn

- Typically, companies not acquired in first two years of launch as potential acquirors wait to see commercial trajectory on first product

Selected M&A Transactions

Transaction Value ($Bn)

Target	Years from Launch	Premium to: LTM High	Premium to: All-Time High
Centocor	6	72%	56%
Abraxis	5	13%	(9%)
OSI	5	44%	(42%)
Millennium	5	45%	(72%)
ImClone	5	42%	(20%)
Immunex	3	(40%)	(64%)
CV Therapeutics	3	20%	(79%)
ICOS	3	11%	(51%)
New River	(0)	8%	(1%)
Myogen	(1)	24%	(0%)
Algenix	(1)	53%	(78%)
Medarex	(1)	58%	(84%)
Vicuron	(1)	59%	0%
Aviron	(2)	(32%)	(33%)
Celltech	(4)	12%	(68%)
Mean	2	26%	(36%)
Median	3	24%	(42%)



Source: Company Data, Mergermarket

Morgan Stanley

Business Proprietary Information – Confidential Treatment Requested

APPENDIX

BioPharma Precedent Transactions

Transactions $2Bn - $10Bn Since 2005

BioPharma Precedent Transactions

$2Bn - $10Bn

Announcement Date	Target	Acquiror	Lead Product(s) - Stage of Development	Upfront AV ($MM) ($MM)	Contingent Value ($MM)	Consideration Mix (% Cash)	% Premium from Unaffected	% Premium from 30 Days Prior	% Premium from 52 Wk High	% Premium from All Time High	Trading Performance 1 Day After	Trading Performance 1 Wk After	Trading Performance 1 Month After
2-May-11	Cephalon	Teva	Multiple - Marketed	6,800	-	100.0%	38.7%	44.7%	14.4%	(3.8%)	0.0%	1.6%	(7.7%)
17-Sep-10	Chiron	Novartis	Vaccines - Marketed	2,238	-	100.0%	57.7%	60.7%	42.2%	(2.6%)	0.3%	0.2%	3.7%
30-Jun-10	Abraxis	Celgene	Abraxane - Marketed	2,747	650	50.6%	17.3%	51.8%	12.6%	(8.9%)	(4.5%)	(7.9%)	0.4%
7-Jun-10	Talecris	Grifols	Gamunex - Marketed	3,949	-	75.0%	94.4%	48.1%	7.2%	7.2%	(6.3%)	(5.3%)	(10.2%)
18-May-10	GSK	Astellas	Tarceva - Marketed	3,548	-	100.0%	55.3%	68.0%	44.4%	(41.7%)	0.0%	(1.8%)	0.7%
3-Sep-09	Sepracor	Dainippon Sumitomo	Lunesta, Aopenex - Marketed	2,400	-	100.0%	27.6%	29.6%	17.4%	(63.6%)	(2.6%)	(8.0%)	(6.1%)
22-Jul-09	Medarex	Bristol-Myers Squibb	Ipilimumab - Phase 3, MDX-1100, MEDI-545 / MEDI-546 - Phase 2	2,100	-	100.0%	90.9%	93.2%	58.1%	(94.5%)	2.6%	6.4%	11.2%
6-Oct-08	ImClone	Eli Lilly	Erbitux - Marketed, IMC-11F8, IMC-A12, IMC-1121B - Phase II	6,488	-	100.0%	50.7%	74.8%	42.3%	(19.6%)	(0.6%)	1.2%	(1.9%)
7-Jul-08	APP Pharmaceuticals	Fresenius SE	Hospital-based Injectable Pharmaceutical Products - Marketed	4,803	970	100.0%	29.1%	60.3%	(10.4%)	(60.6%)	(6.5%)	(1.9%)	3.1%
15-Apr-08	Millennium Pharmaceuticals	Takeda	Velcade - Marketed	8,058	-	100.0%	64.8%	54.4%	45.4%	(72.2%)	(1.1%)	(4.5%)	(8.1%)
10-Dec-07	MGI Pharma	Eisai	Aloxi, Dacogen, Gliadel, Hexalen, Salagen - Marketed	3,759	-	100.0%	36.7%	24.2%	21.3%	18.9%	0.6%	0.2%	(9.5%)
19-Nov-07	Pharmion	Celgene	Vidaza, Thalidomide - Marketed, Amrubicin - Phase III	2,712	-	34.7%	46.1%	48.7%	35.6%	23.1%	(1.4%)	(3.9%)	(22.3%)
20-Feb-07	New River Pharmaceuticals	Shire	Vyvanse - Phase III	2,667	-	100.0%	9.7%	15.0%	6.2%	6.2%	3.7%	5.9%	1.3%
6-Nov-06	Kos Pharma	Abbott	Niaspan, Advicor - Marketed	3,647	-	100.0%	55.7%	58.0%	6.0%	(0.5%)	(0.4%)	(3.5%)	(2.2%)
17-Oct-06	ICOS	Eli Lilly	Cialis - Marketed	2,136	-	100.0%	18.0%	30.9%	4.4%	(54.4%)	(0.3%)	0.4%	(5.7%)
2-Oct-06	Myogen	Gilead Sciences	Ambrisentan - Phase III	2,214	-	100.0%	49.7%	59.9%	24.2%	24.2%	(6.5%)	(5.0%)	(0.9%)
14-Dec-05	Abgenix	Amgen	Panitumumab - Phase III	2,171	-	100.0%	56.6%	57.9%	53.2%	(78.2%)	(0.9%)	1.3%	(0.3%)
Mean				**3,665**	**810**	**90.6%**	**45.4%**	**52.4%**	**25.1%**	**(29.3%)**	**(1.5%)**	**(1.6%)**	**(3.2%)**
Median				**2,747**	**810**	**100.0%**	**49.7%**	**54.4%**	**21.3%**	**(8.9%)**	**(0.6%)**	**(1.8%)**	**(1.6%)**
Mean (Pre-Commercial)				**2,283**	**-**	**100.0%**	**52.1%**	**56.6%**	**35.9%**	**(32.6%)**	**(0.2%)**	**2.2%**	**2.8%**
Median (Pre-Commercial)				**2,193**	**-**	**100.0%**	**54.1%**	**58.4%**	**38.7%**	**(35.0%)**	**1.0%**	**3.6%**	**0.5%**

Largest pre-commercialization transaction since 2005 is $2.7Bn (Shire / New River Pharmaceuticals)

APPENDIX

King Financial Summary

Management Case – POS-adjusted (2011 – 2030)

King Financial Summary
$MM

	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2030
							Redacted									
Total PSI-7977 Revenues	0	0	0	387	2,910	4,947	3,525	3,200	2,799	2,499	2,233	1,997	1,787	1,601	1,435	1,435
Total PSI-938 Revenues	0	0	0	0	24	444	1,060	869	762	682	611	548	492	442	397	397
Total Revenues	**0**	**15**	**0**	**402**	**3,052**	**5,674**	**4,878**	**4,344**	**3,802**	**3,396**	**3,036**	**2,717**	**2,434**	**2,182**	**1,944**	**1,944**
Total PSI-7977 Cost of Goods	0	0	0	19	145	247	175	160	140	125	112	100	89	80	72	72
Total PSI-938 Cost of Goods	0	0	0	0	1	22	53	43	38	34	31	27	25	22	20	20
Total Cost of Goods	**0**	**0**	**0**	**19**	**147**	**270**	**228**	**203**	**178**	**159**	**142**	**127**	**114**	**102**	**92**	**92**
Gross Profit	**0**	**15**	**0**	**383**	**2,906**	**5,404**	**4,648**	**4,141**	**3,624**	**3,237**	**2,894**	**2,590**	**2,320**	**2,080**	**1,852**	**1,852**
% Margin	*NA*	*100%*	*NA*	*95%*	*95%*	*95%*	*95%*	*95%*	*95%*	*95%*	*95%*	*95%*	*95%*	*95%*	*95%*	*95%*
PSI-7977 Outside Development Costs	53	72	69	9	0	0	0	0	0	0	0	0	0	0	0	0
PSI-936 Outside Development Costs	17	31	34	22	0	0	0	0	0	0	0	0	0	0	0	0
Corporate Research & Development	21	19	20	20	21	21	22	23	23	24	25	25	26	27	28	28
Total Research & Development Costs	**91**	**122**	**123**	**51**	**21**	**21**	**22**	**23**	**23**	**24**	**25**	**26**	**26**	**27**	**28**	**28**
PSI-7977 SG&A	0	9	84	155	198	184	164	139	120	121	122	122	123	124	125	125
PSI-938 SG&A	0	3	23	38	43	41	37	32	27	27	28	28	28	28	29	29
Corporate General & Administrative	11	13	13	14	14	15	15	16	16	17	18	18	19	19	20	20
Corporate Sales & Marketing	2	5	8	8	8	8	9	9	9	9	10	10	10	11	11	11
Total SG&A	**14**	**30**	**128**	**215**	**253**	**248**	**226**	**195**	**172**	**174**	**177**	**179**	**181**	**183**	**186**	**186**
EBIT	**(104)**	**(136)**	**(251)**	**117**	**2,632**	**5,134**	**4,401**	**3,923**	**3,428**	**3,038**	**2,693**	**2,386**	**2,113**	**1,869**	**1,838**	**1,838**
% Margin	*NA*	*NA*	*NA*	*29%*	*86%*	*90%*	*90%*	*90%*	*90%*	*89%*	*89%*	*88%*	*87%*	*86%*	*94%*	*94%*
% Effective Tax Rate	*0%*	*0%*	*0%*	*0%*	*36%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*
EBIAT	**(104)**	**(136)**	**(251)**	**117**	**1,691**	**2,824**	**2,421**	**2,158**	**1,885**	**1,671**	**1,481**	**1,312**	**1,162**	**1,028**	**901**	**901**
Depreciation & Amortization	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PSI-7977 Working Capital	0	0	0	(39)	(252)	(204)	142	32	40	30	27	24	21	19	17	0
PSI-938 Working Capital	0	0	0	0	(2)	(42)	(62)	19	11	8	7	6	6	5	4	0
Capital Expenditures	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Unlevered Free Cash Flow	**(106)**	**(136)**	**(250)**	**78**	**1,436**	**2,578**	**2,502**	**2,209**	**1,936**	**1,709**	**1,515**	**1,342**	**1,189**	**1,052**	**922**	**901**
% Margin	*NA*	*NA*	*NA*	*20%*	*47%*	*45%*	*51%*	*51%*	*51%*	*50%*	*50%*	*49%*	*49%*	*48%*	*47%*	*46%*

894

APPENDIX

Weighted Average Cost of Capital

King

- Using current spot Treasury rates as a proxy for the risk free rate and assuming an equity risk premium of 4-6%, CAPM yields a theoretical WACC of 6.5% - 8.5% for King
  - With a focus on the higher end of the risk premium range in light of the current market volatility, indicative analysis on page 11 assumes a discount rate of 7.5% – 8.5%
- Analysis of theoretical WACC utilizes a predicted beta for King
  - Historical 120 day beta is 0.895 vs. predicted beta of 1.01
  - Use of historical beta would reduce WACC by ~50 bps

King WACC

	Assumed Risk Premium		
	4.0%	**5.0%**	**6.0%**
Market Capitalization (17-Nov-11)	5,819	5,819	5,819
Current Debt	3	3	3
Total Capitalization	**5,821**	**5,821**	**5,821**
Equity Portion	100.0%	100.0%	100.0%
Debt Portion	0.0%	0.0%	0.0%
Total	**100.0%**	**100.0%**	**100.0%**
Cost of Debt			
Weighted Average Cost of Debt	NA	NA	NA
Tax Rate	45.0%	45.0%	45.0%
After-tax Cost of Debt	**NA**	**NA**	**NA**
Cost of Equity			
Risk Free Rate [1]	2.5%	2.5%	2.5%
Barra Predicted Beta [2]	1.01	1.01	1.01
Market Risk Premium	4.0%	5.0%	6.0%
Cost of Equity	**6.5%**	**7.5%**	**8.5%**
Weighted Cost of Debt	0.0%	0.0%	0.0%
Weighted Cost of Equity	6.5%	7.5%	8.5%
Weighted Average Cost of Capital	**6.5%**	**7.5%**	**8.5%**

Notes
1. Risk based on a weighted interpolation of the spot 10-year (2.01% as of 17-Nov-11) and 30-year (3.05% as of 17-Nov-11) treasury rates to reflect a 19 year forecast period
2. Predicted King Barra Beta as of 17-Nov-11

Project Royal

APPENDIX

Review of Management Scenarios (1)

Comparison of Current Key Assumptions (As of September 2011)

Management POS (Cumulative) (2):

Redacted

- PSI-7977 – 77%: 2021E
- PSI-938 – 34%: 2017E

- Management Case (previously Scenario A) represents management's view of the most probable scenario in light of recent developments in the Hepatitis C landscape

Overview of Assumptions

Scenario	Management Case NUC+NUC	Management Downside Case NUC+NUC	Management Upside Case NUC+NUC
Redacted			
PSI-7977			
Launch	2014	2014	2014
Peak Sales	$6.5Bn	$6.5Bn	$6.5Bn
Status	Wholly Owned	Wholly Owned	Wholly Owned
Royalty	Japan & BRICE Sales: 30%	Japan & BRICE Sales: 30%	Japan & BRICE Sales: 30%
PSI-938			
Launch	2015	2015	2015
Peak Sales	$3.1Bn	$3.1Bn	$3.1Bn
Status	Wholly Owned	Wholly Owned	Wholly Owned
Royalty	NA	NA	NA
Diagnosis (Dx) Rate	+10% Annually (2014+)	+10% Annually (2014+)	+10% Annually (2014+)
Treatment (Tx) Rate	Lower rate 2012-2013 (warehouse), 2x 2011 Rate 2014+	Lower rate 2012-2013 (warehouse), 2x 2011 Rate 2014+	Lower rate 2012-2013 (warehouse), 2x 2011 Rate 2014+
US Launch Date	GT2/3: 3Q14, GT1: 3Q14	GT2/3: 3Q14, GT1: 3Q14	GT2/3: 3Q14, GT1: 3Q14
EU Revenue Recognition	US + 6 months	US + 6 months	US + 6 months
US Price	$36,000	$36,000	$36,000
US Gross/Net	7.5% growing to 20% w/ competition	7.5% growing to 20% w/ competition	7.5% growing to 20% w/ competition
EU Price	67% of US price	67% of US price	67% of US price
Single Pill	Yes	Yes	Yes
G1 Nuc Share	90% at Peak	90% at Peak	90% at Peak
G1 King Share	60% at Peak	60% at Peak	60% at Peak
GT 2/3 King Share	80% (based on current data)	80% (based on current data)	80% (based on current data)

Notes
1. Based on King Management forecasts as of September 2011
2. POS assumptions applied to all Scenarios

Morgan Stanley

Exhibit 17

DRAFT

Preliminary and Confidential

898

Project Royal

Discussion Materials

6 October 2011

Issues for Board Consideration

- Perspectives on revised offer from Knight
- Determine whether revised offer is sufficient to further explore a potential sale of the Company
- Response / messaging to Knight
  - Value, consideration mix and other terms of offer
  - Next steps
- Merits of conducting a market check
  - Scope of market check / parties to be contacted
  - Sequencing of market check (now vs. later)
  - Messaging to parties
- Process and timeline to potentially announcing a transaction / conducting market check
  - Threshold for qualifying interest of other parties
  - Sequencing of diligence access

DRAFT

Preliminary and Confidential

Project Royal

Review of Knight Proposals

- Knight proposed to acquire all of the outstanding shares of King in a preliminary non-binding bid made on September 2, 2011
  - Knight's follow-on bid was received on [ ]

Summary of Proposed Terms

	Previous Offer (2-Sep-11)		Current Offer (TBD)
Price per Share	$100.00		
Consideration	100% Cash		
Metrics:			
Equity Value ($MM)	$8,011		
Aggregate Value ($MM)	$7,828		
Premiums on Date of Proposal	$64.20 (2-Sep-11)		
– Spot[1]	$64.20	56%	
– 30 Day Spot[1]	$59.89	67%	
– All Time Closing High	$68.49	46%	
– All Time Trading High	$68.91	45%	
– 1 Week VWAP	$65.93	52%	
– 1 Month VWAP	$59.42	68%	
– 3 Month VWAP	$58.79	70%	

Note
1. Spot price based on calendar days

Morgan Stanley

Business Proprietary Information – Confidential Treatment Requested

Project Royal

King Historical Share Price Performance

Last Twelve Months

- King share price has increased by 19% in the last month and 19% since receipt of offer
  - Recent data has been positively received by Street

Market Statistics [1]

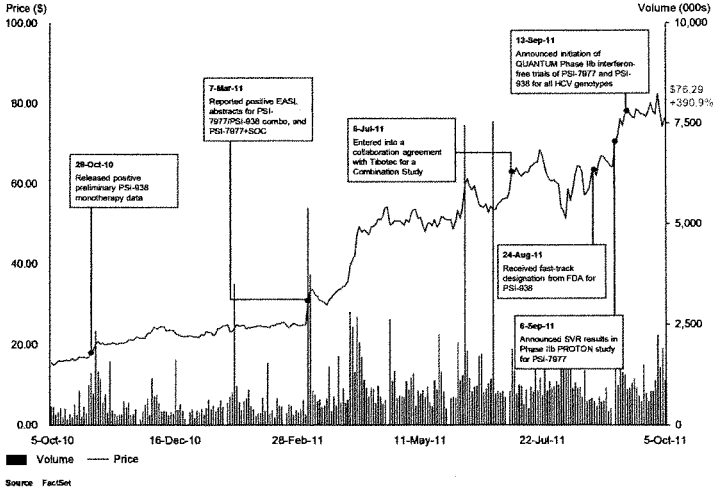
$MM, except per share data

Current Price (5-Oct-11)	$76.29
1-Month Spot Price (5-Sep-11)	$64.20
3-Month Spot Price (5-Jul-11)	$58.37
1-Month Average Price	$77.15
3-Month Average Price	$67.03
52 Week Closing Low (6-Oct-10)	$14.96
52 Week Closing High (30-Sep-11)	$82.37
All Time Closing High (30-Sep-11)	$82.37
All Time Trading High (30-Sep-11)	$85.32
Common Shares Outstanding	75.4
Fully Diluted Shares Outstanding	80.0
Fully Diluted Market Value	**6,102**
Cash & Cash Equivalents	188
Debt	4
Fully Diluted Aggregate Value	**5,918**

FYE 9/30	*Street Statistic*	
AV / CY'16 Revenue	1,359	4.4x
AV / CY'17 Revenue	2,609	2.3x
AV / CY'16 EBITDA	728	8.1x
AV / CY'17 EBITDA	1,821	3.2x

Share Price Performance

Last Twelve Months



Source FactSet

Note
1. Market data as of 5-Oct-11; balance sheet data as of latest filing; estimates based on Wall Street research

Morgan Stanley

Project Royal

Preliminary Summary of Indicative Analyses

As of 10/5/2011

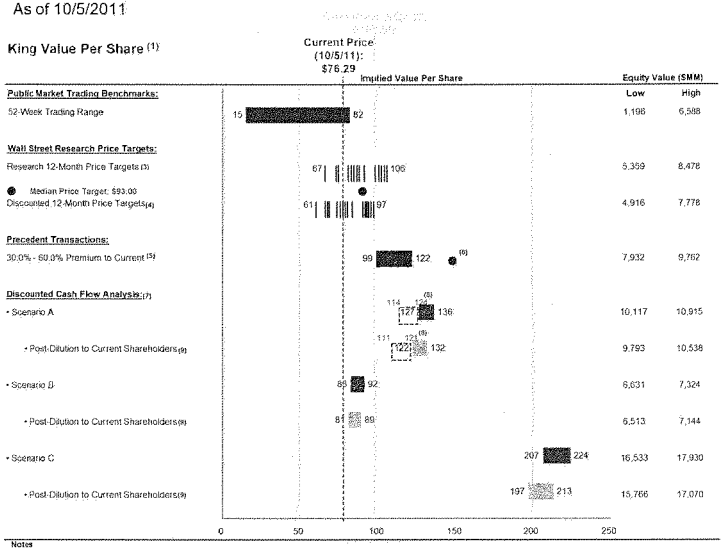
- Using current spot Treasury rates as a proxy for the risk free rate and assuming an equity risk premium of 4-6%, CAPM yields a theoretical WACC of 6.7% - 8.9% for King [10]
  - With a focus on the higher end of the risk premium range in light of the current market volatility, indicative analysis assumes a discount rate of 8.5% – 9.5%
  - Increasing the midpoint discount rate from 9.0% to 10.0% would decrease the value of Scenario A (post-dilution) by ~$9 per share[9]
- A one year delay in the launch of 7977 in Scenario A would decrease the value by ~$11 per share (post-dilution)
  - Further, a decrease in the treatment rate from 2.0x 2011 to 1.5x 2011 rates in Scenario A decreases the value by ~$8 per share (post-dilution)

Pricing Sensitivity - Base Case

$ / Share

Price per Unit - 938 \ Price per Unit - 7977	$24,000	$36,000	$50,000
$24,000	$84	$123	$168
$36,000	$93	$131	$177
$50,000	$103	$141	$188

King Value Per Share [1]



Notes

1. Rounded to the nearest whole $
2. Assumes 75.4MM shares outstanding plus dilutive effect of options and warrants as of 10/5/11
3. Reflects research updated post EASL
4. Discounted back to present at discount rate of 9.0%
5. Based on relevant precedent transaction analysis
6. Based on premium paid in Bristol-Myers Squibb acquisition of Medarex (90.5% = upper limit of precedents)
7. Twenty-year DCF valuation based on probability weighted company estimates; discount rate of 8.5%-9.5%; discounted to 6/30/2011
8. Represents sensitivity of one-year delay on FDA approval / launch of PSI-7977
9. Diluted shares outstanding assumes dilution from future equity financings at cost of equity of 9.0%: Scenario A & C - $360MM offering in 2012 at $78.29 / share; $100MM in 2013 at $83.16 / share; total equity financings equal $460MM; Scenario B - $360MM offering in 2012 at $76.29 / share; $280MM in 2013 at $83.16 / share; $50MM in 2014 at $90.64 / share; total equity financings equal $690MM
10. WACC calculation as of 5-Oct-11; Risk based on interpolation of 10-yr (1.81%) and 30-yr (2.77%) treasuries over 19 year forecast period and predicted Barra Beta as of 10/5/11

Morgan Stanley

DRAFT

Preliminary and Confidential

Project Royal

Illustrative Analytical Matrix

King

King Analytical Matrix (1)(2)

FYE 12/31

Purchase Price ($)	Current 5-Oct-11	Initial Offer Date 2-Sep-11	1 Week VWAP	1 Month VWAP	Premium 3 Month VWAP	All Time Closing High 30-Sep-11	All Time Trading High 9/29/2011	High Price Target	Median Price Target	Equity Value	Aggregate Value
Statistic	$76.29	$84.20	$77.94	$76.09	$87.16	$92.57	$95.32	$109.00	$93.00	9,102	9,916
$76.29	0%	19%	(2%)	(1%)	14%	(7%)	(11%)	(28%)	(18%)	6,102	5,916
$100.00	31%	56%	28%	30%	49%	21%	17%	(6%)	8%	8,011	7,828
$105.00	38%	64%	35%	37%	56%	27%	23%	(1%)	13%	8,414	8,230
$110.00	44%	71%	41%	43%	64%	34%	29%	4%	18%	8,817	8,633
$115.00	51%	79%	48%	50%	71%	40%	35%	8%	24%	9,220	9,036
$120.00	57%	87%	54%	58%	78%	48%	41%	13%	29%	9,622	9,438
$125.00	64%	95%	60%	63%	86%	52%	47%	18%	34%	10,025	9,841
$130.00	70%	102%	67%	70%	94%	58%	52%	23%	40%	10,428	10,244

Selected Precedent Transactions

Target / Acquiror	Date	Size ($Bn)	Premium to: 1-day	30-day	52-wk High
Commercial:					
Millennium / Takeda	4/10/2008	$8.2	05%	54%	45%
Imclone / Eli Lilly	10/8/2008	$6.4	51%	75%	42%
Pre-Commercial:					
New River / Shire	2/20/2007	$2.7	10%	15%	8%
Myogen / Gilead	10/2/2006	$2.2	50%	51%	24%
Medarex / BMS	7/22/2009	$2.1	90%	93%	58%

Notes

1. Market data as of 5-Oct-11; estimates based on Wall Street research
2. Assumes 75.4MM shares outstanding plus the dilutive effect of in-the-money options and warrants, and ($183.8MM) net debt, as of 30-Jun-11

Morgan Stanley

Business Proprietary Information – Confidential Treatment Requested

DRAFT

Preliminary and Confidential

Project Royal

Illustrative Knight Ability to Pay Analysis

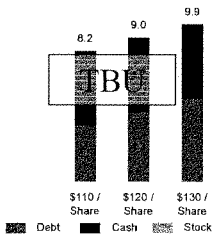
Knight Acquisition of King

- Knight is currently rated Baa1/A-

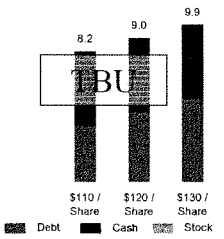
Credit Review

1. Scenario 1:
   - 85% of current cash and 60% of cash and future cash flow reside ex-U.S.
   - Repatriation costs of 0%
   - Knight finances acquisition with 100% cash consisting of current U.S. / ex-U.S. cash and senior notes at 4.5%
2. Scenario 2:
   - 85% of current cash and 60% of cash and future cash flow reside ex-U.S.
   - Repatriation costs of 0%
   - Knight finances acquisition with 75% cash consisting of current U.S. / ex-U.S. cash and senior notes at 4.5%, and 25% equity
3. Scenario 3:
   - 85% of current cash and 60% of cash and future cash flow reside ex-U.S.
   - Repatriation costs of 0%
   - Knight finances acquisition with 50% cash consisting of current U.S. / ex-U.S. cash and senior notes at 4.5%, and 50% equity

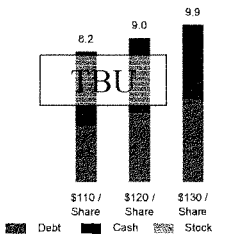
Sources of Financing (1)
$Bn



Sources of Financing (1)
$Bn



Sources of Financing (1)
$Bn



	Scenario 1	Scenario 2	Scenario 3
S&P	BBB+ BBB+ BBB+	BBB+ BBB+ BBB+	BBB+ BBB+ BBB+
Moody's	Baa1 TBU Baa2 Baa2	Baa1 TBU Baa2 Baa2	Baa1 TBU Baa2 Baa2
Outlook	Neg -- --	Neg -- --	Neg -- --

Note

1. All scenarios assume $1Bn operating cash and were run at prices of $110, $125 and $140 per share for management Case A (as of September 2011) and Street case for Knight

Morgan Stanley

Business Proprietary Information -- Confidential Treatment Requested

Economic Impact to Knight

- In a transaction financed with 25% equity, Knight would require approximately 0.4-0.6x P/E multiple expansion to restore share price to stand alone levels
- In a transaction financed with 50% equity, Knight would require approximately 0.8-1.1x P/E multiple expansion to restore share price to stand alone levels

Economic Impact to Knight

Management Case: A ; $110.00 / Share	2012E	2013E	2014E	2015E	2016E	2017E	2012 P/E Multiple Expansion
100% cash; all ex-U.S. cash repatriated at 0% tax							
Accretion / (Dilution) Impact	(9%)	(8%)	11%	51%	75%	62%	
Leverage Ratio	2.0x	1.7x	1.1x	0.7x	0.5x	0.5x	
75% cash; all ex-U.S. cash repatriated at 0% tax							
Accretion / (Dilution) Impact	(13%)	(12%)	5%	42%	64%	52%	0.4x
Leverage Ratio	1.4x	1.2x	0.7x	0.5x	0.3x	0.3x	
50% cash; all ex-U.S. cash repatriated at 0% tax							
Accretion / (Dilution) Impact	(17%)	(16%)	(0%)	34%	55%	43%	0.8x
Leverage Ratio	1.0x	0.8x	0.4x	0.3x	0.1x	0.1x	

Management Case: A ; $120.00 / Share	2012E	2013E	2014E	2015E	2016E	2017E	
100% cash; all ex-U.S. cash repatriated at 0% tax							
Accretion / (Dilution) Impact	(10%)	(9%)	10%	50%	74%	61%	
Leverage Ratio	2.1x	1.8x	1.2x	0.8x	0.6x	0.6x	
75% cash; all ex-U.S. cash repatriated at 0% tax							
Accretion / (Dilution) Impact	(14%)	(13%)	4%	41%	63%	51%	0.5x
Leverage Ratio	1.6x	1.3x	0.8x	0.5x	0.3x	0.4x	
50% cash; all ex-U.S. cash repatriated at 0% tax							
Accretion / (Dilution) Impact	(18%)	(17%)	(2%)	33%	53%	42%	0.9x
Leverage Ratio	1.0x	0.8x	0.4x	0.3x	0.1x	0.1x	

Management Case: A ; $130.00 / Share	2012E	2013E	2014E	2015E	2016E	2017E	
100% cash; all ex-U.S. cash repatriated at 0% tax							
Accretion / (Dilution) Impact	(11%)	(9%)	9%	50%	74%	61%	
Leverage Ratio	2.3x	2.0x	1.4x	0.9x	0.6x	0.7x	
75% cash; all ex-U.S. cash repatriated at 0% tax							
Accretion / (Dilution) Impact	(16%)	(14%)	3%	39%	61%	49%	0.6x
Leverage Ratio	1.7x	1.4x	0.9x	0.6x	0.4x	0.4x	
50% cash; all ex-U.S. cash repatriated at 0% tax							
Accretion / (Dilution) Impact	(19%)	(18%)	(3%)	31%	51%	40%	1.1x
Leverage Ratio	1.1x	0.9x	0.5x	0.3x	0.2x	0.2x	

Review of Potential Acquirors

Potential Acquirors [1]

$Bn

Company	Market Cap	Total Cash	Total Debt	Net Debt	Agg. Value	Credit Rating Moody's / S&P	Commentary	5 Largest Acquisitions (Last 15 Yrs)	Illustrative Cash EPS Accretion / (Dilution) [2] 2012	2016
Knight [3]	31	5	4	(1)	29	Ba3 / A-	• Proposal made on September 2, 2011	• Mycogen - $2.2Bn - 10/00 • CV Therapeutics - $1.7Bn - 3/09 • Cardiogen - $0.3Bn - 3/11 • Nicholas - $0.5Bn - 3/09 • Triangle - $0.5Bn - 12/02	(10%)	30%
Tier I										
Roche	133	9	28	19	153	A2 / AA-	• Existing relationship	• Genentech - $46.7Bn - 8/09 • Ventana Medical - $3.4Bn - 8/07 • Smithkline Beecham (rights to Kytril and Cotem) - $1.6Bn - 8/00 • IGEN Int'l - $1.2Bn - 7/03 • Chugai (10% stake) - $0.9Bn - 11/06	(2%)	13%
MERCK	98	16	18	2	100	A1 / AA	• Previously demonstrated interest	• Schering Plough - $50.7Bn - 3/09 • Banyu - $1.5Bn - 1/03 • Sirna - $1.1Bn - 10/06 • Rosetta Inpharmatics - $0.5Bn - 5/01 • Dev/Mktg Rights of Ridaforolimus - $0.8Bn - 5/10	(2%)	16%
Abbott A Promise for Life	81	9	13	4	85	A1 / AA	• Commitment to HCV but compounds are earlier stage than leading companies • Significant recent acquisition activity	• Solvay - $7.7Bn - 9/09 • BASF AG - $7.1Bn - 12/00 • Abbott Liestal AG - $8.9Bn - 12/00 • Guidant (Vascular/Intervascular Business) - $4.6Bn - 1/06 • Kos Pharma - $3.7Bn - 11/06	(3%)	20%
Bristol-Myers Squibb	57	11	6	(5)	52	A2 / A+	• Strong commitment to HCV; significant financial capacity • $7.7Bn of $10.6Bn of cash is held in the U.S.	• DuPont Pharma - $7.6Bn - 6/01 • Medarex - $2.1Bn - 7/09 • Alder - $1.1Bn - 11/06 • ImClone (19.9% stake) - $1.0Bn - 9/01 • ZymoGenetics - $0.9Bn - 9/10	(8%)	55%
Tier II										
Johnson & Johnson	173	22	19	(4)	169	Aaa / AAA	• Strong acquisition rationale, but historically has not been involved in competitive processes • Potentially distracted by recent Synthes acquisition • If endeavor to maintain AAA rating, constrained on use of leverage	• Synthes - $21.5Bn - 5/11 • Pfizer Consumer Ltd - $16.6Bn - 6/06 • ALZA - $13.9Bn - 3/01 • Centocor - $5.9Bn - 7/99 • DePuy - $3.9Bn - 7/98	(1%)	11%
NOVARTIS	134	6	28	22	156	Aa2 / AA-	• Have publicly stated $50bn size limit for acquisitions • Have HCV assets, but commitment may not be as great as other pharma companies	• Alcon (52.2% stake) - $28.9Bn - 1/10 • Alcon (23.6% stake) - $11.6Bn - 1/10 • Alcon (initial 24.8% stake) - $10.8Bn - 4/08 • Chiron - $8.4Bn - 8/05 • Hexal - $5.7Bn - 2/05	(3%)	15%

Notes

1. Market data as of 5-Oct-11
2. Based on calendar year I/B/E/S median estimates as of 10/5/11; purchase price of $120 / share financed with combination of cash and debt at 4.0%; JNJ (100% Cash); NOVN (51% Cash / 49% Debt); ROG (88% Cash / 12% Debt); MRK (100% Cash); ABT (69% Cash / 29% Debt) ; BMY (69% Cash / 31% Debt); ; assumes operating cash at 15% of cash; assumes synergies at 30% of King SG&A;
3. Assumptions based on scenario 1 on page 7 at $120 per share

Perspectives on Messaging

Illustrative Talking Points

To Knight		To Other Parties if Board Authorizes a Market Check
If Offer is not Sufficient to Warrant Further Consideration	**If Offer is Sufficient to Warrant Further Consideration**	
• Revised offer not at level where Board is inclined to continue discussions • Disappointed your revised offer wasn't more reflective of the intrinsic value we see in the business in light of the new information we shared with you • Confident in our standalone prospects and continue to believe news flow in the near-term will have a materially positive impact on our share price • To the extent your perspective on value meaningfully changes, our Board would not be opposed to considering a revised proposal • In the absence of this, they've instructed us to focus on running the business	• Board did not reach a decision on willingness to entertain a sale of the company at your revised offer • We think there is more value here than you are showing us • However, Board thinks there's merit to further exploring a potential transaction and has authorized us to continue our discussions • As you know, other parties have expressed strategic interest in our company in the past • In light of this and our board's focus on their fiduciary duties, they've directed us and our advisors to contact others • Given our desire to limit the disruption to our business and quickly assess whether there's a path to a transaction, this will be a focused and efficient process • Objective is to bring process to a conclusion at some point following AASLD	• Recently received an unsolicited proposal to buy the company • While the board has made no decision to sell, the proposal is from a credible party and at a level consistent with biotech precedent premiums • In light of this, Board has directed us to contact a very focused list of parties to assess their interest • Process will require you to move quickly and confidentially and price a deal at a meaningful premium to our current trading level • Discuss next steps if interested in proceeding

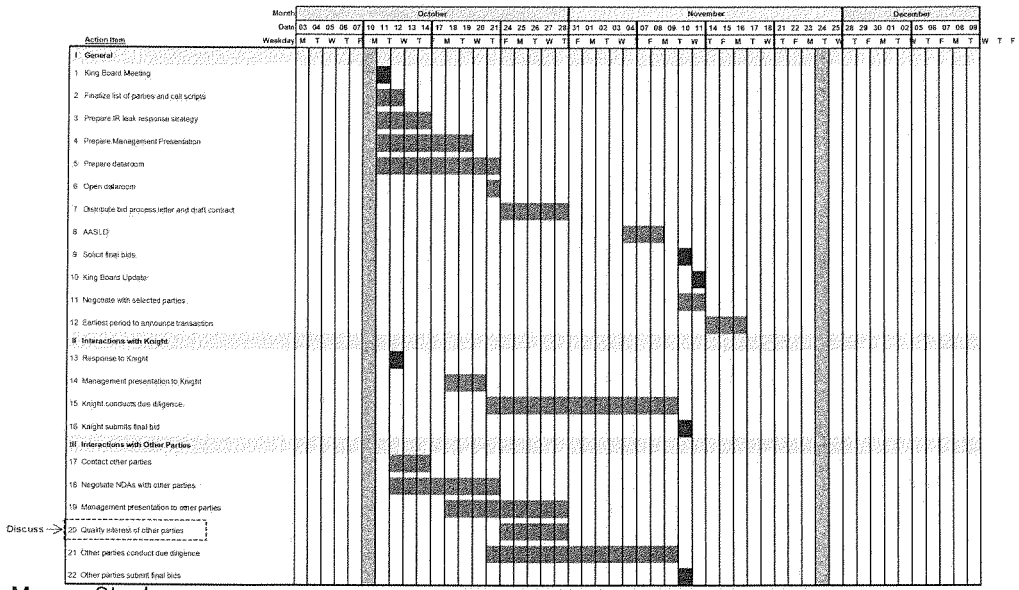
DRAFT

Preliminary and Confidential

Project Royal

Illustrative Process Timeline

Accelerated Version – Assumes Market Check Commenced Immediately



Morgan Stanley

11

Project Royal

Management Presentation Outline

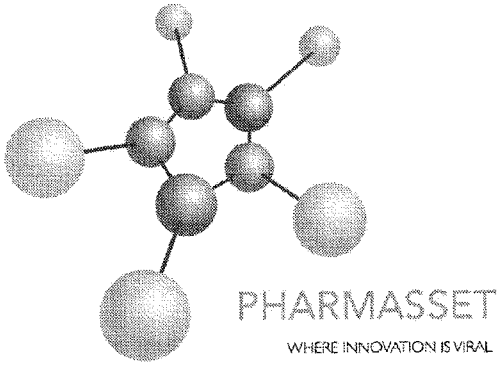
- The Management Presentation will be designed to provide a comprehensive overview of the Company
  - Can be customized for each party

- Company Overview
- Management Team / Organizational Structure
- Detailed Description of Pipeline
  - Summary of Each Drug
  - Key Historical Data
  - Current Studies
  - AASLD Abstracts
  - Key Milestones
- Market Overview
  - Paradigm Shift
  - Market Size
  - Market Opportunity
  - Competitors
- IP
- Regulatory
- Manufacturing
- Financial Summary
- Q&A

Morgan Stanley

Business Proprietary Information – Confidential Treatment Requested

Exhibit 18


PHARMASSET
WHERE INNOVATION IS VIRAL

Management and Employees

Schaefer Price

PHARMASSET

Pharmasset Board of Directors

- Herbert J. Conrad, Chairman of the Board
  - Former President, Roche Pharmaceuticals Division
  - Member of Audit Committee and Nominating and Corporate Governance Committee
- William J. Carney, Esq., Independent Director
  - Professor, Emory University School of Law, Atlanta, GA
    - DE corporate law, M&A
  - Chair of the Nominating and Governance Committee and Member of the Audit Committee
- Elliot F. Hahn, Ph.D., Independent Director
  - Chairman, ACCU-BREAK Pharmaceuticals, Plantation, FL, ex-Andrx
  - Member of Nominating and Governance Committee and Compensation Committee
- Michael K. Inouye, Independent Director
  - Life Sciences Consultant, San Ramon, CA
  - Member of Nominating and Governance Committee and Compensation Committee
- P. Schaefer Price, Director
  - President and Chief Executive Officer, Pharmasset, Princeton, NJ
- Robert F. Williamson III, Independent Director
  - Life Sciences Consultant, Piedmont, CA
  - Chair of Audit Committee and Chair of Compensation Committee

Please visit www.pharmasset.com for additional details

PHARMASSET

Pharmasset Executive Management

- P. Schaefer Price, President and Chief Executive Officer, Director
  - Previously Executive in Residence at Bay City Capital and President of PowderJect Vaccines
- Kurt Leutzinger, Executive Vice President and Chief Financial Officer
  - Formerly Chief Financial Officer at Abgenix, Inc.
- M. Michelle Berrey, MD, Chief Medical Officer
  - Formerly Vice President, Viral Diseases, Clinical Pharmacology & Discovery Medicine at GlaxoSmithKline
- Michael J. Otto, Chief Scientific Officer
  - Formerly Associate Director, Anti-infectives Clinical Research at Rhone-Poulenc Rorer and Vice President for Research & Development at Avid Therapeutics
- Michael D. Rogers, Chief Development Officer
  - Formerly Vice President, Division of Viral Diseases at GlaxoSmithKline
- Patrick T. Higgins, Executive Vice President, Marketing & Sales
  - Formerly Vice President, Sales & Marketing, Virology at Hoffman-LaRoche, Inc. and former executive at Schering Plough
- Abel De La Rosa, Senior Vice President, Business Development and Scientific Affairs
  - Formerly Vice President of Product Development and Director of Strategic Marketing and Latin American Business at Visible Genetics Inc.

Please visit www.pharmasset.com for additional details

PHARMASSET

Pharmasset Executive Management

continued

- Bill Symonds, Senior Vice President, Clinical Pharmacology and Translational Medicine
  - Formerly Director, Antiviral Discovery Medicine at GlaxoSmithKline
- Bryce Roberts, Vice President, Senior Counsel and Secretary
  - Formerly Law Student at Georgia State University of Law
- Mark Meester, Chief Administrative Officer
  - Formerly Director, Finance at Mirus Bio and Vice President of Finance at PowderJect Vaccines
- Michael J. Sofia, Vice President, Chemistry
  - Formerly Group Director, New Leads Chemistry at Bristol Myers Squibb
- Philip A. Furman, Vice President, Biological Sciences
  - Formerly Chief Scientific Officer at Triangle Pharmaceuticals, Inc., ex- Burroughs Wellcome co.
- Richard Smith, Vice President, Investor Relations and Corporate Communications
  - Formerly Vice President, Senior Analyst US Biotechnology at JP Morgan Securities
  - PhD. Oxford, Virology
- Robert Hindes, Vice President, Clinical Development
  - Formerly Group Director, Virology, Global Clinical Research at Bristol Myers Squibb

PHARMASSET

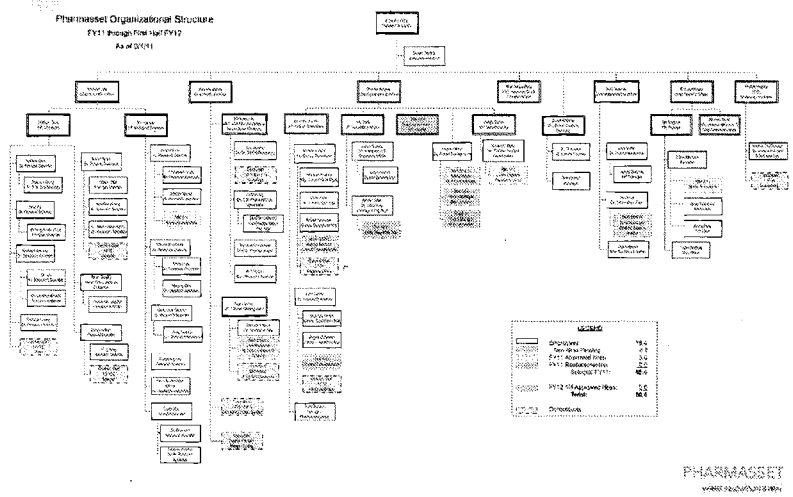
Pharmasset Executive Management
continued

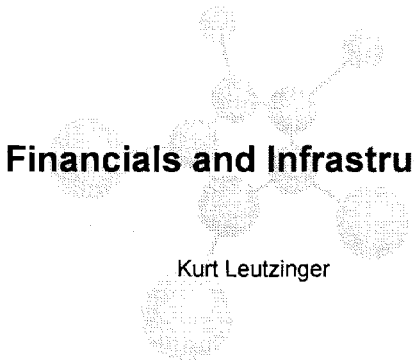
- Kevin Kucharski, Vice President, Clinical Operations
  - Formerly Senior Director, Clinical Operations at ALTANA Pharma
- Joseph S. Sonk, Vice President, Regulatory Affairs
  - Formerly Senior Vice President at Mannkind Pharmaceuticals and former regulatory executive at Berlex Biosciences and Wyeth
- Darryl Cleary, Vice President, Manufacturing
  - Formerly consultant and Senior Research Scientist at Triangle Pharmaceuticals, Inc.
- Jim McGuire, Vice President, Finance
  - Formerly Senior Vice President at Vonage Holdings, Inc.

PHARMASSET

Pharmasset Organizational Chart

As of 9/1/2011, through fiscal 1H12





Financials and Infrastructure

Kurt Leutzinger

PHARMASSET

WHERE INNOVATION IS VIRAL

P&L – Estimated

Fiscal Year Ended 9.30 (in thousands)

	2011
Net Revenue	$898
R&D	$70,697
G&A	$13,133
Total Operating Expense	$83,830
Net Interest Expense	$893
Net Loss	($83,825)

Note – Above does not include non-cash stock compensation or interest expense.

PHARMASSET

Expense Detail – Estimated

Fiscal Year Ended 9.30 (in thousands)

		2011
Research (Internal)	Administration	$3,203
	Chemistry	$3,762
	Biology	$2,396
	Virology	$273
	Facilities – R&D	$833
Research (Contract)		$1,754
Development (Internal)	Administration	$555
	Clinical Development	$2,429
	Clinical Operations	$1,381
	Regulatory Affairs	$1,098
	Quality	$0
	Project Management	$238
	Manufacturing	$445
Development (Contract) – PSI-7977	Preclinical	$728
	Phase 1 Clinical	$4,765
	Phase 2 Clinical	$18,618
	Phase 3 Clinical	$742
	Manufacturing	$10,339
	Toxicology Studies	$2,452
Development (Contract) – PSI-938	Preclinical	$834
	Phase 1 Clinical	$5,035
	Phase 2 Clinical	$2,251
	Manufacturing	$3,986
	Toxicology Studies	$1,311
Development (Contract) – PSI-661		$1,289
Total R&D		$70,697
General and Administrative	Marketing	$1,841
	Legal	$2,629
	CEO	$1,978
	Business Development	$595
	Human Resources	$514
	Finance	$4,458
	Investor Relations	$539
	Information Technology	$716
	Facilities - Administration	$163
Total G&A		$13,133
Total Operating Expenses		$83,830

PHARMASSET

Cash Flow – Estimated

Fiscal Year Ended 9.30 (in thousands)

	2011
Cash @ 10.1.10	$127,100
Equity Financing	$123,351
Operating Expenses	($83,830)
Option Exercise Proceeds	$10,500
Depreciation	$400
Net Interest Expense	($893)
Capital Expenditures	($875)
Debt Repayments	($9,191)
Cash @ 9.30.11	$166,562

PHARMASSET

Fully Diluted Shares

- Shares outstanding: 75,495,986
- Options outstanding: 5,144,786 @ $8.45 ($43.4 MM)
- Option grant 10.10.11: 1,477,800 @ $80.00 ($118.2 MM)
- Fully diluted shares: 81,871,310

PHARMASSET

Severance Cost

- Double trigger
  - Change of Control
  - Involuntary Termination
- Salary + Target Bonus + Benefits
  - CEO: 20 months
  - CEO's Direct Reports: 12 months
  - All Others: 2-6 months
- Total Severance:
  - CEO + Direct Reports: $ 6.0 MM
  - All Others: $ 5.8 MM
  - Total: $11.8 MM

PHARMASSET

Minimum Option Purchase by Acquirer

- CEO and 8 direct reports potential Involuntarily Termination as defined in Change of Control Agreement
- 3,531,033 options held by the group
- $20.97 average weighted exercise price = $74.1 MM

PHARMASSET

Infrastructure

- Princeton Lease: 30,800 SF (12,000 lab & 18,000 office)
  - $836,000/year through 5.22.15
- Durham Lease: 3,880 SF (office)
  - $84,000/year through 12.31.15
- Great Plains accounting system
- Microsoft environment with VMWare
- Comcast fiber optic (50 Mbps)
- Cisco switch
- ShoreTel telephone system
- ChemCart lab IT system with electronic lab notebooks

PHARMASSET

Preclinical, Clinical and Regulatory Review

Michelle Berrey

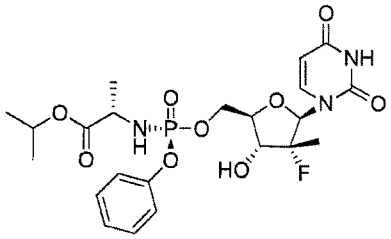
PHARMASSET

Manufacturing: PSI-7977 and PSI-938
Drug Substance and Drug Product Overview

Schaefer Price

PHARMASSET
WHERE INNOVATION IS REAL

PSI-7977 API Manufacturing

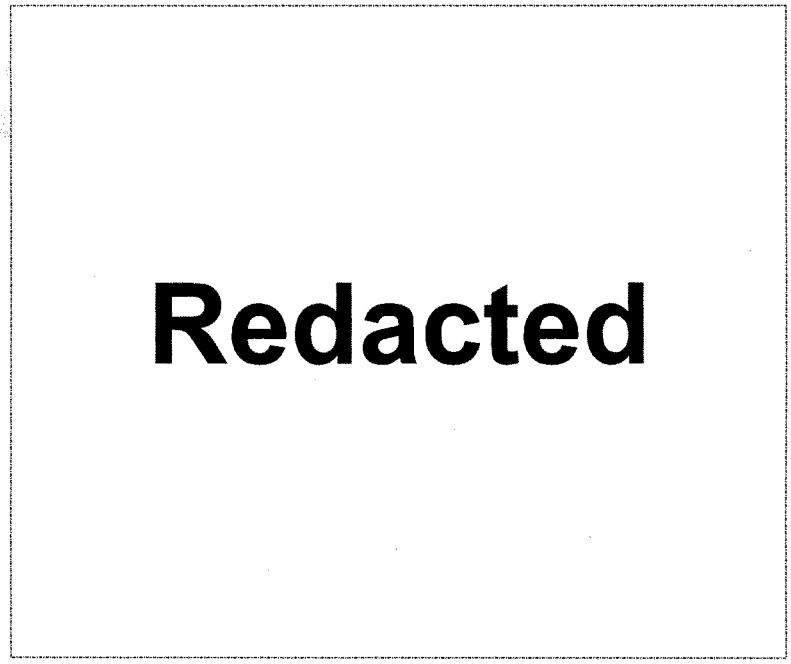


PHARMASSET

Redacted

Redacted

Redacted


Redacted

Redacted

Redacted

Ongoing Improvements in Manufacturing

New Process: **Redacted**

Redacted

- New [Redacted] chemistry should reduce cost by 66% (from $32,000 to ~$ 11,000)

Redacted

PHARMASSET

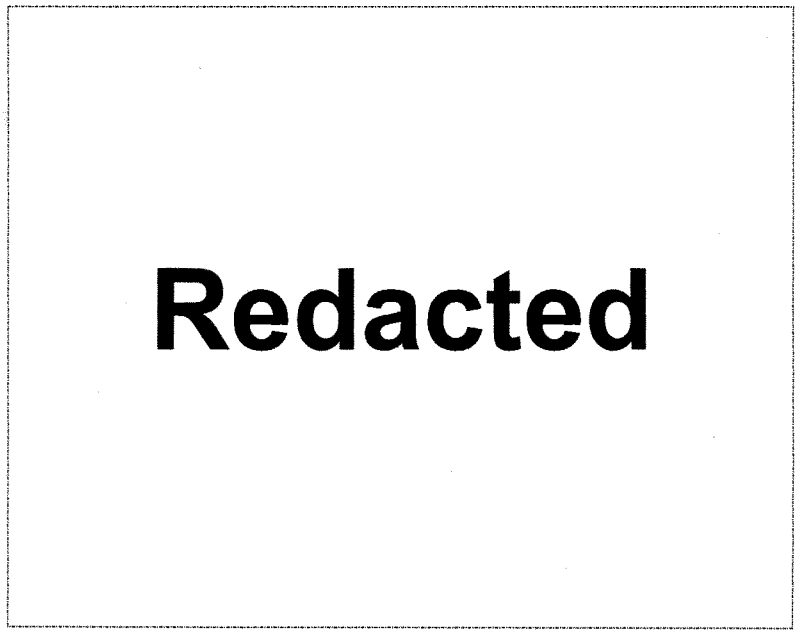
Redacted

PSI-7977 Drug Product Manufacturing

Final commercial presentation with different color

PHARMASSET

Redacted


Redacted

Redacted

Redacted

PSI-7977 Drug Product Summary

- PSI-7977 drug product is currently manufactured at Metrics (Greenville, NC)
- Robust dry granulation process produces 400mg caplet (1200mg total weight) which are subsequently film coated
- Drug Product is produced in 150,000 caplet batches
- DP manufacturing cost is ~$1.00/caplet or ~$30/30 count bottle (reduced when manufacturing at commercial scale).

PHARMASSET

Key milestones

- Production of 400 mg caplet with final embossing scheduled to begin December 2011
- Registration batch of the Drug Product (400 mg strength) will be made after the Registration Batch for the PSI-7977 API is produced (~ 2Q(calendar) 2012)

PHARMASSET

PSI-7977 12 week Regimen Cost of Goods

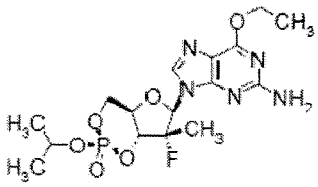
Price per Course of Therapy

API Cost/kg	$50,000	$40,000	$30,000
$32,000	2.3%	2.9%	3.9%
$11,000	0.9%	1.1%	1.5%

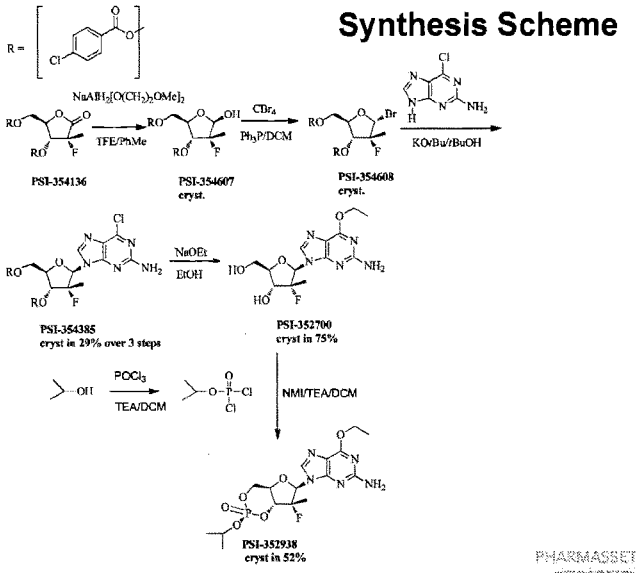
Assumptions:
- Every patient (all genotypes) is treated with 12 week 400mg QD regimen – 84 caplets
- Regimen manufacturing cost (84 caplets) is $370 @ $11,000/Kg and $1075 @ $32,000/Kg
- Drug product cost is ~$1 per 400mg caplet
- API cost and price of therapy indicated above

PHARMASSET

PSI-352938 API Manufacturing



PHARMASSET


Synthesis Scheme
R =
NaAlH2[O(CH2)2OMe]2
TFE/PhMe
CBr4
Ph3P/DCM
KOtBu/tBuOH
PSI-354136
PSI-354607
cryst.
PSI-354608
cryst.
NaOEt
EtOH
PSI-354385
cryst in 29% over 3 steps
PSI-352700
cryst in 75%
POCl3
TEA/DCM
NMI/TEA/DCM
PSI-352938
cryst in 52%

PHARMASSET

Current Status of 938 Manufacturing

- Manufactured at ST Pharm
- Current process is reliable and has produced single batches up to 37 kgs
- A total of 5 batches were made which met all the specifications (see next slide)
- 938 is isolated in high purity via crystallization
- Synthesis has more steps than PSI-7977 and not yet optimized
- Small-scale preps are not predictive of larger scale runs
- Cost of goods is ~ $39,000/kg

PHARMASSET

Batch Manufacturing Summary

Batch no.		41409001	4141001	41410002	4141003	41411001
Batch size (Kg)		3.1 kg	11 kg	21.4 kg	24.0 kg	36.3 kg
Date of Manufacture		11-Aug-2009	06-May-2010	17-Jun-2010	20-Oct-2010	20-Feb-2011
Site of Manufacturing		Sanchully, S. Korea	Sanchully, S. Korea	Sanchully, S. Korea	Sanchully, S. Korea	Sanchully, S. Korea
Use		Development, stability, tox., clinical	Development, stability, tox., clinical	Stability, Tox.	Clinical	Clinical
Test Method	Proposed Specification	Results				
Description	White to off-white solid	Conforms	Conforms	Conforms	Conforms	Conforms
Identification – HPLC	Main peak t_R consistent with reference	Conforms	Conforms	Conforms	Conforms	Conforms
Identification – FTIR	Conforms with reference standard	Conforms	Conforms	Conforms	Conforms	Conforms
Assay, as is	Report	99.3%	99.9%	99.8%	100.4%	99.5%
Assay, corrected	98.0-102.0% (w/w %)	99.5%	99.9%	99.8%	100.4%	99.5%

PHARMASSET

Accelerated Stability of PSI-938 API

Lot Number:	41409001	Container Closure:	Double PE bag/fiber drum	Storage Condition:	40°C/75% RH
Manufacturer:	ST Pharm	Manufacture Date:	08/11/2009	Study Initiation:	12/14/2009

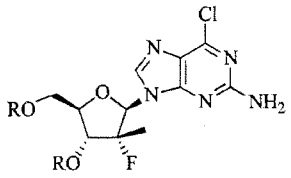
Test Items	Specification	Initial	1 month	3 months	6 months
Description	White to off-white solid	Conforms	Conforms	Conforms	Conforms
Assay, as is	Report	99.30%	99.52%	99.41%	99.02%
Assay, corrected	98.0-102.0% (w/w)	99.32%	99.56%	99.33%	99.22%
Impurities					
- PSI-352939	NMT 0.9%	0.27%	0.17%	0.06%	0.04%
- Unspecified impurities	Report all impurities >0.05%	RRT 1.29 = 0.06% RRT 1.48 = 0.12%	RRT 1.48 = 0.10%	RRT 1.49 = 0.07%	RRT 0.93 = 0.05% RRT 1.29 = 0.08% RRT 1.61 = 0.06%
- Total impurities	NMT 2.0%	0.60%	0.37%	0.30%	0.32%
Water content	Report (wt%)	0.01%	0.05%	0.08%	0.20%

Based on this information, a 2 years expiry date can be assigned

PHARMASSET

Proposed RSM

- The proposed RSM for PSI-938 is PSI-354385 for the following reasons:
  - It provides more predictable chirality in PSI-938
  - It is more stable
  - It has higher purity as compared to lactone



PSI-354385

PHARMASSET

PSI-938 Drug Product Manufacturing

Final commercial presentation with different color
The size and shape will be identical to PSI-7977 with "2" instead of "1"

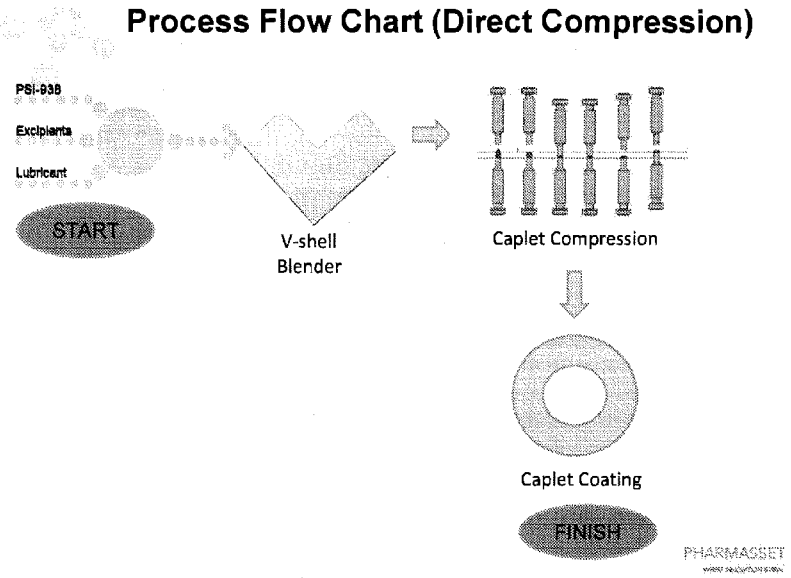
PHARMASSET

Caplet Formulation (for Direct Compression Manufacturing)

PSI-938 Caplet Composition (300 mg)

Component	Function	% Composition	Quantity/Dose Unit (mg/caplet)
PSI-352938	Active	25.00%	300.0
Lactose Monohydrate (foremost 316 Fast Flo) NF/EP	Filler	43.25%	519.0
Microcrystalline Cellulose (Avicel PH-102) NF/EP	Filler	25.00%	300.0
Croscarmellose Sodium (Ac-Di-Sol SD-711) USP/NF/EP	Disintegrant	5.00%	60.0
Sodium LAuryl Sulfate NF/EP	Surfactant	1.00%	12.0
Colloidal Silicon Dioxide (Cab-O-Sil M-5P) NF/EP	Glidant	0.25%	3.0
Magnesium Stearate (non-bovine Hyqual) NF/EP	Lubricant	0.5%	6.0
Caplet Core Total		100.0%	1200.0
Cosmetic Coating			
Opadry II, 85F18422, White	Film-coat	3.0%	36.0
Purified Water, USP	Solvent	-*	-*
Coated Caplet Total			1236.0

PHARMASSET

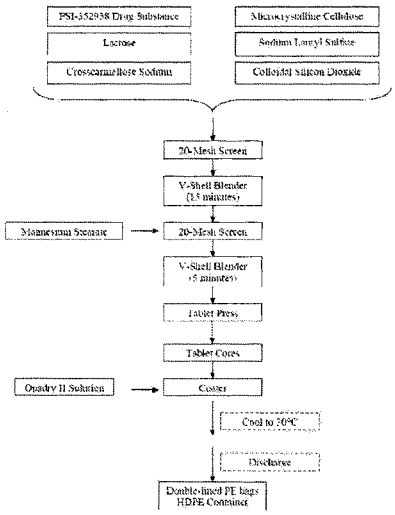

Process Flow Chart (Direct Compression)
PSI-938
Excipients
Lubricant
START
V-shell
Blender
Caplet Compression
Caplet Coating
FINISH
PHARMASSET

Description of Manufacturing Process (Direct Compression)

1. The PSI-352938 drug substance, lactose, microcrystalline cellulose, croscarmellose sodium, sodium lauryl sulfate, and colloidal silicon dioxide are passed through a 20-mesh screen.
2. The screened mixture is charged into a V-shell blender and blended for 15 minutes.
3. Magnesium stearate is passed through a 20-mesh screen and charged into the V-shell blender. Blending continues for an additional 5 minutes.
4. Blend uniformity samples are removed and the remaining blend is discharged into a container double-lined with clean polyethylene bags.
5. The final blend is fed into a tablet press for compression and tablet core production.
6. The film coat solution is prepared by mixing purified water and Opadry II for no less than 45 minutes
7. Tablet cores are separated into two approximately equal portions
8. One portion of the tablet cores is loaded into the 30-inch pan of the coater.
9. Tablets are pre-warmed for approximately five minutes at 55°C. The mean weight of ten warmed tablets is recorded.
10. A film-coat is applied to the warmed core tablets to a weight gain of approximately 3% w/w
11. Tablets are cooled until the exhaust temperature reached 30°C and then discharged into HDPE drums lined with double polyethylene bags.
12. Steps 8 through 11 are repeated for the second portion of tablet cores.

PHARMASSET

Process Flow Chart (detailed)



PHARMASSET

Accelerated Stability of 100 mg Caplets

Product Name:	**PSI-352938 Tablets, 100 mg**	**Manufacture Date:**	**August 20, 2010**	**API Lot:**	**41410001**
Product Lot:	**09/1472-33**	**Container/Closure :**	**HDPE Bottle (30-ct) w/induction seal CRC**	**Storage Condition :**	**40°C/75% RH**
Manufacturer :	**Metrics, Inc.**	**Packager:**	**Metrics, Inc.**	**Study Start Date:**	**September 22, 2010**

Test	Initial	1 month	2 months	3 months	6 months
Appearance	White, plain, elongated tablets	White, plain, elongated tablets	White, plain, elongated tablets	White, plain, elongated tablets	White, plain, elongated tablets
Assay	101.9%	98.3%	99.1%	97.8%	99.3%
Related Substances					
Unknown RRT 0.33	0.07%	0.07%	0.06%	0.05%	<0.06%
Unknown RRT 1.24	0.18%	0.16%	0.14%	0.13%	0.09%
Unknown RRT 1.26	ND	ND	0.05%	0.05%	0.06%
Unknown RRT 1.47	0.06%	0.05%	0.06%	0.05%	<0.06%
Unknown RRT 1.52	0.14%	0.13%	0.13%	0.12%	0.08%
Total Impurities	0.45%	0.41%	0.44%	0.40%	0.32%
Dissolution	Meets requirement	Meets requirement	Meets requirement	Meets requirement	Meets requirement

Based on the above information a 2 year expiry can be expected

PHARMASSET

PSI-938 Drug Product Summary

- PSI-938 drug product is currently manufactured at Metrics (Greenville, NC)
- Robust Direct Compression process produces 300mg caplet (1200mg total weight) which are subsequently film coated
- Drug Product batch size will be 150,000
- Drug Product batch size can be increased significantly
- Cost of drug product manufacturing can be $1 or less per caplet

PHARMASSET

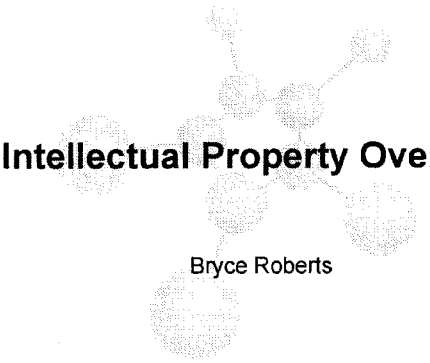
PSI-938 12 week Regimen Cost of Goods

Price per Course of Therapy

API Cost/kg	$50,000	$40,000	$30,000
$39,000	2.1%	2.7%	3.6%
$25,000	1.4%	1.8%	2.4%
$20,000	1.2%	1.5%	2.0%

Assumptions:
- Every patient (all genotypes) is treated with 12 week 300mg QD regimen – 84 caplets
- Regimen manufacturing cost (84 caplets) is $504 @ $20,000/Kg, $630 @ $25,000 and $983 @ $39,000/Kg
- Drug product cost is ~$1 per 400mg caplet
- API cost and price of therapy indicated above

PHARMASSET



Intellectual Property Overview

Bryce Roberts

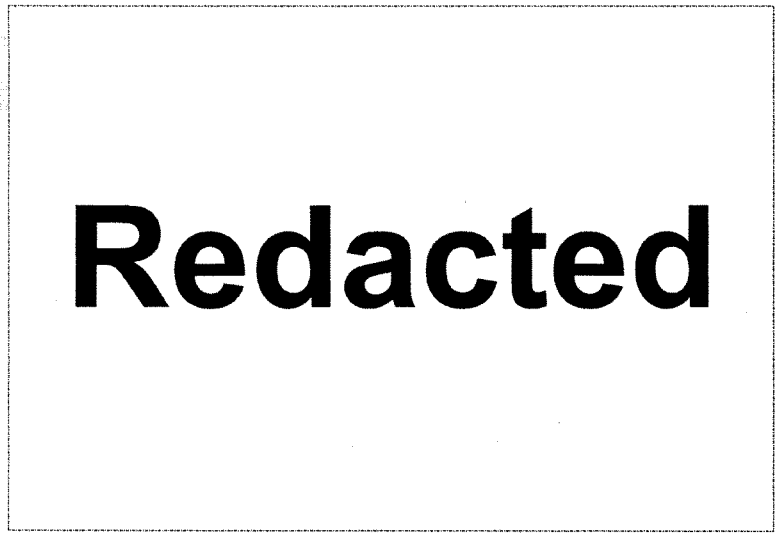
PHARMASSET
WHERE INNOVATION IS VIRAL

Redacted

PHARMASSET

Redacted

PHARMASSET



PHARMASSET

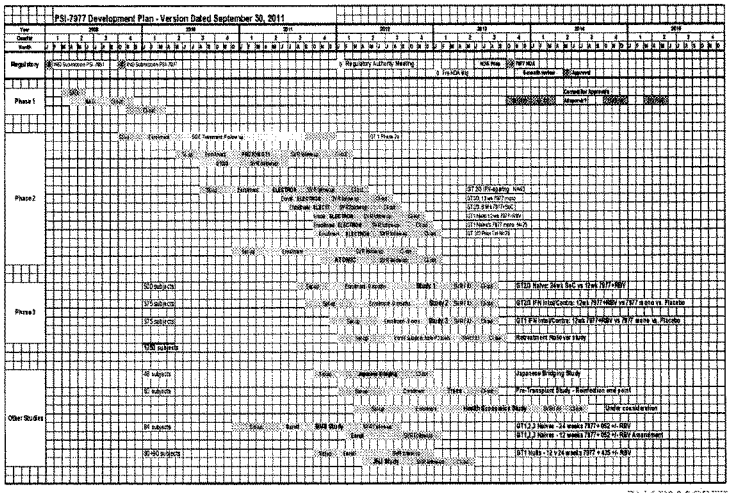
Commercialization Strategy

Schaefer Price

PHARMASSET

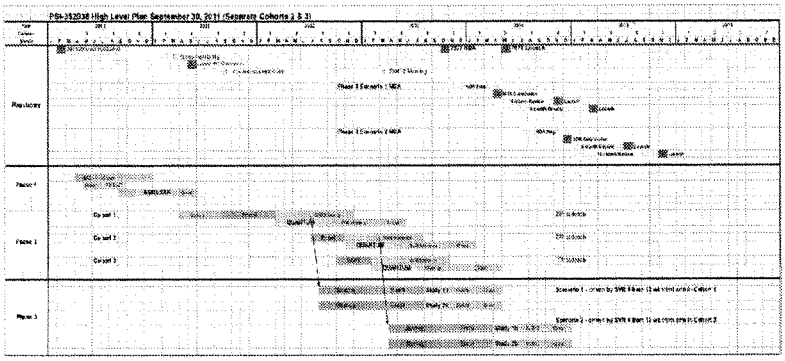
PSI-7977

Clinical Development Plan



PSI-938

Clinical Development Plan

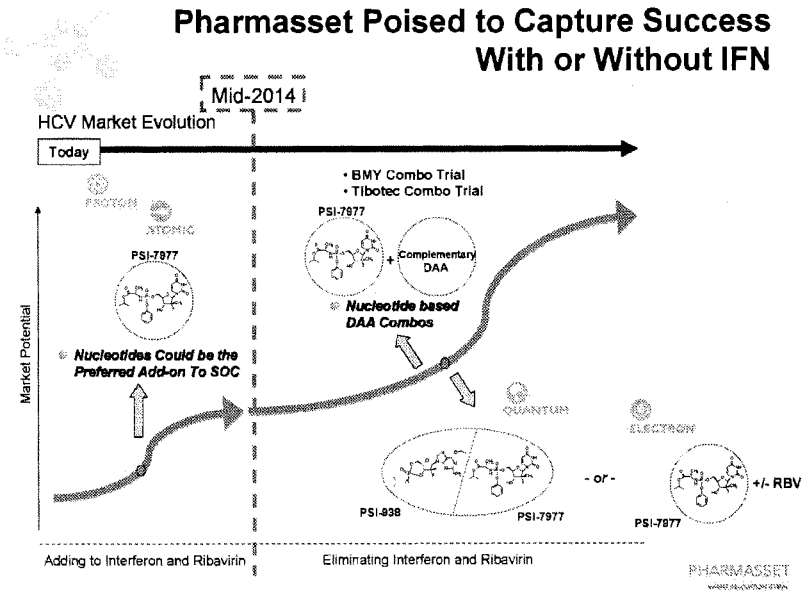


PHARMASSET

Studies Available for 7977 Labeling

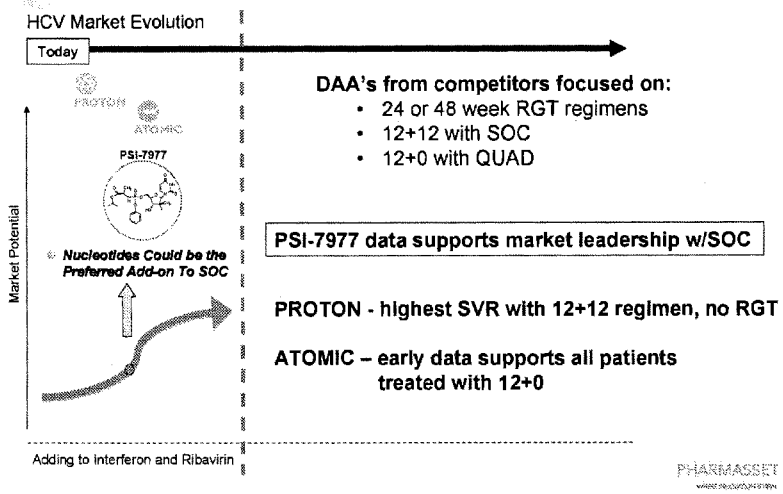
- **Studies available for NDA and EMEA Filings**
  - P3 study 1, G2/3 Naïve
  - P3 study 2, G2/3 Intolerant/Contraindicated
  - P3 study 3, G1 Intolerant/Contraindicated
  - Atomic 12 + 0
  - Quantum results of 7977 + RBV arms (all genotypes)
  - Pre-transplant G1 study
- **Seek filings Oct 2013**
- **Approval and launch in US May 2014**
- **Approval in EU Mid 2014, country launches in second half 2014**

PHARMASSET


Pharmasset Poised to Capture Success With or Without IFN
Mid-2014
HCV Market Evolution
Today
• BMY Combo Trial
• Tibotec Combo Trial
PSI-7977
+ Complementary DAA
Nucleotide based DAA Combos
PSI-7977
Nucleotides Could be the Preferred Add-on To SOC
Market Potential
QUANTUM
ELECTRON
PSI-938
PSI-7977
- or -
PSI-7977
+/- RBV
Adding to Interferon and Ribavirin
Eliminating Interferon and Ribavirin
PHARMASSET

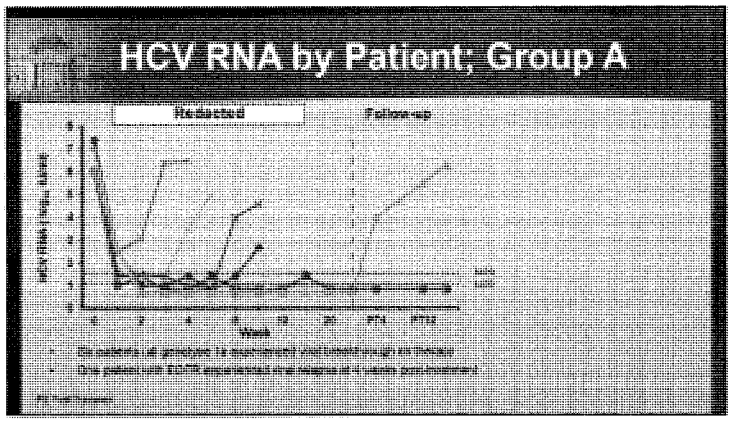
PSI-7977 unsurpassed on top of SOC

Highest SVR, shortest treatment regimens, no response guided



Redacted

EASL 2011



Redacted Maximizing SVR by Controlling Resistance

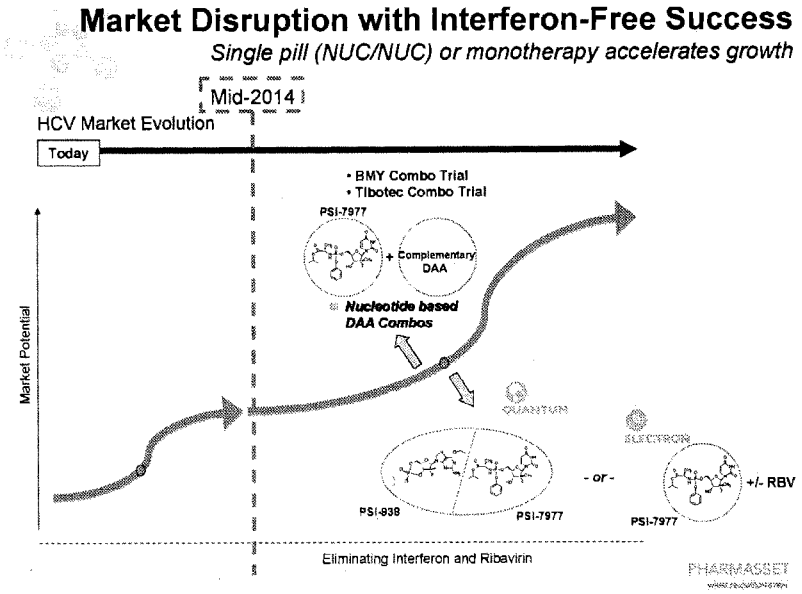
Requires patient selectivity

Redacted: Late-breaking Oral Session at AASLD 2011:

LB-4. Dual Oral Combination Therapy with the NS5A Inhibitor BMS-790052 and the NS3 Protease Inhibitor [Redacted] Achieved 90% Sustained Virologic Response (SVR12) in HCV Genotype 1b-Infected Null Responders. *K. Chayama; S. Takahashi; Y. Kawakami; K. Ikeda; F. Suzuki; J. Toyota; Y. Karino; T. Ohmura; H. Ishikawa; H. Watanabe; T. Guo; F. McPhee; E. A. Hughes; H. Kumada*

Mon, Nov 07 3:30 PM

PHARMASSET

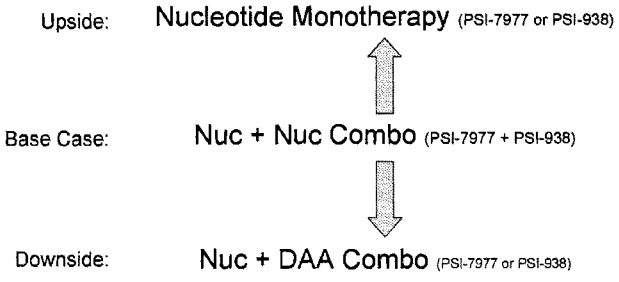

Market Disruption with Interferon-Free Success
Single pill (NUC/NUC) or monotherapy accelerates growth
Mid-2014
HCV Market Evolution
Today
• BMY Combo Trial
• Tibotec Combo Trial
PSI-7977
+ Complementary DAA
Nucleotide based DAA Combos
Market Potential
PSI-938
PSI-7977
- or -
PSI-7977
+/- RBV
Eliminating Interferon and Ribavirin
PHARMASSET

Summary of All Oral DAA Trials/Collaborations

	Pharmasset QUANTUM	Bristol-Myers Squibb	Tibotec
Announced	September 2011	January 2011	July 2011
Combination	PSI-7977+ PSI-938 +/- RBV	PSI-7977+ BMS-790052 +/- RBV	PSI-7977+ TMC435 +/- RBV
Classes	Nuc + Nuc	Nuc + NS5a Inh.	Nuc + Protease Inh.
Patient Type (N)	Treatment naïve (450)	Treatment naïve (84)	Prior Nulls (N/A)
Genotype	All GTs	GT1,2,3	GT1
Treatment Duration	12 / 24 weeks	24 weeks	12 / 24 weeks
Study Region	US/Ex-US	US	N/A
Endpoint	SVR24	SVR24	SVR12
Status	Enrolling	Enrolled	Initiate 2H11
Interim/Final Data Release	TBD	TBD	TBD

PHARMASSET

Possible Roles for VRUS Nucs as Future Interferon-free Backbone



PHARMASSET

NUCs Provide SVR Maximization and Simplicity

- **NUC + DAA, NUC + NUC, or NUC monotherapy: Nuc is the backbone of HCV Tx**
  - Only NUC demonstrating it's capable of eliminating interferon and/or RBV for all genotypes
  - Elimination of SOC reduces costs of care (RN time, patient failures,etc)
  - Unsurpassed efficacy equal to all other classes
  - Improved tolerability with elimination of interferon (and likely RBV)
  - Simple to use
- **One size fits all patient types wins** (all genotypes, no RGT, high barrier to resistance, no impact of BMI, VL, IL28b)
- **One pill/once daily drives compliance, reduces costs, increases utilization and market growth**

PHARMASSET

Simple Tx Regimen Shifts Rxing from Specialty to PCP Footprint

PHARMASSET

PSI-7977 Clinical Benefit Translates into Physician, Patient, and Payer Needs

Fact	Advantage				Benefit
	NUC	Protease	NS5a	Non-Nuc	
Highest Reported SVR's	✔				Reduces TX failure population for payers Patient feels greater likelihood for success
Broad Genotype Coverage	✔				Physician familiarity - One pill fits all types No genotyping needed
High Barrier to Resistance	✔				Less complexity in management Less cost without resistance testing
Safety Profile	✔				Reduces supportive care drugs Reduces consultations (derm, psych, etc.)

PHARMASSET

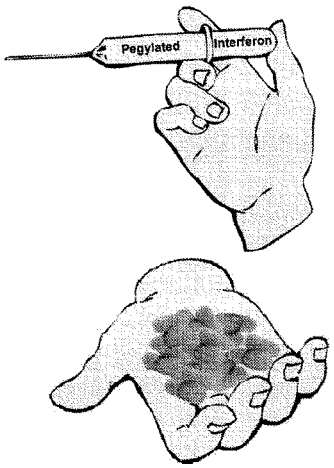
PSI-7977 Clinical Benefit Translates into Physician, Patient, and Payer Needs

Fact	Advantage				Benefit
	NUC	Protease	NS5a	Non-Nuc	
No Response Guided Tx	✔				Fewer VL tests (cost) Fewer patient visits Removes uncertainty
No Interferon Required	✔				Increases # patients complete Tx Increases treatable patient pool Increases #/MDs willing to Tx Potential for IVDU's to TX No IL28b testing
No Ribavirin Required	✔				Removes supportive care (rash and heme)
No Drug/Drug Interactions	✔				Expands available patient populations (methadone, co-infected, transplant, etc.)
One Pill, Once Daily	✔				Moves Tx to where patients are Simplifies the care process (refer only DTT) Improved compliance Changes role of Specialty Pharmacy (?) Reduces the care/guards in prisons

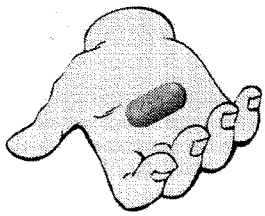
PHARMASSET

Simplification of HCV Treatment

Current



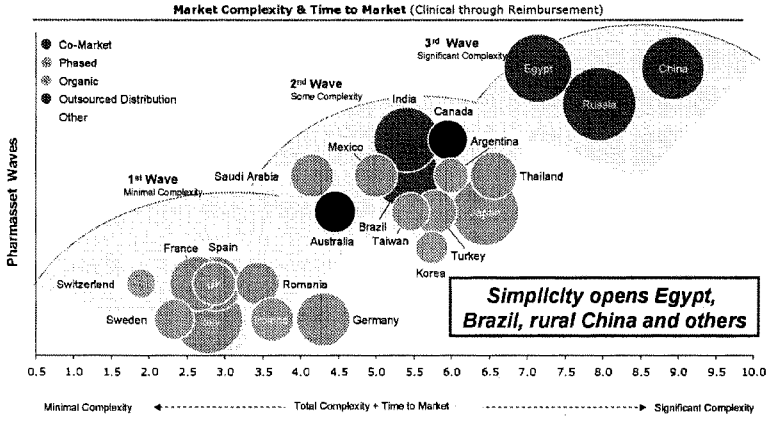
Future



PHARMASSET

Top 24 Countries: Strategy Implications

Post launch in US and EU, growth can be maintained by commercialization expansion

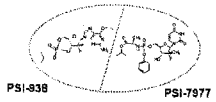


HCV Commercialization Board Pre-Read • July 2011

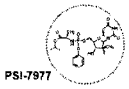
PHARMASSET

Simplicity Drives Market Share and Market Expansion

- Once daily dosing
- Pan-genotype
- No need for response guided therapy
- No concern about resistance
- Fewer safety complications



"The Truvada of HCV"
or
"The Viread of HCV"



PHARMASSET

Back-ups

PHARMASSET

Positioning of Pharmasset NUCs

Multiple combos increases chances of greater penetration
Monotherapy trumps all combos

- **Physicians will combine drugs based on personal preference**
- **Combinations to date that do not contain NUCs have resistance issues**
  - Redacted
  - Gilead/Vertex (Protease + Non-nuc)
- **Pharmasset's strategy is "friend to all" – positioning as the backbone of interferon-free therapy**
  - **Redacted**
- **NUC monotherapy expands utilization and maximizes value per treatment back to Pharmasset**

The common denominator is a Pharmasset NUC – guaranteed minimum 50% market share of all therapies or potentially 100% of combos

PHARMASSET

Competition Product Profile Comparison

Only PSI-7977 ranks highest in all categories

	Potency	Side Effect Profile	Genotype Coverage	Barrier to Resistance	Dosing Convenience
Redacted (NUC)	✓✓	✓✓✓✓	✓✓✓✓	✓✓✓✓	✓✓✓
Redacted (Protease Inh.)	✓✓✓✓	✓✓✓✓	✓✓	✓✓	✓✓✓✓
Redacted (Protease Inh.)	✓✓	✓✓	✓	✓✓	✓
Redacted (Protease Inh.)	✓✓✓	✓	✓	✓✓	✓
Redacted (Protease Inh.)	✓✓✓	✓	✓	✓✓	✓✓✓✓
Redacted (Cyclophilin Inh.)	✓	✓✓✓	✓✓✓✓	✓✓✓✓	✓✓✓✓
Redacted (NS5A Inh.)	✓✓✓✓	✓✓✓✓	✓✓✓	✓	✓✓✓✓
PSI-7977 (NUC)	✓✓✓✓	✓✓✓✓	✓✓✓✓	✓✓✓✓	✓✓✓✓

PHARMASSET

Initial Commercial Headcount

	Sales Reps	Total Infrastructure	Fully Functional (T-9)
United States	86	168	2Q13
EU5 (GR, FR, IT, SP, UK)	120	215	4Q13
Japan	98	TBD	TBD

Initial infrastructure being interviewed and hired today

Note: *Headcount expected to increase as Rxing shifts from GE/HEP/ID to PCP*

Commercialization rollout will focus on targeted countries with expansion to smaller markets based on regulatory, pricing, and commercialization complexity

Sweden	Switzerland
Thailand	Mexico
Saudi Arabia	Poland
Romania	Argentina
Canada	Taiwan
Australia	Korea
Turkey	

BRICE (Brazil, Russia, India, China, and Egypt) launches will lag

PHARMASSET

MM3

Reasons for Sales Force Start-up at T-18 Mos.

- Market penetration curve will be established in first six months of launch
- Relationships in HCV are key to market penetration
  - Redacted have > 10-years of established relationships
  - Redacted have a three-year head start on protease class promotion
- Appropriate messaging is critical to maximizing value of nucs:
  - Many companies will be promoting their class of drug as superior (including Redacted Redacted)
    - None of these companies have the incentive to promote the importance of:
      - viral resistance
      - interferon free/sparing
      - broad genotype coverage
      - simple regimen (no response guided therapy)
  - Share of voice is critical given multiple competing classes
- Payer acceptance and formulary evaluations are often made 6-18 months prior to approval

PHARMASSET

Slide 75

MM3 In previous slides, we've said that the first 13 weeks set the curve (or 18 months for second entrants). We need to be consistent.

I made several suggested changes to this slide FYI.
Mike McElhaugh, 6/24/2011

US Sales Specialists Will be Hired in 2 Phases

Starting T-18 Mos from Approval and Tied to Positive Data Points

	# of MD's	# Reps	Intitial (T-18)	Entire (T-9)
HCV High Prescribers (Top 60%)	1,500	36	✔	✔
Remaining HCV High Prescribers (70-80%)	2,100	50		✔
Remaining HCV Prescribing Audience (90-100%)	10,000	40		
HIV Treating Audience	3,000	36		
High Volume PCP Audiences	15,000	90		
Total Needed			36	86

Assumptions and Calculations for Headcount Requirements:

- High prescribers will be called on a minimum of once every two weeks (24 calls/year)
- 201 days in territory annually x 5 calls/rep/day[1] = 1005 calls/rep/year

$$\frac{\text{1,500 targets x 24 calls/year}}{\text{1005 calls/rep/year}} = 36 \text{ reps}$$

$$\frac{\text{3,600 targets x 24 calls/year}}{\text{1005 calls/rep/year}} = 86 \text{ reps}$$

- 6-12 calls/year for expanded audiences

PHARMASSET

Commercial Headcount Requirements

	Intitial (T-18)	Entire (T-9)
Reps	**36**	**86**
DSM's (6-7 to 1 Ratio)	6	12
Market Specialists (RN Coordinators)	-	12
RSD's	-	2
Business Manager	1	2
Sales Training	1	2
Sales Operations	1	2
VP, Sales	1	1
Marketing Managers/Directors	2	3
Market Research	1	2
Public Affairs/CommunityAdvocate	1	1
Interactive Marketing	1	1
VP, Marketing	-	1
Account Management	6	6
Government Affairs	2	4
Strategic Pricing	-	1
Customer Planning & Contracting	-	3
Distribution Management	-	1
VP, Account Management/Services	1	1
Medical Directors	1	2
Medical Liaisons	6	12
Finance	2	2
Human Resources	1	2
Legal	1	2
IT	1	2
Admin	2	2
Total Headcount	**74**	**168**

Pharmasset's projections are consistent with competition:

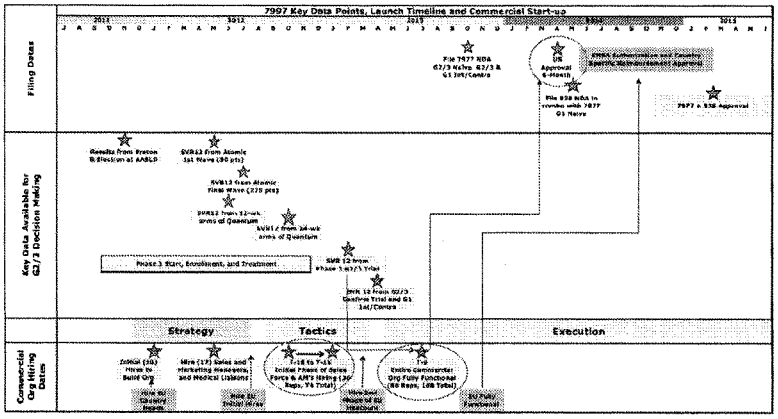
Genentech	125 Specialists
Merck	110 Specialists
Vertex	96 Specialists*

* Expanding by 12 in 2012

PHARMASSET

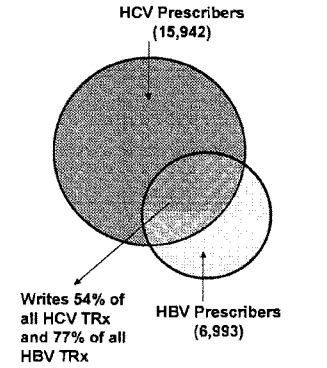
Commercial Hiring and Data Availability

Initial hiring in 2012, balance in mid-year 2013, Launch early 2014



PHARMASSET

Overlap of HCV and HBV Prescribers (US)



- GIs still constitute the majority of the hepatitis scripts, especially in the overlapping community

Note: Size of the circles is roughly proportional to the number of writers
Source: IMS Xponent (HCV data MAT June 2004; HBV data MAT February 2004; HIV data MAT June 2004)

PHARMASSET