DIAGNOSING THE PROBLEM: EXPLORING THE EFFECTS OF CONSOLIDATION AND ANTICOMPETITIVE CONDUCT IN HEALTHCARE MARKETS

HEARING

BEFORE THE

SUBCOMMITTEE ON ANTITRUST, COMMERCIAL AND ADMINISTRATIVE LAW

OF THE

COMMITTEE ON THE JUDICIARY

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C O N T E N T S

THURSDAY, MARCH 7, 2019

DIAGNOSING THE PROBLEM: EXPLORING THE EFFECTS OF CONSOLIDATION AND ANTI-COMPETITIVE CONDUCT IN HEALTHCARE MARKETS

THURSDAY, MARCH 7, 2019

HOUSE OF REPRESENTATIVES

SUBCOMMITTEE ON ANTITRUST, COMMERCIAL AND ADMINISTRATIVE LAW

COMMITTEE ON THE JUDICIARY

Washington, DC

The Subcommittee met, pursuant to call, at 2:01 p.m., in Room 2141, Rayburn Office Building, Hon. David Cicilline [chairman of the subcommittee] presiding.

Present: Representatives Cicilline, Nadler, H. Johnson, Jayapal, Demings, Scanlon, Neguse, McBath, Sensenbrenner, Collins, Gaetz, Buck, and Armstrong.

Staff present: Slade Bond, Chief Counsel; Amanda Lewis, Counsel on Detail from the FTC; Madeline Strasser, Chief Clerk; Josephy Van Wye, Professional Staff; Julian Gerson, Staff Assistant; Susan Jensen, Parliamentarian; Moh Sharma, Member Services and Outreach Advisor; Daniel Flores, Minority Counsel; Andrea Woodard, Professional Staff.

Mr. CICILLINE. The Subcommittee will come to order. Without objection, the chair is authorized to declare a recess of the Committee at any time.

We welcome everyone to today's hearing on Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Healthcare Markets.

I thank our witnesses for being here and I also want to say that it is our first meeting of this Subcommittee and I particularly want to acknowledge the presence of the Ranking Member, Jim Sensenbrenner, who I look forward to continuing to work with who has done a lot of important work in the jurisdiction of this Subcommittee and will bring great wisdom to our collective effort.

Mr. SENSENBRENNER. If you say so.

Mr. CICILLINE. Yes, absolutely. Without objection.

Our healthcare system is in a State of crisis. The costs of prescription medicine have increased by 200 percent over the past decade.

Americans spend, roughly $1,200 on average on prescription drugs every year, which is more than people in any other country. The average cost of a hospital stay for a child with cancer is $40,000.

The price for many types of organ transplants and post-operation treatment is more than a million dollars. Even a short ambulance ride to the hospital without medical care may cost patients thousands of dollars.

These outrageous, unsustainable, and immoral costs are ruining lives. Prices are skyrocketing and people are dying or bankrupted as a result.

Kaiser Health reports that a quarter of Americans cannot afford their medicine while many, and I quote, "cancer patients are delaying care, cutting their pills in half, or skipping drug treatment entirely," end quote.

Despite decades of rising costs, the United States ranks dead last in health outcomes among other high-income countries. For too many Americans it is a dark reality that the life of a loved one depends on whether they can raise enough money on a crowdfunding platform to pay for treatment before it is too late.

Faced with no other options, Americans are left to plead to strangers for help to keep their loved ones alive. This must end.

The American people deserve a government that is in their corner fighting for them to take on drug profiteering and other barriers to affordable healthcare. Ending this moral crisis is a top priority of mine as chairman of the Antitrust Subcommittee and a top priority for House Democrats to keep our promise to work for the people and to make healthcare affordable for everyone.

Our competition system is the backbone of promoting open and fair markets. This competition is absolutely essential in healthcare markets. For drug prices, the entry of generic drug competitors can reduce the cost of branded drugs significantly and hospital and health insurance markets consolidation threaten the quality and affordability of care.

In too many cases, effective antitrust enforcement takes far too long to deliver meaningful results to people in need. For example, some branded drug companies have abused safety protocols to thwart generics and to preserve their monopoly for more than a decade.

As Professor Robin Feldman has noted, even months of delay can be worth hundreds of millions of dollars in additional monopoly revenues as the generic sits on the sideline.

While this anticompetitive conduct should violate the antitrust laws, even successful cases are often too time consuming to provide effective relief, as the Federal Trade Commission testified before the Subcommittee last Congress.

That is why I have introduced the CREATES Act with Chair Nadler and Ranking Member Sensenbrenner and Collins to end these delay tactics. The CREATES Act establishes a tailored path for generic drug manufacturers to bring low-cost drugs to market.

The Congressional Budget Office estimates that the bill would result in nearly $4 billion in federal savings along with an additional $5.4 billion in savings for consumers, according to private estimates.

It is also imperative that we examine and address other anticompetitive tactics that lead to higher drug prices. Last week, the FTC settled a complaint against a drug company for paying off its competitor to keep out of the marketplace.

According to a 2010 report by the Commission, this type of conduct, also called a "pay for delay" settlement, costs about $3.5 billion per year in the form of higher drug prices.

This settlement occurred nearly seven years after the Supreme Court's landmark decision in *Actavis* where it held that these settlements risk significantly anticompetitive effects and more than 10 years after the FTC originally filed its complaint.

It is unacceptable that it took a full decade to address this abuse of our patent system. Moreover, this egregious behavior is still taking place today.

As Dr. Aaron Kesselheim of Harvard Medical School noted in his testimony before the Subcommittee last Congress, corporations continue to engage in "pay for delay" settlements in the wake of *Actavis* decision, driving up the cost of prescription drugs.

I look forward to working with Chair Nadler and Senators Klobuchar and Grassley on legislation to confront and reverse this problem.

In closing, today's hearing is an important opportunity to examine other competitive threats that raise costs, lower quality, and reduce choices in healthcare markets.

It is my hope that our discussion today can focus on continuing our work to diagnose the problems associated with consolidation and anticompetitive conduct in healthcare markets as well as finding solutions to provide a better deal for hardworking Americans on prescription drugs and other healthcare costs.

I thank our esteemed witnesses today for appearing before the subcommittee. It is now my great pleasure to recognize the Ranking Member of the subcommittee, Mr. Sensenbrenner of Wisconsin.

Mr. SENSENBRENNER. Thank you, Mr. Chair, and I thank you and extend a warm welcome to all my colleagues, our witnesses, and the audience Members.

It is a pleasure to begin the subcommittee's proceedings for this term of Congress. I look forward to working with Chair Cicilline to accomplish as much as we can together to meet the needs of the American people.

Today's hearing focuses on the issues of vital importance. According to the Centers for Medicare and Medicaid Services, American spending on healthcare now accounts for 17.8 percent of the United States' GDP. That is over $3.6 trillion, or over $10,000 per person.

These astronomical costs are the result of many factors. Lurking always is the misguided Obamacare legislation. Sold as a means to protect patients and make healthcare affordable, it has produced just the opposite.

Rising costs, loss of doctors and insurance policies, and increasingly monopolized hospital and insurance markets in states and counties all across the nation.

Today's hearing offers us a chance to focus on some of the other important factors in the healthcare cost problems. These include obstacles to patients' access to low-cost generic drugs, anticompeti-

tive practices engaged by pharmacy benefit managers, and rising consolidation in hospital and insurance markets.

To help tackle the first of these problems, Chair Cicilline and I have introduced in the first weeks of this Congress the Creating and Restoring Equal Access to Equivalent Samples Act—a mouthful—also known as the CREATES Act.

Our bill is strong and bipartisan legislation that will prefer branded pharmaceutical companies from manipulating test sample availability to block cheaper generic alternatives from obtaining FDA approval and entering the marketplace.

The CREATES Act will lead to lower costs for patients by assuring that they have faster access to safe and effective FDA-approved generic drugs.

The CBO has estimated that our bill would produce a multi-billion-dollar decrease in the federal deficit. Savings to consumers and private insurers will likely be greater than that amount.

I look forward to hearing the witnesses' testimony on the CREATES Act and other important issues the Subcommittee will examine today.

I would like unanimous consent to insert into the record at this point a statement by the National Community Pharmacists Association—statement for the record and also pharma's statement to the House of Representatives on the topic of this hearing today.

Mr. CICILLINE. Without objection.

[The information follows:]

JAMES SENSENBRENNER FOR THE RECORD

National Community Pharmacists Association's Statement for the Record
United States House Subcommittee on Antitrust, Commercial, and Administrative Law
Hearing: "Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets"
March 7, 2019

Dear Chairman Cicilline, Ranking Member Sensenbrenner, and Members of the Subcommittee:

The National Community Pharmacists Association ("NCPA") appreciates the opportunity to submit this statement on the Subcommittee's hearing titled, "Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets." NCPA represents America's community pharmacists, including 22,000 independent community pharmacies. Together they represent a $76 billion health care marketplace, employ 250,000 individuals on a full or part-time basis, and provide pharmacy services to millions of patients every day.

In this statement, NCPA will address the potential implications consolidation in the industry, including the recently consummated merger of Express Scripts ("ESI") and Cigna as well as the CVS Health Corporation/Aetna merger, for which a consent decree is currently under review at the United States District Court for the District of Columbia. NCPA will highlight how consolidation in the health care industry may be contributing to higher costs and negatively impacting patient choice. In particular, to address pharmacy benefit manager ("PBM") market dominance, NCPA has long argued for additional scrutiny of PBMs, including their inherent conflicts of interest, lack of transparency, and one-sided take-it-or-leave-it contract negotiations with independent pharmacies. We urge Congress to work with the antitrust agencies to take a closer look at PBM consolidation and vertical mergers in the health care market for their effects on patient access, costs, and competition and whether the purported savings from these mergers will, in fact, be passed on to customers.

Continued Consolidation Will Lead to Decreased Competition and Fewer Choices for Patients

Recent consolidation among major PBMs and health plans has contributed to increasing health care costs and negatively impacted consumer choice. Health care costs have continued to rise despite previous vertical mergers. Continued vertical healthcare consolidation could further impede competition and foreclose any meaningful entry into the market, leading to fewer choices and higher healthcare costs. In addition, these huge entities increasingly rely on limited preferred networks that have negatively impacted consumer choice. For example, not all Medicare Part D ("Part D") sponsors and their PBMs prioritize access to local community pharmacies in their preferred networks. Instead, these networks are often limited to a smaller number of select pharmacies and regularly exclude community pharmacies even when such pharmacies are willing to accept the terms and conditions of a Part D sponsor's network. As a result, seniors' choice of pharmacy is limited and their access to quality care is hindered, especially in underserved areas. For this reason, NCPA is concerned that with consolidation, major PBMs will continue to limit their networks and further worsen patient choice and access.

The CVS/Aetna merger is an example of a specific transaction that is likely to significantly decrease competition for pharmacy products and services. Although CVS and Aetna agreed to sell Aetna's Part D prescription drug plan business to address their horizontal competitive overlap as a condition of approval of the deal, substantial anticompetitive concerns were not addressed. In fact, Aetna's Part D

assets were sold to WellCare Health Plans, Inc. who uses CVS Caremark as their PBM. Therefore, this divestiture of Aetna's Part D business essentially maintains CVS' market share instead of resolving any anticompetitive concerns.

CVS Caremark, the PBM for CVS, is the second largest PBM in the U.S., accounting for nearly 34% of covered lives.[1] This significant market share allows CVS Caremark (as well as the other largest PBMs) to exercise undue market leverage and generate outsized profits for themselves. Community pharmacies have very little negotiating power when contracting with PBMs like CVS Caremark, and routinely must agree to take-it-or-leave-it contracts to be part of a PBM's pharmacy network. In some cases, even if a pharmacy is willing to accept onerous contract terms, the PBM will exclude certain pharmacies from their preferred networks altogether, limiting patient choice and access. Having the opportunity to be part of a plan's preferred network can be critical, as nearly all Part D plans include preferred networks that offer lower co-pays to beneficiaries.

The merger of the largest pharmacy chain/PBM with a major health plan shows how health care consolidation will only solidify these problems with respect to competition and patient choice, especially in underserved areas. CVS Caremark, for example, already routinely steers patients to its own pharmacies based on the prescription benefit design that it has structured for plan customers. One plan design CVS Caremark offers, ironically called Maintenance Choice, generally limits patients to the pharmacy of their choice for only the prescription's first fill. Thereafter, in order to benefit from their prescription insurance, the consumers' "choice" is a CVS retail or CVS mail order pharmacy.

As the largest pharmacy chain in the United States with approximately 9,700 retail locations and significant share in many geographic markets, the merged entity is likely to be able to use its dominant position to increase payments to its own CVS pharmacies and effectively foreclose other pharmacies from its networks, a practice that other health care entities could engage in as well if this trend of health care consolidation continues.

Further, some states have found that CVS and other large PBMs engage in questionable pricing and reimbursement practices towards pharmacies. Last year, the Kentucky Department of Insurance fined CVS Caremark a $1.5 million civil penalty for violations related to reimbursements to pharmacists, including claim denial violations and providing inaccurate information.[2] In addition, the Auditor of the State of Ohio found that Ohio, where CVS Caremark is the PBM for four of Medicaid's five managed care plans, was charged around $225 million in spread amounts for Medicaid prescription drugs in a one-year period while other pharmacies were reimbursed at, or below, cost. [3] Of the total $225 million, Optum Rx was paid $28.9 million in spread. The report also confirmed that these drastic reimbursement cuts from the Ohio Medicaid PBMs caused a significant amount of independent pharmacy closures in the state.

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[1] According to CVS, it has 90 million PBM plan members. *See* CVS, *available at* https://cvshealth.com/about/facts-and-company-information. The Pharmaceutical Care Management Association testified that PBMs administer drug plans for more than 266 million Americans. *See also* Testimony of Mark Merritt, PCMA.

[2] Kentucky Department of Insurance Issues Penalty Against PBM, CaremarkPCS Health LLC, a subsidiary of CVS Caremark, Commonwealth of Kentucky Public Protection Cabinet Department of Insurance, *available at* http://ppc.ky.gov/Lists/News%20Releases/Kentucky%20Department%20of%20Insurance%20Issues%20Penalty%20Against%20PBM,%20CaremarkPCS%20Health%20LLC,%20a%20subsidiary%20of%20CVS%20Caremark.pdf.

[3] Ohio's Medicaid Managed Care Pharmacy Services, Auditor of State Report (Aug. 16, 2018), *available at* https://audits.ohioauditor.gov/Reports/AuditReports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf.

Lastly, the Auditor General in Pennsylvania conducted a similar investigation, indicating that three PBMs made between $2 million and nearly $40 million on spread pricing.[4] **Thus, NCPA recommends that Congress work with the antitrust agencies to more thoroughly evaluate the effects of consolidation on the health care market to ensure that plan sponsors and consumers continue to have competitive choices.**

No Evidence to Support that the Purported Cost Savings of Consolidation Will Be Passed on to Consumers

Merging parties typically state that proposed transactions will create efficiencies and save hundreds of millions of dollars for consumers. They often do not explain, however, whether or how those purported savings will be passed on to consumers. The largest PBMs already claim their size enables them to achieve significant efficiencies and cost savings. As patients' out of pocket costs and premiums continue to rise, there is evidence to suggest that these savings are not, in fact, being passed on to consumers. NCPA suggests that whether the purported cost savings will be passed on to consumers remains unclear.

As discussed above, using the example of the CVS/Aetna merger, many patients that visit CVS Minute Clinics are likely to pick up their drugs at the CVS pharmacy. Yet, there is ample evidence that many times CVS pharmacies are not the lowest cost providers. In fact, Consumer Reports determined that CVS pharmacies often have the highest retail prices, which were found to be 400% higher than independent pharmacies' retail prices for the same prescription drugs.[5]

In addition, CVS will have every incentive to force more patients into their own mail order pharmacy, disingenuously arguing that mail order will likely lower costs. It is a common misconception that steering patients into mail order will lower drug costs for consumers.[6] Evidence demonstrates that mail order pharmacies consistently dispense costlier brand-name drugs and fewer generics than retail pharmacies.[7] Using data from industry source, IQVIA, the average mail order prescription is $626.44 compared to under $60 at a community pharmacy. As a "price giver" and a "price taker," mail order firms can manipulate pricing schemes. Plan Sponsors (employers, the federal government, individual purchasers) are often misled into thinking their overall prescription drug costs will be lowered by moving to mail order. In fact, the Centers for Medicare and Medicaid Services ("CMS") has determined that mail order does not result in cost savings in Part D.[8] **Therefore, NCPA urges Congress and the agencies to evaluate whether cost savings actually occur post-merger and to monitor whether these savings would indeed be passed on to consumers.**

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[4] Auditor General DePasquale, *Bringing Transparency & Accountability to Drug Pricing* (Dec. 2018), *available at* https://www.paauditor.gov/Media/Default/Reports/RPT_PBMs_FINAL.pdf.
[5] Gill, Lisa L., Shop Around for Lower Drug Prices, (Apr. 5, 2018), *available at* https://www.consumerreports.org/drug-prices/shop-around-for-better-drug-prices/.
[6] Carroll, Norman V., A Comparison of the Costs of Dispensing Prescriptions through Retail and Mail Order Pharmacies, *available at* http://www.ncpanet.org/pdf/leg/feb13/comparison_costs_dispensing_prescriptions_retail_mail_order.pdf.
[7] Johnsrud M, Lawson KA, Shepherd MD. Comparison of mail-order with community pharmacy in plan sponsor cost and member cost in two large pharmacy benefit plans. J Manage Care Pharm 2007; 13:122-134.
[8] Part D Claims Analysis: Negotiated Pricing Between General Mail Order and Retail Pharmacies, *available at* https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovgenin/downloads/negotiated-pricing-between-general-mail-order-and-retail-pharmaciesdec92013.pdf.

Several States have Acknowledged the Need of Protections from Consolidation

States are increasingly raising concerns about recent health care mergers. For example, Georgia, New York, and California obtained concessions from CVS and Aetna prior to approving the deal. Georgia obtained several patient and pharmacy protections before approving the merger, requiring that CVS/Aetna invite non-CVS health care providers and pharmacies to join its networks; allow patients to use any health care provider if that provider accepts the same conditions as those within the network; disclose the amount of rebates it receives from drug makers and how much of those it passed on to insurers; and that CVS/Aetna must not require patients to use CVS-owned pharmacies.[9]

In New York, regulators set conditions on the merger, including enhanced consumer and health insurance rate protections, privacy controls, cybersecurity compliance, and a $40 million commitment to support health insurance education, enrollment, and other consumer health protections.[10] Regulators required that participating provider networks for insured products will maintain access to non-chain New York pharmacies for three years. Lastly, in California, regulators approved the merger only if CVS and Aetna agreed to keep premium increases "to a minimum."[11]

Similarly, California and New York imposed conditions on the ESI/Cigna merger prior to approving the vertical integration of a PBM and a health insurance company. The California Department of Managed Health Care approved the deal provided that ESI and Cigna do not increase premiums to cover acquisition costs and, as in CVS/Aetna, keep premium rate increases to a minimum.[12] In addition, New York's Department of Financial Services approved the transaction on the conditions that Cigna and Express Scripts maintain their current networks of providers, "including pharmacies," adopt a firewall policy to separate competitively sensitive information, and required that the deal would be subject to ongoing regulatory oversight.[13] **Significant concerns have been validated at the state level through these concessions as states acknowledge that the CVS/Aetna and ESI/Cigna mergers will likely impose anticompetitive restrictions on patient access to their preferred pharmacies and health care providers.**

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[9] *As CVS and Aetna Prepare to Merge, Georgia Wins Major Concessions*, Georgia Watch (Nov. 27, 2018), *available at* https://www.georgiawatch.org/as-cvs-and-aetna-prepare-to-merge-georgia-wins-major-concessions/.
[10] John Commins, *CVS-Aetna Merger Gets NY Approval, to be Finalized This Week*, Health Leaders (Nov. 26, 2018), *available at* https://www.healthleadersmedia.com/cvs-aetna-merger-gets-ny-approval-be-finalized-week.
[11] *DMHC Approves CVS's Acquisition of Aetna*, Press Release, Department of Managed Health Care (Nov. 15, 2018), *available at* http://www.dmhc.ca.gov/Portals/0/Docs/DO/pressRelease111518_1.pdf?ver=2018-11-15-100917-533.
[12] Cigna-Express Scripts Undertakings (Dec. 11, 2018), *available at* http://www.dmhc.ca.gov/Portals/0/Docs/DO/FinalCigna-ExpressScriptsUTs.pdf.
[13] Application by Cigna Corporation and Halfmoon Parent, Inc. for Approval to Acquire Control of Medco Containment Insurance Company of New York (Dec. 12, 2018), *available at* https://www.dfs.ny.gov/system/files/documents/2019/01/cigna_opinion_decision_12132018.pdf.

Continued Consolidation Will Only Exacerbate Existing PBM Market Power and Conflicts of Interest

PBMs already have extraordinary market power; the top three PBMs control approximately 85-89% of the market: 238 million lives[14] out of 266 million lives. [15] This dominance has allowed PBMs to leverage their market power to the detriment of plan sponsors (government and commercial payors), providers, and consumers. Additionally, PBMs claim that they help plan sponsors generate savings by negotiating rebates, however, recent reports have shown the opposite. A report from 2017 found that PBMs have been utilizing their market power to try to increase their profits and encourage higher list prices for prescription drugs, which increases co-pays for patients.[16]

PBMs are manipulating the system to increase their own profits at the expense of consumers, employers, and government programs. PBMs have a unique vantage point in the middle of the supply chain to have access to critical claims and financial data by their contracts with manufacturers and pharmacies and due to their multitude of revenue streams. They negotiate rebates with pharmaceutical manufacturers and determine which drugs are included on PBM formularies, ultimately determining what drugs patients will have access to and at what cost. They also contract with employers to manage their prescription drug benefit, and in doing so, heavily influence prescription drug benefit designs.

PBMs' inherent conflicts of interest in the health care marketplace warrant further scrutiny. Each of the largest PBMs own mail order pharmacies and specialty pharmacies. PBMs also contract with all other retail pharmacies to form pharmacy networks that are direct competitors to the PBM-owned pharmacies. PBMs regularly design plans, including plans with preferred networks, that require or incentivize patients to use the PBM-owned pharmacy option over a retail pharmacy. Moreover, when a PBM contracts with a retail pharmacy, PBMs have wide latitude in setting requirements for a pharmacy to be included in a network: the PBM determines how much the pharmacy will be reimbursed, which drugs will be covered, the day supply that the pharmacy can dispense, the patient co-pay, and many other factors. PBMs also routinely audit retail pharmacies and through this process have access to purchasing records and invoices.

When PBMs own mail order or specialty pharmacies, they utilize such road blocks to steer patients to PBM-owned pharmacies. Specifically, in the specialty pharmacy space, due to the lack of an industry-wide definition of a specialty drug, PBMs arbitrarily define high-cost drugs as "specialty drugs" and encourage or require that beneficiaries fill these prescriptions at PBM-owned or affiliated specialty pharmacies. Forcing patients, particularly those who have complex conditions and require specialty drugs, to get their prescriptions from a pharmacy with which it has no personal relationship severely limits patients' choice and may impact the quality of care and adherence. **Because PBMs are hindering patient choice and access, while steering patients towards costlier drugs, we urge Congress to**

[14] Mathematical calculation based on number of covered lives CMS/Caremark, UnitedHealth and ESI self-reported.
[15] Council of Economic Advisers, Reforming Biopharmaceutical Pricing at Home and Abroad, Feb. 2018, *available at* https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf; *see also* testimony of PCMA CEO Mark Merritt before the U.S. House of Representatives Energy & Commerce Committee Subcommittee on Health, December 13, 2017.
[16] Steve Pociask, "Pharmacy Benefit Managers: Market Power and Lack of Transparency," Am. Consumer Inst. ConsumerGram (2017), *available at* http://www.theamericanconsumer.org/wp-content/uploads/2017/03/ACI-PBM-CG-Final.pdf.

encourage the antitrust agencies to closely examine PBM-owned mail order and specialty pharmacies for conflicts of interest misconduct.

Ongoing Post-Merger Review is Necessary

The federal antitrust agencies are tasked with reviewing and approving health care consolidation transactions to evaluate the impact of these mergers on the "quality of goods or services."[17] The agencies' purview of merger review as it relates to health care settings may not be comprehensive enough to consider the impact on patients and the quality of care. NCPA believes that while reviewing health care mergers, the effects of the transaction on the quality of care is a necessary component.

In addition, while NCPA values the agencies' pre-merger review processes, we believe it is inadequate in assessing the actual effects once a health care merger becomes operational. **Therefore, NCPA recommends that Congress and the antitrust agencies create an ongoing post-health care consolidation evaluation process. We also suggest that Congress work with the agencies to streamline an open and continuous dialogue between all stakeholders to assure patient access to care.**

Conclusion

In conclusion, NCPA appreciates the subcommittee's efforts to closely examine the effects of health care market consolidation and anticompetitive conduct. As established above, these issues cannot be solved without addressing the role of PBMs. Members of this subcommittee should be concerned with PBM anticompetitive conduct, as well as the trend of large vertical mergers like CVS/Aetna and ESI/Cigna. We urge Congress to collaborate with the antitrust agencies to ensure patient care is considered and prioritized during health care merger review.

[17] Federal Trade Commission, Merger Review, *available at* https://www.ftc.gov/enforcement/merger-review.

Mr. SENSENBRENNER. I yield back.

Mr. CICILLINE. Thank you to the Ranking Member.

Now, it is my pleasure to recognize Chair of the full committee, the gentleman from New York, Mr. Nadler, for his opening statement.

Mr. NADLER. Thank you, Mr. Chair.

The Judiciary Committee has a strong tradition of bipartisan efforts to promote competition in healthcare markets, particularly with respect to helping to make prescription drugs and other healthcare services more affordable through the full benefits of competition.

Over the past several years, the Subcommittee has held numerous hearings in this area examining the topics of consolidation in the market for health insurance, competition in the drug supply chain, and anticompetitive practices by prescription drug companies.

It is essential that we continue this important work through today's hearing and throughout this Congress as we seek to provide meaningful relief to Americans who struggle every day with the high cost of medicine, insurance premiums, and hospital bills.

Today, one-quarter of Americans report that it is difficult to afford their medicines—one-quarter. Exorbitant medical bills are one of the major causes of why Americans seek bankruptcy relief.

It is painfully clear that the soaring costs of healthcare are bad for the health and well being of American families. It is unacceptable that seniors cannot afford the arthritis medication they need to perform everyday tasks such as buttoning their coats or opening a jar without excruciating pain.

It is unacceptable that hundreds of thousands of cancer patients are reportedly delaying life-saving care, cutting their pills in half or skipping drug treatment entirely because of high drug prices.

It is unacceptable that those suffering from diabetes have to worry about the life-threatening consequences of not being able to afford insulin because of its unaffordable costs.

Last week, when confronted with the facts surrounding skyrocketing prescription drug prices, executives of seven major drug manufacturers responded by pointing fingers somewhere else, including insurers and pharmacy benefit managers.

As many experts have noted, including some of the witnesses who will testify here today, a lack of competition in healthcare markets is one of the primary causes of escalating costs.

In fact, the CEOs of some major drug companies acknowledge that—acknowledge that competition plays a key role in driving down prices.

For example, one testified just last week that, quote, "Competition is a key component to reducing costs," end quote. Frankly, we didn't need him to tell us that. Louis Brandeis told us that a long time ago.

The significance of competition from lower-priced generic drugs in particular cannot be overstated. According to the Federal Trade Commission, the first generic competitor's product is typically offered at a price 20 to 30 percent below the branded product's price.

Subsequent generic entry creates greater price competition with price drops reaching 85 percent or more off the brand price.

Similarly, the Congressional Budget Office reported in 2010 that the retail price of a generic is 75 percent lower on average—75 percent lower than the retail price of a brand name drug.

In response to the threat of generic entry which, of course, threatens the ability of branded drug companies to charge monopoly prices, these companies, or some of them, have engaged in numerous anticompetitive tactics.

This Committee has been and will continue to be active in stopping drug companies from reaping monopoly profits at the expense of the health of working American families.

For example, I am proud to be an original co-sponsor of H.R. 965, the Creating and Restoring Equal Access to Equivalent Samples Act of 2019, or the CREATES Act.

This bipartisan legislation, introduced last month by Subcommittee Chair Cicilline and Ranking Member Sensenbrenner, seeks to remove an obstacle to generic competition by making it easier for generic drug companies to obtain the samples they need to enter the marketplace.

Another concern involves so-called "pay for delay" settlements which occur when a branded drug firm pays a potential generic competitor to abandon a patent challenge and thereby delay entering the market with a lower cost generic product.

These agreements can be a win for both drug companies. The brand name drug company gets to keep its monopoly and the generic gets paid off with a portion of the monopoly profits. The consumers lose.

According to an FTC study, "pay for delay" agreements are estimated to cost American consumers $3.5 billion per year, $35 billion over the decade from 2010 to 2020.

That is why I plan to introduce bipartisan legislation this Congress to help end "pay for delay" settlements. As we all know, a lack of competition and anticompetitive conduct is not just limited to the pharmaceutical marketplace.

These problems show up in hospital markets as well. For example, it is well documented that hospital mergers can lead to higher prices and lower quality of care.

Hospital consolidation also results in fewer options for patients. This is especially harmful for expecting mothers or women seeking reproductive health services who depend on a full range of options for care and may be faced by a regional hospital that doesn't give a full range of options.

I hope that our discussion today will continue our bipartisan work to diagnose the problems associated with consolidation and anticompetitive conduct in healthcare markets as well as break new ground on confronting the harmful effects of hospital consolidation.

Accordingly, I look forward to hearing from our witnesses today. I thank them for their participation and yield back the balance of my time.

Mr. CICILLINE. I thank the gentleman.

Now, I am pleased to recognize the Ranking Member of the full committee, the gentleman from Georgia, Mr. Collins, for his opening statement.

Mr. COLLINS. Thank you, Chair Cicilline and Ranking Member Sensenbrenner, for holding this hearing. I would also like to thank both of you for the works in the CREATES Act and I believe this legislation is a good starting point and I look forward to continuing to work with both of you to ultimately get this bill signed into law this term.

Over the past decade, consolidation across healthcare and prescription drug markets have been rapidly increasing. Nowhere is this more prevalent than in the pharmacy benefit manager marketplace.

PBMs, in theory, should bring down the cost for consumers. However, they are not doing that. There are only three major PBM companies and they control 85 percent of the marketplace, which yields each company a great deal of power, and these companies have consolidated horizontally as well as vertically, as they go forward, and they have merged vertically with major pharmacies and health insurers.

That means patients' insurers have financial incentives to push the patients toward their pharmacies. This consolidation has enabled PBMs to engage in anticompetitive behavior by targeting competing pharmacies with unfair audits and under reimbursement.

These audits provide PBMs with the pharmacies' acquisition cost and patient data. PBMs then use this data to steer patients to their own pharmacies and reimburse competitive pharmacies at a much lower rate.

This results in PBMs lining their own wallets. It harms community pharmacists who have decided—have to decide between losing money and filling a prescription or losing customers to big-box pharmacies owned by PBMs.

If you look at Ohio, CVS, and OptumRX charge that State more than $400,000,000 more than they paid out to pharmacies. It is just amazing to me that we will continue to turn an eye and not have the discussion.

If we wanted to lower drug costs in this country right now, start with the PBMs. Start right where they are at. I have been talking about this for six years. I just laid it out.

They are going full throttle trying to kill independent pharmacists and pharmacies in our communities. They offer little more than anecdotal evidence that will save you money. In fact, when others have actually—states such as Texas and companies such as Caterpillar and others have actually gone away from their PBM system they saved money.

PBMs—it is just amazing having immense control over patient formularies, allowing them to push patients to a high-cost medication because these medications give the PBM higher rebates.

As a result, PBMs increase patient co-pays and incentivize manufacturers to increase drug costs to pay PBMs higher rebate demands. So, PBMs are actually costing patients money.

PBMs' role as an intermediary also allows them to extract rebates and price concessions for competing pharmacies and manufacturers without passing them on to the patients.

You know what is really amazing about them and talking about these six years? I have never had a PBM come in and deny what

I say. Never. They just don't like the way I talk about them. They don't care that their practices are bad.

They just don't like that I call them out for it. It is amazing. This lack of transparency in the price concessions are often withheld from patients and payers and increasing PBM profits while failing to decrease drug costs.

I recently introduced legislation called the Fair Pricing Act with Representative Gonzalez a Democrat from Texas, and also Senator John Kennedy from Louisiana.

This legislation will require PBMs to pass pharmacy rebates and price concessions on to patients at the point of sale. That will save patients an estimated $9.2 billion over the next 10 years.

Key provisions from my legislation are also included in the proposed Rule from the Department of Health and Human Services Secretary Alex Azar.

Additionally, states across the country, including my home State of Georgia, have realized this lack of transparency in the marketplace and legislators are passing laws requiring transparency for PBMs regarding the rebates prices concessions they are receiving from pharmacies and manufacturers. These laws aim to ensure that patients are receiving and seeing the savings PBMs claim to be offering and negotiated on their behalf.

I do want to talk, Mr. Chair, about another issue that is dear, especially in Georgia, and that is hospital consolidation that the full Committee chair also talked about in rural communities.

These communities often already have few options for quality care so when hospital consolidation is increased over the past 10 years rural communities like my own have been hurt the most.

At times, these mergers and acquisitions can help rural communities by keeping facilities open. They result in full or partial closes and shifting patients from nearby facilities to those hours away.

This doesn't benefit patients. Instead, it hurts them because they are unable to receive the lifesaving treatment they need. In some areas of my state, we have seen mergers limit emergency care, increase patient travel time by hours.

Imagine if a woman has a difficult labor but had to travel hours to a healthcare facility. These changes can literally mean the difference in life and death.

I have also seen hospitals acquire other pharmacy and physician practices in their area to steer patients away from their competitors. I am concerned that these practices will result in fewer options for patients, higher cost, and a lower quality of care.

I want to commend this Subcommittee for reviewing the consolidation and anticompetitive practice across the healthcare marketplace and I am looking forward to working with the Chair and others on this across the aisle to find real solutions because we must decrease the cost of our healthcare and prescription drugs while increasing patients' access to the best care possible and that means taking a look at everything on the table and it is time the pharmacy benefit managers realize your time of terrorizing this marketplace is over.

With that, I yield back to Chair.

Mr. CICILLINE. Thank you, Mr. Collins.

It is now my pleasure to introduce today's witnesses. Our first witness on today's panel is Dr. Fiona Scott Morton, the Theodore Nierenberg Professor of Economics at Yale University School of Management.

Dr. Scott Morton is nationally recognized as a leading scholar on issues of competition and has published articles that range widely across industries and leading economic journals.

From 2011 to 2012, she served as the deputy assistant attorney general for economics at the Antitrust Division in the U.S. Department of Justice where she helped enforce the nation's antitrust laws.

Dr. Scott Morton received her BA from Yale and her Ph.D. from the Massachusetts Institute of Technology. Welcome.

Our next witness is Michael Kades, the director of markets and competition policy at the Washington Center for Equitable Growth. Prior to joining Equitable Growth, Mr. Kades served as antitrust counsel for Senator Amy Klobuchar and before that as an attorney at the Federal Trade Commission for 20 years.

His work on anticompetitive pharmaceutical patent settlements led to the Commission's victory before the Supreme Court in *FTC* v. *Actavis*. During his time at the Commission, he was also an attorney advisor to Chair Jon Leibowitz and the deputy trial counsel.

Prior to working at the Commission, Mr. Kades clerked for the Honorable John Reynolds at the United States District Court for the Eastern District of Wisconsin and is a graduate of Yale University and the University of Wisconsin Law School.

Our third witness is Dr. Martin Gaynor, the E.J. Barone Professor of Economics and Health Policy at Carnegie Mellon University. Dr. Gaynor is widely recognized as a leading scholar on competition and, in particular, the study of consolidation and market power within hospital markets and healthcare systems.

Dr. Gaynor previously served as the director of the Federal Trade Commission's Bureau of Economics and is a research fellow at the National Bureau of Economic research. He received his BA from the University of California San Diego and his Ph.D. in economics for Northwestern University.

Our final witness in today's hearing is Dr. Craig Garthwaite, the Herman Smith Research Professor in Hospital and Health Service and the director of the program on healthcare at the Kellogg School of Management at Northwestern University.

Dr. Garthwaite's research examines the effects of government policies with a focus on health and biopharmaceutical sectors. He has appeared as a guest on various television and radio shows such as NPR Marketplace and has appeared in journals like the American Economic Review and Health Affairs. Dr. Garthwaite received his BA and Master's in public policy from the University of Michigan and his Ph.D. in economics from the University of Maryland.

So, we welcome all of the distinguished witnesses and thank them very much for participating in today's hearing.

Now, if you would please rise I will begin our hearing by administering the oath and swearing you in. Please rise your right hands.

Do you swear or affirm under penalty of perjury that the testimony you are about to give is true and correct to the best of your knowledge, information, and belief, so help you God?

[A chorus of ayes.]

Mr. CICILLINE. The record should reflect that the witnesses answered in the affirmative. You may be seated. Thank you very much.

Please note that each of your written statements will be entered into the record in its entirety. Accordingly, I ask that you summarize your testimony in five minutes.

To help you stay within that time, there is a timing light on your table. When the light switches from green to yellow you have about a minute to conclude your testimony. When the light turns red it signals that your five minutes has expired and I would ask you to please conclude.

We will begin with Dr. Scott Morton. If you would just hit the button so we can—

TESTIMONY OF DR. FIONA SCOTT MORTON

Ms. SCOTT MORTON. Thank you, Mr. Chair, and Members of the Committee for the invitation to testify.

Today in the United States we are choosing to use the private sector to provide healthcare without establishing enough rules to ensure competition. The result is that we have providers who are profit seeking without the restraint imposed by competition.

My belief is that if we do not fix this that the ever-increasing costs are going to lead to a different kind of solution, which is just price regulation by the government.

That is not my preferred solution. I think markets would be much better, but they have to be working markets. It is not obvious that price regulation would be worse than unrestrained private monopolies, which is what we are faced with today.

You will hear from the other Members at my table is that we have good news. High prices in many areas of pharmaceutical and medical care are eminently fixable. It is not rocket science what we are going to tell you.

There is a great deal of evidence about how to bring down these prices. The bad news is that the providers, whose prices will come down should they face vigorous competition, are going to lobby for any—against any changes in the law and, historically, have been very successful at doing that.

For the conservatives in the room, if you claim to like markets and you like market solutions over government, this is what you are going to hear today. I think all of us want markets, but we want working markets, ones that enable competition.

I have two main points to discuss from my testimony. The first is the area of biologics and physician-administered drugs. This is the area with the most growth currently. These are very high-priced products. They are growing very quickly both in terms of price and in terms of quantity.

We procure these drugs primarily through the Part B program as well as on the commercial side. This is run quite differently from Part D. Part D, like dog, okay, that is the one where we outsource to private insurance companies who have a formulary, and they bargain to get low prices.

Part B, like boy, that is the one where we do nothing. We allow the manufacturer to announce a price and then the government

pays that. Okay. So, it is not really very surprising that it is only 18 percent of GDP we spend on healthcare. Probably should be more.

So, why—what is the restraint? Well, the manufacturer does have to sell in the commercial marketplace and as prices get higher that gets difficult. There is no restraint on the government side.

So, this is something that Congress should fix. We should be procuring Part B drugs in a way that is competitive. One way to do that would be to change the system of J–Codes.

Currently, if there is a branded product that is a biologic and biosimilars enter, each of those manufacturers gets their own reference price—their own J–Code. So, if the brand costs $1,000 and the biosimilar costs $600, a doctor that dispenses the biosimilar gets paid $600 plus a markup and the one that chooses the brand gets paid $1,000 plus a markup.

If we had one payment for all the drugs that are the same, all the same molecule, then the branded drug would have to come down or else the doctors would all pick the biosimilar because they would be being reimbursed at $600. They would not choose to buy a $1,000 drug.

That same principle works in other areas. We, for a brief while, had a low-cost alternative in the area of prostrate drugs. That caused doctors to go out and actually seek the lowest cost therapy in that class and the result of that was such good competition that the brands in question sued the government and—over the fact that the government—CMS did not have the authority to procure drugs in that competitive a manner, and they won.

So, it would be useful if Congress would enable the government to procure drugs in that cost-effective manner.

My second point is about consumer out-of-pocket costs. These have gotten very high with the popularity of high deductible plans. When you have an out-of-pocket cost that is based on the list price of the drug this generates kind of negative insurance.

You buy insurance and instead of paying market price for the drug—let us say, $300, and you pay list price for the drug, $600. So, you are getting the opposite of what insurance is supposed to do, which is to smooth these financial shocks when you get sick.

The HHS solution, which makes consumers' out-of-pocket costs depend on the net price, I think something like that is a good idea. It could be the true net price.

It could be some well-defined average to make the net price continue to be confidential, which is very important for getting low prices in general, or it could just be below—equal to or below the net price so that a plan could choose to have a $50 out-of-pocket cost and we would never know what the net price was and that would also be fine.

The important thing about this solution that HHS has come up with is that it is going to restrain competition between manufacturers. I believe this is why manufacturers are in favor of this rule, because it is not going to intensify price competition. It is going to lessen price competition.

Why? Because there won't be able to be performance-based rebates where a plan says, I will deliver you a high market share

from Drug A to Drug B, and Drug B says, okay, if you deliver that high market share, I am willing to sell to you at a low price.

We don't know until the end of the year if the market share gets delivered and therefore what the price should be. So there needs to be built into whatever the safe harbor is the ability for the plan to negotiate that way with the manufacturer, extract a really low price, and then—sorry, I will stop—and then—and then deliver that to the patient. So that is key.

[The statement of Ms. Scott Morton follows:]

STATEMENT OF FIONA M. SCOTT MORTON

Framing

Why are U.S. healthcare costs rising so fast?[1] One reason is a lack of competition. The narrative that healthcare costs are high because we use markets, rather than government, to provide healthcare is not correct in my view. Rather, healthcare costs are high because we do not have competitive markets for these services. Private providers that are not subject to competitive forces create the worst of both worlds. Because the sector is so regulated there are many ways for private healthcare providers to successfully lobby for regulations and practices that shield themselves from competition. For the last decade or so, Congress has been explicitly enabling this lack of competition by designing, or failing to correct, the methods by which the public sector procures drugs and controls access to markets so as to benefit providers. The good news, therefore, is that high prices in many areas of pharmaceutical and medical care are eminently fixable and there is a great deal of evidence about what policies will bring down prices. The bad news is that the providers whose prices will come down—should they have to vigorously compete for business—will lobby against any changes in the law, and have historically been very successful at doing that.

Some of the behaviors detailed below are violations of existing antitrust law. However, antitrust enforcement has become weak in the U.S. for a variety of reasons and, in addition, it is a slow and expensive way to deal with many healthcare markets that regularly experience new product entry. Even if the leadership of the antitrust agencies found increasing competition in healthcare markets to be a priority, they likely do not have the resources to address all the known competition problems, much less new problems driven by changing regulations and new technologies or products.

Congress could significantly lower healthcare costs and restrain cost increases with some relatively simple statutes that create more competition in this sector. Congress could also instruct—and fund—the FTC to pursue particular enforcement projects in this sector that Congress finds critical to restraining healthcare costs. Significant increases in the budgets of the antitrust enforcement agencies are absolutely necessary if Congress wishes to have more competition in any market, including in healthcare markets. Those funds would be leveraged, and therefore more effective, if combined with some statutory changes recommended below.

The sources of market power in many healthcare markets come from both intellectual property and the nature of government programs. My colleague and co-author, Professor Craig Garthwaite, has provided the background reasons for market power in his statement. I will not repeat that material here, but rather move on to particular solutions.

Specific Topics

1. Behavior That Could Be a Violation of Antitrust Laws

When brands try to use FDA regulations concerning provision of samples or protection of consumers from dangerous drugs as a means to improperly exclude generic entrants, they may be violating antitrust laws. The CREATES Act requires brands to sell generic and biosimilar firms samples under reasonable terms and pre-

[1] For example, *see* Professor Martin Gaynor's previous House testimony: *https://docs.house.gov/meetings/IF/IF02/20180214/106855/HHRG-115-IF02-Wstate-GaynorM-20180214.pdf*. For recent work on hospital prices *see* Cooper, Zack, Stuart V. Craig, Martin Gaynor, John Van Reenen (2019). "The Price Ain't Right? Hospital Prices and Health Spending on the Privately Insured, *The Quarterly Journal of Economics* 134(1):51–107.

vents abuse of a REMS restricted distribution system. This new legislation will help keep brands from hampering and delaying the entry of generics and biosimilars after the brand's patent has expired. It should be enacted promptly. The abuse of citizens' petitions should also be addressed by Congress.

The Supreme Court's *Actavis* decision[2] is helpful in preventing pay-for-delay schemes and therefore promoting new generic and biosimilar entry that lowers prices. However, firms continue to enter into these agreements and the FTC continues to expend resources investigating and litigating against this abusive behavior. Congress could end this wasteful situation by passing more specific laws against pay for delay in both small molecule and biologic markets.

This would save enforcement resources in the drug markets, and also control a practice that is spreading to the biologics markets.[3] Enforcement is weaker in biologics because competition among biosimilars and the reference biologic product are slightly different than the well-studied small molecule drug case, and therefore there is uncertainty about how courts will Rule on these cases. In the United States, biologics grew from just 13% of biopharmaceutical spending in 2006 to 27% in 2016, and growth continues, so timely entry of biosimilar (clinically equivalent) products at patent expiration is critical to limiting biopharmaceutical expenditures.[4]

Another industry tactic that insulates a reference biologic or branded small molecule product with a large and durable market share from price competition is a loyalty rebate. A loyalty rebate gives a customer a large *ex post* rebate on its drug purchases, but only if the customer has stayed loyal to the brand (either exclusively or with a high share such as 90%), meaning the buyer has not purchased any significant share from the generic or biosimilar entrant. A loyalty rebate successfully excludes the newest entrants when the brand has an entrenched share of the market (known as non-contestable share). Non-contestable share is the segment of the market that the generic or entrant cannot serve (perhaps it is a version they do not make, an indication they are not approved for, or the segment of chronic patients that are taking the brand and are stable and happy on it). The generic or biosimilar entrant cannot compete for *all* the business of the buyer because of this non-contestable share, so it competes for only part—but at a lower price. The new entrant comes in with a lower price for the contestable share, but critically, it cannot compete for 100% of the needs of the buyer. This is where the loyalty rebate has a harmful effect on competition. A brand with large and durable market share will create a rebate in exchange for the buyer making purchases (or adopting formularies) that exclude entirely a new entrant or reduce the share of the new entrant.

Buyers (plans or PBMs) that must purchase the brand to serve their non-contestable share (*e.g.*, the patients stabilized on the brand) realize they will be buying those branded units on unfavorable terms—unless they agree to the loyalty rebate. The buyer faces a choice between staying loyal (buying 100% from the brand and receiving the rebate on all those purchases) or buying the contestable share from the entrant at a low price and the balance of their needs from the brand at a high price (forfeiting the rebate). An anticompetitive loyalty rebate scheme causes buyers to avoid purchasing from the new entrant for no reason related to the entrant's quality or price, but because of the brand's ability to withhold a rebate on the share of purchases the new entrant cannot supply. The entrant therefore earns less share than it would under competition on the merits. Loyalty rebates can be designed so that even if the new entrant charges zero for its product, the buyer still pays more in total by forgoing the rebates on the noncontestable share. Such rebates generate a larger share for the brand than it would have secured through competition on the merits, dose by dose.[5]

There are now two biosimilar infliximab molecules that compete with the brand, Remicade. Those biosimilars offer prices 30% below the branded price and yet, combined, have a 7% market share.[6] Why is it that demand does not shift to an almost identical product with a lower price? On the public side it is likely due to Medicare reimbursement (explained below) and on the commercial side it is likely due to anti-

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[2] *FTC* v. *Actavis, Inc.*, 570 U.S. 136 (2013).

[3] Feldman, Robin and Misra, Prianka, The Fatal Attraction of Pay-for-Delay (January 15, 2019). Chicago—Kent Journal of Intellectual Property, Forthcoming. Available at SSRN: *https://ssrn.com/abstract=3316339*.

[4] *https://www.brookings.edu/wp-content/uploads/2017/05/wp30__scottmorton__competitioninpharma1.pdf* (pages 5–6, and figure 2).

[5] Scott Morton, Fiona and Zachary Abrahamson (2017), "A Unifying Analytical Framework for Loyalty Rebates," *Antitrust Law Journal* 81(3): 777–836.

[6] Ronny Gal, Sanford Bernstein (Feb. 26, 2019), Global Specialty Pharma & U.S. Biotech, "Biosimilars: adoption update in EU & U.S.—Dec '18 data: Herceptin & Rituxan moving; Remicade U.S. will not adopt in 2019."

competitive loyalty rebate contracts. By way of contrast, the U.S. Veterans Administration has a financial incentive to procure drugs at the lowest possible price and controls physician prescribing. The U.S. VA has been able to negotiate more than an 80% lower price for a biosimilar as compared to the reference product.[7] Data from Europe demonstrate similar levels of savings. Given the ease of enabling competition in this sector, these are savings that Congress is choosing to forgo on behalf of U.S. taxpayers and patients.

A second way that reference biologics exclude biosimilar entrants is by continually updating their FDA application file. A biologic medication may have its BLA approved by the FDA and therefore be selling on the market while its manufacturer continues to make changes to its file. Those changes then become part of the reference product. Thus a biosimilar, instead of attempting to imitate a product that is fixed at the moment of launch, is chasing a moving target. The reference product can choose to make changes at any time that make imitation more difficult or costly. In particular, the reference biologic can patent the changes it makes and in that way create a thicket of dozens of patents that take decades to expire. The migration of the reference product in this way is a huge barrier to entry for competing products. Biologics already have 12 years of market exclusivity (granted to them because they claimed to the government that their patents would be weak and so the market exclusivity would be a necessary substitute). Instead we see products on the market with 30 or more years of patent protection. There are 17 biosimilar products approved by the FDA that cannot launch because of patent issues. For example, the biosimilar competitors of Humira, a product that sells over 13 billion per year in the U.S., have settled with Abbvie that they will launch in 2023 in the U.S.[8] In Europe, these biosimilars are already on the market and Abbvie has offered discounts of 80% in order to retain its market share. These are cost savings the United States is foregoing with its suboptimal regulation.[9]

The solution is straightforward. A new regulation stipulates that at the time of launch the file constituting the reference product's BLA is fixed; and this product is the one the biosimilar must match. Any additional improvement the reference product maker would like to make can become an improved, different, product as is normally done in small molecule drugs. Any intellectual property needed to make the reference product would be notified to the FDA at the time of the original BLA; any subsequent products could have subsequent intellectual property attached to them. This would prevent the migration of the reference product and its role as a barrier to entry.

2. Pharmaceutical Procurement Is a Problem

Medicare Part B is a growing area of expenditure—due to biologics and oncology drugs[10]—and yet Medicare procures these drugs in a way that avoids almost all competitive forces. Physicians typically purchase the drugs and are reimbursed by Part B for whatever they choose to give the patient. Because physicians are paid a markup over the average cost of purchasing the drug, they have no incentive to consider equally effective, but lower-priced product.[11] Indeed, because the physician earns a percentage margin on the medication, a physician has a financial incentive to use a higher priced branded product. Demand from Medicare patients does not decline appreciably with high prices (many enrollees are insured for their 20%

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[7] AB Bernstein report 18 January 2019.

[8] Abbvie Press Release: AbbVie Reports Full-Year and Fourth-Quarter 2018 Financial Results (Jan 25, 2019), *https://news.abbvie.com/news/abbvie-reports-full-year-and-fourth-quarter-2018-financial-results.htm*; Peter Loftus, AbbVie, By Adding Patents, Drugmaker Keeps Cheaper Humira Copies Out of U.S., WALL ST. JOURNAL (Oct. 16, 2018), *https://www.wsj.com/articles/biosimilar-humira-goes-on-sale-in-europe-widening-gap-with-u-s-11539687603*.

[9] A/B Bernstein reports 18 Jan 2019 and 26 Feb 2019.

[10] "61% of Part B drugs approved by the FDA in 2006–2013 were biologics, and two-thirds of all biologics approved by FDA during this time were paid for by Part B." (p10) "Expenditures for the 75 new Part B drugs for which we identified claims in 2013 were concentrated among a small number of drugs. The 20 highest expenditure drugs accounted for 92 percent of 2013 expenditures on new Part B drugs and 26 percent of total Part B drug expenditures. Biologics accounted for 13 of the top 20 highest expenditure new Part B drugs and 82 percent of expenditures for these 20 drugs (see table 2)." Page 14 of *Medicare Part B, Expenditures for New Drugs Concentrated among a Few Drugs, and Most Were Costly for Beneficiaries*, Report to the Ranking Member, Committee on the Budget, House of Representatives (Government Accountability Office, October 2015), *https://www.gao.gov/assets/680/673304.pdf*, at 10, 14.

[11] *Medicare Part B, Expenditures for New Drugs Concentrated among a Few Drugs, and Most Were Costly for Beneficiaries*, Report to the Ranking Member, Committee on the Budget, House of Representatives (Government Accountability Office, October 2015), *https://www.gao.gov/assets/680/673304.pdf*, at 10 and note 27.

copay, so their costs are zero), so a manufacturer wants to set a high list price when it anticipates high Medicare sales. That high list price must then be paid by commercial customers. The manufacturer faces a strong incentive not to give discounts in order to sustain its high price to Medicare. So the Part B procurement policy is actively harmful to privately insured patients.

The situation is particularly bad when a reference biologic experiences entry and competition from a much cheaper, but clinically identical, biosimilar. Under current Medicare rules each manufacturer of a biologic gets its own reimbursement price from Medicare. Each product is labeled with a different "J-code" and associated price. A physician that continues buying a $1,000 reference product rather than switching to the $600 biosimilar need not worry about payment because he or she gets reimbursed the full $1000 for using the brand. The entry of a cheaper version of the same product has no impact on Medicare's payment for the brand. In particular, the way Medicare pays the doctor means she has zero incentive to use a lower priced product in a case when there is choice. The solution here is to adopt one reimbursement amount (one "J-code") for Medicare to pay for any of either the reference biologic or its competing biosimilars.[12] These are all the same molecule that deliver the same therapeutic benefit and should therefore be competition with one another, but current regulations insulate them from this price competition. This is a massive waste of Medicare funds. If there were one price across the group, a physician would be reimbursed that fixed amount for administering any one of those products, and would therefore care about seeking out a manufacturer charging a low price. This in turn would cause manufacturers to compete by lowering prices.

Secondly, Congress should authorize Medicare to use "least costly alternative" models of payment for Medicare Part B drugs where several equivalent competing therapies (possibly still under patent protection) are grouped and one payment amount is set for the group. This causes expensive drugs that are not superior in efficacy to lose sales—or lower their price. OIG has studied this way of procuring drugs and found it delivers large cost savings.[13]

Part D purchases drugs using the technique of a formulary run by a private insurer. This allows for much stronger negotiation of prices for some drugs. However, the protected classes in Part D most effectively 'protect' manufacturers from competition. Requiring Part D plans to have a robust formulary that offers covered options for every patient is critical, but that regulation can be paired with a relaxation of rigid protected class rules. In addition, the Part D catastrophic region appears to create incentives that cause higher list prices and consumer costs, and needs to be reformed as suggested by Craig Garthwaite.

3. High Consumer Out-of-Pocket Costs are a Problem

High out-of-pocket costs for drugs are inconsistent with one purpose of insurance, which is to smooth financial shocks over time by paying a regular premium to cover infrequent healthcare expenditures. If a person has pharmaceutical insurance we ideally want it to reduce her out-of-pocket costs below the market price for the drug, not make them more than the market price for the drug. For example, if the list price of a drug is $600 while a plan has negotiated a price of $300, a consumer with a $1000 deductible will pay the full $600 list price. Her plan will receive a $300 rebate from the manufacturer, but will have paid out nothing for the claim. In this situation, not only is the patient paying more than the competitive price for the medication, but the employer or plan has made a profit on the claim. This practice generates a transfer from the sick to the healthy, which is the opposite of the purpose of insurance. The solution is a regulation that requires insurers to design their insurance so that patients' out of pocket payments in the deductible are equal or less than the final net price of the medication incurred by the insurer (or perhaps less than some kind of average of that final net price).

The recent HHS Rule would effectively require any patient out-of-pocket payment that depends on the list price of the drug be calculated based on the net price after rebates. This Rule will do at least two helpful things: lower patient out-of-pocket prices and reduce the ability to exclude with a loyalty rebate contract. However, the Rule is likely to weaken price competition between branded products, and this may be why pharmaceutical manufacturers are in favor of the Rule change. The way in

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[12] MEDPAC, *Medicare Part B drug payment policy issues*, (June 2017) ("Require the Secretary to use a common billing code to pay for a reference biologic and its biosimilars). *Available at http://www.medpac.gov/docs/default-source/reports/jun17_ch2.pdf?sfvrsn=0.*

[13] *Least Costly Alternative Policies: Impact on Prostate Cancer Drugs Covered Under Medicare Part B*, Department of Health and Human Services (Office of Inspector General, November 2012), *https://oig.hhs.gov/oei/reports/oei-12-12-00210.pdf*, at 12.

which the Rule change would soften price competition works as follows (as far as I understand the Rule at present). First, a patient payment that is a function of the negotiated price has the potential to reveal negotiated prices, which is likely to reduce discounts (as described in Craig Garthwaite's testimony). However, a plan could design out-of-pocket payments to be fixed amounts (*e.g.*, $25) rather than percentages of a medication's price. More importantly, the Rule may prevent performance-based contracts. A PBM that commits to move 50% share from drug A to drug B in a calendar year in exchange for a low price may not succeed. The maker of drug B might not want to offer a very low price because it worries that the PBM will not deliver its end of the deal. That manufacturer may want to offer one price in case the PBM does not move 50% share, and a lower price if it does—a performance-based contract. Consumers could not be charged that lower price before either side knows if it is in fact the true net price. If such contracts are ruled out by the change in the safe harbor definition, then price competition will become less vigorous. Prices will rise in equilibrium when PBMs cannot condition low prices on achieving certain shares. Higher prices will raise manufacturer profits, which may be the analysis manufacturers have carried out, and the reason they support the rule. The Rule should be structured so that the safe harbor still applies if the patient's out-of-pocket costs are fixed, if the patient's out-of-pocket costs are a function of a price that is below the final net price the plan pays, or if they are a function of a well-defined average price the plan expects to pay. In this way performance-based contracts and confidential price discounts will both be permitted and will bring down prices.

The HHS proposed Rule would also encourage intermediaries in the supply chain to be paid in some way that is not as a percentage of the list price. A wholesaler that is transporting drugs could be paid a dollar amount per box, for example, and would then no longer have an incentive to support higher list prices.

Recent evidence demonstrates another method by which drug manufacturers avoid competition; they use various techniques to make side payments to patients in order to undo the incentives created by the PBM and thereby shift consumption toward more expensive branded drugs. These side payments can take the form of coupons, in-kind benefits provided under the guise of marketing, or charitable assistance programs. For example, a brand gives a patient a coupon for $80 that reduces the patient's co-pay from $90 down to $10. Suppose that in the consumer's plan the generic equivalent has a copay of $10. Now the patient is happy to choose the brand (which has a much higher list price, *e.g.*, $250) because both options cost her $10.

Meanwhile healthcare costs have risen because the plan is paying for a $250 brand instead of a $15 generic. In addition, the plan loses bargaining leverage with manufacturers and must acquiesce to higher prices. Why? Because when the coupons or financial aid undo the financial incentives put in place by the plan, it has lost one of its main tools to move patients to the cheaper drug. Without being able to "shift share" in response to price, the plan doesn't have bargaining power. With less plan bargaining power, pharmaceutical prices rise. It is important to note that these coupons are banned in the Medicare and Medicaid programs because they are a violation of the anti-kickback statues and raise costs to the government. However, they are permitted in commercial insurance where we have no reason to believe the effects are any different. Indeed, the research finding that coupons lead to higher drug costs and less generic competition studied the time when Massachusetts banned these coupons.[14]

Such practices are particularly extensive and problematic in populations with high per-patient expenditure, such as hemophilia, that are often treated with biologics. Insurance companies cannot typically see exactly what source of funds is used for a co-payment and therefore cannot monitor these kickbacks. In addition, by driving the effective price borne by patients to zero, manufacturers can encourage over-consumption of their drug, increasing costs for insurers and driving up premiums.[15]

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[14] Dafny, Leemore, Christopher Ody, and Matt Schmitt (2017), "When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization," *American Economic Journal: Economic Policy*, 9(2): 91–123; Scott Morton, Fiona and Lysle T. Boller (2017), "Enabling Competition in Pharmaceutical Markets," Brookings Institution, Hutchins Center Working Paper No. 30, *https://www.brookings.edu/wp-content/uploads/2017/05/wp30__scottmorton__competitioninpharma1.pdf*, at 26–27.

[15] Scott Morton, Fiona and Lysle T. Boller (2017), "Enabling Competition in Pharmaceutical Markets," Brookings Institution, Hutchins Center Working Paper No. 30, *https://www.brookings.edu/wp-content/uploads/2017/05/wp30__scottmorton__competitioninpharma1.pdf*, at 26–27.

The solution to this problem is to implement two policies simultaneously: First, a ban on any kind of manufacturer payment to patients whether coupons, financial aid, wrap-around services, etc., paired with a limit on out of pocket expenditure per prescription (or 30 day supply) at some reasonable level such as $200. The limit on out of pocket expenditure protects the patient who has purchased insurance; the ban on coupons and financial aid to patients empowers the PBM to create formularies that can shift share and drive down prices while preventing manufacturers from "buying" sales they cannot achieve on the merits. A plan will be able to shift share by adjusting the out of pocket payment between zero and $200 and thus be well positioned to bargain for lower prices from manufacturers.

A solution to tackle the problem of high out-of-pocket consumer costs that also promotes competition, such as the proposal above, is more desirable than one that reduces competition, such as the HHS rule. The HHS rule, by reducing competition between drugs, will lead to higher equilibrium prices.

4. PBM's Dual Role

PBMs can play a good role in today's pharmaceutical markets, and also, potentially, a bad one. The good role of the PBM is to create price competition among branded and generic treatments. In pharmaceutical and device markets, final consumers are generally both uninformed and insured, so on their own they cannot respond to a price discount by moving their purchases, nor are they able to ask for one as individuals. The institutional innovation that creates competition in pharmaceuticals is the PBM. The PBM is informed about available substitute treatments, is sensitive to price, and controls a large group of final consumers. Of course, the PBM has far less bargaining power in markets where there is insufficient competition, for example, a monopoly market structure or a government requirement to buy a particular product. In a market with competitive alternatives the PBM has the ability to negotiate for lower prices in exchange for market share. Those lower prices take the form of a rebate from the manufacturer back to the PBM (because the patient has purchased the drug at a pharmacy that typically serves many different PBMs). The PBM's role of seeking out discounts from manufacturers is critical because it is one of the few agents *in our commercial pharmaceutical marketplace that creates price competition*.

It is also key that these rebates stay confidential. Suppose a small staff-model HMO says it will be able to move 99% of patients to a substitute drug and, with that threat of walking away, obtains a huge rebate on the drug. If that discount were to become public, other buyers who cannot move as much share would nonetheless demand the same discount, and those bargaining costs would likely stop the manufacturer from offering it to the small HMO in the first place. We have seen this dynamic before in the Medicaid MFN rules.[16] One reason pharmaceutical manufacturers like restrictions on rebates, such as those in the proposed HHS rule, is that such restrictions suppress price competition and less price competition increase manufacturer profits.

The side of PBMs that needs policy attention is their increasing consolidation and market power; however, this is fixable and may already be weakening. The FTC has allowed many PBM mergers over the last 20 years while there may not have been enough competition among PBMs to protect end consumers, particularly given PBMs' use of MFNs, limited information disclosures, and other practices detailed in the Garthwaite testimony. Under these conditions, some PBMs may have stopped being good agents for final consumers without losing business.

This a phenomenon Craig Garthwaite and I wrote about 18 months ago.[17] If the rebate process is opaque, the PBM may find that a good way to raise prices is to keep more of the rebate dollars. This in turn leads to an incentive for the PBM to encourage the manufacturer to raise the list price of the drug (*e.g.*, by $100), increase the rebate (*e.g.*, by $80 so that the manufacturer gains an extra $20), thereby allowing the PBM to pass only some of the increased rebate to the customer (*e.g.*, $50 so that the PBM's profits rise by $30). This tactic leads to rising list prices, rising net prices, and rising rebates, the last of which benefits the PBM. There are

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[16] Scott Morton, Fiona (1997), "The Strategic Response by Pharmaceutical Firms to the Medicaid Most-Favored-Customer Rules," *The RAND Journal of Economics* 28(2): 269–290.

[17] Garthwaite, Craig and Fiona Scott Morton, "Perverse Market Incentives Encourage High Prescription Drug Prices," Pro-Market blog (November 1, 2017), Stigler Center at the University of Chicago Booth School of Business, *https://promarket.org/perverse-market-incentives-encourage-high-prescription-drug-prices*.

a number of possible solutions. Congress could require a PBM to have a fiduciary duty to its clients.

Alternatively, PBM contracts could require all payments from the manufacturer, whether labeled as rebates, administrative fees, consulting fees, marketing fees, or any other title, flow directly to the end client (the employer). Indeed, there could be a safe harbor for payments from the manufacturer to the end client, rather than to the PBM. If the employer and PBM so choose, they can specify in a contract how to share them with the PBM. A third point is that competition in the health insurance market may improve the agency of PBMs. Due to recent mergers between PBMs and health insurers, all the large PBMs in the U.S. are now vertically integrated. This integration may be due to both parties' interest in internalizing the externalities between pharmaceutical consumption and medical care. Between the mergers and significant public exposure, the agency problems outlined above may be on the wane already.

5. Many Past Mergers Were Anticompetitive

Unlike many other sectors, healthcare providers often have geographically spaced facilities that limit the extent to which company activities can be combined and made more efficient in the event of a merger. This integration is often referred to as "scrambling the eggs" because such it is difficult to undo after a merger. Because there is no time limit on Clayton Act violations, Congress could instruct the FTC to open a unit to revisit healthcare mergers that have harmed competition. A substantial literature concludes that there have been many anticompetitive hospital mergers over the last 30 years.[18]

A second area of focus for consummated anticompetitive mergers are transactions that fall below the Hart-Scott-Rodino Antitrust Improvements Act ("HSR") threshold. Professors Thomas Wollmann (University of Chicago) and Paul Eliason (Brigham Young) have work in the area of dialysis clinics that shows the harm from mergers.[19] Wollmann's dialysis paper shows that when a transaction falls below the HSR threshold, the FTC essentially requires no divestitures. This is true regardless of the geographic overlap of the clinics; in particular it is true when a similar case reported under HSR would be required to divest in order to merge.[20] The paper shows that the bulk of the increase in concentration in the dialysis industry comes from these small, unreported mergers. Revisiting those past transactions and requiring appropriate divestitures of dialysis clinics could increase competition.

Lowering the HSR threshold for merger review going forward would also allow for more vigorous enforcement. Indeed, if an automated process were adopted, a very low threshold could also be cost-effective. For example, Congress could instruct the FTC to design a form "EZ-merge" for mergers between $2 and $20 m, with a standard HSR process for anything larger.mBusinesses could choose their type (*e.g.*, auto tire retailer, primary care physicians, or funeral home) from a drop-down menu and enter the zipcodes of their customers. An algorithm could determine if, for example, two small orthopedic groups serve the same geographic area, or two dialysis clinics are in the same town. Flagged mergers could be passed on to FTC staff for further review. We know that simply notifying a merger to federal authorities creates a deterrent effect; therefore, the simple adoption of Form EZ-merge might cause dialysis clinics and other local businesses in the same town to stop proposing anticompetitive mergers.

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[18] *See, e.g.*, Fulton, Brent D. (2017), "Healthcare Market Concentration Trends in the United States: Evidence and Policy Responses," *Health Affairs* 36(9):1530–1538; Cutler, David M. and Fiona Scott Morton (2013), "Hospitals, Market Share, and Consolidation," *JAMA* 310(18): 1964–1970; Cooper, Zack, *et al.* (2019), "The Price Ain't Right? Hospital Prices and Health Spending on the Privately Insured," *Quarterly Journal of Economics* 134(1): 51–107; Gaynor, Martin and Robert Town (2012), *The Impact of Hospital Consolidation—Update*, Robert Wood Johnson Foundation Synthesis Project, *https://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261*. *See also* Cuellar, Alison Evans and Paul J. Gertler (2003), "Trends in Hospital Consolidation: The Formation of Local Systems," *Health Affairs* 22(6): 77–87.

[19] Eliason, Paul J., *et al.* (2018), "How Acquisitions Affect Firm Behavior and Performance: Evidence from the Dialysis Industry," Manuscript, *available at https://www.ftc.gov/system/files/documents/public_events/1349883/eliasonheebshmcdevittroberts.pdf*.

[20] Wollmann, Thomas (2018), "Stealth Consolidation: Evidence from an amendment to the Hart-Scott-Rodino Act," Manuscript, *http://faculty.chicagobooth.edu/thomas.wollmann/docs/stealth_consolidation_2_19.pdf* and Wollman, Thomas (2019) "Getting away with merger: The case of dialysis clinics in the United States."

6. Nonprofits

U.S. competition laws should apply to nonprofits just as they do for for-profit companies. In Healthcare, many hospitals and insurers are nonprofits, but their nonprofit status exempts them from the Federal Trade Commission Act and its prohibition on unfair methods of competition and unfair and deceptive acts or practices. (The FTC has jurisdiction over nonprofits for section 7 violations.) Congress should eliminate this exemption.

Mr. CICILLINE. Great. Thank you so much, Doctor.

I now recognize Mr. Kades for five minutes.

TESTIMONY OF MICHAEL KADES

Mr. KADES. Thank you, Chair Cicilline and Ranking Member Sensenbrenner and full committee—Mr. Nadler stepped out.

So, I just want to start with Ranking Member Sensenbrenner—just would for the record—

Mr. CICILLINE. Mr. Kades, would you just pull your microphone close to you so folks can hear it? Yeah.

Mr. KADES. So, Ranking Member Sensenbrenner, I just want to State for the record I was born and raised in Beloit, Wisconsin, fairly close to your 5th District, and when you have said Wisconsin, you have said it all.

It is an honor to testify before this Subcommittee on competition in prescription drug prices. This issue is vital to the healthcare system and affects all Americans.

I am Michael Kades, the director of Market and Competition Policy at the Washington Center for Equitable Growth. We seek to advance evidence-based ideas and policies that promote strong, stable, and broad-based economic growth.

The exploitation of monopoly power is the kind of inequality that is at the core of the most important challenges that our economy and Nation face. Prescription drug costs are and continue to be a burden.

In 2017, the United States spent $333 billion on prescription drugs. That is over $2,600 per family. Three out of 10 Americans are not taking prescriptions as directed because of cost. So, this isn't just about money. It is about people's health and well being.

No silver bullet exists to ensuring prescription medicine is affordable. It requires a broad range of policies. Increased competition should be part of the answer.

Stopping anticompetitive conduct will both lower prices and promote innovation. For 20 years at the Federal Trade Commission, I was on the front line of what has been and continues to be a never-ending struggle to protect competition in pharmaceutical markets.

I litigated and investigated dozens of pharmaceutical antitrust matters and I am here to tell you the system is broken. The incentives for anticompetitive activity in these markets is substantial.

For example, delaying competition on a blockbuster drug for just a year can mean hundreds of millions if not billions of dollars in additional profit.

The antitrust laws should stand as a bulwark against anticompetitive conduct. Unfortunately, courts have stripped those laws of their potency, narrowing the scope of the law and imposing ever-higher burdens of proof.

Easy cases have become hard and hard cases escape condemnation. Companies have been emboldened to push the limits of business conduct because the rewards are great and the risks are minimal. Even if they get caught, the penalties are low.

The result? Consumers pay hundreds if not thousands of dollars more each month for their prescriptions.

I want to focus on three practical policies that would help focus competition in the pharmaceutical markets, which this Committee can work on this year.

First, pass the CREATES Act. Chair and Ranking Member Cicilline, Sensenbrenner, Nadler, and Collins, this bill—this, obviously, bipartisan but also a bicameral supported bill would stop one of the most egregious strategies that limits competition.

Sometimes it is hard to explain. I like to put it down into one simple phrase. No samples, no competition. Break that chain and you will save billions of dollars for the government and American citizens.

Second, pass legislation to stop branded companies paying generic companies not to compete in the marketplace—what is called a "pay for delay" patent settlement.

Despite the Supreme Court's clear signal that these deals can be anticompetitive, the FTC still expends substantial resources challenging clear antitrust violations.

Chair Cicilline, you referred to the *Actavis* case which just got settled. When that case was filed, my daughter was learning how to read. She is coming home for her spring break of her first year of college. That is how long it took to get a resolution of that case. That is too long.

Enacting a law with clear standards such as the Preserve Access to Affordable Generics Act would deter this practice and free up limited resources to attack other anticompetitive conduct.

Third, make bad actors pay a real penalty. The key to deterring anticompetitive conduct is that when somebody violates the law, they shouldn't benefit from it. In the world of antitrust law we call this disgorgement. You make them give up their profits.

Even in this area, the federal Third Circuit of Appeals just last week, ignoring 35 years of precedent, clipped the ability of the FTC to obtain this type of relief.

This Congress should modify the Federal Trade Commission Act to clarify explicitly that the FTC can obtain this type of relief. It is critical to deterring highly probable—profitable, I am sorry—anticompetitive conduct.

Thank you, and I look forward to listen to your questions.

[The statement of Mr. Kades follows:]

Washington Center
for Equitable Growth

1500 K Street NW, Suite 850
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"Competition's Role in Controlling Prescription Drug Prices"

Michael Kades

Director, Markets and Competition Policy,
Washington Center for Equitable Growth

March 6, 2019

Testimony Before the Subcommittee on Antitrust, Commercial, and Administrative Law "Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets"

Thank you Chairman Cicilline, Ranking Member Sensenbrenner, full committee Chairman Nadler and full committee Ranking Member Collins for the honor of testifying before this Subcommittee on competition and prescription drug prices.

My name is Michael Kades, Director of Markets and Competition Policy at the Washington Center for Equitable Growth. We seek to advance evidence-backed ideas and policies that promote strong, stable, and broad-based economic growth. Anticompetitive conduct in prescription drugs is emblematic of the kind of inequality that is at the core of the most important challenges facing our economy and our nation.

Health care costs in general and prescription drugs specifically, are, and will continue to be, a major burden on American families, employers, and taxpayers. In 2017, the United States spent $333 billion on prescription drugs, accounting for roughly 1 out of every 10 dollars spent on healthcare.[1] This challenge is not simply about costs. When prescription drugs cost too much, it affects the patient, not just her pocketbook. Thirty percent of Americans are not taking their prescriptions as directed, due to costs.[2] Behind these numbers are real people facing real problems, such as Adalyn Watts, who, on a fixed income, can't afford her insulin and still buy food and pay the rent.[3]

There is no silver bullet to controlling prescription drug costs. Rather, it will take a broad range of policies to address the problem. Within that context, competition can play a vital role in promoting the development of new drugs and controlling costs. In 1984, Congress passed the Hatch-Waxman Act, which spurred both innovation and price competition by creating a pathway for the approval of generic drugs. Today, however, competition is broken. It has become far too easy for companies to manipulate the system to delay competition and increase prescription drug costs.

Delaying and suppressing competition in prescriptions can be enormously profitable, increasing the cost of prescription drugs by millions of dollars a year and prevent competition for years. Unless a strong deterrent exists, many companies will see antitrust liability simply as a cost of doing business. Yet even as the public and Congress are turning their attention to high prescription drug costs, the federal courts have questioned and limited the Federal Trade Commission's ability to deprive defendants of the profits they earn by violating the Federal Trade Commission Act.

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[1] Center for Medicare and Medicaid Services, "National Health Expenditure Data" Table 2, https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nationalhealthaccountshistorical.html

[2] Kaiser Health Network, "Americans Ready to Crack Down on Drug Prices That Force Some to Skip Doses," (March 1, 2019), https://khn.org/news/americans-ready-to-crack-down-on-drug-prices-that-force-some-to-skip-doses/ (29 percent did not take medicine due to cost), Thomas Goetz, GoodRX "Health Insurance Aside, American Still Struggle to Pay for the Medications," https://www.goodrx.com/blog/health-insurance-aside-americans-still-struggle-to-pay-for-their-medications/?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top (1/3 report skipped filling a prescription one or more times because of costs).

[3] Adalyn Watts, Patients for Affordable Drugs, https://www.patientsforaffordabledrugs.org/story/adalyn-watts/. Patients for Affordable Drugs, and its founder David Mitchell, have put a human face on this issue by collecting and publishing the stories of individuals bearing the burden on high cost prescription drugs.

Allowing companies to engage in anticompetitive activity also may undermine innovation. If a company can maintain its monopoly by excluding competition or by paying off a competitor, then it will have less incentive to innovate. This is likely to be a particular problem in pharmaceutical markets. Oftentimes, a small tweak to a product will extend the exclusivity of a product for years at little cost. Instead of undertaking costly and risky research that could lead to a breakthrough, companies may rely on anticompetitive conduct to protect their profits.

There are three simple policy proposals that could bolster competition in pharmaceutical markets.

- *Stopping Strategies that Delay Generic Approvals*: This Subcommittee, along with the Senate Judiciary Committee, has been a leader in addressing sample blockades and safety protocol filibusters. The CREATES Act would stop both practices.

- *Stopping Pay-for-Delay Agreements*: Despite the U.S. Supreme Court's clear signal in the Actavis case that pay-for-delay can be anticompetitive, the FTC continues to spend substantial resources and time challenging clear violations. Tougher laws, such as the Preserve Access to Affordable Generics Act, would deter such conduct and free up limited resources to attack other anticompetitive conduct.

- *Restore and Confirm the Federal Trade Commission's Disgorgement Authority*: A relatively simple modification to the Federal Trade Commission Act would clarify the FTC's authority to deprive companies of any illegal profits they earned—authority that is critical to deterring highly profitable but anticompetitive conduct.

I make these recommendations based on my career spent fighting anticompetitive practices in the health care industry and elsewhere. For 20 years at the Federal Trade Commission, much of my time was spent on the frontline of what has been, and continues to be, a never-ending struggle to protect competition in pharmaceutical markets.

In principle, the antitrust laws stand as a bulwark against anticompetitive conduct. But the courts have increasingly stripped those antitrust laws of their potency. With few exceptions, courts have imposed ever higher burdens of proof on the government, creating incentives for companies to violate the antitrust laws. What should be easy cases have become difficult to prove, and many types of conduct escape condemnation. As a result, companies are emboldened to push the limits of business conduct because the rewards are great, and the risks of liability are low. All the while, consumers are paying the price with higher drug costs.

Over the course of my career I have seen the power of antitrust enforcement to protect consumers from activity that, when left unchecked, costs consumers millions and puts lives at risk and what happens when courts circumscribe antitrust doctrine and cripple enforcement. As a young attorney, I was part of the FTC team that successfully challenged a generic company's strategy to lock-up a key supply ingredient on three drugs and raise prices by more than 2,000 percent, thus earning more than $100 million in illegal profits. I played a leading role in the FTC case challenging Schering-Plough's $60 million payment to a potential competitor to delay its

entry, which protected close to $1 billion in revenue for Schering-Plough's branded K-Dur product. Unfortunately, the federal courts initially decided that the branded companies could pay to eliminate potential competition, at least until the patent expired, legitimizing what came to be known as pay-for-delay patent settlements.

Then, as an attorney advisor to Federal Trade Commissioner, and later, FTC Chairman Jon Leibowitz, I coordinated the Federal Trade Commission's strategy to stop this practice, which delayed cost-saving competition by, on average, 17 months and cost consumers $3.5 billion a year.[4] After a concerted, decade-long effort that involved virtually all parts of the agency, the Department Justice's Antitrust Division and the Solicitor General's Office, the Supreme Court in *Federal Trade Commission v. Actavis*[5] held that such agreements can violate the antitrust laws. Although the decision prevents the worst-case scenario, it is taking years and, in a recent case, a decade for the FTC to obtain relief in even the most blatant pay-for-delay case.

Even as the Federal Trade Commission made progress on stopping pay-for-delay patent settlements, companies found new ways to subvert competition. Two related tactics are sample blockades and safety protocol filibusters. FDA approval to sell a generic drug requires a company to prove that its product is the same as the branded drug product, by comparing its product to the branded product.[6] Certain branded pharmaceutical companies are preventing companies from obtaining branded samples, which prevents the generic manufacturer from obtaining approval to market its product. Relatedly, in certain circumstances, the law requires the brand company and the generic company to negotiate safety protocols. Some branded companies filibuster these negotiations. As Deputy Chief Trial Counsel for the Bureau of Competition, I worked on investigations into, and cases challenging, branded companies use of these tactics to delay competition.

My testimony begins by describing generic drug competition, the unique role it plays in controlling the prices for prescription drugs, how that competition is fragile, and how it can easily be disrupted by anticompetitive practices. Then, I propose three policy reforms that will bolster competition and deliver more affordable medicine to consumers and save lives. My comments will be motivated by a simple idea: the focus of policy should be to understand the experiences of—and improving the living standards of—American families, particularly middle-class families and families striving to reach the middle class.

A. The Nature of Competition in Pharmaceutical Markets Creates Incentives to Delay and Prevent Competition

Competition plays a unique and fragile role in determining prescription drug costs: Unique because competition from generic alternatives are the only competition that dramatically reduces costs and fragile because this competitive dynamic can be circumvented in many ways.

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[4] Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billion," An FTC Staff Study at 2 (2009), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf

[5] 570 US ___, 133 S.Ct. 2223 (2013).

[6] The technical term is proving the generic product is bioequivalent to the branded drug.

Prescription drugs fall into two broad categories. The more traditional and common ones are called small molecule drugs (ibuprofen, antibiotics, etc.) A newer but growing category is biologics, which are protein-based and derived from living matter or manufactured in living cells using recombinant DNA biotechnologies (Humira).[7]

1. Generic Competition for Small Molecule Drugs

The impact of the Hatch-Waxman Act on competition for small molecule drugs cannot be overstated. Prior to its passage, few generics were available. Today, generic competition has a dramatic impact. As figure 1 shows, in a matter of months (and sometimes even faster), a generic drug takes the vast share of the branded product's sales. This phenomenon is similar for almost all small molecule drugs. Figure 1 depict a generic entry event that occurred in 1999. Currently, a generic product gains market share at even a faster rate than in the late 1990s. Now, a generic product, on average, captures 90 percent of the market within a year of entering the market.[8] And, the branded company's profits plummet; simply delaying generic competition can be very profitable.

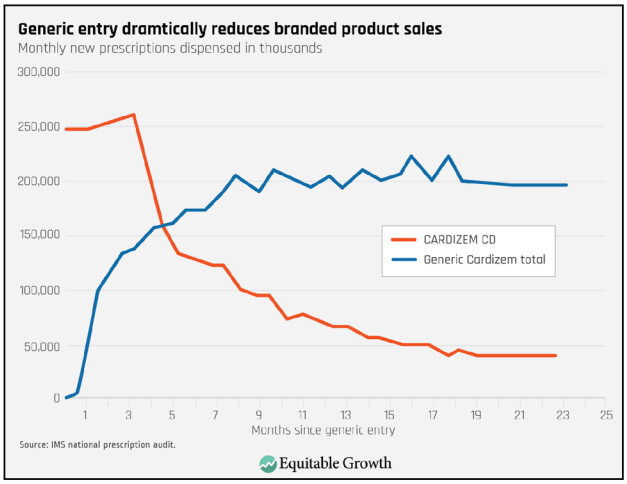

Figure 1

Both generic companies and consumers, however, benefit from competition. As Figure 2 shows, generic competition leads to substantial price decreases. Eventually those prices fall to roughly

[7] Federal Trade Commission, "Emerging Health Care Issues: Follow-on Biologic Competition," (June 2009) at i, www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf

[8] Department of Health and Human Services, "Some Observation Related to the Generic Drug Market (May 6, 2015) at 4, https://aspe.hhs.gov/system/files/pdf/139331/ib_GenericMarket.pdf ("Generic Drug Market Letter")

15 percent of the branded price.[9] While generic companies earn profits, the big winners are consumers who end up receiving the same therapeutic benefit at a far lower cost.

Critically, price competition, whether for small molecule drugs or biologics, comes from a limited set of potential competitors. And the incentives to prevent that competition are large.

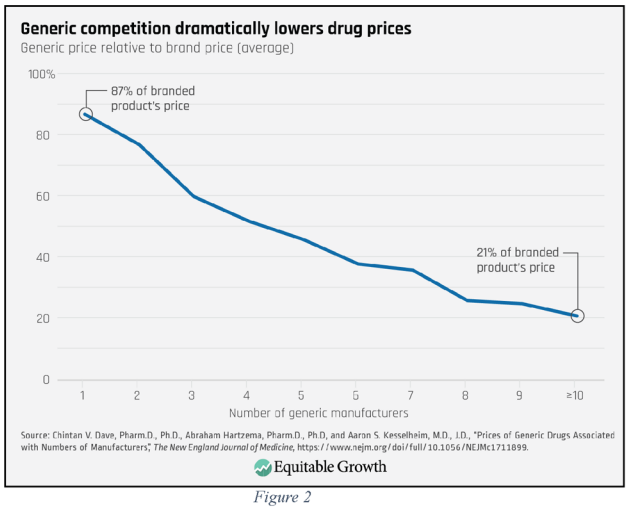

Figure 2

2. Biosimilar Competition for Biologics

Biologics drugs, such as Humira, represent an increasingly large portion of prescription drug costs, accounting for 25 percent of all prescription drug sales in 2016.[10] They offer great promise in in combating debilitating and rare diseases.[11] But they tend to be very expensive, costing patients tens, or even hundreds, of thousands of dollars per year.

In 2010, in the Biologics Price Competition and Innovation Act, Congress attempted to create a similar competitive dynamic for biologics that exists for small molecule drugs. The Act created an abbreviated path for approval of biosimilar drugs. Like generics, biosimilars have no clinically meaningful difference from the corresponding biologic drug.[12] Biosimilar drugs, however, are more expensive to develop than generic small molecule products, and they require

[9] Generic Drug Market Letter at 4
[10] Ian Hayden, "Biologics: The Price Drugs Transforming Medicine," The Conversation, Scientific American, (July 28, 2017), https://www.scientificamerican.com/article/biologics-the-pricey-drugs-transforming-medicine/
[11] BIO Issue Brief, "What is Biotechnology," https://www.bio.org/toolkit/issue-briefs/what-biotechnology
[12] Food and Drug Administration, "What is a Biosimilar," https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM585738.pdf

more testing. And, as of yet, none are deemed interchangeable. Even when BPCIA was enacted, experts expected that biosimilar production would be priced at less of a discount and achieve a lower level of market penetration than generic small molecule drugs are.[13] With many biologics having high prices and large revenues—Humira sales exceed $13 billion, Enbrel sales fall just short of $5 billion, Rituxan sales exceed $4 billion—biosimilar competition can save hundreds of millions of dollars per year per drug even if the biosimilar product is priced at a modest discount (25 percent) and gains only a modest share (30 percent).[14]

So far, in the United States, experience has not lived up to those expectations. The European Union approved[15] its first biosimilar in 2006, but the FDA did not approve a biosimilar until 2015. Today, according to NPR,[16] Europeans have access to some 50 biosimilars. The FDA has approved 17 biosimilars and only seven are on the market.[17] In Europe, biosimilars accounted for over 25 percent of reference molecule share for Remicade within two years of launching (which has risen to more than 60 percent). In contrast, in the United States, biosimilar versions of Remicade account for just 7 percent of the market after two years.[18] Although a biosimilar version of Humira will not be available in the United States until 2023, competition from biosimilars in Europe forced AbbVie to lower Humira's price 80 percent.[19]

Biosimilars are delivering significant savings in Europe but not in the United States. There are many reasons for the lack of success in the United States, which Professor Scott-Morton discusses. A successful biosimilar market must develop in the United State in order to control prescription drug costs.

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[13] Federal Trade Commission, "Emerging Health Care Issues: Follow-on Biologic Drug Competition," at 14-24 (2009), www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf.

[14] AbbVie Reports Full-Year and Fourth-Quarter 2018 Financial Results (January 25, 2019)(Humira); https://news.abbvie.com/news/abbvie-reports-full-year-and-fourth-quarter-2018-financial-results.htm; Amgen Reports Fourth Quarter and Full Year 2018 Financial Results (January 29, 2019)(Enbrel), https://www.amgen.com/media/news-releases/2019/01/amgen-reports-fourth-quarter-and-full-year-2018-financial-results/; Roche Finance Report 2018 at 13 (Rituxan) www.roche.com/dam/jcr:933329c4-4564-4b17-a29b-246ac7e617d5/en/fb18e.pdf.

[15] Martin Schiestl et al. "Ten years of biosimilars in Europe: development and evolution of the regulatory pathways" *Drug design, development and therapy,"* vol. 11 1509-1515. 16 May. 2017, doi:10.2147/DDDT.S130318

[16] Sarah Jane Tribble, "Why the U.S. Remains the Most Expensive Market For 'Biologic' Drugs in The World" (December 19, 2018). https://www.npr.org/sections/health-shots/2018/12/19/676401634/why-the-u-s-remains-the-most-expensive-market-for-biologic-drugs-in-the-world

[17] Food and Drug Administration, "Biosimilar Product Information," https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm580432.htm (17 approved products); Association for Accessible Medicines, "Statement for the Record, House Committee on Oversight and Reform, Hearing on Prescription Drug Prices," at 6 (January 29, 2019) (seven marketed biosimilar products). https://docs.house.gov/meetings/GO/GO00/20190129/108817/HHRG-116-GO00-20190129-SD003.pdf

[18] Aaron Gall, "Biosimilars: adoption update in EU & US – Dec. '18 data: Herceptin & Rituxan moving; Remicade US will not adopt in 2019 (Feb. 26, 2019).

[19] Bob Herman, "AbbVie cuts Humira's price by 80% (in Europe), Axios, Nov. 1, 2018. https://www.axios.com/abbvie-cuts-humira-price-europe-biosimilars-cc2d3d61-5782-4042-8c24-b322ea8285b4.html

Critically, price competition, whether for small molecule drugs or biologics, comes from a limited set of potential competitors. And the incentives to prevent that competition are large.

That competitive dynamic is fragile because there are many decisionmakers and overlapping legal and regulatory structures. Successful competition means the product has obtained approval from the Food and Drug Administration, it has gotten a preferred status on the insurer's formulary, and a doctor, who has little or no financial incentive, has prescribed it.[20] If competition breaks down at any point in that chain, prescription drug costs increase.

B. Breaking the Chain: Preventing Approval of Generic or Biosimilars through Sample Blockades and Filibustered Negotiations

Obviously, a product without FDA approval cannot compete in the marketplace. If the company cannot satisfy the FDA's requirements, then the system is working as it should. Yet some branded companies have found two ways to manipulate the system to prevent generic approvals through Sample Blockades and Filibustered Negotiations

1. Sample Blockade

If a company seeking approval for a generic drug (or a biosimilar) cannot obtain samples of the branded product, then it cannot perform the testing required to obtain approval. No samples; no testing; no FDA approvals, all of which means no competition and higher prescription drug prices.

Typically, companies seeking to develop a generic drug or biosimilar product obtain samples from drug wholesalers. In the case of a restricted or closed distribution system, the branded company is the only source for the sample. Some companies simply refuse to sell the sample to a potential competitor, thereby, protecting the branded franchise. This strategy can delay competition for years and sometimes for a decade or longer. For example, Mylan Pharmaceuticals alleges that it tried, unsuccessfully, to buy samples for Thalomid beginning in 2004 and for Revlimid in 2008, drugs both subject to Risk Evaluation Mitigation Strategy (REMS), but the manufacturer, Celgene, refused.[21] In 2014, Mylan sued Celgene[22] in a case that is scheduled to go to trial this year.

This strategy arose from a manipulation of the REMS systems.[23] Some drug products present unique dangers, and the FDA imposes additional safety requirements to ensure that the drug's

[20] If the FDA has deemed a product bioequivalent to the branded drug, a pharmacy can fill a prescription for the branded drug with the bioequivalent generic.
[21] See Michael Carrier, "Sharing, Samples, and Generics: An Antitrust Framework," 101 Cor. L. Rev. 1, 14-15. https://www.ssrn.com/abstract=2979565
[22] Jonathon Stempel, "Mylan sues Celgene for blocking Revlimid, Thalomid generics," (April 3, 2014); https://www.reuters.com/article/celgene-mylan-lawsuit/mylan-sues-celgene-for-blocking-revlimid-thalomid-generics-idUSL1N0MV2A820140403
[23] Food and Drug Administration "A Brief Overview of Risk Evaluation & Mitigation Strategies (REMS)," https://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM328784.pdf

benefits outweigh its risks.[24] The most restrictive of these requires a closed distribution system in which the manufacturer may not sell through normal distribution channels (through wholesalers). Instead it sells directly to pharmacies or through a specified distributor.[25] REMS systems with restricted distribution revealed that a branded company could easily prevent the generic company from obtaining samples. Over time, some companies have taken the position that REMS or not, a company has no obligation to provide its product to companies seeking to market a competing product.[26] According to the FDA, 28 out of 54 products in which drug companies cannot obtain samples are products with no REMS requirement.[27]

2. Safety Protocol Filibusters

The second tactic occurs only with drugs subject to a REMS. By law, when a company seeks approval to sell a generic version of a branded drug subject to a REMS, there is a presumption that the branded company and the generic companies should develop a shared REMS distribution system and a shared set of safety protocols for the distribution of the drug, known as a single-shared REMS.[28] Before receiving FDA approval, the generic must reach an agreement with the branded company on the shared system or seek a waiver of the requirement from the FDA. The branded company, which is already approved and on market with its REMS distribution system, by contrast, faces no repercussions for refusing to negotiate. Dragging out negotiations delays approval of the generic product and protects the branded company's profits.

The presumption has failed. Since Congress created the presumption of a single-shared REMS system more than a decade ago, the FDA has approved only one single-shared REMS system where the generic product was not on the market.[29] Two examples stand out. In the case of Suboxone, a drug used to treat opioid addiction, the branded company allegedly delayed negotiations of a shared REMS so that it could switch its franchise to a new form of the drug that insulated its $1.5 billion franchise from generic competition.[30] For more than three years, generic companies tried unsuccessfully to negotiate a shared REMS system with Jazz Pharmaceutical for Xyrem, a billion dollar drug used to treat narcolepsy, before the FDA granted a waiver from the shared REMS requirement.[31]

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[24] The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355-1, as amended by the Food and Drug Administration Amendments Act of 2007, Public Law 110-85, 121 Stat. 823 (Sept. 27, 2007)

[25] "A Brief Overview of Risk Evaluation & Mitigation Strategies (REMS). These are known as Elements to Assure Safe Use (ETASU). https://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM328784.pdf.

[26] *See Actelion Pharm LTD v. Apoatex,* 2013 U.S Dist. Lexis 135524, *3.

[27] Food and Drug Administration, "Reference Listed Drug (RLD) Access Inquiries, https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm

[28] 21 U.S.C. § 505-1(i)(1)(B)

[29] Letter from Dayle Cristinzio, Associate Commissioner for Legislation, Food and Drug Administration to Senator Patrick Leahy, at 5 (Dec. 22, 2016). Attached as Appendix A. In six other single-shared REMS, the generic product was on the market before 2007 when Congress created the REMS system.

[30] See Robin Feldman, Drug Wars, 87-90 (Cambridge 2017)

[31] Carrier, "Sharing, Samples, and Generics: An Antitrust Framework, 103 Cornell L. Rev. at 45. (2017). https://www.ssrn.com/abstract=2979565

In some cases, the generic may not have received approval even without these delay tactics. But it makes little sense for a monopolist to serve as the gatekeeper for competition.

3. Failed Solutions

These strategies are neither new nor unexpected. Congress has said explicitly that a company shall not use a REMS system to "block or delay approval" of an ANDA.[32] But the statute provides no enforcement mechanism. On multiple occasions the FDA has tried to address the situation. In response to branded companies' arguments that generics would adopt insufficient safety precautions in their testing, the FDA began reviewing generic companies' testing procedures. If the FDA is satisfied, it will send a letter confirming that the generic companies' protocols contain safety protections comparable to the applicable REMs for the branded drug. Further, the letter states that selling product to the generic company would not violate the applicable REMS.[33] Finally, starting last year, the FDA began disclosing all drugs for which a potential generic company has said that it could not obtain the branded product.[34] Disclosure has had little impact. The current list identifies more than 170 inquiries covering more than 50 products.[35]

Monopolization is illegal under Section 2 of the Sherman Act and this tactic should fall within the scope of Section 2. Over the past two decades, however, the Supreme Court has significantly limited the scope of monopolization law, in particular for monopolists' refusals to deal with competitors.[36] Although the Federal Trade Commission has argued in Amicus Briefs that refusing to provide samples could violate the antitrust laws, it has not brought an enforcement action.[37] Some private action, antitrust cases have survived motions to dismiss and summary judgment. No case has been successfully litigated to judgment. At best, antitrust enforcement in this area takes years, by which time the conduct may have achieved its goal.

4. The CREATES Act: A Practical Solution

The Creating and Restoring Equal Access to Equivalent Samples Act (CREATES),[38] a bipartisan bill introduced by the Chairman and Ranking members of the House Judiciary Committee and

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[32] 21 U.S.C. § 344-1(f)(8).
[33] FDA Draft Industry Guidance, "How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD," https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm425662.pdf
[34] Food and Drug Administration, "Reference Listed Drug (RLD) Access Inquiry," https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm
[35] Food and Drug Administration, "Reference Listed Drug (RLD) Access Inquiry," https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm
[36] *Verizon Communications, Inc. v. Law Offices of Curtis V. Trinco, LLP*, 540 US 498 (2004); see also, *Louisiana Wholesale Drug Co. v. Shire*, 754 F.3d 128 (2014) (finding a refusal to deal claim requires a prior course of dealing).
[37] *See Federal Trade Commission*, Brief as *Amicus Curiae, Mylan Pharm. v. Celgene Corp.*, 2:14-CV-2094 (D.NJ June 17, 2014), https://www.ftc.gov/system/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.v.celgene-corporation/140617celgeneamicusbrief.pdf
[38] As a detailee counsel to Senator Klobuchar, I worked on the introduction of this legislation in 2017.

the Antitrust subcommittee, is a practical and narrowly tailored solution to these problems.[39] First, a generic or biosimilar developer could sue a branded company for samples if the product is not available in the normal channels of commerce and the branded company has refused to sell to the developer. If successful, the court would order the branded company to sell sufficient samples to the generic for testing purposes. To ensure the branded company does not simply force every generic competitor to bring an action, the bill provides for attorney fees for the plaintiff if successful. And, the court assesses a penalty if the branded company lacks a legitimate business reason for refusing to sell the samples or if it fails to obey the court order to sell the product. Second, the bill would eliminate the presumption in favor of a shared REMS.

This solution is simpler than requiring the FDA to wade into commercial disputes between private parties. Also, the remedies are narrower than under the antitrust laws. A clear rule bolstered by a simple enforcement mechanism will eliminate the incentive and ability for companies to use a sample blockade to delay entry.

Objections to the bill are unfounded. Taking a step back, bioequivalency and biosimilar testing, which is the issue being addressed in the CREATES Act, occurs in a tightly controlled setting, and involves a relatively small number of samples. The FDA estimates the testing requires roughly 1,500 to 5,000 units (capsules or tablets) and relatively few subjects. That setting presents a lower level of risk than occur in the real world with everyday use by patients, which are situations that REMS address.[40]

Some have argued that the bill eliminates the FDA's authority to ensure that testing procedures are safe and will pose a danger because some drug developers will mishandle the samples during the testing process. The FDA flatly disagrees: "The CREATES Act would—appropriately—leave unchanged FDA's authority to ensure that generic developers are using acceptable safety standards in bioequivalence testing."[41] The FDA would have the same authority and responsibility to ensure safety as it does currently. Section 3(b)(2(B) of the CREATES Act requires drug developers to obtain FDA approval for its bioequivalent or biosimilar testing before it can bring an action for samples for any drug subject to a REMS. Further, the FDA can impose any requirement it deems necessary.

Enacting the bill will not lead to frivolous litigation. The primary relief is that the plaintiff will receive enough samples to conduct the necessary testing for FDA approval. Only a company with the interest and capacity in developing and marketing a generic or biosimilar product will benefit from this injunctive relief. Nor will the penalty provision trigger frivolous law suits. A defendant can always avoid the monetary award by simply supplying the drug. Further, the monetary penalty occurs only if the defendant has no legitimate business reason for having refused to sell the samples to the plaintiff. The penalty provision will deter companies from abusing the system.

Without any deterrence, some companies might simply require every generic company to sue them before providing the samples, which would defeat the purpose of the bill. Others have

[39] H.R 965 https://www.congress.gov/bill/116th-congress/house-bill/965/text
[40] Letter from Cristinzio to Sen. Leahy at 2-4 (attached as Appendix A).
[41] Letter from Cristinzio to Sen. Leahy at 4 (attached as Appendix A).

suggested that the penalty should go to the U.S. Treasury, either in whole or in party. Such a change would diminish or eliminate the incentive of the plaintiff to undertake the additional and difficult burden of establishing that the penalties are merited. Similarly, giving the FTC the responsibility to enforce the statute or to obtain monetary penalties would force the agency to choose between its broader mission or spend significant resources enforcing this one issue.

A monetary penalty may not be only the deterrence that could work. Alternatively, another possible penalty would be to reduce the branded company's exclusivity by some multiple of the days that the branded company did not provide the samples.

C. Breaking the Chain: Pay-for-Delay Patent Settlements

The competition chain also breaks if a branded company pays the generic or biosimilar company to delay launching its competitive product. These agreements arise in patent litigation. The branded company has sued the generic company for patent infringement. If the brand wins the litigation, the generic company cannot enter the market, and the brand keeps its monopoly profits. If the generic wins, it can enter the market. The brand quickly loses sales as described in Section A1. The generic earns a profit—but far less than what the brand earned) —and consumers pay lower prices.

Beginning in the 1990s, a new form of settlement arose. The brand company would eliminate the potential for competition and pay the generic company not to market its product for a period of time. This strategy circumvents the Hatch-Waxman structure to encourage competition. Both the branded and generic company profit at the expense of the consumers.

1. The Problem

The antitrust battle over these settlements has raged for more than 15 years. In a series of decisions that began in 2003, various courts concluded that this practice was acceptable.[42] In these courts' view, the fact that the branded company's patent might exclude the generic meant that the branded company could pay the generic not to compete for any period of time until the patent expired.

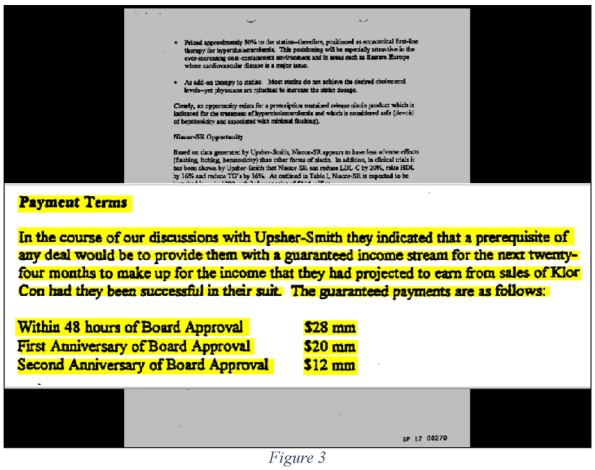
These rulings had a devastating impact on generic competition. The number of potential pay-for-delay deals increased from zero in FY 2004 to a high of 40 in FY 2012.[43] On average, these deals delayed generic competition by 17 months and increased total prescription drug costs by $3.5 billion a year.

These cases reveal the powerful incentives for branded and generic companies alike. Branded companies are calculating how much the generic could earn by competing and compensating them for not competing. Take the FTC's case against Schering-Plough and Upsher-Smith. The

[42] *Federal Trade Commission v. Watson Pharms., Inc.*, 877 F.3d 1298 (11th Cir. 2012); *Ark. Carpenters Health and Welfare Fund v. Bayer AG*, 544 F.3d 1323 (Fed. Cir. 2008) *In re* Tamoxifen, 466 F.3d 187 (2nd Cir. 2005); Valley *Drug Co. v. Geneva Pharms.*, 344 F. 3d 1294 (11th Cir. 2003).

[43] https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/overview_of_fy_2015_mma_agreements_0.pdf

case involved Schering's branded product, K-Dur 20, a potassium supplement. Schering alleged that Upsher's generic version would infringe the patent on the coating of its K-Dur product. Under the settlement, Upsher agreed to stay off the market for four years. In addition, Schering paid Upsher $60 million. Upsher also gave Schering the rights to sell four unrelated products outside of North America. Figure 3 shows a page from a document presented to Schering's Board that describes the settlement. The board was told explicitly that the payments were to replace the income Upsher would have made selling the generic product.[44]



Payment Terms

In the course of our discussions with Upsher-Smith they indicated that a prerequisite of any deal would be to provide them with a guaranteed income stream for the next twenty-four months to make up for the income that they had projected to earn from sales of Klor Con had they been successful in their suit. The guaranteed payments are as follows:

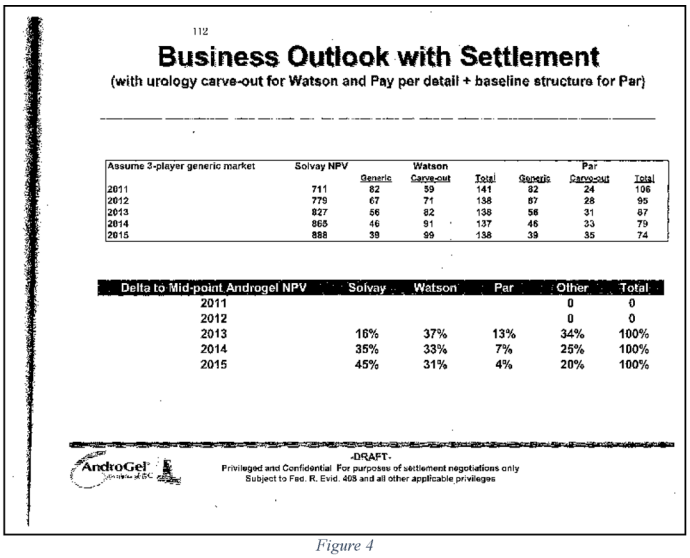
Within 48 hours of Board Approval	**$28 mm**
First Anniversary of Board Approval	**$20 mm**
Second Anniversary of Board Approval	**$12 mm**

SP 12 08270

Figure 3

In the Androgel litigation,[45] the FTC challenged a settlement in which Watson Pharmaceuticals, the generic company, agreed to keep its generic Androgel product off the market until 2015. Until then, Watson would market Solvay's branded product and receive a royalty on the branded product's sales. Instead of trying to take sales from the monopolist, Watson would be trying to increase them; Watson was literally sharing in Solvay's monopoly profits. Figure 4 is an excerpt from a Solvay document analyzing potential settlements with the copromotion agreement. The left column shows the date of generic competition. Not surprisingly, the later competition occurs, the more Solvay earns (the Solvay NPV) and the less Watson makes ("Generic column"). The Watson carve-out column shows how much Watson will make from the copromotion. The later the generic competition occurs, the more Watson makes on promoting branded Androgel. Indeed, with a share of branded Solvay's Androgel profits, Watson would make the same profit whether it launches a generic in 2011 or 2015. Consumers, who do not appear in the document, are worse off as they lose the benefit of competition for four years.

[44] Nevertheless, the 11th Circuit found that the payments were not made to delay entry.
[45] Also known as the *Federal Trade Commission v. Actavis* or the Actavis case.



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Business Outlook with Settlement

(with urology carve-out for Watson and Par per detail + baseline structure for Par)

Assume 3-player generic market	Solvay NPV	Watson			Par		
		Generic	Carve-out	Total	Generic	Carve-out	Total
2011	711	82	59	141	82	24	106
2012	779	67	71	138	67	28	95
2013	827	56	82	138	56	31	87
2014	865	46	91	137	46	33	79
2015	888	39	99	138	39	35	74

Delta to Mid-point Androgel NPV	Solvay	Watson	Par	Other	Total
2011				0	0
2012				0	0
2013	16%	37%	13%	34%	100%
2014	35%	33%	7%	25%	100%
2015	45%	31%	4%	20%	100%

AndroGel

-DRAFT-

Privileged and Confidential For purposes of settlement negotiations only
Subject to Fed. R. Evid. 408 and all other applicable privileges

Figure 4

2. The Supreme Court's Partial Solution

In 2013, in the Androgel Case (*FTC v. Actavis*), the Supreme Court rejected the lenient view that patent holders could simply pay potential infringers to stay off the market. According to the Supreme Court, an agreement in which the branded and generic companies eliminate potential competition and share the resulting monopoly profits likely violates the antitrust laws, absent some justification.[46] The Supreme Court's decision has limited pay-for-delay deals. In FY 2015, the most recent year of reported data, the number of potential pay-for-delay deals fell to 14.[47]

That success has been incomplete, and it overlooks the cost of enforcement. The Supreme Court approach requires a case-by-case analysis of a practice that virtually always is anticompetitive. That allows companies to find new ways to hide compensation or offer a plethora of alternative justifications for their conduct. Based on the past mistakes and some open hostility to the Supreme Court's decision, courts could accept one of these defenses and create a costly loophole. Some courts are openly hostile to the Supreme Court's decision.[48]

Further, the approach is resource intensive. The FTC has had to litigate multiple pay-for-delay cases since the since the Supreme Court's decision. As former Acting Chairman Maureen

[46] *Federal Trade Commission* v. 570 US 136, 158 (2013).
[47] https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/overview_of_fy_2015_mma_agreements_0.pdf
[48] See, *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132 (3rd Cir. 2017).

Ohlhausen explains, for first two years after the Androgel decision, the Commission was "relegated to damage control," having to file " a series of amicus briefs across the country to rectify misconceptions."[49] Indeed, the FTC finally resolved the Androgel case itself last week, almost six years after the Supreme Court decision allowing the case to go forward and over a decade after the case was filed.

3. Lessons from the fight over Pay-for-Delay Settlements

First, pay-for-delay underscore how strong the incentives are for companies to eliminate competition, which benefits them but harms consumers. Further, branded and generic companies are aware of those incentives and act on them.

Second, antitrust rules matter. When courts treated pay-for-delay agreements as legal, their use skyrocketed. (See Figure 5). When the Supreme Court rejected that approach, they use declined, but they are still occurring.

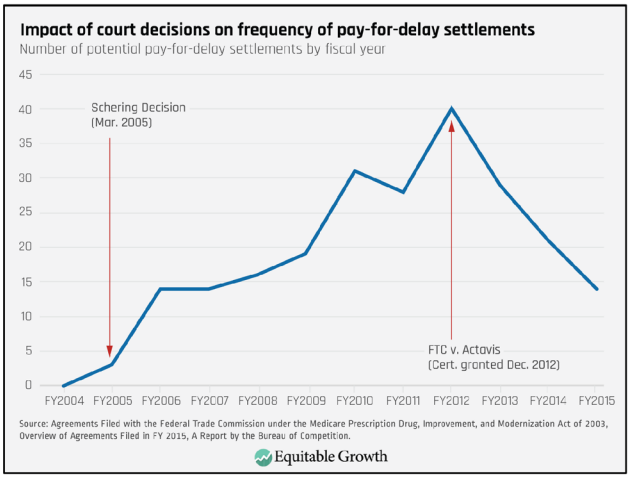

Figure 5

Third, although the current Supreme Court rule on pay-for-delay settlements protects competition better than the lower courts had, it still has required the FTC to spend substantial resources to prevent clearly anticompetitive conduct.

[49] Maureen K. Ohlhausen, "Dollars, Doctrine, and Damage Control: How Disgorgement Affects the FTC's Antitrust Mission," April 20, 2016, https://www.ftc.gov/es/system/files/documents/public_statements/945623/160420dollarsdoctrinespeech.pdf. Commission Ohlhausen was making the point that the FTC's focus on obtaining. disgorgement had led to this situation.

Congress should pass legislation that creates a strong presumption against pay-for-delay deals, such as the Preserve Access to Affordable Generics Act.[50] Not only would such legislation stop the practice. It also would free up resources so that the FTC could investigate and challenge other anticompetitive activity in the pharmaceutical industry.

D. Stopping Anticompetitive Conduct Before it Starts: The Need for Strong Deterrence

Some practices, such as pay-for-delay and sample blockade, can be addressed through industry-specific legislation as I have discussed. But Congress cannot legislate a specific statute for every type of conduct. Over the years, the courts have limited the reach of the antitrust laws, particularly regarding conduct by monopolists or vertical agreements (those that are between actors at different levels of the supply chain, such as a branded manufacturer and a Pharmacy Benefit Manager).[51] This development is problematic in the context of pharmaceutical markets. When combined with the substantial benefits of limiting generic competition, complex and vague doctrines are an invitation for companies to act on those incentives, which will increase prescription drug pricing.

This dynamic increases the importance of monetary remedies. The Federal Trade Commission has deprived companies of the profits they earned while violating the antitrust laws.[52] Recently, the Third Circuit Court of Appeals clipped the FTC's ability to seek monetary remedies in precisely the type of case where it is most needed.

The FTC alleged that Viropharma had illegally maintained its monopoly over Vancocin capsules (a drug that treats a potentially life-threatening gastrointestinal infection) by filing sham petitions to delay the approval of generic competition:

> ViroPharma illegally maintained its monopoly over Vancocin Capsules by filing 43 repetitive and unsupported (or sham) petitions with the FDA, as well as three lawsuits, between 2006 and 2012, all in an effort to obstruct and delay approval of a generic version of its branded drug. Even after a panel of 16 independent scientific and medical experts convened by the FDA considered and rejected ViroPharma's unsupported arguments, ViroPharma continued to repeat its rejected arguments, the complaint alleges. The FTC alleged that ViroPharma's conduct significantly delayed the FDA approval of a generic, costing consumers hundreds of millions of dollars.[53]

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[50] While serving as a Counsel-Detailee for Senator Klobuchar, I worked on the Preserve Access to Affordable Generics Act, which take this approach.

[51] For a general discussion of this issue, *see Howard A. Shelanski, "The Case for Rebalancing Antirust and Regulation,"* 109 Mich. L. Rev. 683, 684 (2011). The time has come for Congress to review the state of antitrust law and consider whether the courts hare interpreting the laws correctly. It has been more than 50 years since Congress last made substantive changes to the antitrust laws.

[52] See Compl. ¶¶ 16-19, *FTC v. The Hearst Trust*, No. 01-cv-00734 (D.D.C. filed Apr. 5, 2001); Amd. Compl., *FTC v. Mylan Labs, Inc.*, No. 98-cv-03114 (D.D.C. filed Feb. 8, 1999): Compl., *FTC v. Perrigo Co.*, No. 1:04CV01397 (D.D.C. Aug. 12, 2004); *FTC v. Cephalon, Inc.*, Statement of the Fed. Trade Comm'n (May 28, 2015), https://www.ftc.gov/public-statements/2015/05/statement-federal-trade-commission-ftc-v-cephalon-inc

[53] Markus Meier, "Antitrust Concerns and the FDA Approval Process," Testimony before the United State House of Representatives Judiciary Committee, Subcommittee on Regulatory Reform, Commercial and Antitrust Law, at 15-

In essence, the FTC alleged that ViroPharma bombarded the FDA with multiple and repetitive requests to make it harder for generic companies to obtain approval. Although the FDA rejected the petitions, the review process itself delayed generic approval.

The allegations, if true, are egregious and without a legitimate justification. Because they involved an attempt to influence the government (petitioning), the government must show that the petitioning is a sham, a high standard of proof.[54] Practically, the FTC could not bring a case until the FDA had resolved all, or at least most, of the petitions. At that point, the FDA typically also approves the generic product. The FTC can probably challenge a sham petition case only when the conduct is complete.

The FTC had two choices. It could file an administrative action, in which case, the only relief would be a conduct remedy (ordering the defendant not to engage in similar conduct in the future). Or, it could file an action in federal court, where it could also seek disgorgement. Because of the allegedly egregious conduct, the profitability of the sham petitioning (hundreds of millions of dollars), and the difficulty of proving the case, it would make little sense to bring a case that did not seek a monetary remedy.

The Third Circuit Court of Appeals recently affirmed the dismissal of the action, holding that the FTC did not allege that Viropharma "is violating, or is about to violate" the law as required by statute.[55] Although one can criticize the decision on multiple grounds, the relevant point for the Committee, is that, if correct, the decision would severely limit the FTC's ability to seek monetary remedies in pharmaceutical cases.

The decision essentially puts the FTC in a Catch-22. Particularly in a sham petitioning case, if the FTC files the action before the conduct is complete (before the petitions have been denied), then it will be difficult to establish the petitioning is a shame. If the FTC files the case after the conduct is complete, then the defendant will argue that it is no longer violating or about to violate the FTC Act and that, therefore, the FTC cannot bring a case in federal court and cannot seek disgorgement. But a sham petition case is precisely the type of conduct that will be deterred only if there are significant repercussions.

Certainly, other courts have taken a different position. Rather than wait for years as the courts sort through this issue, Congress should clarify that, under the Federal Trade Commission Act,[56] the FTC can seek a permanent injunction for any violation of the Act, including any ancillary equitable relief such as disgorgement or restitution. Clarifying this authority is critical for the FTC to effectively deter anticompetitive conduct.

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17. https://www.ftc.gov/system/files/documents/public_statements/1234663/p859900_commission_testimony_re_at_concerns_and_the_fda_approval_process_house_7-27-17.pdf

[54] Such a claim requires proof that the petitioning was objectively baseless and that the defendant intended to use the government process, not the outcome of the process, to harm competition. *See Professional Real Estate Investors, Inc., v. Columbia Pictures Industries, Inc.*, 508 U.S. 49 (1993).

[55] *Federal Trade Commission v. Shire Viropharma, Inc.* No `8-1807 (3rd Cir. Feb. 25, 2019).

[56] 15 USC §53(b).

F. Conclusion

A lack of competition in pharmaceutical markets contributes to higher prescription drug prices. Because of the unique nature of generic competition, anticompetitive conduct can yield hundreds of millions or even billions of dollars in monopoly profits. For consumers, that can mean an additional hundreds, or thousands, of dollars in prescription drug costs each month. Further, over the past four decades, courts have consistently weakened antitrust doctrine making easy cases difficult to win. As a result, antitrust enforcers have spent significant time and resources to stop even the most egregious violations.

Three policy changes would limit anticompetitive conduct in pharmaceutical markets and bolster competition:

- Legislation, such as the CREATES Act, would stop both sample blockades and safety protocol filibusters, which delay competition with no countervailing benefit. The CREATES Act would stop both practices.

- Legislation, such as the Preserve Access to Affordable Generics Act, would create a strong presumption against pay-for-delay patent settlements, deterring such agreements and freeing up limited resources to attack other anticompetitive conduct.

- Legislation to restore and confirm the Federal Trade Commission's authority, ensuring that the FTC's enforcement actions have teeth.

Thank-you again for the opportunity to testify on this critical issue.

Appendix

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

DEC 22 2016

The Honorable Patrick Leahy
United States Senate
Washington, D.C. 20510-4502

Dear Senator Leahy:

Thank you for your letter of October 31, 2016, co-signed by Senators Charles Grassley, Amy Klobuchar, and Mike Lee, regarding your concern about behaviors by brand name drug manufacturers that are delaying entry of generic competition and contributing to the growing problem of high prescription drug costs. You identified two such tactics: withholding samples of the brand name drug needed by the generic for bioequivalence testing, and refusing to agree to a shared safety agreement for certain categories of drugs.

In your letter, you asked the Food and Drug Administration (FDA or the Agency) for information on these issues. Below, we have restated your questions in bold followed by our response.

1. **In your testimony before the Senate HELP Committee earlier this year, you said that the Agency has received over 100 inquiries from generic companies who have been unable to obtain the samples needed for bioequivalence testing.**

   a. **How does an inability to obtain samples for bioequivalence testing impact the approval of generic drug products?**

   To obtain approval for a generic drug, the generic company must show, among other things, that its version of the drug product is bioequivalent to the brand drug (also called the "reference listed drug" or "RLD"). This usually requires the generic company to conduct bioequivalence studies comparing their product to the RLD. To do these studies and submit a generic drug application, they need samples of the RLD. Without these samples, generic drug developers cannot conduct bioequivalence testing required for FDA approval. This reduces market competition, which typically drives down drug prices.

   b. **Since your testimony in January, how many additional inquiries have you received?**

   We have received 19 additional inquiries since the January 2016 hearing, bringing the total number of inquiries to more than 150. Many of these brand drug products are quite expensive. A significant majority of these drug products are listed online at a retail price of over $600 per patient per month, and many are in the range of thousands of dollars per

patient per month. These inquiries have involved products with Risk Evaluation and Mitigation Strategies (REMS) and products without a REMS.

c. Of the total such inquiries you have received, how many are inquiring about drugs that are subject to a REMS with ETASU?

Of the 19 inquiries, 18 were for products in which the RLD was subject to a REMS with Elements to Assure Safe Use (ETASU). FDA has issued draft guidance for industry describing the Agency's current views on its role in facilitating the provision of RLD samples for bioequivalence testing (see draft guidance for industry on *How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD (Protocols Guidance)*, available at *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM425662.pdf*). The Protocols Guidance makes clear that the described process (through which generic companies may seek a letter to the brand company stating that the provision of samples to the firm for generic drug development does not violate the brand product's REMS) is not available for products that are not subject to REMS with ETASU. This may account (at least in part) for the reduced number of inquiries about non-REMS products since the draft Protocols Guidance's issuance.

2. In the context of authorization requests to FDA for access to samples for drugs for the purposes of bioequivalence testing, what is the general range of the quantity of the brand name drug that is typically necessary?

The total amount of RLD product required to conduct bioequivalence studies, in vitro dissolution tests, and maintain retention samples necessary to support a generic drug application is typically between 1,500 and 5,000 units (e.g., tablets or capsules) of the product. This range reflects factors such as the type of bioequivalence studies recommended for the product, the number of doses required, the number of strengths being tested, the need for retention samples, the number of required in vitro tests, and whether the product is available in a variety of packaging configurations or not.

3. Concerns have been raised that any efforts to address restrictions on distribution of samples to generic competitors will endanger patient safety, particularly with respect to drugs that may be subject to a REMS.

a. What role does FDA currently play in authorizing access to samples for a drug subject to a REMS? What role does FDA currently play in authorizing access to samples for a drug that is not subject to a REMS?

In cases where limitations on the distribution of a drug product occur in connection with a REMS with ETASU, FDA, upon request, reviews a prospective generic applicant's draft bioequivalence study protocols, informed consent document(s), and informational materials, and determines whether they contain safety protections comparable to those in the applicable brand drug's REMS with ETASU. Once we have determined that they do, we notify the prospective generic applicant. Upon request of the prospective generic

applicant, we will also notify the brand company of this determination and inform them that selling samples of the RLD to the generic company for testing and development will not be considered a violation of the REMS. We note that this is a voluntary process, and FDA developed this process in an effort to help facilitate access to RLD samples for generic development. We also encourage companies to contact the Federal Trade Commission if they believe a company's refusal to sell samples to them constitutes anticompetitive behavior.

This process is described in our draft guidance, *How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD (Protocols Guidance)*, available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM425662.pdf.

In cases where there are no REMS with ETASU impacting distribution, we do not conduct a protocol review or send letters to RLD holders. Instead, we encourage companies to contact the Federal Trade Commission if they believe a company's refusal to sell samples to them constitutes anticompetitive behavior.

b. Is there a statutory requirement that FDA review a New Drug Application (NDA) applicant's compliance history and/or require the NDA applicant to establish that it can store/handle/administer its test product in a manner that complies with the Food, Drug, and Cosmetic Act before dosing can begin in a clinical trial?

No, there is no such requirement. When the brand product itself is seeking approval, FDA is not required to review the applicant's compliance history or determine that the applicant can store/handle/administer its test product in a manner that complies with the FD&C Act before dosing can begin in clinical trials to support the application. We note that bioequivalence testing typically involves a relatively small number of human subjects and a small number of doses (often only one dose), and a correspondingly lower level of risk. The regulatory regime applicable to bioequivalence testing – including the exemption of certain bioequivalence testing from the Investigational New Drug (IND) requirements – reflects this relatively low level of risk associated with bioequivalence testing when compared with other kinds of clinical testing that occur during the drug development process.

c. Does FDA believe that additional safety protections, beyond what are currently in place during bioequivalence testing, are necessary to ensure patient safety?

No, we do not believe that additional requirements are necessary. As described above, bioequivalence testing typically involves a relatively small number of human subjects and a small number of doses and, therefore, a relatively low level of risk. The regulatory regime applicable to bioequivalence testing – including the exemption of most bioequivalence testing from FDA review under the IND requirements – reflects the generally lower level of risk associated with bioequivalence testing when compared with

other kinds of clinical testing that occur during the drug development process. Further, the protections in the REMS are designed to mitigate risks that occur during real world, everyday use by patients, and safety concerns are expected to be lower in the more tightly-controlled context and limited scope of bioequivalence testing.

Further, FDA regulations (at 21 CFR Part 56) require that before bioequivalence testing can begin, it must be reviewed and approved by an Institutional Review Board (IRB) to ensure that risks are minimized. The steps outlined in FDA's draft Protocols Guidance provide additional confirmation that the bioequivalence study protocols contain safety protections comparable to those in the REMS for the brand product.

d. Are REMS developed and approved with consideration of how a drug will be used in bioequivalence testing?

As described above, the protections in REMS are designed to mitigate risks that occur during real world, everyday use by patients. In the more tightly-controlled context and limited scope of bioequivalence testing, safety concerns are likely to be lower. Further, the IRB review and approval process – which is required before bioequivalence testing can begin -- is designed to help ensure that risks during bioequivalence testing are minimized.

e. Are there any additional regulatory requirements that you believe are necessary to ensure that generic developers have access to samples for bioequivalence testing and that patients are adequately protected in any such testing?

Legislation that creates a clearly-defined pathway for generic developers to access samples of RLD and a private right of action to seek relief if a brand company refuses to provide samples of the RLD could help significantly to facilitate and expedite generic development. However, no additional FDA regulatory requirements are necessary outside such a legislative pathway to ensure that generic developers have access to samples, and no additional requirements are needed to protect patient safety during bioequivalence testing. In fact, we are concerned that the imposition of unnecessary regulatory requirements on bioequivalence testing is likely to delay (or prevent entirely) access to RLD samples for bioequivalence testing, and potentially make things worse than they currently are.

4. The Creating and Restoring Equal Access to Equivalent Samples Act of 2016 (CREATES Act) would codify FDA's product authorization process. Based on your review of the legislative text, how would the CREATES Act affect FDA's authority to ensure that generic developers are using acceptable safety standards?

The CREATES Act would – appropriately – leave unchanged FDA's authority to ensure that generic developers are using acceptable safety standards in bioequivalence testing. As noted above, additional safety protections are unnecessary.

5. The law creating the REMS with ETASU requirements has a strong presumption in favor of requiring single, shared systems for safe use.

a. Since the law's enactment in 2007, how many single, shared systems for safe use have been approved by FDA?

Since the law's enactment in 2007, FDA has approved six single, shared system (SSS) REMS with ETASU under section 505-1(i)(1)(B). One of the six (rosiglitazone) was released from its ETASU requirements in 2013, and the rest of its REMS requirements in 2015.

b. Of the approved single, shared systems, how many are for products where a generic competitor was already on the market in 2007?

All but one of the SSS FDA has approved have been for products that already had generic competition. For the one that did not have generic competition, the generic applicant had agreed not to market for a given period of time following approval.

c. Of the approved single, shared systems, how many are for products where a generic competitor had not yet entered the market in 2007?

To date, FDA has only approved one SSS REMS where a generic competitor had not yet entered the market. In that one case, the generic applicant had agreed not to market for a given period of time following approval.

d. What role does FDA play in the negotiations between ANDA applicants and NDA holders for the development of a single, shared system?

When a generic application (an ANDA) for a product subject to a REMS with ETASU is found to be acceptable for filing, FDA notifies the ANDA applicant of the requirement for a SSS REMS through a REMS notification letter, which directs the ANDA applicant to contact the sponsor of the RLD (the NDA holder) regarding the development of a SSS REMS.

Shortly after notifying the ANDA applicant of the requirement, FDA hosts a meeting between the RLD holder and any existing ANDA applicants where the Agency communicates its expectations for the formation of a SSS REMS, including specific timelines for various milestones (i.e., confidentiality agreement, memorandum of understanding, and REMS submission).

FDA typically monitors the sponsors' progress on developing a REMS by requesting bi-weekly updates from the sponsors and holding teleconferences as needed. In the past, when a company indicates to the Agency that another company (brand or generic) is not receptive or responsive to efforts to negotiate, the Agency has held teleconferences, individually and jointly, with firms involved to help facilitate resolution of any issues that were preventing moving forward on a SSS. Ultimately, however, cost-sharing,

governance, and other business issues relating to the implementation of SSS REMS are left to the discretion of the sponsors. FDA cannot force the parties to negotiate or agree to particular terms.

e. How many ANDA applicants and NDA holders are currently in the process of negotiating a single, shared system?

There are currently 12 SSS REMS programs in various stages of negotiation. Collectively, these negotiations involve a total of 31 ANDA applicants and 12 NDA holders. Many of these innovator drugs are among the costliest medications to patients and to Medicare spending as a whole – and have experienced the greatest price increases in recent years. Without generic competition, there is no pressure to drive down the costs of these medications.

f. To the extent FDA has negotiation milestones that the parties should meet by certain time period, how many of the current negotiations have met the relevant milestones within the relevant time periods? What is the longest period of time that these negotiations have been ongoing?

Shortly after an ANDA is filed, FDA hosts a meeting between the RLD holder and ANDA holder(s) where the Agency communicates its expectations for the formation of a SSS REMS, including specific timelines for various milestones (i.e., confidentiality agreement, memorandum of understanding, and REMS submission). Of the 12 programs currently in negotiations, all but one have missed at least one of their milestones and none have submitted a proposed SSS REMS by the date set forth by the Agency. The longest period of time that SSS negotiations have proceeded without agreement is approximately 35 months to date.

6. FDA has the authority to permit a generic competitor to develop a comparable separate system for safe use if the agency determines that the burden of creating a single, shared system outweighs the benefit of creating such a system.

a. How many such waivers has the FDA granted?

To date, FDA has granted two waivers of the SSS requirement.

b. With respect to any such waivers, how much time elapsed between the filing of the ANDA by the generic competitor and the approval of the separate system?

The first waiver was issued to the ANDAs for buprenorphine referencing Suboxone. In that case, the ANDA products were approved with a waiver approximately a year after SSS REMS negotiations began. The waiver of the SSS requirement for the alosetron ANDAs was the second, and most recent occasion on which the Agency has waived the SSS REMS requirement. In that case, the ANDA products were approved with a SSS REMS waiver approximately three years after SSS REMS negotiations began.

c. How does the current presumption of a single, shared system and corresponding waiver standard impact the time it takes the FDA to review and approve ANDAs subject to REMS with ETASU?

The requirement that the RLD and any ANDAs referencing it use a SSS REMS for elements to assure safe use has been extremely challenging to implement, particularly in cases where there are no generics yet on the market. Since a REMS is a requirement for approval of an ANDA, RLD-holders have a strong incentive to delay the negotiations in order to forestall approval of the first generic product. Moreover, FDA lacks an enforcement mechanism to compel the parties to form a SSS REMS or to agree to particular terms. As a result, the negotiations for a SSS REMS have often been extremely protracted, and have resulted in delays in the approval of first generics on multiple occasions.

Impasses occur frequently, consuming additional Agency and industry resources – and delaying generic approval. These delays directly impact the Agency's ability to complete an evaluation of the ANDA and these additional resources are not available for other regulatory activities.

d. Is FDA concerned about the potential burden of having additional separate systems for safe use?

SSS REMS have the potential to increase efficiencies for the healthcare system and for industry, for example, by utilizing a single set of educational materials, enrollment forms, or web portal for certification.

When considering a waiver of the single shared system requirement and allowing separate systems, the Food, Drug, and Cosmetic Act requires that FDA determine whether the burdens of forming a shared system outweigh the benefits of having one by considering "the impact on health care providers, patients, the generic applicant, and the innovator" (section 505-1(i)(1)(B)(i)). FDA evaluates waivers on a case-by-case basis to determine whether the burdens of creating a particular single, shared system outweigh its benefits.

On the two occasions where FDA granted waivers of the SSS requirement, we found that the burden of creating a SSS outweighed the potential benefits of having one, in large part because of the indefinite delay in the approval of a first generic and the resulting burden on patient access to generic versions of the drug (see response to question 6b above) caused by negotiations for a SSS REMS.

Prior to approving a separate REMS system, FDA carefully analyzes the potential impact on the healthcare delivery system of having separate REMS for innovator and generic drugs. In addition, post-approval FDA may require an assessment of the REMS programs to evaluate whether they should be modified to ensure the benefits of the drug continue to outweigh the risks or to minimize the burden on the health care delivery system.

To minimize this burden of having separate REMS programs, in both instances where FDA approved a waiver, FDA required that the waived generic program be open to all current and future sponsors of ANDAs or NDAs. This limited the number of separate programs for each REMS product to two.

Thank you for your interest in promoting greater prescription drug competition by facilitating generic access. Please let us know if you have any additional questions. The same letter has been sent to your cosigners.

Sincerely,

Dayle Cristinzio
Associate Commissioner
for Legislation

Mr. CICILLINE. Thank you, Mr. Kades.

I now recognize Dr. Gaynor for five minutes.

TESTIMONY OF MARTIN GAYNOR

Mr. GAYNOR. Thank you. Chair Cicilline, Ranking Member Sensenbrenner, and Members of the subcommittee, thank you for holding a hearing on this vitally important topic and for giving me the opportunity to testify in front of you today.

The focus of my testimony is on healthcare—hospitals, doctors, insurers—which, collectively, account for almost 60 percent of all of U.S. healthcare spending. Over the next few minutes, I will briefly summarize for the Committee the basic facts about healthcare markets, the considerable research on competition in healthcare, and my views on steps that can be taken to help make these markets work for the benefit of consumers.

Healthcare is a very large and important sector of our economy. Not only is it almost one-fifth of the entire economy, but it also has a critical impact on our health and well being.

Our healthcare system is based on markets. That system is only going to work as well as the markets that underpin it. Unfortunately, these markets do not function as well as they could or should.

Prices are high and rising. There are egregious pricing practices. Quality is suboptimal and the sector is sluggish and unresponsive, in contrast to the innovation and dynamism that characterize much of the rest of our economy.

Lack of competition has a lot to do with these problems. There has been a great deal of consolidation in healthcare. There have been nearly 1,600 hospital mergers in the past 20 years.

The result is the majority of local areas are now dominated by one large powerful healthcare system such as Pittsburgh, my home, by University of Pittsburgh Medical Center, Boston by Partners, and San Francisco Bay Area by Sutter.

The same is true of health insurance markets. The two largest insurers have 70 percent of the market and over one-half of all local insurance markets. Physician services markets have also become increasingly more concentrated. Two-thirds of specialist physician markets are concentrated and 29 percent are primary care physicians.

Moreover, there were nearly 31,000 physician practice acquisitions by hospitals from 2008 to 2012 and about a third—at least a third—of all doctors are now in hospital-owned practices. This massive consolidation in healthcare has not delivered for Americans. It has not given us better care or enhanced efficiency.

On the contrary, extensive research shows us that consolidation between close competitors results in higher prices and patient quality of care suffers from lack of competition.

Moreover, competition affects the form of payment. Hospitals with fewer competitors negotiate more favorable forms of payment and reject those they dislike. This poses a serious challenge for payment reform.

Hospital mergers can also harm competition in labor markets. They can depress wages, distort hiring decisions, and harm incen-

tives for investment in human capital. Recent evidence shows impacts of hospital mergers is consistent with these concerns.

There are also concerns about anticompetitive conduct. Firms who have acquired market power want to keep it. Some dominant health systems have been using restrictive contracts with insurers to try and hamper the free flow of patients to competitors, thereby harming competition and enhancing their market power.

There are extensive reports of health systems engaging in data blocking, impeding the flow of patient information to providers outside the system. This has the potential to harm competition by making it more difficult for patients to switch providers.

Now that most hospital markets are dominated by one large health system, there is considerable potential for this kind of conduct to seriously harm competition. All of this is causing serious harm to patients and to the healthcare system as a whole.

Policies are needed to support and promote competition in healthcare markets. These include ending policies that unintentionally incentivize consolidation, ending policies that impede new competitors and impede competition, focusing and strengthening antitrust enforcement, in particular, giving the DOJ and FTC resources so that not only can they do more enforcement in existing areas but can proactively invest to address new and developing issues.

Permit the FTC to enforce against anticompetitive conduct by not-for-profits. Permit the FTC to use its section 6(b) authority to study the insurance industry. Require simple reporting of small transactions that fall below the Hart-Scott-Rodino reporting requirements to the enforcement agencies can track physician practice mergers—they currently can't—and hospital acquisitions of physician practices.

Study vertical aspects of hospital physician acquisitions and develop theory and evidence on competitive impacts. Study anticompetitive conduct and develop theories and evidence.

Last, consider legislation to alter the antitrust laws, specifically, changing the standard plaintiffs have to meet and changing criteria to be met for presumption of harm to competition.

Thank you very much.

[The statement of Mr. Gaynor follows:]

Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets

Statement before the Committee on the Judiciary
Subcomittee on Antitrust, Commercial, and Administrative Law
U.S. House of Representatives

by

Martin Gaynor
E.J. Barone University Professor of Economics and Public Policy
Heinz College
Carnegie Mellon University

Washington, D.C.
March 7, 2019

Summary of Statement

- Health care is a very large and important sector of our economy. Not only is the health care sector 1/5th of the economy, it has a critical impact on our health and wellbeing.
- The U.S. health care system is based on markets. The system will work only as well as the markets that underpin it.
- These markets do not function as well as they could, or should. Prices are high and rising, there are egregious pricing practices, quality is suboptimal, and the sector is sluggish and unresponsive, in contrast to the innovation and dynamism which characterize much of the rest of our economy.
- Lack of competition has a lot to do with these problems.
- There has been a great deal of consolidation in health care. There have been nearly 1,600 hospital mergers in the past twenty years, with over 450 since 2012. The result is that the majority of local areas are now dominated by one large, powerful health system, e.g., Boston (Partners), Pittsburgh (UPMC), and San Francisco (Sutter).
- Insurance markets are also highly consolidated. The two largest insurers have 70 percent of the market or more in one-half of all local insurance markets.
- Physician services markets have also become increasingly more concentrated. Two-thirds of specialist physician markets are highly concentrated, and 29 percent for primary care physicians.
- There were nearly 31,000 physician practice acquisitions by hospitals from 2008-2012, and over 33 percent of all physicians are now in hospital owned practices.
- Extensive research evidence shows that consolidation between close competitors leads to substantial price increases for hospitals, insurers, and physicians, without offsetting gains in improved quality or enhanced efficiency. Further, recent evidence shows that mergers between hospitals not in the same geographic area can also lead to increases in price. Just as seriously, if not more, evidence shows that patient quality of care suffers from lack of competition. Last, competition affects the form of payment – hospitals with fewer competitors negotiate more favorable forms of payment and reject those they dislike. This poses a serious challenge for payment reform.
- Research evidence shows not-for-profit hospitals exploit market power just as much as for-profits.
- It is also possible that hospital mergers lead to, or enhance monopsony power in labor markets. This can depress wages below the efficient level, distort hiring decisions, and in the long run, harm incentives for investment in human capital. Recent evidence shows impacts of hospital mergers consistent with these concerns.

- There are also concerns about anticompetitive conduct. Firms who have acquired market power have an incentive to maintain or enhance it.
  - Some dominant health systems have been using restrictive contracts with insurers to try to hamper the free flow of patients to competitors, thereby harming competition and enhancing their market power.
  - There are extensive reports of health systems engaging in "data blocking" – impeding the flow of patient information to providers outside the system. This has the potential to harm competition by making it more difficult for patients to switch providers.

  Now that most hospital markets are dominated by one large health system, there is considerable potential for this kind of conduct seriously harming competition.
- This is causing serious harm to patients and to the health care system as a whole.
- Americans who live in rural areas are particularly vulnerable to these harms because their alternatives to a dominant or monopoly provider are often far away.
- Policies are needed to support and promote competition in health care markets. This includes ending distortions that unintentionally incentivize consolidation, and policies to strengthen choice and competition.
- These include:
  - End policies that unintentionally incentivize consolidation.
  - End policies that hamper new competitors and impede competition.
  - Promote transparency, so employers, policymakers, and consumers have access to information about health care costs and quality.
  - Focus and strengthen antitrust enforcement. In particular:
    * Give the DOJ and FTC the resources they need to be effective, not just to do more enforcement in existing areas, but to be able to proactively invest to address new and developing issues.
    * Permit the FTC to enforce against anticompetitive actions by not-for-profits.
    * Permit the FTC to use its Section 6b authority to study the insurance industry.
    * Require simple reporting of small transactions that fall below the Hart-Scott-Rodino reporting requirements, so that the enforcement agencies can track physician practice mergers and hospital acquisitions of physician practices.
    * Study "vertical" aspects of hospital-physician acquisitions and develop theory and evidence on competitive impacts, including harms and efficiencies.

* Study anticompetitive conduct in health care, particularly the use of restrictive clauses in health system-insurer contracts and data blocking, and develop theories and evidence on their competitive impacts (both harms and efficiencies).
* Consider legislation to alter the antitrust laws, specifically changing the standard plaintiffs have to meet, and changing the criteria to be met for presumption of harm to competition.

Statement

Chair Ciciline, Ranking Member Sensenbrenner, and Members of the Subcommittee, thank you for holding a hearing on this vitally important topic and for giving me the opportunity to testify in front of you today.

1 My Background

I am an economist who has been studying the health care sector, and specifically health care markets and competition, for nearly 40 years. I am a Professor of Economics and Public Policy at the Heinz College of Public Policy at Carnegie Mellon University in Pittsburgh. I served as the Director of the Bureau of Economics at the Federal Trade Commission during 2013-2014, during which time I was involved in the many health care matters that came before the Commission. I have also served the Commonwealth of Pennsylvania as a member of the Governor's Health Advisory Board and as Co-Chair of its Working Group on Shoppable Health Care.

Much of my research is directly relevant to the topic of this hearing. My project with colleagues Zack Cooper, Stuart Craig, and John Van Reenen exploits newly available data on nearly 90 million individuals with private, employer sponsored health insurance nationwide to examine variation in health care spending and prices for the privately insured (Cooper et al., 2019). One of our key findings is that hospitals that have fewer potential competitors nearby have substantially higher prices. For example, monopoly hospitals' prices are on average 12 percent higher than hospitals with 3 or more potential competitors nearby. The prices of hospitals who have one other nearby potential competitor are on average 7.3 percent higher. We also examine all hospital mergers in the United States over a five year period, and find that the average merger between two nearby hospitals (5 miles or closer) leads to a price increase of 6 percent. Further, our evidence shows that prices continue to rise for at least two years after the merger. Last, we find that hospitals that face fewer competitors can negotiate more favorable forms of payments, and resist those they dislike – a serious issue for payment reform.

My papers with Katherine Ho and Robert Town, "The Industrial Organization of Health Care Market," (Gaynor et al., 2015), with Robert Town, "Competition in Health Care Markets," (Gaynor and Town, 2012a), and "The Impact of Hospital Consolidation: Update" (Gaynor and Town, 2012b) are also relevant to the topic of this hearing. In those papers my co-authors and I review the research evidence on health care markets and competition. We find that there is extensive evidence that competition leads to lower prices, and often improves quality, whereas consolidation between close competitors does the opposite.

My recent White Paper with Farzad Mostashari and Paul Ginsburg (Gaynor et al., 2017) is also directly relevant to the topic of this hearing. In this White Paper Mostashari, Ginsburg, and I identify factors that are impeding the effective functioning of health care markets and propose a number of actionable solutions to make health care markets work better.

It is also notable that there is a great deal of overlap between the analysis and recommendations in our White Paper and recent reports by the Departments of Health and Human Services, Treasury, and Labor (Azar et al., 2018), Center for American Progress (Gee and Gurwitz, 2018), and the American Enterprise Institute and the Brookings Institution (Aaron et al., 2019).

2 Introduction

Health care is a very large and important industry. Health care spending is now over $3.5 trillion and accounts for approximately 18 percent of GDP – nearly one-fifth of the entire U.S. economy (Martin et al., 2019). Hospital and physician services are a large part of the U.S. economy. In 2017, hospital care alone accounted for almost one-third of total health spending and 5.9% of GDP – roughly twice the size of automobile manufacturing, agriculture, or mining, and larger than all manufacturing sectors except food and beverage and tobacco products, which is approximately the same size. Physician services comprise 3.6% of GDP (Martin et al., 2019). The net cost of health insurance – current year premiums minus current year medical benefits paid – was 1.2% of GDP in 2017. The share of the economy accounted for by these sectors has risen dramatically over the last 30 years. In 1980, hospitals and physicians accounted for 3.6% and 1.7% of U.S. GDP, respectively, while the net cost of health insurance in 1980 was 0.34% (Martin et al., 2011).

Of course, health care is important not only because of its size. Health care services can save lives or dramatically affect the quality of life, thereby substantially improving well being and productivity.

As a consequence, the functioning of the health care sector is vitally important. A well functioning health care sector is an asset to the economy and improves quality of life for the citizenry. By the same token, problems in the health care sector act as a drag on the economy and impose a burden on individuals.

The U.S. health care system is based on markets. The vast majority of health care is privately provided (with some exceptions, such as public hospitals, the Veterans Administration, and the Indian Health Service) and over half of health care is privately financed (Martin et al., 2019). As a consequence, the health care system will only work as well as the markets that underpin it. If those markets function poorly, then we will get health care that's not as good as it could be and that costs more than it should. Moreover, attempts at reform, no matter how important or clever, will not prove successful if they are built on top of dysfunctional markets.

There is widespread agreement that these markets do not work as well as they could, or should. Prices are high and rising (Rosenthal, 2017; National Academy of Social Insurance, 2015; New York State Health Foundation, 2016), they vary in seemingly incoherent ways, there are egregious pricing practices (Cooper and Scott Morton, 2016; Rosenthal, 2017; Gar-

mon and Chartock, 2017; Kliff, 2019), there are serious concerns about the quality of care (Institute of Medicine, 2001; Kohn et al., 1999; Kessler and McClellan, 2000), and the system is sluggish and unresponsive, lacking the innovation and dynamism that characterize much of the rest of our economy (Cutler, 2010; Chin et al., 2015; Herzlinger, 2006).

One of the reasons for this is lack of competition. The research evidence shows that hospitals and doctors who face less competition charge higher prices to private payers, without accompanying gains in efficiency or quality. Research shows the same for insurance markets. Insurers who face less competition charge higher premiums, and may pay lower prices to providers. Moreover, the evidence also shows that lack of competition can cause serious harm to the quality of care received by patients.

It's important to recognize that the burden of higher provider prices falls on individuals, not insurers or employers. Health care is not like commodity products, such as milk or gasoline. If the price of milk or gasoline goes up, consumers experience directly when they purchase these products. However, even though individuals with private employer provided health insurance pay a small portion of provider fees directly out of their own pockets, they end up paying for increased prices in the end. Insurers facing higher provider prices increase their premiums to employers. Employers then pass those increased premiums on to their workers, either in the form of lower wages (or smaller wage increases) or reduced benefits (greater premium sharing or less extensive coverage, including the loss of coverage) (Gruber, 1994; Bhattacharya and Bundorf, 2005; Baicker and Chandra, 2006; Emanuel and Fuchs, 2008; Baicker and Chandra, 2006; Currie and Madrian, 2000; Anand, 2017). As mentioned previously, when consolidation leads to providers obtaining higher prices from insurers the impact ultimately falls on consumers, not insurers or employers. Figure 1 illustrates this. Workers' contributions to health insurance premiums grew 259 percent from 1999 to 2018, while wages grew by only 68 percent (Henry J. Kaiser Family Foundation, 2018).

The burden of private health care spending on U.S. households has been growing, so much so that it's taking up a larger and larger share of household spending and exceeding increases in pay for many workers. Figure 2 illustrates that middle class families' spending on health care has increased 25 percent since 2007, crowding out spending on other goods and services, including food, housing, and clothing. Health insurance fringe benefits for workers, chief among which is health care, increased as a share of workers' total compensation over this same period, growing from 12 to 14.5 percent, while wages stayed flat (see Monaco and Pierce, 2015, Table 1).

As documented below, there has been a tremendous amount of consolidation among health care providers. Consolidation has also been occurring among health insurers. It's important to be clear that consolidation can be either beneficial or harmful. Consolidation can bring efficiencies – it can reduce inefficient duplication of services, allow firms to combine to achieve efficient size, or facilitate investment in quality or efficiency improvements. Successful firms may also expand by acquiring others. If firms get larger by being better at giving consumers what they want or driving down costs so their goods are cheaper, that's a good

thing (big does not equal bad), so long as they don't engage in actions to attempt to then limit competition. On the other hand, consolidation can reduce competition and enhance market power and thereby lead to increased prices or reduced quality. Moreover, firms that have acquired market power have strong incentives to maintain or enhance it. This leads to the potential for anticompetitive conduct by firms that have acquired dominant positions through consolidation.

3 Consolidation

There has been a tremendous amount of consolidation in the health care industry over the last 20 years. A recent paper by Fulton (2017) documents these trends and shows high and increasing concentration in U.S. hospital, physician, and insurance markets. Figure 5 illustrates these trends from 2010 to 2016, using the Herfindahl-Hirschman Index (HHI) measure of market concentration.[1]

3.1 Hospitals

The American Hospital Association documents 1,577 hospital mergers from 1998 to 2017, with 456 occurring over the five years from 2013 to 2017. Figure 3 illustrates the number of mergers and the number of hospitals involved in these transactions from 1998 to 2017. A trade publication documents an additional 90 announced hospital mergers in 2018 (Kaufman Hall, 2019).

While some of these mergers may have little or no impact on competition, many include mergers between close competitors, especially given that hospital markets are already highly concentrated. Figure 4 shows that almost half of the hospital mergers occurring from 2010 to 2012 were between hospitals in the same area.[2] Further, as indicated below, recent evidence indicates that even mergers between hospitals in different may lead to higher priceas.

As a result of this consolidation, the majority of hospital markets are highly concentrated, and many areas of the country are dominated by one or two large hospital systems with no close competitors (Cutler and Scott Morton, 2013; Fulton, 2017).[3] This includes places

[1]The HHI is equal to the sum of firms' market shares. It reaches a maximum of 10,000 when there is only one firm in the market. It gets smaller the more equal are firms' market shares and the more firms there are in the market.

[2]The areas used are Core Based Statistical Areas. For a definition see (p. A-15 in U.S. Census Bureau, 2012)

[3]Fulton (2017) reports that 90 percent of Metropolitan Statistical Areas (MSAs) were highly concentrated for hospitals. The U.S. antitrust enforcement agencies define an HHI of 2,500 or above as "highly concentrated" (Federal Trade Commission and Department of Justice, 1992). My co-authors Zack Cooper, Stuart Craig, John Van Reenen, and I have calculated that the largest health system has over 50 percent of the market in 62 percent of areas in the country (commuting zones).

like Boston (Partners), Cleveland (Cleveland Clinic and University Hospital), Pittsburgh (UPMC), and San Francisco (Sutter). Mergers that eliminate close competitors cause direct harm to competition. In addition, once a firm has obtained a dominant position it has an incentive to maintain or enhance it, including by engaging in anticompetitive practices.

3.2 Physicians

Capps et al. (2017) find that there has been major consolidation among physician practices. Physician practices with 11 or more doctors grew larger from 2007 to 2013, mainly through acquisitions of smaller physician practices, while practices with 10 or fewer doctors grew smaller. Muhlestein and Smith (2016) also report that the proportion of physicians in small practices dropped from 2013 to 2015, while the proportion in large practices increased. Kane (2017) reports similar trends. Fulton (2017) reports that 65 percent of MSAs were highly concentrated for specialist physicians, and 39 percent for primary care physicians. He finds a particularly pronounced increase in market concentration for primary care physicians.

Moreover, there have been a very large number of acquisitions of physician practices by hospitals. In 2006, 28 percent of primary physicians were employed by hospitals. By 2016, that number had risen to 44 percent (Fulton, 2017). The American Medical Association reports that 33 percent of all physicians were employed by hospitals in 2016, and less than half own their own practice (Kane, 2017). Fulton (2017) finds that increased concentration in primary care physician markets is associated with practices being owned by hospitals. Venkatesh (2019) documents nearly 31,000 physician practice acquisitions by hospitals from 2008-2012, and that over 55 percent of physicians are in hospital owned practices.

It's important to note that the vast majority of physician practice mergers and many hospital acquisitions of physician practices are not reported to the federal antitrust enforcement agencies, because these transactions are too small to fall under the Hart-Scott-Rodino reporting guidelines (Capps et al., 2017).[4] Consideration should be given to adopting simple, streamlined reporting requirements for smaller transactions so that the enforcement agencies are able to properly track them and consider whether any are of concern.

3.3 Insurers

The insurance industry is also highly concentrated. Fulton (2017) finds that 57 percent of health insurance markets were highly concentrated in 2016. The American Medical Association reports that 69 percent were highly concentrated (American Medical Association, 2017). The market share of the top four insurers in the fully insured commercial segment was 76 percent in 2013, up from 61 percent in 2001 (see Figure 6). If one looks at the state or local

[4] Wollmann (2018) shows that a change in the Hart-Scott-Rodino reporting thresholds led to many transactions not being reported to the agencies, and therefore for most of those transactions to escape antitrust scrutiny.

level, the concentration is more pronounced. In 2014, the two largest insurers had 70 percent or more of the market in one half of all MSAs (Figure 7).

4 Evidence on the Impacts of Consolidation

There is now a considerable body of scientific research evidence on the impacts of consolidation in health care. Most of the research studies are on the hospital sector, because data have typically been more readily available for hospitals than for physicians or for insurers, but there are now a considerable number of research studies on those industries as well (see Gaynor et al., 2015; Tsai and Jha, 2014; Gaynor and Town, 2012a,b; Dranove and Satterthwaite, 2000; Gaynor and Vogt, 2000; Vogt and Town, 2006, for reviews of the evidence).

4.1 Impacts on Prices

4.1.1 Hospitals

There are many studies of hospital mergers. These studies look at many different mergers in different places in different time periods, and find substantial increases in price resulting from mergers in concentrated markets (e.g., Town and Vistnes, 2001; Krishnan, 2001; Vita and Sacher, 2001; Gaynor and Vogt, 2003; Capps et al., 2003; Capps and Dranove, 2004; Dafny, 2009; Haas-Wilson and Garmon, 2011; Tenn, 2011; Thompson, 2011; Gowrisankaran et al., 2015). Price increases on the order of 20 or 30 percent are common, with some increases as high as 65 percent.[5]

These results make sense. Hospitals' negotiations with insurers determine prices and whether they are in an insurer's provider network. Insurers want to build a provider network that employers (and consumers) will value. If two hospitals are viewed as good alternatives to each other by consumers (close substitutes), then the insurer can substitute one for the other with little loss to the value of their product, and therefore each hospital's bargaining leverage is limited. If one hospital declines to join the network, customers will be "almost as happy" with access to the other. If the two hospitals merge, the insurer will now lose substantial value if they offer a network without the merged entity (if there are no other hospitals viewed as good alternatives by consumers). The merger therefore generates bargaining leverage and hospitals can negotiate a price increase.

Overall, these studies consistently show that when hospital consolidation is between close competitors it raises prices, and by substantial amounts. Consolidated hospitals that are able

[5]These include estimates of price increases of 64.9 percent due to the Evanston Northwestern-Highland Park merger in the Chicago area, 44.2 percent due to the Sutter-Summit merger in the San Francisco Bay area, and 65.3 percent due to the merger of Cape Fear and New Hanover hospitals in Wilmington, North Carolina.

to charge higher prices due to reduced competition are able to do so on an ongoing basis, making this a permanent rather than a transitory problem.

There is also more recent evidence that mergers between hospitals that are not near to each other can lead to price increases. Quite a few hospital mergers are between hospitals that are not in the same area (see Figure 4). Many employers have locations with employees in a number of geographic areas. These employers will most likely prefer insurance plans with provider networks that cover their employees in all of these locations. An insurance plan thus has an incentive to have a provider network that covers the multiple locations of employers. It is therefore costly for that insurer to lose a hospital system that has hospitals in multiple locations – their network would become less attractive. This means that a merger between hospitals in these locations can increase their bargaining power, and hence their prices.

There are two recent papers find evidence that such mergers lead to significant hospital price increases. Lewis and Pflum (2017) find that such mergers lead to price increases of 17 percent. Dafny et al. (2019) find that mergers between hospitals in different markets in the same state (but not in different states) lead to price increases of 10 percent.

Understanding the competitive effects of cross-market hospital mergers is an important area for further investigation, and determining appropriate policy responses.

4.1.2 Physicians

There is also substantial evidence that physician practices facing less competition have substantially higher prices. Koch and Ulrick (2017) examine the effects of a merger of six orthopedic groups in southeastern Pennsylvania and find that the merger generated large price increases – nearly 25 percent for one payer and 15 percent for another (see Figure 8). Dunn and Shapiro (2014), Baker et al. (2014b), Austin and Baker (2015) all find that physician practices that face fewer potential competitors have substantially higher prices.

Moreover, studies that examine the impacts of hospital acquisitions of physician practices find that such acquisitions result in significantly higher prices and more spending (Capps et al., 2016; Neprash et al., 2015; Baker et al., 2014a; Robinson and Miller, 2014). For example, Capps et al. (2016) find that hospital acquisitions of physician practices led to prices increasing by an average of 14 percent and patient spending increasing by 4.9 percent.

4.1.3 Insurers

Insurance premiums also respond strongly to competition. Markets with more insurers have substantially lower premiums. Insurer premiums are driven in large part by medical expenses. Premiums cover the majority of health care expenses of enrollees, so factors that increase health care spending also increase health insurance premiums. However, the cost of private health insurance net of medical expenses also has grown rapidly in recent years (12.4 percent

in 2014 and 7.6 percent in 2016), such that health insurance costs comprised 6.6 percent of total health spending in 2015, compared to 5.5 percent in 2009 (Martin et al., 2016). Further, there is substantial geographic variation in health insurance premiums. For example, premiums for an individual silver plan in the ACA marketplaces ranged from $163 to $1,119 per month (Robert Wood Johnson Foundation, HIX Compare https://hixcompare.org).

Research evidence indicates that premiums are higher in more consolidated insurance markets, leading to concerns about competition among insurers and about increasing consolidation (Dafny, 2015, 2010; Dafny et al., 2012). For example, the merger between Aetna and Prudential in 1999 was found to have led to a 7 percent increase in premiums for large employers. Similarly, the Sierra United merger in 2008 was found to have led to an almost 14 percent increase in small group premiums (Guardado et al., 2013). Moreover, researchers have found that adding one more insurer to an ACA marketplace reduces premiums by 4.5 percent (Dafny et al., 2015), and that eliminating an insurer for an employer to choose from can lead to large (16.6 percent) premium increases (Ho and Lee, 2017).

4.2 Impacts on Quality

Just as, if not more, important than impacts on prices are impacts on the quality of care. The quality of health care can have profound impacts on patients' lives, including their probability of survival.

4.2.1 Hospitals

A number of studies have found that patient health outcomes are substantially worse at hospitals in more concentrated markets, where those hospitals face less potential competition.

Studies of markets with administered prices (e.g., Medicare) find that less competition leads to worse quality. One of the most striking results is from Kessler and McClellan (2000), who find that risk-adjusted one year mortality for Medicare heart attack (acute myocardial infarction, or AMI) patients is significantly higher in more concentrated markets.[6] In particular, patients in the most concentrated markets had mortality probabilities 1.46 points higher than those in the least concentrated markets (this constitutes a 4.4% difference) as of 1991. This is an extremely large difference – it amounts to over 2,000 fewer (statistical) deaths in the least concentrated vs. most concentrated markets.

There are similar results from studies of the English National Health Service (NHS). The NHS adopted a set of reforms in 2006 that were intended to increase patient choice and hospital competition, and introduced administered prices for hospitals based on patient diagnoses (analogous to the Medicare Prospective Payment System). Two recent studies

[6]Concentrated markets have fewer competitors or are dominated by a small number of competitors, e.g., one large hospital.

examine the impacts of this reform (Cooper et al., 2011; Gaynor et al., 2013) and find that, following the reform, risk-adjusted mortality from heart attacks fell more at hospitals in less concentrated markets than at hospitals in more concentrated markets. Gaynor et al. (2013) also look at mortality from all causes and find that patients fared worse at hospitals in more consolidated markets.

Studies of markets where prices are market determined (e.g., markets for those with private health insurance) find that consolidation can lead to lower quality, although some studies go the other way. In my opinion the strongest scientific studies find that quality is lower where there's less competition. For example, Romano and Balan (2011) find that the merger of Evanston Northwestern and Highland Park hospitals had no effect on some quality indicators, while it harmed others. Capps (2005) finds that hospital mergers in New York state had no impacts on many quality indicators, but led to increases in mortality for patients suffering from heart attacks and from failure. Hayford (2012) finds that hospital mergers in California led to substantially increased mortality rates for patients with heart disease. Cutler et al. (2010) find that the removal of barriers to entry led to increased market shares for low mortality rate CABG surgeons in Pennsylvania. Haas et al. (2018) find that system expansions (such as those due to merger or acquisition) can pose significant patient safety risks. Short and Ho (2019) find that hospital market concentration is strongly negatively associated with multiple measures of patient satisfaction.

4.2.2 Physicians

There is also evidence that the quality of care delivered by physicians suffers when physician practices face less competition. Koch et al. (2018) find that an increase in consolidation among cardiology practices leads to increases in negative health outcomes for their patients. They find that moving from a zip code at the 25th percentile of the cardiology market concentration to one at the 75th percentile is associated with 5 to 7 percent increases in risk-adjusted mortality. Eisenberg (2011) finds that cardiologists who face less competition have patients with higher mortality rates. McWilliams et al. (2013) find that larger hospital owned physician practices have higher readmission rates and perform no better than smaller practices on process based measures of quality. Roberts et al. (2017) find that quality of care at high priced physicians practices is no better than at low priced physician practices. (Scott et al., 2018) find no improvement in quality of care at hospitals that acquired physician practices compared to those that did not. Further, the testimony of Dr. Kenneth Kizer in a recent physician practice merger case (Federal Trade Commission and State of Idaho v. St. Luke's Health System, Ltd, and Saltzer Medical Group, P.A.) documents that clinical integration is achieved with many different forms of organization, i.e., that consolidation isn't necessary to achieve the benefits of clinical integration.[7]

[7] https://www.ftc.gov/system/files/documents/cases/131021stlukedemokizer.pdf

4.2.3 Patient Referrals

There has been concern about the possible impact of hospital ownership of physician practices on where those physicians refer their patients, and whether that is in the patients' best interests (Mathews and Evans, 2018). A number of studies have found that patient referrals are substantially altered by hospital acquisition of a physician practice. (Brot-Goldberg and de Vaan, 2018) find that if primary care physicians in Massachusetts are in a practice owned by a health system they are substantially more likely to refer to an orthopedist within the health system that owns the practice. They also estimate that this is largely due to anti-competitive steering. (Venkatesh, 2019) examines Medicare data and finds a 9-fold increase in the probability that a physician refers to a hospital once their practice is acquired by the hospital. Hospital divestiture of a practice has the opposite effect (Figure 9). A study by Walden (2017) also employs Medicare data and finds that hospital acquisitions of physician practices "increases referrals to specialists employed by the acquirer by 52 percent after acquisition", and reduces referrals to specialists employed by competitors by 7 percent.

4.2.4 Labor Market Impacts, Monopsony Power

It is also possible that health care consolidation can have impacts on labor markets. Consolidation that causes competitive harm in the output market does not necessarily cause harm to competition in the input market (monopsony power is the term for market power in buying inputs). For example, two local grocery stores may merge to monopoly in an area, but they purchase frozen food items on a national market with lots of competition. Conversely, it is possible that a merger may have no harm to competition in the output market, but cause competitive harm in an input market. For example, consider two coal mines located in the same area that merge. Coal is sold on a national market, so the merger will not cause competitive harm. However, if the coal mines are the largest (or only) employers in the area, then the merger will cause harm to competition in the labor market.

In the case of health care, both the output market for health care services and the input market for labor are local. As a consequence, a merger that causes harm to competition in the market for health care services has nontrivial potential to harm competition in the labor market. The extent to which such a merger will cause labor market harms depends on the alternatives that workers have in terms of the types of other jobs available and where they are located. Nonspecialized workers, such as custodians, food service workers, and security guards are less likely to be affected by a merger, since their skills are readily transferable to other employers in other sectors.[8] Workers who have specialized skills that are not readily transferable to other employers in other sectors are more likely to be harmed. For example, consider a town with two hospitals, a large automobile assembly plant, and multiple retail and service establishments. If the two hospitals merge to monopoly, hospital custodians

[8]However, even workers with readily transferable skills can be harmed by a merger if the merged firm is the dominant employer overall in an area.

and security guards will have alternatives at the assembly plant or at the retail or service establishments. As a consequence, competition for these workers may be little affected by the merger. Nurses and medical technicians, however, have nowhere else to turn in the local market, so there will be substantial harm to competition for health care workers.

There are a number of papers that have demonstrated the presence of monopsony power in the market for nurses (see e.g., Sullivan, 1989; Currie et al., 2005; Staiger et al., 2010). These papers demonstrate that hospitals possess and exercise monopsony power in the market for nurses. They do not, however, provide direct evidence on the impacts of consolidation. A recent paper, however, looks directly at the impacts of hospital mergers on workers' wages. Prager and Schmitt (2019) look at the impacts of 84 hospital mergers nationally between 2000 and 2010. They find that hospital mergers that resulted in large increases in concentration substantially reduced wage growth for workers with industry specific skills, but not for unskilled workers. They find that "Following such mergers, annual wage growth is 1.1 percentage points slower for skilled non-health professionals and 1.7 percentage points slower for nursing and pharmacy workers than in markets without mergers." This suggests that hospital mergers can harm competition in the labor market for workers with skills specific to the hospital industry.

The impacts of consolidation on labor markets (and input markets generally) is an area where study is needed to understand the nature of the impacts of consolidation and evidence of those effects. Moreover, antitrust authorities need to know to what extent merger enforcement focused on output markets addresses potential input market competitive harms, and to what extent input markets require a separate focus. Further, if the agencies are to pursue enforcement in this area they need to develop economic and legal approaches to this issue.

4.3 Impacts on Costs, Coordination, Quality

It is plausible that consolidation between hospital, physician practices or insurers, in a number of combinations, could reduce costs, increase care coordination, or enhance efficiency. There may be gains from operating at a larger scale, eliminating wasteful duplication, improved communications, enhanced incentives for mutually beneficial investments, etc. However, it is important to realize that consolidation is not integration. Acquiring another firm changes ownership, but in and of itself does nothing to achieve integration. Integration, if it happens, is a long process that occurs after acquisition.

While the intuition, and the rhetoric, surrounding consolidation, has been positive, the reality is less encouraging. The evidence on the effects of consolidation is mixed, but it's safe to say that it does not show overall gains from consolidation. Merged hospitals, insurers, physician practices, or integrated systems are not systematically less costly, higher quality, or more effective than independent firms (see Burns and Muller, 2008; Burns et al., 2015; Goldsmith et al., 2015; Burns et al., 2013; McWilliams et al., 2013; Tsai and Jha, 2014). For example, Burns et al. (2015) find no evidence that hospital systems are lower cost,

Goldsmith et al. (2015) find no evidence that integrated delivery systems perform better than independents, Koch et al. (2018) find higher Medicare expenditures for cardiology practices in consolidated markets, and McWilliams et al. (2013) find higher Medicare expenditures for large hospital-based practices. After more than 3 decades of extensive consolidation in health care, it seems likely that the promised gains from consolidation would have materialized by now if they were truly there.

5 Anticompetitive Conduct

Firms that acquire a dominant market position usually wish to keep it. The incentive to maintain or enhance a dominant position can be beneficial when it leads the firm to deliver value to consumers in order to keep or gain their business. This can result in lower prices, higher quality, better service, or enhanced innovation. There may also be strong incentives for such firms to engage in anticompetitive practices in order to disadvantage competitors or make it difficult for new products or firms to enter the market and compete.

There are prominent instances of firms in the health care industry engaging in what appear to be anticompetitive tactics. Cooper et al. (2019) find that hospitals with fewer potential competitors are more likely to negotiate contracts with insurers that have payment forms that are more favorable to them (e.g., fee for service) and reject payment forms they dislike (e.g., DRG based payment). While this is not an anticompetitive practice, it suggests that hospitals with market power are able to negotiate contracts with insurers that contain anticompetitive elements. This indeed is the issue in two recent antitrust cases. Both cases revolve around the use of restrictive clauses in hospital contracts with insurers.[9]

These clauses prevent insurers from using methods to direct their enrollees to less costly or better hospitals. One of these methods is called tiering - a practice where enrollees pay less out of their own pockets for care received from providers in a more favorable group ("tier"), and pay more if they see a provider in a less favorable tier. Insurers use tiering to give enrollees incentives to obtain care at less costly or higher quality providers. This system thus gives providers an incentive to do the things it takes to be in the more favorable tier, and is a way to promote competition. Another method is steering - enrollees are directed to providers who are preferred, due to lower costs or higher quality. Steering also promotes competition - providers have incentives to agree to lower prices or provide better quality or service in order to be in the preferred group. A third method employed by insurers is transparency – providing enrollees with information about the costs or quality of care at different providers. The intent is to provide enrollees with the information they need to choose the right provider,

[9]United States and the State of North Carolina v. The Charlotte-Mecklenburg Hospital Authority, d/b/a Carolinas Healthcare System, https://www.justice.gov/atr/case/us-and-state-north-carolina-v-charlotte-mecklenburg-hosptial-authority-dba-carolinas; People of the State of California Ex Rel. Xavier Becerra v. Sutter Health, https://oag.ca.gov/news/press-releases/attorney-general-becerra-sues-sutter-health-anti-competitive-practices-increase

and by doing so to give providers incentives to compete on those factors.

In both of the antitrust suits mentioned above, the health systems had negotiated clauses in their contracts with insurers which prohibited the insurers from using any of these methods to try to direct patients to lower cost or better providers. The clauses prohibiting the use of these methods are called "anti-tiering," "anti-steering," and "gag" clauses. The concern with the use of these restrictive clauses is that they harm competition by preventing insurers by using methods that provide incentives to providers to compete to attract patients. The lawsuit by the DOJ against Carolinas Health System was settled, with the health system agreeing not to use these restrictive clauses.[10] The California Attorney General's lawsuit against Sutter Health System is ongoing.

At present there is no systematic evidence on the extent to which anti-tiering, anti-steering, and gag clauses are being employed by health systems in their contracts with insurers, nor analysis of their impacts. This is an area which needs investigation to document the extent of the practice and its impacts.

Another practice that raises concerns is "data blocking" (Savage et al., 2019). Data blocking is a practice in which health systems impede or prevent the flow of patients' clinical data to providers outside their system. It is also refers to a practice by electronic medical record (EMR) providers to impede the flow of data to rival EMR systems via lack of compatibility. Data blocking by providers makes it more difficult for patients to go to rival providers, locking them in, since their medical information doesn't go with them. Reducing patient mobility across providers harms competition and benefits incumbents. While there are extensive reports of data blocking, there isn't systematic evidence on the extent of the practice, or on its impacts. Study is needed to understand the nature of data blocking, and the extent to which it leads to harm to competition or to efficiencies.

6 Policies to Make Health Care Markets Work

As I have discussed, consolidation in health care has not delivered on lower costs, improved coordination of care, or enhanced quality. What has happened is that consolidation between hospitals, physician practices, and insurers who are close competitors has reduced competition, leading to higher prices and harming quality. Even worse, reduced competition tends to preserve the status quo in health care by protecting existing firms and making it more difficult for new firms to enter markets and succeed. This leads to excessive rigidity and resistance to change, as opposed to the innovation and dynamism that we need.

Farzad Mostashari, Paul Ginsburg and I have proposed a set of policies to enhance competition in health care (Gaynor et al., 2017). Rather than recapping what has already been written, let me briefly summarize some key points, and add a few new thoughts.

[10] https://www.justice.gov/atr/case-document/file/1111581/download.

- One key set of actions is to end policies that unintentionally provide incentives for consolidation. It has been well documented that certain Medicare payment policies have the unintended effect of doing this (Forlines, 2018; Desai and McWilliams, 2018). Putting an end to policies that artificially encourage consolidation will help by reducing consolidation, and thereby consolidation that harms competition along with it.

- Another set of things that can be done to reduce unintended incentives to consolidate is to reduce administrative burdens that generate more costs than benefits. One example of these is quality reporting. Multiple entities: Medicare, Medicaid, multiple private insurers require provider reporting of a large set of quality measures. Coordination among payers could reduce administrative burden and thereby reduce incentives to consolidate.

- Some states have regulations that unintentionally make it difficult for new firms to enter or artificially alter the negotiating positions of providers and payers. These include certificate of need laws, any willing provider laws, scope of practice laws, and licensing board decisions. Negative impacts of these laws can particularly affect residents of rural areas, where access to alternative suppliers (e.g., via telehealth and appropriate services from nurse practitioners or pharmacists) is particularly scarce. States should examine these laws and practices to make sure they are narrowly tailored to benefit the public and do not unintentionally protect incumbents and harm competition.

- This also applies to state certificate of public advantage legislation. These laws, when passed, shield merging parties from federal antitrust scrutiny and impose state supervision. If certificates of public advantage continue to be issued, omitting provisions that exempt merging parties from antitrust scrutiny will help to preserve competition.

- Federal and state agencies can pursue and prevent practices that are intended to limit competition. For example, anti-tiering, anti-steering, and gag clauses prevent insurers from providing information to enrollees about more or less expensive (or better or worse) providers, or from providing incentives to enrollees to go to less expensive or better providers. The federal antitrust enforcement agencies and state attorneys general can pursue these and other anticompetitive practices. In addition, state insurance commissioners can review contracts between insurers and providers and scrutinize them for clauses that harm competition and consumers. Legislative bodies can consider enacting legislation that bans or limits the use of such clauses in provider-insurer contracts. While there is anecdotal evidence about such practices, systematic knowledge is lacking. This is an area that needs further study and development of antitrust theories and evidence.

- Many mergers in the hospital industry are between hospitals in disparate geographic areas that do not overlap in the traditional antitrust sense. Nonetheless, such mergers may harm competition, if, for example, the hospitals are important to have in a regional or national network to offer to employers who operate regionally or nationally. There

evidence that such mergers can lead to significant price increase. At this point, however, this is an area that requires investigation to learn more about the phenomenon and to develop antitrust theories and evidence.

- There is a great deal of "vertical" consolidation in health care in the form of hospitals acquiring physician practices. To date these acquisitions have been pursued by enforcement agencies as horizontal mergers.[11] Vertical cases are more difficult, however, the enforcement agencies should to consider vertical approaches to such acquisitions, and the necessary antitrust theory and evidence.

- There are many reports of health systems engaging in "data blocking" - preventing or impeding patients' clinical information from flowing to providers outside the system. This practice has the potential to harm competition, but making it difficult for patients to move across providers. Much more needs to be known about the extent and nature of this practice, its impacts, and the extent of competitive harms or efficiencies.

- Health care consolidation has the potential to harm competition not only in the market for health care services (output), but in labor markets (input). There is some recent evidence demonstrating that mergers that result in large increases in concentration adversely affect wage growth for workers with skills specific to the hospital industry. While this is welcome evidence, more investigation and study is required to learn more about the impacts of health care consolidation on labor markets and to develop antitrust theories and evidence.

- Transparency about health care costs and quality can be enhanced. At present there are no national, publicly available data on total U.S. health care costs and utilization, let alone on prices for specific services or providers. Data and information are now as vital a part of our national infrastructure as are our bridges and roads. It's time to invest in a national health care data warehouse that brings together private and public data to inform employers, policymakers, and consumers.

- Antitrust enforcement in health care by federal and state governments, both horizontal and vertical, needs to be continued and enhanced.

  - Of course if we expect the antitrust enforcement agencies to do more in health care without reducing their efforts in the rest of the economy, then they will need more resources. The demands on the agencies have risen in terms of number of merger filings, while their inflation adjusted appropriations have declined (see Figure 10). The decline in resources relative to demands not only makes it hard for the agencies to address antitrust issues as they arise, it makes it extremely difficult

[11] When a health system acquistion of a physician practice involves combining competing practices (Federal Trade Commission and State of Idaho v. St. Luke's Health System, Ltd, and Saltzer Medical Group, P.A., https://www.ftc.gov/enforcement/cases-proceedings/121-0069/st-lukes-health-system-ltd-saltzer-medical-group-pa).

for them to allocate the necessary resources to proactively invest in important new and developing areas.

- In addition, at present the FTC is prohibited from enforcing against anticompetitive conduct by not-for-profit firms (FTC Act, Section 45(a)(2), Section 44) and is not permitted to study the insurance industry under its Section 6b authority without an explicit request from Congress (Section 5(a) of the Federal Trade Commission Improvements Act of 1980). Removing these restrictions on the FTC will enable it to function to the full extent of its capabilities to protect competition and consumers in health care markets.
- Requiring parties in small transactions to report in a simple, streamlined way will enable the agencies to track the many small transactions in health care involving physician practices (both horizontal and vertical) that at present are not reported and many of which escape antitrust scrutiny.
- Legislation to strengthen antitrust can be considered, specifically altering the standard for competitive harm and changing the criteria under which mergers or conduct would be presumptively illegal (thereby shifting the burden to defendants to establish that they are not). If this comes to pass it would strengthen the antitrust enforcement agencies' positions in dealing with health care mergers they judge to be harmful, as well as mergers in general.

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Figure 1: Growth in Health Insurance Premiums, Workers' Contributions to Premiums, Wages, and Inflation (Source: Kaiser Family Foundation)

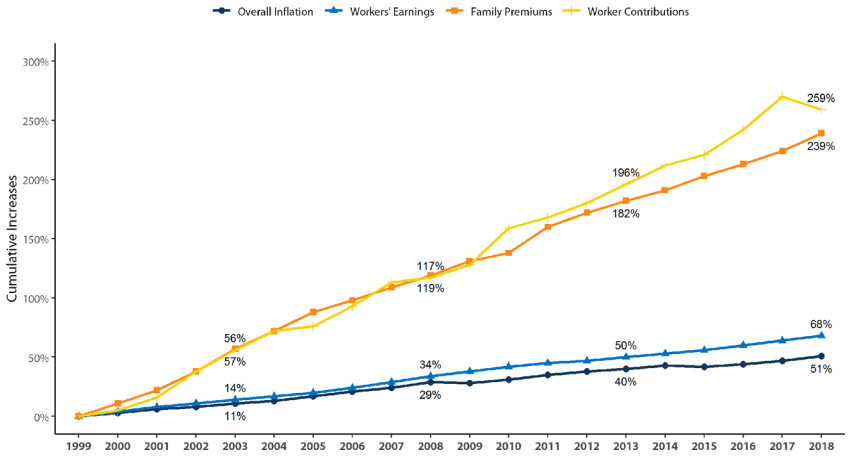


Figure 2: Change in Household Spending on Health Care and Other Basics

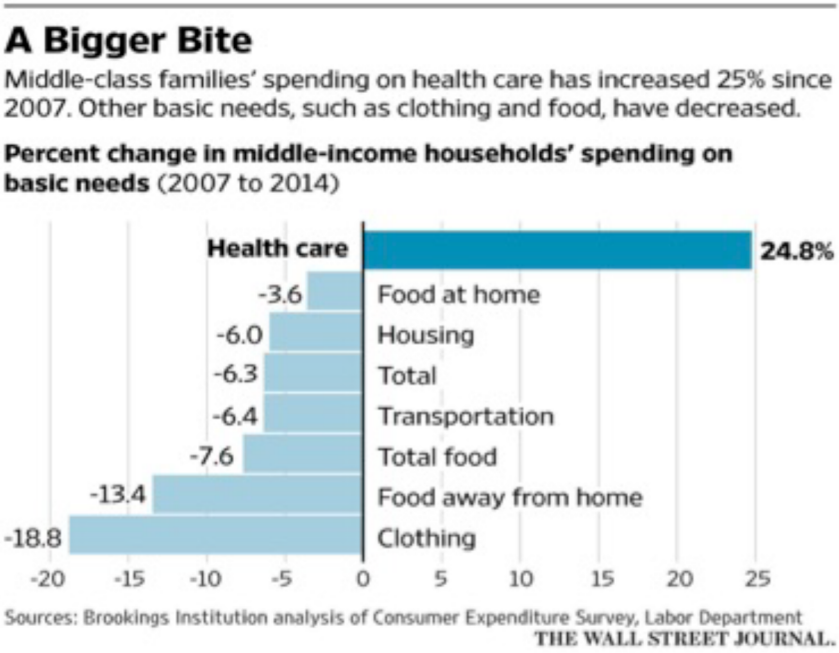


Figure 3: Number of Hospital Mergers, 1998-2017 (Source: American Hospital Association)

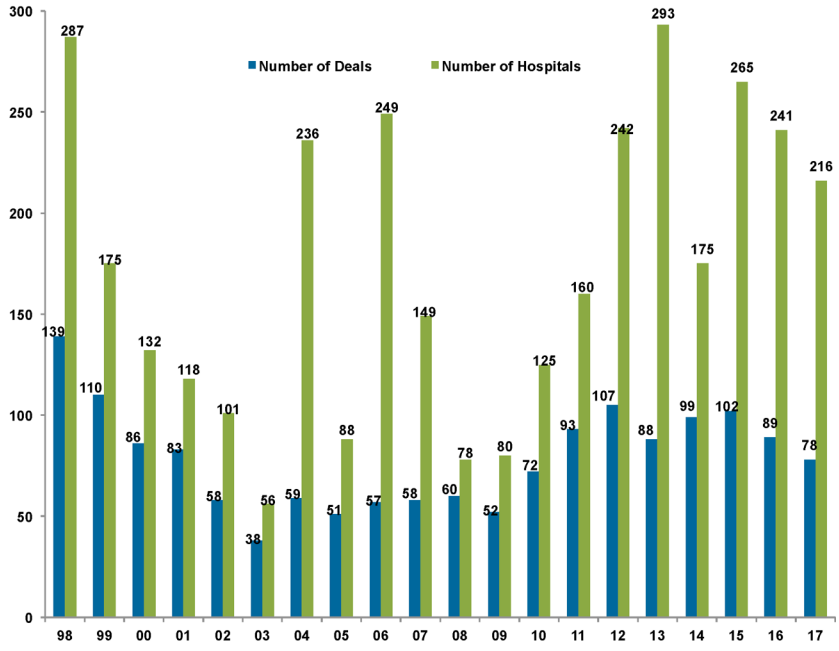


Figure 4: Percent of Mergers Between Hospitals in Same Area, 2010-2012 (Source: Dafny et al., 2019)

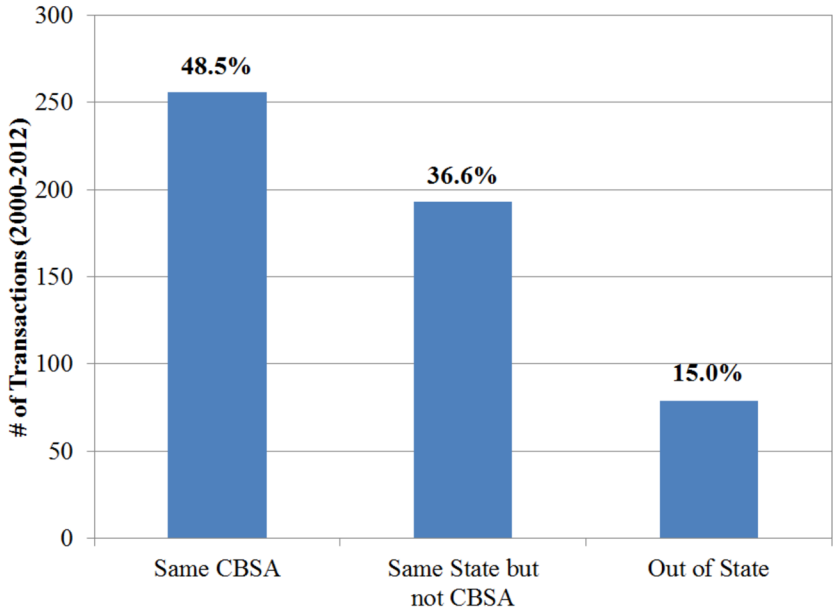


Figure 5: Market Concentration (HHI) for hospitals, physicians, and insurers, 2010-2016 (Source: Fulton (2017))

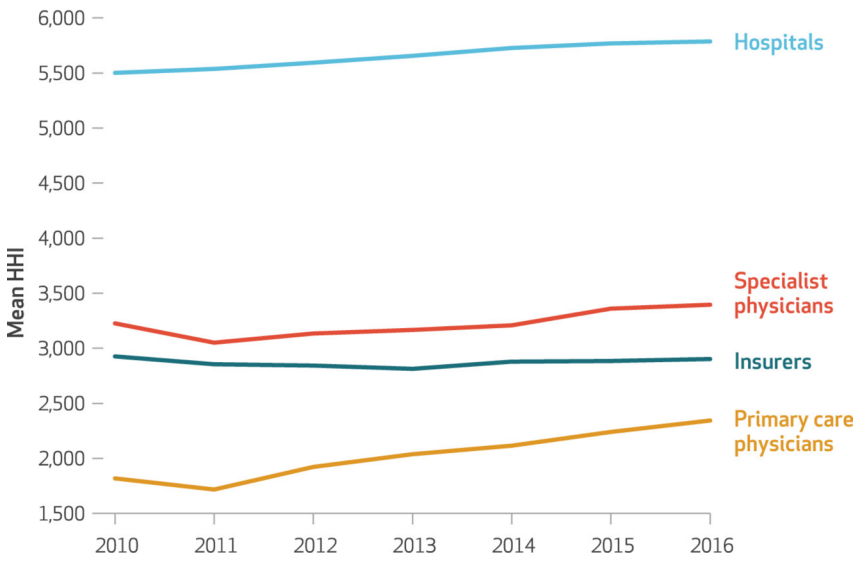


Figure 6: Market Share of Top 4 Insurers, Fully-Insured Commercial (Source: Courtesy Prof. Leemore Dafny)

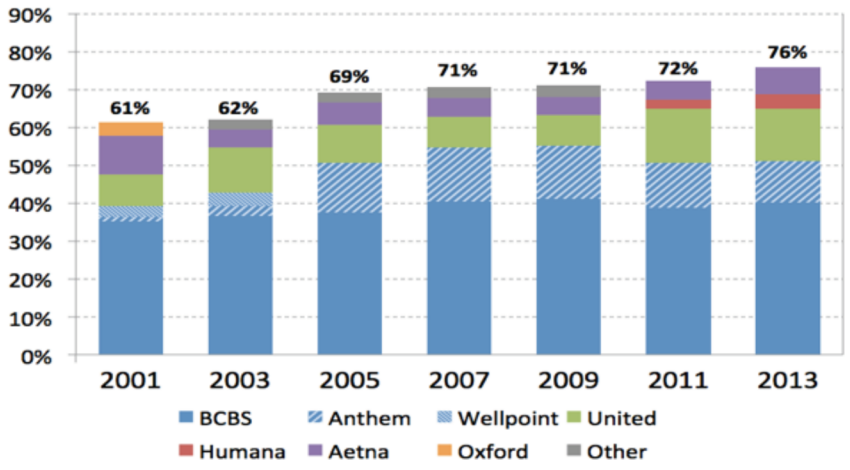


Figure 7: Market Share of Top 2 Insurers, Self and Full Insurance, State and MSA (Source: Courtesy Prof. Leemore Dafny)

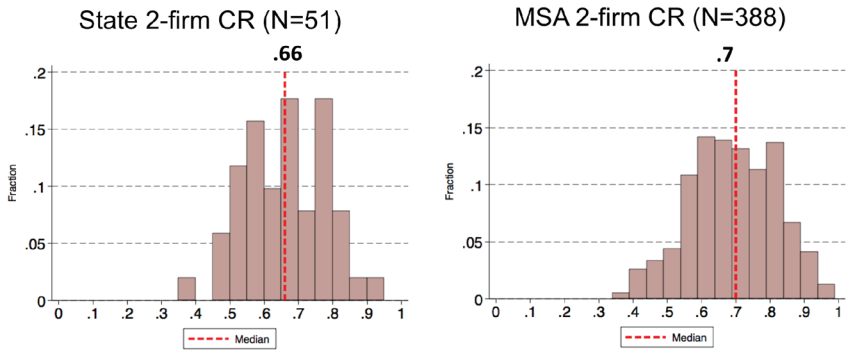


Figure 8: Price Effects of Orthopedic Practice Merger in Pennsylvania (Source: Koch and Ulrick, 2017)

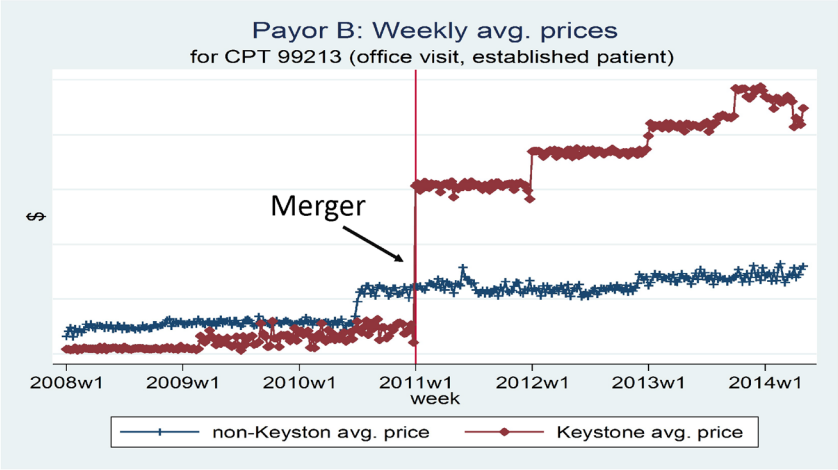


Figure 9: Effects on Physician Referrals of Hospital Practice Acquisitions and Divestitures (Sources: Venkatesh, 2019; Mathews and Evans, 2018)

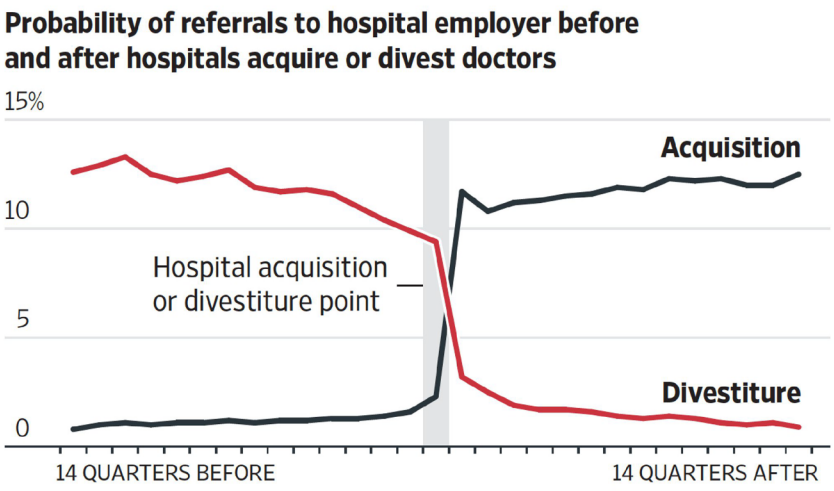
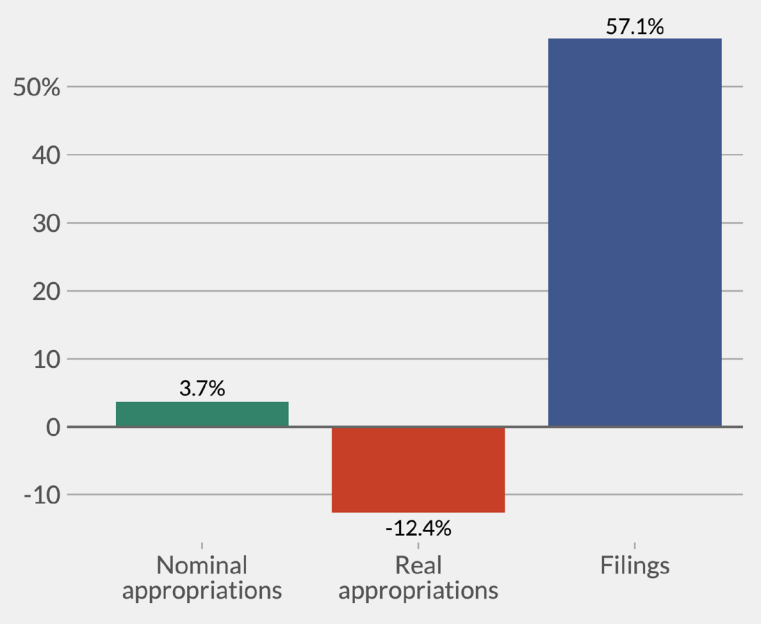


Figure 10: DOJ, FTC Appropriations vs. Merger Filings, 2010-2016
(Source: Courtesy Michael Kades, Washington Center for Equitable Growth, https://equitablegrowth.org/presentation-merger-enforcement-statistics/)



Mr. CICILLINE. Thank you, Dr. Gaynor.

I now recognize Dr. Garthwaite for five minutes.

TESTIMONY OF CRAIG GARTHWAITE

Mr. GARTHWAITE. Thank you, Chair Cicilline, Ranking Member Sensenbrenner, and Members of the Committee for holding a hearing to examine the role of competition in healthcare.

I am here today to talk about why markets can work in healthcare with a particular focus on the pharmaceutical sector. I have prepared a longer written statement outlining more specific details that I have submitted to the committee.

Unlike most other developed countries, the United States primarily relies on lightly regulated private markets for the provision of healthcare services. This choice makes sense because private firms respond to market incentives and create products and services that maximize welfare either by lowering costs or by increasing quality.

In this way, the profit-seeking motives of private firms benefit society in ways that even the most benevolent government entities cannot. Optimal healthcare policy then harnesses these market forces while maintaining no illusions about the motivations of the firms we employ to efficiently provide these goods and services.

However, relying on the private market for the provision of such a vital set of goods and services requires recognizing two key facts.

First, healthcare markets, like any other markets, can fail, and second, all markets require vigilant protection of the structures and institutions that support robust and vigorous competition.

Complicating matters is the uniquely public-private nature of the U.S. healthcare system where even government-financed social insurance and medical services are increasingly the domain of private firms reacting to these market incentives.

While I think the benefit of the markets is clear, I fear there are a number of areas where a combination of the market structure and poorly developed regulations limit the ability of the market to deliver its most efficient outcome.

There are many areas of healthcare where this is true, which all the witnesses have already testified to. Today, I will concentrate my remarks on pharmaceutical markets, a sector that generates meaningful value but all too often attracts the ire of policymakers and the general public.

It is not surprising that such negative attention is focused on the pharmaceutical sector. Certainly, some of this is the result of bad actors by some industry participants. Poor behavior is hardly unique to this sector. Far more is about the simple fact that the products are sold for many multiples at marginal cost.

However, claims that these prices solely represent corporate greed ignore the vital societal tradeoff where we accept limited access to drugs' high prices today in order to provide incentives for the development of new and innovative products in the future.

That said, our goal is not to give firms unlimited profits but instead to provide a time-limited period of increased market power in order to encourage innovative firms to make the necessary investments.

During this time period of exclusivity we want to ensure that firms offering therapeutic substitutes still compete for patients and, therefore, the greatest profits go to the firms that have the most uniquely valuable products.

Following exclusivity welfare is then maximized by a robust and competitive generic market. Today I will briefly highlight some specific proposals I believe sensibly address these concerns.

The first set of proposals are for generic markets. First, as Mr. Kades said, Congress should immediately pass the CREATES Act in order to facilitate the availability of necessary product samples for potential generic entrants.

Second, Congress should authorize regulators to investigate the abuse of citizen petitions, which artificially delay the entry of generic competitors.

Third, Congress should create a new form of generic exclusivity targeting molecules with small patient populations. Markets that are too small to attract multiple competitors allow incumbent firms to set prices as natural monopolists. This was most apparent in the case of Martin Shkreli and Turing Pharmaceuticals. This practice is now widespread across many firms.

The FDA should create an RFP process where firms can apply to be the sole supplier of these small markets at a fixed margin over production costs.

The next proposals are for the branded market where policies should facilitate robust competition between therapeutic substitutes. This competition currently takes the forms of rebates negotiated by pharmacy benefit managers, or PBMs.

While confidential rebates have become a much maligned part of the system, they are actually a vital component that results in large discounts. When rebates are confidential, firms are more willing to give large discounts in the first place and less able to tacitly collude on high prices.

That said, there are some improvements that can be made to the rebate system and I would highlight two particular suggestions.

First, we must provide a means of passing along the rebates to consumers at the point of sale—a way that supports competition and confidentiality while restoring the insurance benefit to these sick patients.

This can be accomplished by basing cost sharing not on the list price of the drug but on some other discounted price such as the average price across payers for the molecule.

Second, we must provide the structure to ensure that PBMs Act as good agents for their payers. Currently, many policymakers are worried this is not occurring. In particular, they are worried that PBMs are capturing an inappropriately large amount of the discounts that are provided by the manufacturers.

In order to improve competition, I propose, along with Dr. Scott Morton, that we increase the amount of information payers have about the money flowing between PBMs and manufacturers.

For example, Congress could ban payments directly between PBMs and manufacturers and require all discounts and fees be paid first to the final payer. Payers and PBMs can then negotiate about efficient distribution of that surplus.

While I understand the temptation to abandon markets in the favor of a greater use of government purchasing power and regulated prices, such policies are shortsighted and they ultimately through the baby out with the bath water.

Thank you.

[The statement of Mr. Garthwaite follows:]

TESTIMONY OF CRAIG L. GARTHWAITE, Ph.D.

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Herman Smith Research Professor in
Hospital and Health Services Management
Director of Program on Healthcare at Kellogg (HCAK)
Kellogg School of Management
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Before the
House Judiciary Committee
Subcommittee on Regulatory Reform, Commercial and Antitrust Law

On

"Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets"

March 7, 2019

In contrast to most other developed countries, the United States relies more heavily on private markets to finance and provide healthcare services for its citizens. While this is a source of consternation for some, there are many advantages to using markets for healthcare. A large and diverse country such as the United States has a wide variety of preferences and meaningful differences in the willingness to pay for quality. In this setting, regulated prices and central planning (by either a government entity or an independent third party) are unlikely to maximize welfare, and an economic market is the superior method of allocating goods and services. This is even more true once we consider the variety of economic actors necessary for the development of innovative new healthcare products and services. It is hard to imagine what omniscient actor could more efficiently balance these forces. Therefore, despite many contentions to the contrary, a market-based system remains the best mechanism for providing the appropriate incentives for welfare maximization.

However, relying on the market for the provision of such a vital set of goods and services requires both recognizing that healthcare markets, like any other market, can fail and that all markets require vigilant protection of the structures and institutions necessary to promote robust and vigorous competition. Complicating matters is the fact that healthcare is a unique product for which society places particular value on an individual's ability to access services regardless of their ability to pay. For this reason, the United States has developed a series of social insurance and transfer programs that allow low-income residents to access healthcare services. Over time these programs have grown, and public spending now accounts for just over half of all healthcare spending in the United States – a fact that makes healthcare markets distinct from the rest of the economy.

Given the economically meaningful role of the public sector in the healthcare market, the ability to maintain a competitive market inherently relies, at least in part, on government policies and regulations. Ultimately, healthcare is our nation's most meaningful public-private partnership. This has become even more apparent as the United States increasingly relies on private markets and firms for the provision of publicly funded social insurance benefits. This includes the Medicare Advantage program, Medicaid Managed Care, and even the much-derided Affordable Care Act – which I've previously noted is perhaps the most conservative market based approach to the provision of health insurance for such a large number of low-income individuals.[1] Private firms are being used to provide these services because, at their core, they have the strong incentive to respond to consumer demand in a quest to maximize profits. These incentives allocate resources in ways that increase welfare. It is unlikely that a government entity could achieve a similar result, and

[1] Garthwaite, Craig. 2017. "Why replacing Obamacare is so hard: It's fundamentally conservative." The Washington Post. July 10.

therefore optimal healthcare policy harnesses market forces while maintaining no illusions about the motivations of the firms it employs to efficiently provide goods and services.

Currently there are many concerns about the rising cost of healthcare in the United States. These rising costs exist across all healthcare markets – and have caused increased calls for an abandonment of the market and for greater use of government purchasing power, central planning, and regulated prices.[2]

These calls have perhaps been greatest in the markets for prescription drugs, which have attracted the ire of policymakers and the general public. It is not surprising that such attention has focused on the pharmaceutical sector. Patented prescription drugs are sold for many multiples of the marginal cost of production and, as a result, firms appear to be profiteering at the expense of patients. Complaints that high prices are simply about corporate greed ignore that they are the result of deliberate government policies intended to provide the necessary incentives for the development of innovative products. By granting intellectual property protection, the government allows innovative firms to earn large profits without the threat of competition resulting from the immediate entry of a firm making an identical product. Economic research suggests that this profit incentive matters and consistently documents that pharmaceutical R&D responds to potential market size.[3] Pretending this is not the case ignores reality and will only lead to inefficient value-destroying policies.

Intellectual property protections are necessary because the development of new pharmaceutical products involves large investments in research and development, with uncertain prospects for financial success. Once products are patented and approved for sale, generating an exact bioequivalent copy is a relatively simple and inexpensive exercise.[4] As a result, absent intellectual property protections an innovative firm would rightly suspect it would be unable to earn back its fixed R&D investments before the entry of competitors drove prices towards marginal cost. Realizing they would be unable to recover value from their initial investments,

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[2] Kliff, Sarah, and Dylan Scott. 2018. "We read Democrats' 8 plans for universal health care. Here's how they work." Vox. December 19.

[3] Acemoglu, Daron, and Joshua Linn. 2004. "Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry." The Quarterly Journal of Economics 119 (3): 1049-1090.
Finkelstein, Amy. 2004. "Static and Dynamic Effects of Health Policy: Evidence from the Vaccine Industry." The Quarterly Journal of Economics 119 (2): 527-564.
Blume-Kohout, Margaret E., and Neeraj Sood. 2013. "Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development." Journal of Public Economics 97: 327-336.
Dranove, David, Craig Garthwaite, and Manuel Hermosilla. 2014. "Pharmaceutical Profits and the Social Value of Innovation." NBER Working Paper No. 20212. June.
Dubois, Pierre, Olivier de Mouzon, Fiona Scott-Morton, and Paul Seabright. 2015. "Market Size and Pharmaceutical Innovation." The RAND Journal of Economics 46 (4): 844-871.

[4] This ability to generate a bioequivalent generic copy of a medication is limited to the small-molecule market. For biologics, bioequivalent copies are not possible and the process of developing biosimilar products is far more complicated.

rational firms lacking the protection of market exclusivity would never make potentially value-creating investments in the first place.

In order to encourage firms to make these investments, society allows a time-limited period during which innovative firms can exploit the market power that results from no other firm being allowed to manufacture the patented product. As a result, the innovative firm can set an optimal price for its product in competition with others that treat the same therapeutic condition. This does not mean a pharmaceutical manufacturer can charge any price it desires. Ultimately, its pricing decisions are still dictated by market forces (e.g., competition from therapeutic substitutes) and consumer demand. Products that provide truly unique treatments have fewer potential substitutes and can successfully command higher prices. Those offering limited advances over current products face stiffer competition for customers and must offer lower prices to gain market share.

Effectively, policies governing the development of pharmaceutical products involve trading off the static inefficiency of reduced access to products today in order to create the dynamic efficiency of increased development of new products in the future. This tradeoff is a source of much of the controversy around the prescription drug market, because the reduced access today involves readily identifiable individuals who are unable to access existing medications because of price.[5] Unsurprisingly, this lack of access garners large amounts of press and political attention. However, it is important to remember a perhaps far greater access problem for patients suffering from conditions for which no treatment options exist at all. For these individuals, there is no price at which they can purchase a treatment, and they will only be assisted in the future by the dynamic efficiency created by intellectual property protection. As we consider the optimality of policies governing the pharmaceutical market, it is critical to balance the oft-discussed need for access to existing products with the less-discussed lack of access from the absence of effective treatments.

While the optimality of trading off some amount of access today in order to gain access tomorrow is clear, the parameters of the length and breadth of this tradeoff are policy decisions for which there is no definitive economic answer. These policy parameters reflect the relative value society places on lost access today and potential welfare gains from innovation in the future. What is clear is that once policymakers have decided on the preferred degree of intellectual property protection required to encourage the desired level and type of innovation, it is incumbent on regulators to monitor and enforce these systems. This includes providing the necessary structures for strong competition between therapeutic substitutes during periods of exclusivity and the development of robust generic competition beginning immediately at the end of the exclusivity period.

[5] Garthwaite, Craig, and Benedic Ippolito. 2019. "Drug pricing conversations must take the cost of innovation into consideration." STAT. January 11.

Our goal is not to provide unlimited benefits to firms, but instead to provide appropriate market-based incentives that encourage firms to develop innovative products that increase welfare. Ultimately, firms will optimally respond to any incentives government creates – and therefore a well-functioning healthcare market requires policies that embrace economic reality rather than hope for a preferred outcome.

I have growing concerns that a lack of competition between various healthcare entities inhibits the ability of the market to operate as efficiently as possible. Some of this lack of competition results from a series of institutional features that inhibit the ability of markets to function. However, the lack of competition is also the result of a series of unhelpful and counterproductive regulations that either limit competition or can be manipulated by incumbent firms to dissuade competition.

Thankfully, there are a series of targeted steps Congress and other regulators could take to harness market forces to moderate the growth of healthcare costs in the United States. These suggestions retain and improve upon the centrality of the market in the provision of healthcare services while recognizing areas where existing regulations and other market structures may inhibit efficiency. While there are many areas in healthcare where I fear that competition is failing, I will focus the majority of my comments on the pharmaceutical market[6] – which has been the focus of a number of proposed policies and regulations by both Congress and the Trump Administration.

I. Policies to Support a Robust Generic Market

Providing the incentives for the development of new products requires allowing firms a time-limited period of high price-cost margins. However, this is not meant to be an infinite time period, and after intellectual property protections expire, regulators and policymakers should support robust and active competition from generic products. Unfortunately, there are several existing market forces and regulations that currently work against generic competition. This includes firms abusing existing Food and Drug Administration (FDA) regulations to deter the entry of generic competition. It also includes market structures that limit the existence of multiple competitors and allow firms without patent protection to effectively act as monopolists and earn excessively high price-cost margins. I will discuss each of these factors in turn.

I.A. Reducing Barriers to Generic Entry

Firms attempting to enter the market with a generic substitute for an approved FDA product must file an Abbreviated New Drug Application (ANDA). As part of this process, the generic manufacturer must

[6] As a general note, throughout this testimony when I use the terms "market," "healthcare market," or "pharmaceutical market," this is meant as a general descriptive term and is not intended to describe a market for the purpose of antitrust enforcement.

demonstrate that its product is bioequivalent to the reference product – a scientific process that obviously requires the generic firm to have access to samples of the reference product. Without access to a sufficient quantity of samples, a generic firm faces meaningful difficulty demonstrating bioequivalence and entering the market – extending the time period during which incumbent firms can earn excess economic profits.

Currently, a number of brand-name pharmaceutical manufacturers are allegedly limiting access to these necessary samples. Some of these firms are exploiting the Risk Evaluation and Mitigation Strategies (REMS) system, which is a well-meaning regulation intended to provide a means for firms to monitor the access to and safety of their pharmaceuticals.[7] While the intention of REMS is to improve safety and monitoring of programs, there are growing concerns that firms are using this system as a means of delaying access by asserting they are unable to certify that distributing such samples would comply with their REMS program. Other firms, such as Turing Pharmaceuticals, allegedly denied access to these products by simply limiting distribution to a closed network of pharmacies.[8] Regardless of the rationale, denying access to samples deters potential entrants and extends the period of higher price-cost margins.

Recognizing the importance of these samples to a robust generic market, there is existing legislation titled the Creating and Restoring Equal Access to Equivalent Samples Act (CREATES). CREATES does a good job of balancing a number of competing interests in an attempt to promote generic competition. Its primary focus is on creating a cause of action for generic firms to sue brand-name manufacturers that work to deny them access to samples. In addition, CREATES establishes a series of monetary penalties intended to dissuade incumbent firms from engaging in this behavior in the first place. However, the act also recognizes that there are time periods of legitimate drug shortages, and in those time periods the welfare-maximizing course of action is for existing product to be delivered to patients rather than to generic firms. Cognizant of the potential gaming that could occur regarding shortages, the act separates conditions of long-term and short-term shortages – and does not allow firms to fail to provide samples when there is a long-term shortage that they should address. Overall, CREATES is an attractive piece of legislation that should be passed at the earliest opportunity.

While passing CREATES would be a meaningful first step towards reducing barriers to entry for generic competitors, there are additional regulatory barriers to entry for generic firms that Congress and regulators should investigate. For example, as part of the process for approval of generic drugs, individuals are allowed

[7] Manne, Geoffrey. 2016. "Senator Lee's prescription for regulatory failure in the generic drug market." Truth on the Market. June 14.
[8] Pollack, Andrew. 2015. "New York Attorney General Examining Whether Turing Restricted Drug Access." The New York Times. October 12.

to file Citizen Petitions about the safety and efficacy of a product. With roots in the First Amendment, Citizen Petitions (like the REMS system) have the potential to serve a vital role in ensuring the safety of the pharmaceutical market. However, like many well-meaning regulations, the existence of the Citizen Petition process creates the opportunity for abuse as some incumbent firms file unnecessary petitions in order to slow down the process of generic products reaching the market. This delay results from the fact that the FDA must carefully evaluate every Citizen Petition – even those primarily intended to create artificial delays. During the time period of this review, the brand name retains greater market power and society continues to pay supracompetitive price-cost margins for the medication.

While Citizen Petitions can serve a valuable role in the approval process, this value must be weighed against the possibility of creating unnecessary and costly delays in the entry of generic products. Therefore, I encourage Congress to ask the Federal Trade Commission (FTC) to investigate the characteristics of Citizen Petitions that appear likely to be attempts by firms to gain an anti-competitive advantage in the marketplace – noting that there are many potentially valid petitions filed by both individual citizens and firms.

I.B. A Lack of Competition for Generic Products Treating Small Patient Populations

Markets for generic small molecule products are intended to have fierce price competition facilitated by the automatic substitution of prescriptions towards less-expensive generic products. In a well-functioning generic market, firms compete primarily on price and therefore profits are determined by a firm's ability to manufacture products at the lowest marginal cost. This fierce price competition means that successful entrants must be able to produce enough to reach the minimum efficient scale (MES) of their production process. Absent sufficient quantity, entrants realize they will find themselves at a perpetual cost disadvantage to incumbent firms and therefore will rationally decline to enter the market. For sufficiently small markets, there is only enough demand for a single manufacturer to reach MES – and the incumbent firm is a natural monopolist that maintains meaningful pricing power.

In recent years, several firms have recognized the pricing power available to ANDA holders for generic products with sufficiently small potential markets. This was perhaps best personified by the pricing strategies of Turing Pharmaceuticals, but aspects of this strategy have been implemented by other firms and thoroughly documented in several media outlets.[9] The ability for these firms to charge monopoly prices for generic products is not the result of the above-discussed tradeoff between access today and innovation tomorrow –

[9] Hopkins, Jared S., and Andrew Martin. 2018. "These New Pharma Bros Are Wreaking Havoc on Prescription Drug Prices." Bloomberg. April 6.
Pollack, Andrew. 2015. "Drug Goes From $13.50 a Tablet to $750, Overnight." The New York Times. September 20.
Rockoff, Jonathan D., and Ed Silverman. 2015. "Pharmaceutical Companies Buy Rivals' Drugs, Then Jack Up the Prices." The Wall Street Journal. April 26.

society has long since paid for the innovation from any of these products. Instead, the high prices represent firms taking advantage of a market failure created by the small patient population. While large pharmaceutical firms were historically either unwilling to exploit this pricing power or unaware of this financial strategy, the practice of firms charging high prices without fear of entry in small generic markets is now widespread throughout the industry (albeit the strategy is typically employed by smaller firms with fewer invested assets in the industry). If Congress hopes that for-profit firms will simply avoid this pricing strategy going forward, they will be sorely mistaken. Instead, solutions to market failures for small-market generics will need to come either from firms being harmed by this practice or through government action.

For some of these products, private firms are stepping forward with market-based solutions. Specifically, a consortium of hospitals led by Intermountain Healthcare has created CivicaRx – a joint venture designed to address the high prices charged for many generics that are administered in a hospital setting.[10] For products administered in the hospital, providers are unable to pass the increased costs along to patients or payers and have therefore decided to vertically integrate and manufacture the products themselves.

While vertical integration in this setting is an efficient response by hospitals in response to a market failure in their supplier market, CivicaRx will likely not find it valuable to undertake the manufacturing of products that are sold directly to patients through retail or specialty pharmacies. Those products do not impact the financial health of the hospitals involved in the joint venture. Therefore, solutions for these other products must come from new government policies that either reduce the number of natural monopoly markets or use economic tools to more directly intervene in the natural monopoly markets that remain.

If high fixed entry costs make it difficult for multiple firms to profitably produce small-market generics, one potential policy solution is to lower these fixed costs. This would decrease the quantity required for a new entrant to reach MES and compete with the incumbent manufacturer. In recent years, the FDA has been focused on programs to accomplish this goal. For example, there have been efforts to streamline and harmonize the generic application process across developed countries.[11] There have also been attempts to increase the speed and efficiency of the ANDA process, which would decrease barriers to entry and potentially increase the number of markets that could support multiple firms.[12]

[10] Abelson, Reed, and Katie Thomas. 2018. "Fed Up With Drug Companies, Hospitals Decide to Start Their Own." The New York Times. January 18.
[11] Gottlieb, Scott. 2018. "Advancing Toward the Goal of Global Approval for Generic Drugs: FDA Proposes Critical First Steps to Harmonize the Global Scientific and Technical Standards for Generic Drugs." FDA. October 18.
[12] Elvidge, Suzanne. 2018. "FDA sets another record in 2018 for generic drug approvals." BioPharma Dive. October 12.

I would encourage the FDA to continue to evaluate the approval process to look for additional efficiencies that would decrease entry costs. However, even the most efficient process for entering a generic market will require some expenditures to demonstrate the safety and bioequivalence of the product – and this will always represent a meaningful fixed-cost investment. Therefore, another potential solution to promote entry is to attempt to increase the size of some generic markets. While this can't be accomplished within any geographic boundary (i.e., we are unlikely to uncover more patients with these types of conditions), I would encourage Congress and regulators to consider a broader system of importation across developed countries with similar safety and regulatory systems (i.e., the countries the FDA is currently empowered to turn to in the case of drug shortages). Aggregating demand across these markets would increase total quantity and the number of products that could successfully be produced by multiple manufacturers. Some have argued the FDA could implement this strategy today by considering generic products with large price hikes to be a situation of shortage.[13] However, it is likely that Congressional investigation and debate are needed before we implement such an important change to the sourcing of generic medications.

Even after efforts to decrease costs and increase market sizes, there likely will remain some markets that still cannot support multiple firms. In this case, further regulations are likely necessary to reach an efficient outcome. Recently, Senator Elizabeth Warren has proposed that the government step in to manufacture generic drugs when products have small market sizes and large drug price increases.[14] I understand and appreciate the motivation for Senator Warren's proposal and think that it is a potentially viable policy option for addressing this particular market failure, i.e., the lack of competition in markets for generic products without sufficient size to support multiple firms.

However, I fear that a government entity will likely fail at being an efficient producer of these products – after all, this is not an enterprise in which they specialize. As a result, the marginal costs of a government producer would likely be higher than for a private firm with experience in drug production. Before the government undertakes such a new and complicated economic activity, I would propose a private-sector solution in which Congress empowers the FDA to provide a new form of market exclusivity for generic products with market sizes that do not support multiple competitors.

The exact specifics of such an exclusivity would need to be worked out, but a first step would be for Congress to ask the FTC to examine how many potential patients are necessary for a market to support

[13] Greene, Jeremy A., Gerard Anderson, and Joshua M. Sharfstein. 2016. "Role of the FDA in Affordability of Off-Patent Pharmaceuticals." JAMA 315 (5): 461-462. doi:10.1001/jama.2015.18720.
[14] Warren, Elizabeth. 2018. "It's time to let the government manufacture generic drugs." The Washington Post. December 17.

multiple generic firms. While most generic prescriptions are likely for molecules that can support multiple competitors, there are potentially a large number of molecules with small patient populations that can't support multiple manufacturers. For example, there has been an increase in the number of exits by ANDA holders in recent years, with many firms citing a lack of profitability. The median generic market currently has only two manufacturers, and approximately 40% have a single manufacturer – which likely is the result of limited market potential for these molecules.[15] That said, the current number of firms participating in the market in equilibrium does not provide sufficient information to understand whether the market could ultimately support multiple firms. After all, it is the threat of entry and not actual entry that disciplines profits. Inferring the number of firms that a particular generic market could support based on the number of current firms could be particularly problematic given the ongoing allegation of collusion in this market.[16] Therefore, it is important for economists at the FTC to determine the exact market size and structure that would indicate that the market for the generic product is a natural monopoly where the incumbent firms possesses significant pricing power. Ideally this investigation would incorporate the potential market-expanding policies of decreasing entry costs and potentially increasing the market size to include some limited foreign markets.

After establishing the market characteristics likely to lead to natural monopolies, I would propose the FDA be required to undertake a request for proposal (RFP) process for those markets. Under this RFP process, any private firm could apply for the rights to be the exclusive manufacturer of a natural monopoly generic medicine at a certain fixed percentage above manufacturing costs. As part of this RFP process, firms would compete on the amount of margin they would require to serve the market. The winning firm would possess the exclusive rights to sell the drug at this regulated price for a time period sufficient to recover the fixed costs of entry. At that time, the FDA would have the option of re-auctioning off the market exclusivity. In order to ensure the efficient operation of this process, it may also be necessary for the FDA to set a maximum percentage that they will accept before they will turn to a non-profit or government supplier for the product. This will limit any ability of firms to collude to divide up the markets in which they choose to enter.

I would encourage Congress to immediately investigate solutions in the area of small-market generics, as this problem will only grow in importance. Recent scientific advances have allowed for an increasing personalization of medicine. Along with co-authors, I have documented the rising share of clinical trials involving a patient-specific biomarker to determine either efficacy or safety.[17] As can be seen in Exhibit 1, in

[15] Berndt, Ernst R., Rena M. Conti, and Stephen J. Murphy. 2017. "The Landscape of US Generic Prescription Drug Markets, 2004-2016." NBER Working Paper No. 23640.
[16] Silverman, Ed. 2019. "Here's how prosecutors say generic drug makers schemed to fix prices." STAT. February 19.
[17] Chandra, Amitabh, Craig Garthwaite, and Ariel Dora Stern. 2018. "Characterizing the Drug Development Pipeline for Precision Medicines." NBER Working Paper No. 24026.

recent years there has been a marked increase in trials for these types of products. Almost by definition, personalized medicine will involve products with limited patient populations, and for many of these products we should be worried about whether robust generic competition will ever emerge.[18] Therefore, while the problem of small-market generics is not a dominant feature of today's market, it will only grow in importance. It will likely be far easier to address the problem now than it will be when the number of powerful interests manufacturing such products increases.

II. **Policies to Promote Robust Competition Between Branded Therapeutic Substitutes**

While innovative firms maintain time-limited exclusivity to manufacture their patented products, competition should still emerge from therapeutic substitutes that can provide meaningful pricing pressure that transfers surplus to consumers and/or increases output. Prescription drug price competition in pharmaceuticals results from intense negotiations between manufacturers and pharmacy benefit managers (PBMs). These negotiations take the following form (which is graphically summarized in Exhibit 2).

First, the actual payer (i.e., a self-funded employer or fully funded insurer) enters into a contract with a PBM. Under the terms of this contract, the PBM manages the payer's pharmacy claims, a process that includes activities such as administering the prescription drug benefits, designing formularies to negotiate price discounts, implementing utilization management, and creating retail pharmacy networks. The compensation received by PBMs in these contracts is complicated and detailed, but at a high level it involves a per-member administrative fee and a portion of negotiated discounts that the PBM can retain.

While PBMs undertake a large number of functions, perhaps the most meaningful economic activity is negotiating discounts or "rebates" from pharmaceutical manufacturers. This negotiation process begins with manufacturers setting a list price, which is the price initially paid by the payer. PBMs and manufacturers then negotiate economically meaningful rebates in order to arrive at a net price. The negotiating power of the manufacturer is determined by the unique value created by its product, and so manufacturers whose products have a large number of potential therapeutic substitutes have less negotiating power. The negotiating power of PBMs results from the number of customers they represent and their willingness and/or ability to move those customers across products after receiving a large discount. The more customers a PBM can credibly shift, the greater the discount they can negotiate. In order to shift share, PBMs use a combination of consumer cost sharing and utilization management techniques such as prior authorization and step therapy.

[18] The problem of competition for precision medicine will be further complicated in situations where the patented product is a biologic product.

To the chagrin of many, rebates negotiated between manufacturers and PBMs are closely guarded secrets. However, for many reasons maintaining this confidentiality improves market efficiency by increasing the size of the rebate and expanding output. Perhaps the most important reason is that manufacturers are less likely to give large discounts if they believe other consumers will observe the size of this rebate and use it as a starting point for subsequent negotiations. A rational manufacturer would anticipate such an outcome and ultimately offer smaller rebates to the entire market. For this reason, economic research suggests that widely known negotiated prices will raise prices rather than increase competition.[19,20] In addition, the public posting of prices can facilitate tacit collusion among firms. When negotiated discounts are publicly observable, firms have more certainty that other competitors in the market are not offering lower prices in order to steal share. In a setting with limited potential entry, this knowledge can serve as the basis for tacit collusion. Previous research in other settings has discussed and documented how public knowledge about price discounts therefore can facilitate such tacit collusion – a separate channel through which ending the confidentiality of rebates would lead to higher prices.[21]

The final step of the negotiation process is that PBMs transfer some amount of the rebate back to the payer, which initially purchased the drug at its list price. The amount of the rebate that is transferred is dictated by the contract between the payer and the PBM. Exhibit 3 depicts the contract structure regarding the amount of the rebate kept by firms based on employer size in 2014 and 2017. Both large and small employers are increasingly likely to have contracts under which they are supposed to receive the entirety of the rebate. However, a meaningful share of both large and small employers are contractually entitled to only a portion of the rebate negotiated by the PBM.

II.A. Improving Information about Flow of Funds Between Manufacturers and PBMs

Rebates have gained an undeserved bad reputation, resulting from a lack of understanding of their important role in controlling pharmaceutical prices. This has culminated in a recent Department of Health and Human Services proposal to end the safe harbor protections for rebates under the Medicare program – a regulatory change that would effectively end the use of rebates for publicly insured consumers (and potentially for the entire market).[22]

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[19] Albæk, Svend, Peter Møllgaard, and Per B. Overgaard. 1997. "Government-Assisted Oligopoly Coordination? A Concrete Case." The Journal of Industrial Economics. Vol. 45, No. 4, pp. 429-443. December.

[20] Byrne, David and Nicolas Roos. 2015. "Learning to Coordinate: A Study in Retail Gasoline." American Economic Review 109(2): 591-619.

[21] Cutler, David, and Leemore Dafny. 2011. "Designing Transparency Systems for Medical Care Prices." New England Journal of Medicine 364 (10): 894-895. doi:10.1056/NEJMp1100540.
Cooper, Thomas E. 1986. "Most-Favored-Customer Pricing and Tacit Collusion." The RAND Journal of Economics 17 (3): 377-388.

[22] Office of Inspector General and Department of Health and Human Services. 2019. 84 FR 2340. February 6.

The proposed rule appears to be motivated by a belief that rebates offered as a discount off of the list price are partially responsible for rising drug prices. However, this belief is misguided. There is nothing about rebates that inherently causes higher pharmaceutical spending. Ultimately, there are two primary concerns about rebates highlighted as rationales for the proposed safe harbor regulation. First, many cost-sharing provisions of prescription drug insurance contracts expose patients to the list rather than the net price of the drug. For example, patients who pay percentage-based coinsurance or who have a deductible that applies to pharmaceutical spending purchase drugs based on the list rather than the net price. As Exhibit 4 shows, the share of the population in such situations has grown markedly and now comprises approximately half the market.

The purpose of consumer cost sharing (copayments, coinsurance, and deductibles) for pharmaceuticals is to address moral hazard, i.e., either the excess consumption of products or consumers purchasing an expensive version of a product when a lower-priced alternative is available. Cost-sharing provisions are based on list prices in an attempt to maintain the confidentiality of negotiated discounts. If patients in the deductible period paid the negotiated price for the medication or if percentage-based coinsurance was based on the negotiated rather than list price, then it would be trivial for rival firms to gather information on the menu of discounts available in the market. As discussed above, maintaining confidentiality of these rebates likely increases price competition and leads to lower net prices – which overall is good for consumers. That said, forcing consumers to pay artificially high cost sharing is likely inefficient, as it unwinds the insurance contract by forcing sicker individuals to pay greater costs and can potentially decrease adherence to prescription protocols.

It is clear we should find policy solutions to pass along more of the negotiated discounts to consumers. However, it is critical that any policy solution saves the proverbial baby while throwing out the bathwater by maintaining the ability of PBMs to effectively negotiate larger rebates with manufacturers. Therefore, I propose that PBMs be required to base cost-sharing payments on a number that more closely approximates the net price of the product. This number could be the average net price across PBMs for that product, the average net price for the therapeutic class, or the minimum price paid in the market, i.e., the Medicaid best price. Assuming that PBMs have sufficient ability to modify their formularies, any of these options should still expose the patient to enough of the cost of the product to address moral hazard concerns while not exposing consumers to artificially high prices that unwind the generosity and efficiency of the insurance contract.

Note that some have complained that policies that pass along rebates to consumers at the point of sale would lead to higher premiums. While it is true that this would be the case, it is not clear this is necessarily a problem. These higher premiums would reflect, in part, a more complete insurance product. It is not immediately clear consumers are fully aware of the financial exposure they have to expensive medications, and therefore we should not think that increasing the completeness of insurance in this setting is clearly a negative outcome.

A second concern about the current system of confidential rebates and other payments between manufacturers and PBMs is that it creates a potential incentive for a PBM to give preference to a higher-list-price drug that offers greater rebates and other fees. Effectively, the concern is that the PBM will not be a good agent for its principal, i.e., the final payer. I argue that to the extent this is a concern, it is actually not about the structure of the rebate contract and instead reflects a more fundamental question about the amount of competition in the market for PBM services. If that is the case, policies to address this practice should focus on the market structure rather than the contractual form.

In a competitive market, the structure of the PBM contract would not matter. PBMs would compete for a payer's business by offering a set of services of specific cost and quality, and fully informed insurers would pick the preferred combination of these characteristics. If we believe PBMs are using rebates to capture a larger share of surplus in this market, this reflects a lack of competition for these services rather than an inherent problem with this contractual form.

Whether or not the PBM market is competitive is currently unclear. On the one hand, there are reasons why we might be concerned about competition in this market. As shown in Exhibit 5, a series of mergers over the last decade have left three firms with nearly 80 percent market share – a structure that might make one concerned about the degree of competition. Some of these concerns were expressed by FTC Commissioner Brill in a dissenting opinion regarding the merger of Express Scripts and Medco in 2012.[23] However, simple measures of market concentration are not proof of a lack of competition. With three large competitors, it is possible there is sufficient competition, and the actual level of competition in this market is fundamentally an empirical question.

The concern about PBMs being attracted to higher-rebate drugs can be best demonstrated by a simple example. Consider a drug that currently has a list price of $100. The manufacturer proposes to the PBM a

[23] Brill, Julie. 2012. "Dissenting Statement Of Commissioner Julie Brill Concerning The Proposed Acquisition Of Medco Health Solutions Inc. (Medco) By Express Scripts, Inc. (Esi)." FTC File No. 111-0210. April 2.

20% list price increase – resulting in a new list price of $120, which is initially payed by the payer (i.e., employer or fully funded insurer). The manufacturer also proposes to increase the rebate paid to the PBM by $15, resulting in a net price increase of only 5% (i.e., the number that is reported in charts such the one shown in Exhibit 6). However, the PBM is only required by its contract to transfer 50% of rebates to the payer, meaning it keeps $7.50 of the rebate and the payer gets $7.50. Therefore, the payer spends $12.50 more, with $5 going to the manufacturer and $7.50 for the PBM.

Ultimately, the unanswered question is whether the $7.50 collected by the PBM represents too much surplus or instead is the appropriate payment for its negotiating activities. In a well-functioning competitive market, we would expect that if the $7.50 the PBM captures from the example above represents too much of the surplus, the PBM would ultimately face competition from another PBM offering a better contract to the payer. Such a contract would propose to decrease the total spending to the payer. However, this requires a market with multiple PBMs actively competing for contracts, a situation that may not exist in the current market. Competition is even less likely to emerge if the firms in the market realize there are large barriers to entry and the incumbent firms would be better off not actively engaging in price wars to gain share.

Strong competition is even less likely to emerge if payers are unaware of the full scope of surplus created by their prescriptions. Many large firms hire sophisticated benefit consultants and increasingly demand fully transparent contracts that provide them full information on all "rebate" dollars. In theory, this provides information about the surplus created by their prescriptions. That said, there are reasons to be concerned that despite these efforts payers may still be unaware of all of the funds flowing between the PBM and the manufacturer. In addition to rebates, PBMs also receive various administrative fees and other payments from manufacturers. Ultimately, the PBM determines which of these payments are rebates (and therefore covered by the price transparency and rebate sharing requirements), and what is instead a fee (that does not need to be disclosed or shared).[24] These fees are not trivial – for some contracts they can account for 25-30% of the money moving between the manufacturer and the PBM.[25] If we consider the simple example above, the situation for the payer could be even worse if, instead of offering a rebate of $15, the manufacturer offers an administrative fee to the PBM. In that case, the payer would bear the full cost (i.e., $20) of the list price increase, and the PBM and manufacturer would split the surplus. Ultimately, manufacturers are agnostic between describing payments to the PBM as "fees" or "rebates" – they simply care about the total amount of money they collect and distribute as a result of these negotiations.

[24] Eickelberg, Henry C. 2015. "The Prescription Drug Supply Chain 'Black Box': How it Works and Why You Should Care." American Health Policy Institute. December.
[25] Dross, David. 2017. "Will Point-of-Sale Rebates Disrupt the PBM Business?" Mercer. July 31.

To further complicate matters, sophisticated payers hoping to gather more information about the flow of funds between the PBM and manufacturers that results from their prescriptions often face meaningful restrictions on the ability to audit their PBM-payer contracts.[26] These can include the exclusion of particular auditors that are deemed to hold views that are hostile to PBMs, requirements that audits be held at the headquarters of the PBM, unwillingness to provide contracts with manufacturers, restricted access to claims data, and strict limitations on the number of years that can be audited.[27] While many of these restrictions can be cast as attempts to maintain rebate confidentiality, they also increase the amount of asymmetric information between PBMs and payers about the amount of available surplus.

The current proposal from the Department of Health and Human Services to address this problem is to eliminate the safe harbor for rebates in the Medicare program. The goal of this policy is to end confidential rebates based on the price of the drug and shift the market to a series of up-front price discounts and flat fees negotiated between PBMs and manufacturers.[28] This would effectively end the confidentiality of negotiated prices while also not decreasing the amount of surplus captured by PBMs – after all, a PBM with market power can calculate a flat fee as easily as the current percentage based-rebate system.

It is perhaps not surprising that policies from both parties are coalescing on attempting to end rebates. Frustrated by rising drug prices, people are looking for a scapegoat and a system of shrouded prices by large firms fits a convenient narrative. That said, it would be extremely unwise to limit the ability of PBMs to negotiate large discounts. Instead of ending the current system of confidential rebates, I've proposed (along with Fiona Scott Morton) that we move to a system where all payments currently paid between the manufacturer and the PBM flow first to the payer before being split between the payer and the PBM.[29] PBMs and payers would be free to negotiate any split of the rebates, fees, and other funds that are paid by the manufacturer – but such a negotiation would now occur between two parties with equal information about the amount of money at stake. There are variety of ways to implement the move to such a system. One possible solution would be for regulators to end the safe harbor for payments between manufacturers and PBMs and instead create a separate safe harbor for payments between manufacturers and payers. I'd note that if the current PBM market is competitive, this proposed policy solution should have little effect on the distribution of surplus.

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[26] Weinberg, Neil, and Robert Langreth. 2017. "Inside the 'Scorpion Room' Where Drug Price Secrets Are Guarded." Bloomberg. May 4.
[27] Advisory Council on Employee Welfare and Pension Benefit Plans. 2014. "PBM Compensation and Fee Disclosure." Report to the United States Secretary of Labor.
[28] U.S. Department of Health and Human Services. 2019. "Trump Administration Proposes to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients." January 31.
[29] Garthwaite, Craig, and Fiona Scott Morton. 2017. "Perverse Market Incentives Encourage High Prescription Drug Prices." ProMarket Blog. November 1.

II.B. Biosimilar Adoption and Rebates

While rebates serve a vital function in drug price negotiations, there are also situations where the structure of the rebate contract can create a barrier to entry for new competing products. For example, rebate contracts sometimes reference rival products, particularly with respect to a rival's placement on the formulary. Depending on the economic context, such rival-referencing contracts could be either anti-competitive or pro-competitive. For example, a manufacturer may offer larger rebates if its product is the only one in a therapeutic area on the preferred tiers of the formulary. If there are many potential products that are competitors for the entire market, such a contract could be efficient. In fact, these types of contracts are at the heart of the PBM strategy. In describing his strategy, the Chief Medical Officer of Express Scripts said, "So we went to the companies, and we told them, we're going to be pitting you all against each other. Who is going to give use the best price? If you give us the best price, we will move the market share to you. We will move it effectively. We'll exclude the other products."[30] Exhibit 7 contains the number of excluded products by two large PBMs over time. Since 2012, there has been marked growth in the use of these lists. Likely related to this fact, since 2012 there has also been a large increase in the amount of rebates in the system (as shown in Exhibit 8).

In situations where manufacturers are competing for access to the PBM's entire patient population, these types of contracts can be pro-competitive, leading to large discounts and increased welfare. However, for some types of products, large portions of the market are not truly contestable, i.e., the PBM will not be able to effectively move a fraction of the patients to the low-price product. For example, patients who are currently using a biologic product are unlikely to be willing to switch to a competing biosimilar at almost any price. In addition, PBMs might find that payers would not be happy with strategies that forced their patients to move across biologic products in this manner.

In a situation where a new entrant cannot effectively compete for a large fraction of patients, a rebate contract for the incumbent product that is contingent on the absence of the rival entrant on the formulary can serve as an almost impenetrable barrier to entry. This situation is sometimes referred to as a rebate "wall" or "trap." Effectively, the new entrant finds that it cannot offer the PBM a large enough rebate on its products (which represent a relatively small share of sales) to overcome the lost rebate dollars from the incumbent (which represents a majority of the market). In such a situation, the new entrant would find it quite hard to ever gain meaningful market share. Perhaps more concerning, realizing the existence of these

[30] Wehrwein, Peter. 2015. "A Conversation with Steve Miller, MD: Come in and Talk With Us, Pharma." Managed Care. April 5.

rival-referencing contracts, potential biosimilar firms may never choose to attempt to create products in the first place. Concerns about the use of rebates in this manner have been raised by many individuals, including FDA Chairman Scott Gottlieb and the CEO of Novartis Vas Narasimhan.[31,32] They are also the subject of antitrust litigation between reference products and biosimilar firms, which is winding its way through the court system and should provide additional guidance about the legality of these practices.[33,34]

Given the potential for the rebates contingent on rival products to block potential entrants, regulators should consider more careful oversight and monitoring of rebate contracts that reference rivals. In situations where a large portion of the market is not contestable by the new entrant – for example, in the case of the first biosimilar entering against a reference product – it may be advisable for regulators to create additional restrictions on the ability of rebate contracts to reference the position of rival products on the formulary.

III. Increasing Incentives for Price Negotiation under Medicare Part D

While many policymakers often claim that Medicare does not negotiate for the prices paid for prescription drugs,[35] they are not correct. Under the structure of Medicare Part D, private firms undertake vigorous negotiations on behalf of the government. Given that the primary commercial activities of these firms involve negotiating with pharmaceutical manufacturers, they have amassed the skills and expertise to be quite good at this process. Using private firms in this way should be an efficient means of securing large discounts for the public insurer. However, two regulations within the current structure of the Medicare Part D program limit the ability of the market to effectively deliver efficient prices. Congress should act to remove or reform these regulations immediately.

The first regulation subverting competition is Medicare Part D's reinsurance program, which blunts the incentives of firms to negotiate price discounts for the most expensive drugs. Exhibit 9 shows the distribution of spending responsibilities under Part D. During the deductible period, the beneficiary is responsible for all the spending. Then, during the initial coverage phase, enrollees are responsible for 25% of their drug spending and the plans are responsible for 75% of spending. If individuals spend through the initial

[31] Liu, Yanchun. 2018. "FDA chief says pharmas use rebates to block biosimilar competition." MarketWatch. July 19.
[32] Narasimhan, Vas. 2018. "Novartis CEO: How To Create Cheaper Alternatives To The Most Expensive Drugs." Forbes. April 12.
[33] Biosimilars Council. 2018. "Brief Of The Biosimilars Council As Amicus Curiae In Opposition To Defendants' Motion To Dismiss." Civil Action No. 2:17-cv-04180-JCJ. United States District Court For The Eastern District Of Pennsylvania, January 26. Accessed March 4, 2019. https://www.accessiblemeds.org/sites/default/files/2018-01/AAM-Amicus-Brief-Pfizer-vs-J%26J-1-26-18.pdf.
[34] United States District Court for the Eastern District of Pennsylvania. 2017. "Complaint, Case 2:17-cv-04180-JCJ." September 20. Accessed March 4, 2019. https://www.courtlistener.com/recap/gov.uscourts.paed.534730.1.0.pdf.
[35] Office of United States Congressman Peter Welch. 2019. "Welch, Rooney Introduce Bill Requiring HHS Secretary to Negotiate Medicare Prescription Drug Prices." January 8.

coverage period, they find themselves in the coverage gap where they are responsible for 25% of spending, the plan is responsible for 5%, and manufacturers are required to give a discount of 70%. If an individual spends more than the catastrophic coverage threshold (approximately $8,000 in 2019), then the government is responsible for 80% of all additional costs, firms are responsible for 15%, and beneficiaries are responsible for the final 5%.

Therefore, for products with exceptionally high prices, the private firms empowered to negotiate on behalf of Medicare are largely shielded from the costs of most price increases – effectively limiting the ability of the market to lower these drug prices. Perhaps more concerning, PBMs operating in both the commercial and the Part D markets may face different incentives for rebates across these different markets and could use the confidential nature of rebates to unnecessarily increase government Part D spending. Exhibit 10 shows the average national plan bid across Part D firms by its component parts – the direct subsidy from the government, the base premium from the enrollee, and the expected reinsurance payment. These data show that from 2007 to 2018, the reinsurance component of Part D spending has grown from a relatively minor part of the program (25% of the plan bid) to the dominant source of payments to firms under Part D (60% of the plan bid).

This level of reinsurance shields plans from the costs of expensive specialty drugs – which are a growing share of the prescription drug market. While such a large amount of reinsurance may have been necessary to attract plans to the newly established Part D market, it is not clear this remains true today. Part D is now an established market where firms have sufficient data to make reasonable projections about potential risk. Therefore, I propose that Congress either remove catastrophic reinsurance entirely from Part D (and force plans to pay 95% of the cost of these expensive products) or switch the cost sharing so that the plan is responsible for 80% of the spending above the catastrophic limit and the government is responsible for 15%. This would provide the appropriate incentives for firms to strongly negotiate for larger rebates and lower prices within Part D.

A second feature of Part D that lessens competition and results in higher prices is the institution of protected drug classes. In an effort to ensure full insurance coverage and to limit the ability of firms to use formularies to deter the enrollment of sick individuals, Medicare Part D contains a number of restrictions on formulary construction. For all drug classes, plans must include at least two chemically distinct products. In addition, Medicare Part D identifies six protected classes (immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics) for which firms must cover every product on the market. Limiting the formulary in this way drastically constrains the ability of private firms to negotiate price discounts – which was a primary rationale for having the Part D program administered by private firms in the

first place. Obviously, in developing the optimal formulary adequacy restrictions, we must balance a tradeoff between price and access. The current system of protected classes appears to err too far on the side of access by providing very few tools for private firms to negotiate lower prices for important and expensive drug classes. Therefore, regulators and Congress should consider amending the protected class rule to maintain a minimum level of formulary adequacy while allowing plans to exclude some products that experience large price increases and to implement more utilization management strategies on expensive drugs within these categories.

IV. Implementing Price Negotiation in Medicare Part B

While Medicare Part D involves a large amount of price negotiation, there are still many drugs paid for by Medicare that involve absolutely no price negotiation. These drugs are those that are administered by providers and covered under the Medicare Part B benefit. Rather than use private firms to negotiate prices for these products, Medicare operates under a "buy and bill" system. Physicians purchase these drugs and then are reimbursed a fixed percentage above the average sales price (ASP) of the product – a price measure intended to account for rebates paid by manufacturers to payers. The purpose of this reimbursement system is to provide doctors with simplicity and predictability of reimbursement. These attractive features, however, come at a meaningful cost for the entire system, as the Part B procurement rules increase prices for the public and private markets while also shifting share at the margin to more expensive treatment options.

In order to understand the widespread effects of Part B, consider the motivations of a pharmaceutical manufacturer negotiating with PBMs and payers to determine its optimal price. Given that these firms are attempting to maximize profits, they set prices that are expected to earn the greatest profits. Higher prices will, by definition, decrease the firm's total profits because the increased margin will not make up for the lost quantity that comes from a greater use of prior authorization, step therapy, increased cost sharing, or other utilization management tools.

By linking public and private prices, the Part B purchasing rule distorts the optimal pricing decision in the private market. Firms are willing to increase private prices, and so suffer declining profits from the private market, because they know they can make up those lost profits and more from the public market. In addition, because they know that physicians earn more money from administering a higher-priced drug, they have an additional incentive related to Part B for raising prices.

The combination of these factors means that the Part B procurement rules create the incentives for firms to offer fewer discounts in the private market, resulting in a higher ASP and greater profits from the public market. As a result, the current Part B rules for purchasing physician-administered drugs result in higher

prices in both the public and the private markets. The effects of these incentives increase with Medicare's market share in each drug – a larger Medicare market share means the potentially higher reimbursement from the public pay is more important for determining profits than the lost sales in the private market. Given the age and disease profile of Part B enrollees, there are a large number of high-cost drugs for which Medicare has a meaningfully large market. For example, Exhibit 11 depicts Medicare's market share for the 84 drugs that are either in the top 50 for overall Medicare spending or the top 50 for spending per enrollee (there are not 100 different drugs because of overlap between these two categories). This exhibit shows that Medicare has an economically meaningful role in this market and that, for 22 drugs, Medicare is responsible for a majority of sales.

As we look for policy solutions to address the lack of competition created by the Part B reimbursement rules, we must be careful not to create incentives for physicians to inappropriately prescribe lower-cost drugs. For example, attempts to reform the Part B procurement rules that switch to simply paying physicians a flat fee for each administered drug ignore the fact that physicians can face meaningful inventory costs for stocking and maintaining a large volume of high-cost drugs. These costs could be particularly acute for small practices, which may lack sufficient liquidity to maintain sufficient stock of medications and may make prescription choices to limit these costs.

Concerned about the high prices for products covered under the Part B program (and, in particular, the high levels compared to similar products in foreign markets), the Department of Health and Human Services has proposed an International Pricing Index (IPI) model for these types of products.[36] Most of the attention for this regulation has focused on the introduction of a reference price for Part B drugs that is based on an average of prices paid in a number of comparable developed countries.

For a variety of reasons, the IPI policy is inadvisable. First, the policy as proposed is quite unclear about what happens if pharmaceutical firms are unwilling to provide the product for the reference price. Given that all drugs must be covered under Part B, it is unclear what providers would do in this case. Second, as discussed above, reducing the prices paid for products of this nature to the levels in other developed countries that use monopsony power to artificially decrease prices would likely have a large impact on innovation. Finally, and perhaps most importantly, the proposal is simply an abrogation of responsibility by our nation's elected officials. If we hope to exploit the market power of Medicare to gain lower drug prices, this will result in decreased investments into new products. The specific nature of that tradeoff is something that we should

[36] Centers for Medicare & Medicaid Services. 2018. 83 FR 54546. October 30.

internally debate and decide upon. It is not a decision we should farm out to policymakers in other developed countries who are making decisions intended to maximize the welfare of their citizens and not ours.

While the reference-pricing component of the proposed regulation is inadvisable, the policy also proposes a vendor model for the distribution of physician-administered drugs that would transform that market from the existing "buy and bill" system to one where physicians have little financial incentive to prescribe particular medications. The details of such a fundamental shift in the market are important and must be worked out, but this portion of the IPI proposal has a number of attractive features. I would encourage policymakers to follow the policy lead of Part D and find ways to utilize private-sector vendors to negotiate lower prices for Part B, rather than turning this portion of Medicare into a price taker. Failing to do so will continue to perpetuate a policy that increases spending across the system.

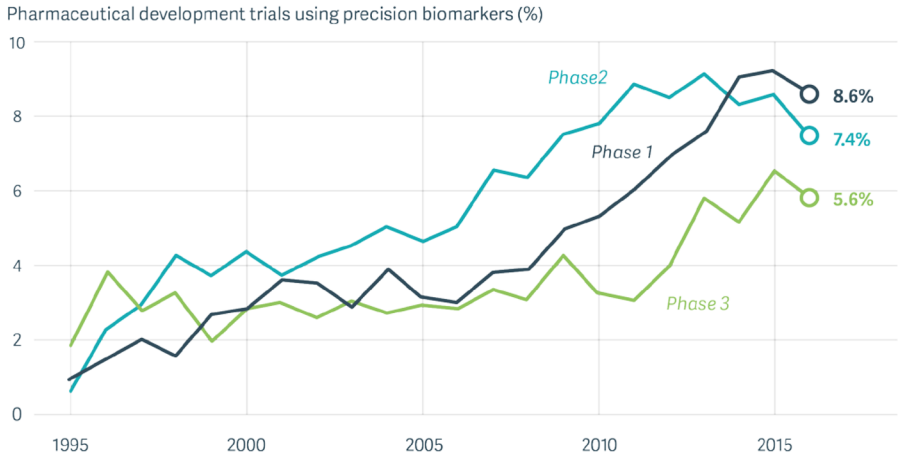
V. Conclusion

The ability of the market to provide an efficient outcome is a function of the degree of competition between market participants. Sustaining competition in healthcare markets requires both addressing features of the market the lead to failure and avoiding the creation of government policies that diminish competitive forces. Given the large role of government actors in the financing and provision of healthcare, it is critical that the policies of the public insurers are routinely evaluated and vetted. After all, public entities are not subject to the competitive forces that would cause private firms to change their policies and protocols.

As policymakers consider policies to address rising costs in the prescription drug market, it is important that they realize that there will not be a single grand solution to addressing this issue. Instead, progress will be made through a series of small, concrete, and addressable policies that target specific areas where competition is thwarted.

EXHIBIT 1

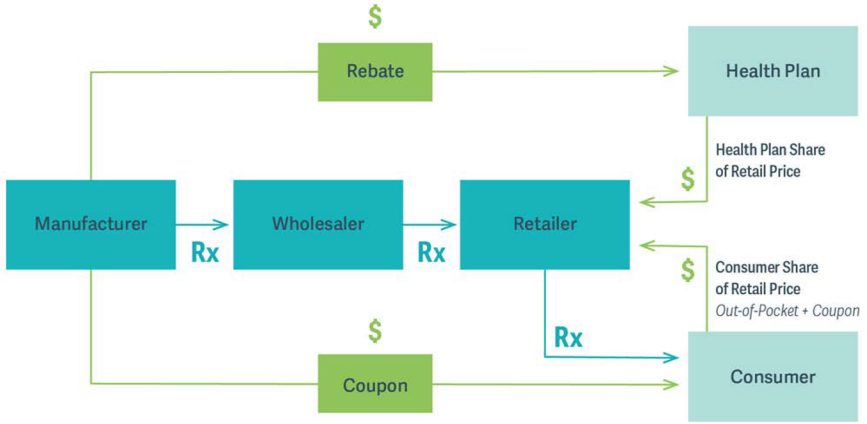
Precision Medicine Development Trials, 1995-2016



Source: A. Chandra, C. Garthwaite, and A.D. Stern, NBER Working Paper No. 24026 and forthcoming in E. Berndt, D. Goldman, and J. Rowe, eds., *Economic Dimensions of Personalized and Precision Medicine*, University of Chicago Press

EXHIBIT 2

Simplified Flow of Products (Rx) and Payments ($) in the Prescription Drug Supply Chain



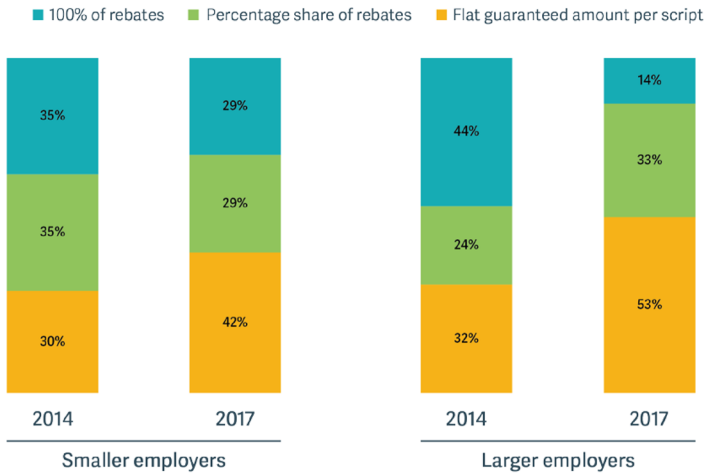
Impact of prescription drug rebates on health plans and consumers
April 2018

Page 3

Source: https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf

EXHIBIT 3

PBM Rebate Arrangements for Traditional Medications in Employer-Sponsored Plans, by Employer Size, 2014 v. 2017



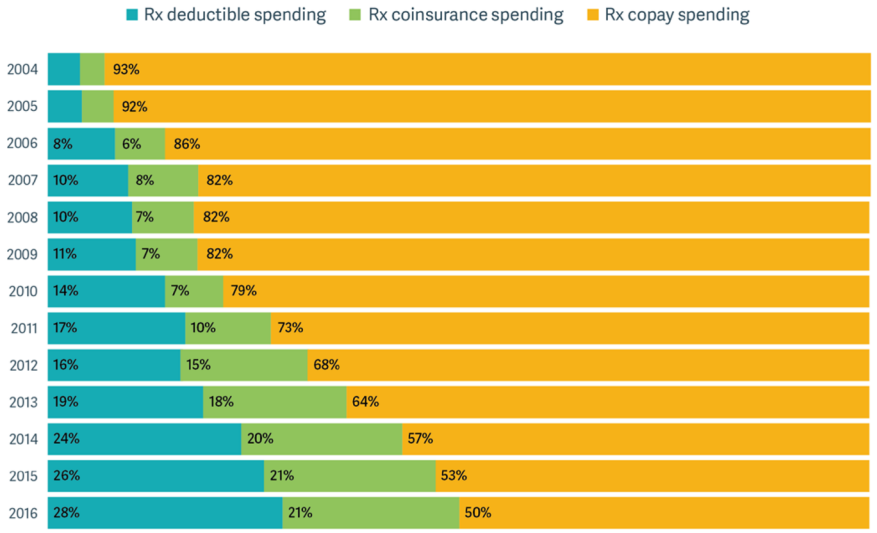
Smaller employers = 5,000 or fewer covered lives; Larger employers = more than 5,000 covered lives. Number of covered lives includes employees and dependents. Source: Drug Channels Institute analysis of *Trends in Drug Benefit Design*, PBMI, various years. Data include only responding firms that receive rebates. 2014 figures recomputed to exclude those who were not sure about their company's rebate arrangements.

Published on Drug Channels (www.DrugChannels.net) on January 17, 2018.

DRUG CHANNELS INSTITUTE

EXHIBIT 4

Distribution of Cost-Sharing Payments for Retail Prescription Drugs in Large Employer Plans, by Type of Payment, 2004-2016

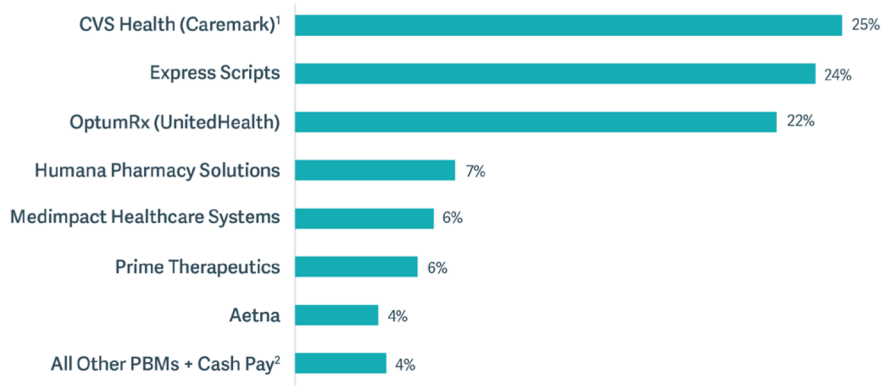


Source: Kaiser Family Foundation analysis of Truven Health Analytics MarketScan Commercial Claims and Encounters Database, 2004-2016 - Get the data - PNG

Peterson-Kaiser Health System Tracker

EXHIBIT 5

PBM Market Share, by Total Equivalent Prescription Claims Managed, 2017



1. Excludes claims processed by Aetna. For 2017, CVS Health changed its publicly reported computation of equivalent prescription claims filled in network pharmacies.
2. Figure excludes cash pay prescriptions that use a discount card processed by one of the 7 PBMs shown on the chart.
Source: Drug Channels Institute research and estimates. Total equivalent prescription claims includes claims at a PBM's network pharmacies plus prescriptions filled by a PBM's mail and specialty pharmacies. Includes discount card claims. Note that figures may not be comparable with those of previous reports due to changes in publicly reported figures of equivalent prescription claims. Total may not sum due to rounding.

This table appears as Exhibit 75 in *The 2018 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Drug Channels Institute*. Available at http://drugch.nl/pharmacy

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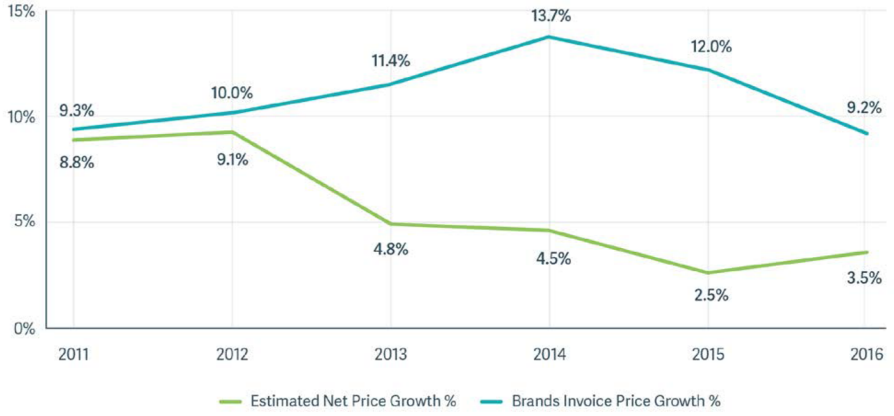
EXHIBIT 6

Protected Brand Invoice and Net Price Growth



Source: IQVIA, National Sales Perspectives, Dec 2016; IQVIA Institute of Human Data Science

Chart notes:
"Invoice" values are IQVIA Health reported values from wholesaler transactions measured at trade/invoice prices and exclude off-invoice discounts and rebates that reduce net revenue by manufacturers. "Net" value denote company recognized revenue after discounts, rebates and other price concessions. Results are based on a comparative analysis of company reported net sales and IQVIA reported sales and prices at product level for branded products representing 79.93% of brand spending in the period displayed. All growth numbers calculated over same cohort of products in the prior year. See Methodology section for more details.

EXHIBIT 7

Number of Products on PBM Formulary Exclusion Lists, 2012-2018

Note: Express Scripts did not publish exclusion lists for 2012 and 2013.
Source: Pembroke Consulting analysis of company reports

Published on Drug Channels (www.DrugChannels.net) on August 3, 2017.

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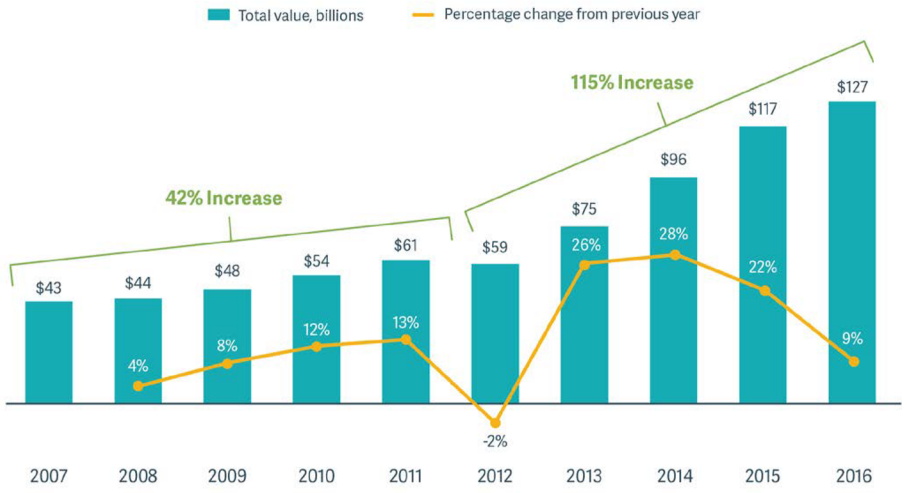
EXHIBIT 8

Pharmaceutical Manufacturers' Off-Invoice Discounts, Rebates, and Price Concessions, 2007-2016



Source: Pembroke Consulting analysis of *Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021*, QuintilesIMS, May 2017. Published on Drug Channels (www.DrugChannels.net) on June 14, 2017.

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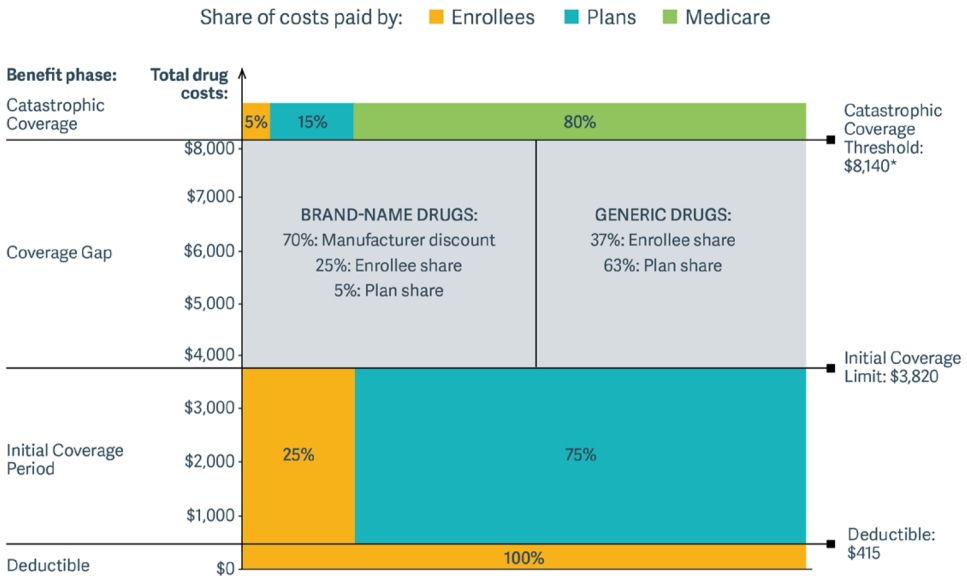
EXHIBIT 9

Medicare Part D Standard Benefit Design in 2019

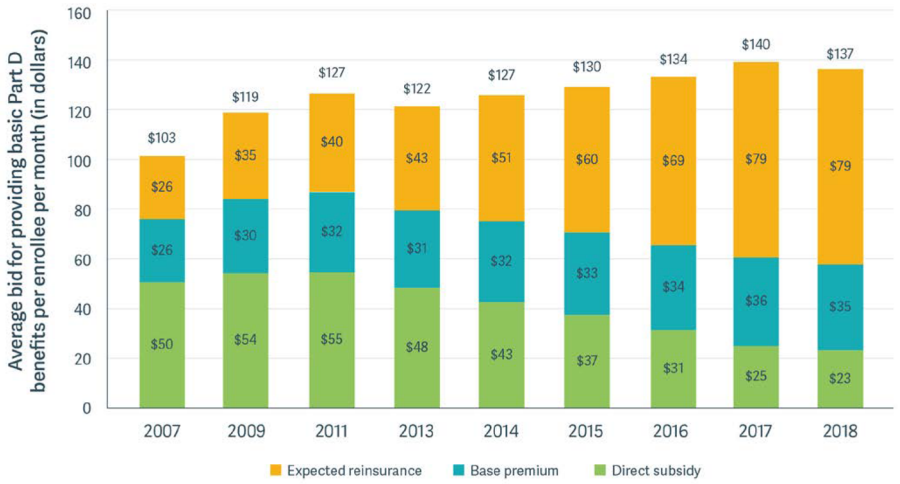


Note: Some amounts rounded to nearest dollar. *The estimate of $8,140 in total drug costs corresponds to a $5,110 out-of-pocket threshold for catastrophic coverage in 2019.
Source: KFF, based on 2019 Part D benefit parameters.

KFF
HENRY J. KAISER FAMILY FOUNDATION

EXHIBIT 10

National Average Plan Bid for Basic Part D Benefits



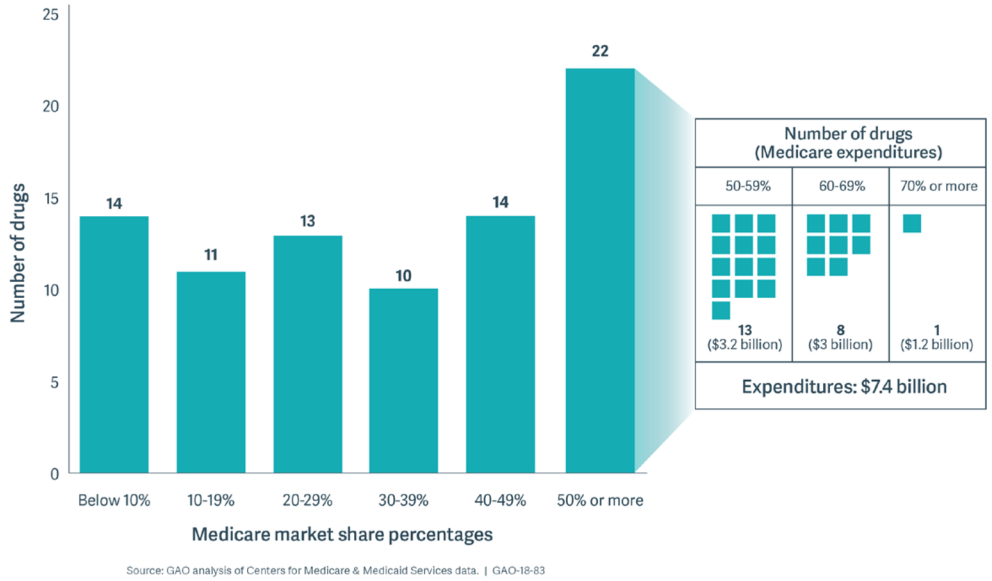
Note: The averages shown are weighted by the previous year's plan enrollment. Amounts do not net out subsequent reconciliation amounts with CMS. Components may not sum to stated totals due to rounding.

Source: MedPAC based on data from CMS.

Source: http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf

EXHIBIT 11

Medicare's Market Share for the 84 Most Expensive Part B Drugs in 2015



Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-18-83

Source: https://www.gao.gov/assets/690/689082.pdf

Mr. CICILLINE. Thank you, Doctor. Thank you to all of our witnesses for your opening statements. We will now proceed under the five-minute Rule with questions and I will begin by recognizing the gentleman from Georgia, Mr. Johnson.

Mr. JOHNSON of Georgia. Thank you, Mr. Chair, and thank the witnesses for your appearance today.

Drug prices are rising every day and the burden is being felt most acutely at the lowest level, the consumer. Yes, this problem is complex and unwieldy with a variety of competing interests, and it seems that these competing interests threaten any incentive to keep costs down.

Lack of competition in the market is driving prices up and every day Americans are paying a higher and higher amount for life-saving medications.

Ms. Morton, do you believe that the American government is utilizing our antitrust protections in the drug-pricing chain properly?

Ms. SCOTT MORTON. No.

Mr. JOHNSON of Georgia. Why do you think antitrust enforcement has weakened?

Ms. SCOTT MORTON. The answer to that is probably longer than we have for time today. Mr. Kades' remarks about the CREATES Act, about defending "pay for delay," citizens petitions, blocking of biosimilar entry in various ways—all of these are potentially anti-competitive behavior that the FTC could go after.

The FTC is limited by the courts' negative views of antitrust enforcement, the limits of the FTC on nonprofits, and other areas that are highlighted in his testimony. I think Congress could fix many of those things.

Mr. JOHNSON of Georgia. So, more laws and more regulations would be the fix?

Ms. SCOTT MORTON. I think more laws making it clear what the antitrust law is supposed to capture and giving the FTC authority to go after those cases.

Mr. JOHNSON of Georgia. Now, it wasn't the Affordable Care Act passage that caused this dilemma, is it?

Ms. SCOTT MORTON. No.

Mr. JOHNSON of Georgia. In fact, the tens of millions of people who were brought into the healthcare system upon passage of the Affordable Care Act, that is not the cause of these—of consolidation in the insurance and the hospital industries and in terms of the high cost of prescription drugs. Is that correct?

Ms. SCOTT MORTON. To the best of my knowledge, that is correct.

Mr. JOHNSON of Georgia. Well, let me ask you this question about prescription drugs. Federal law prohibits itself from negotiating with drug manufacturers over the cost of prescription drugs for Medicare Part D enrollees.

Would removing this handcuff result in lower costs for Medicare Part D employees and the Medicare program?

Ms. SCOTT MORTON. Medicare Part D is run as an outsourced privatized program where insurance companies negotiate with drug manufacturers.

Mr. JOHNSON of Georgia. Instead of—

Ms. SCOTT MORTON. So, they do pretty well. They have a formulary. They can walk away. I think it is very difficult for the sec-

retary of Health and Human Services to walk away from a drug manufacturer and say, I am sorry, Drug A will not be available to anybody—any of America's seniors.

That is a hard thing to say. It is not very credible. Whereas, an individual insurance company can say, oh, we are going to put Drug A low on a high tier with a high co-pay and Drug B is going to be our preferred drug.

So, I think Part D works pretty well. It is Part B that is really not good.

Mr. JOHNSON of Georgia. Do you think the handcuffs on Part B should be removed?

Ms. SCOTT MORTON. Correct.

Mr. JOHNSON of Georgia. That would lower costs for the 15 percent of consumers enrolled in that program?

Ms. SCOTT MORTON. Well, we all pay the taxes for it.

Mr. JOHNSON of Georgia. Well, you are right about that.

Well, let me ask you this question also. With respect to consolidation in the health insurance industry, would passage of legislation that allowed for what is known as the public option—passage of that legislation—would it result in a competition that would lower prices for consumers?

Ms. SCOTT MORTON. The public option has a lot of different definitions but, certainly, anything we can do to make the Affordable Care Act marketplaces more competitive with more choices for consumers, that would be a great help and it would lead to lower prices.

Mr. JOHNSON of Georgia. Thank you. So, the constant attempts to destroy the Affordable Care Act, which enabled tens of millions of people to have access to the system don't do anything to cut the consolidation in the hospital and insurance industries or the rise in prescription drug prices. Do you all agree with that?

Yes, yes, yes, and yes?

[A chorus of ayes.]

Ms. SCOTT MORTON. Yes.

Mr. JOHNSON of Georgia. Okay. Well, let the record show everybody agrees with that.

With that, I will yield back.

Mr. CICILLINE. Thank you, Mr. Johnson.

The chair now recognizes the gentleman from Wisconsin, Mr. Sensenbrenner, for five minutes.

Mr. SENSENBRENNER. Thank you, Mr. Chair.

I have some questions for Dr. Gaynor. First, you note in your written testimony that Americans who live in rural areas are vulnerable to harms from hospital consolidations and anticompetitive behavior.

My home State of Wisconsin has been particularly affected by rural hospital mergers with 19 mergers taken place between 2005 and 2016.

Why does this happen more in rural areas than in urban areas?

Mr. GAYNOR. Thanks for your question, Member Sensenbrenner.

I don't know that I can answer why it is happening more frequently in rural than in urban areas at this point in time. I am happy to consider it further and submit an answer in written testimony.

Nonetheless, there are quite a few mergers that are happening across the board, not just in rural areas, and there are lots of things that are driving those mergers.

As we all know, there is a merger wave in the U.S. economy happening that is affecting what is happening in healthcare. There are motives on the part of merging parties to enhance their negotiating positions by merging and eliminating or harming competition.

There is sometimes a game of musical chairs that happens where they see everybody else merging and they don't want to be the last one left standing when the music stops.

Nonetheless, Americans that live in rural areas are particularly vulnerable because if there only one provider or dominant provider it is very difficult for them to go elsewhere. So they can be particularly harmed by the mergers that enhance or consolidate market power in the areas that they live.

Mr. SENSENBRENNER. Okay. Second, in your written testimony you explain that some states have regulations that unintentionally make it difficult for new care providers to enter the market and that the negative impacts of these laws can particularly affect residents of rural areas.

Can you tell me what kind of State regulations or laws make it difficult for new hospitals or other providers to offer healthcare services and, again, why does this happen more often in rural areas than in urban areas?

Mr. GAYNOR. Thanks again for your question, Ranking Member Sensenbrenner.

So, there are a number of examples of this. There are a set of laws called certificate of need laws. About 26 states in the Union still have certificate of need laws.

Mr. SENSENBRENNER. We had them in Wisconsin and repealed them.

Mr. GAYNOR. Yes. Yes. Pennsylvania, for example, had such a law. It sunset about '95 or '96. About half of all states still have them and that requires review and approval by a regulatory commission to create a new facility or expand a new facility, whether it is a hospital, an ambulatory surgery center—that sort of thing.

Another area that is particularly important has to do with the decisions of State licensing boards about what sorts of entities are allowed to practice and provide healthcare.

Telehealth is one example where State licensing boards have discretion over the provision of telehealth. The scope of practice for nurses is another area—what nurses are allowed to do and not do, what sort of supervision is required. Last but not least, independent pharmacists are also subject to these regulations.

Now, the regulations are statewide but why might they affect folks in rural areas particularly more? Well, telehealth is easy to see. If you live in an area where there are not a lot of providers physically, the ability to obtain care through telehealth for some kinds of services can greatly expand the opportunities for care.

If nurses can do more, if pharmacists are allowed to do more, that expands the supply of healthcare professionals and so creates more opportunities, more care, and more competition in those areas.

Mr. SENSENBRENNER. Thank you very much. I yield back.

Mr. CICILLINE. Thank you, Mr. Sensenbrenner.

The chair now recognizes the distinguished gentlelady from Washington State, Ms. Jayapal, for five minutes.

Ms. JAYAPAL. Thank you, Mr. Chair, and thank you so much for having this hearing. Thank you all for your testimony today.

I think it is important that we remind people that might be watching what we are talking about which undergirds everything you have said, which is that today in the United States we spend about 18 percent of our GDP on healthcare, which is double what every other major industrialized country—almost double what every other major industrialized country in the world spends on healthcare.

You might think, if you were listening to this, that that means we have great outcomes. In fact, the United States is worst of our peer countries on maternal mortality. That is moms that die in childbirth.

We are worst in terms of infant mortality. That is kids that die when they are young. We are worst in terms of life expectancy. We have the lowest life expectancy.

So, this is a marketplace that truly is broken and I think you all have raised important considerations. I wanted to point out that this is also a marketplace where the top five private health insurance companies bring an annual profit of $90 billion a year.

The top pharmaceutical companies bring in $75 billion a year, and this is as people are dying because they can't afford insulin or cancer treatments.

So, I have introduced our Medicare for All bill here in the House and have 106 distinguished original co-sponsors. So, I wanted to just turn, Professor Gaynor, to you first.i

You are an expert on competition and antitrust policy and particularly in the healthcare markets, as was evident from your testimony, and you stated that the U.S. healthcare system is functioning at a subpar level which has resulted in this egregious pricing that we see and the poor quality of care.

You attribute that largely to the lack of competition caused by a highly consolidated healthcare market. So, can you just explain in the simplest terms why this consolidation is occurring? Why are all these firms merging and what is driving that?

Mr. GAYNOR. Representative Jayapal, thank you for your question.

There are multiple reasons. So, one reason that consolidation occurs is very simple. The consolidating firms want and can get negotiating power, get higher prices, and have higher profits, and sometimes the executives of these firms actually admit that in public.

That is rather rare. Usually, the lawyers are none too pleased. For example, Toby Cosgrove, a very, very accomplished CEO—former CEO of the Cleveland Clinic, was interviewed by the Wall Street Journal in 2012 and said as much—that is exactly why we do those things.

So, that is one reason, and though there are others, I think that is important. Another reason has to do with sort of a—not a virtuous but a vicious cycle in which consolidation can happen on one side of the market and then the providers or the insurance on the other side feel that their negotiating position has been harmed so

they consolidate in order to try and shore that up, and this can go back and forth and back and forth in a vicious cycle.

Ms. JAYAPAL. Right.

Mr. GAYNOR. As I said previously, there can also be a musical chairs—

Ms. JAYAPAL. I am going to—I am so sorry.

Mr. GAYNOR. No. That is fine.

Ms. JAYAPAL. I want to ask you a couple other questions and I am going to run out of time.

Mr. GAYNOR. Of course. Yeah, we could go on for some time.

Ms. JAYAPAL. Really important, I just want to emphasize. So, merging is happening because when you merge you have greater negotiating power, which means you can drive up prices and profit really simply.

So, do you believe that the goal of the healthcare system should be to serve patients and improve health and not to increase profits?

Mr. GAYNOR. Absolutely.

Ms. JAYAPAL. Okay. Great. Is this increasing concentration in our healthcare markets targeted at improving patient outcomes at that primary goal of getting better patient outcomes, better healthcare, and making care more affordable?

Mr. GAYNOR. No.

Ms. JAYAPAL. So, who is paying for the rapidly increasing prices that we are seeing from these hospital and healthcare consolidations? Is it just patients? Who is paying for that?

Mr. GAYNOR. Ultimately, actually it is all of us. When we have prices go up in healthcare, we don't see it directly in the same way if, say, there is a merger of grocery stores or paper supplier, or that kind of thing.

Nonetheless, it comes back to all of our wallets. For example, just simple statistics—over the past 20 years worker contributions to health insurance have risen by 239 percent. Over that period wages rose by 68 percent.

So, what happens when prices go up, costs go up to health insurance companies. Health insurance premiums are 80 to 90 percent of greater medical expenses. So, health insurance premiums go up. What happens?

Well, employers pay higher health insurance premiums. Their healthcare costs go up. They are not going to alter total compensation to workers.

I am only worth a certain amount to Carnegie Mellon University, although you are free to tell my dean I am not getting paid enough. Yes. Dean Ramayya Krishnan.

[Laughter.]

Ms. JAYAPAL. So, wages go down because, basically, any money that is in the system is going to pay for these increasing healthcare costs.

Mr. GAYNOR. Something has got—exactly. Something has to give. If the employer is faced with higher healthcare costs, what happens? Wages fall or they don't rise as much as they otherwise would, workers pay more of health insurance contributions, or benefits are cut. In some cases, in the past anyhow, workers lose coverage entirely.

Ms. JAYAPAL. Thank you so much. I think it is important that everybody understands that small businesses, employers, and patients are footing the bill and they are already paying these enormous costs.

Thank you, Dr. Gaynor. I yield back.

Mr. CICILLINE. Thank you.

I now recognize the gentleman from Florida, Mr. Gaetz, for five minutes.

Mr. GAETZ. Thank you, Mr. Chair.

I want to begin by praising your leadership and thanking you for this important subcommittee, and while I know the important work of the full Judiciary Committee has been flavored a bit partisan at times, as I look at the work you have done on lowering prescription drug prices, taking on the excesses of bit tech, I think that this Subcommittee is poised for some major bipartisan successes and I thank you for your efforts.

Specifically, as it relates to the subject matter before us here, I am hopeful that the substance of the CREATES Act will ultimately be marked up in Committee and I am also hopeful that some of the PBM transparency issues that we have discussed are able to be fully exposed.

I also want to praise Florida's governor, Ron DeSantis. Right now, one of the major challenges we face is Florida is the rising cost of prescription drugs creates a massive cost structure on our corrections system and there is currently a real opportunity for Florida and other states to import drugs from foreign markets and then to be able to lower costs substantially.

That is allowed under current law in Florida. We are currently working toward that with President Trump. So, I would implore President Trump to look favorably on Governor DeSantis's request and that other states might be able to unlock the potential of lower drug prices.

Mr. Chair, as we are gathered here talking about the anticompetitive practices in medicine, it is really noteworthy to me that one of the most anticompetitive things that occurs is the heavy hand of the Federal Government constraining access to medical cannabis.

As we look at the types of prescription drugs that are sought to deal with opioids in particular, we continue to see evidence—substantial evidence, in fact, according to the National Academy of Sciences—that cannabis is helpful in dealing with chronic pain, treatment of chemotherapy and vomiting, and multiple sclerosis symptoms.

So, it is my sincere hope with all the energy and passion among my Democrat colleagues on the Judiciary Committee that in looking at prescription drug use, prescription drug abuse, and prescription drug cost we unlock the potential of medical cannabis and that we get the government out of the way so that it is not impairing the relationship between physicians and patients.

I want to take a moment to ask Mr. Garthwaite, in this broader discussion we are having about consolidation what role does the Federal Government have in spurring consolidation through excessive regulation of the health marketplace?

By that, I mean, as the Federal Government becomes more and more involved in what qualifies for draw downs to states in the provision of healthcare does that excessive regulation and the compliance cost it drives, is that a contributing factor in your review of maybe a consolidation incentive?

Mr. GARTHWAITE. I think part of what you are getting at is there is some fixed cost with dealing with regulations and compliance. I think at the State of the sort of landscape at this point, most of these firms are big enough that they are able to cover that fixed cost and I would agree with Dr. Gaynor that a lot of this is not about being driven by federal regulation. It is being driven by either attempts to seek higher prices or attempts to coordinate care.

Mr. GAETZ. Dr. Gaynor, would you reflect on the role that PBMs have in the health of the prescription drug marketplace?

Mr. GAYNOR. I wasn't asked to prepare testimony on that topic. I am happy to reflect on it and submit a written response to your question.

Mr. GAETZ. Great. Thank you.

Those are my questions, Mr. Chair. I will yield back.

Mr. CICILLINE. Thank you very much.

I now recognize the gentlelady from Florida, Mrs. Demings, for five minutes.

Mrs. DEMINGS. Thank you so much, Mr. Chair, and thank you to our witnesses for being here with us today as we discuss this very, very important topic.

I am reminded of a quote from Dr. King, who said, "Of all of the injustices, and there are many that exist, the lack of healthcare is the most inhumane."

So, this is a critical subject to all of our districts and our communities. My colleague, the Ranking Member, talked about the merger—the number of mergers that have occurred in rural areas and I know, Dr. Gaynor, you mentioned that it is not just occurring in rural areas but across our nation.

I do believe that in rural areas the effects can be much more devastating because the lack of access, quality of care, access to services—all of those dynamics.

So, could you just please talk about the extra harm, if you will, that mergers do or have the effects—the negative impact that they have on rural communities?

Mr. GAYNOR. Representative Demings, thank you for—thanks for your question. Yes.

Well, because folks in rural communities live much farther from other healthcare providers—hospitals, doctors, nurses, *et cetera*—if there are mergers in rural areas that leave them with few alternatives, their next best alternative can often be miles and miles away.

Of course, for some kinds of care it is either very difficult or impossible for people to travel—emergency care and obstetric delivery. Even if they are willing to travel it is a long way.

So, that imposes real costs on them and that means that if there are providers in the area they have more ability to have higher prices. They are under much less pressure to do better and have better quality, provide better service, better access, and better community benefits.

I think that those of us in America who live in rural areas are particularly vulnerable to these kinds of harms.

Mrs. DEMINGS. Could you also talk about what type of positions in terms of employees when hospitals mergers occur who—what type of employee or hospital worker is really the most vulnerable in that environment?

Mr. GAYNOR. Well, it is the folks who have skills as workers that are most specific to working in a hospital because if their best alternative is to working in a given hospital and now there is a merger and the next hospital over is no longer available to move to because they are now one firm, then they don't have such great alternatives.

If their workers who have very general skills—so, if you are a food service worker in a hospital you might not prefer to work somewhere else, but you could go and work at another company and be a food service worker there.

So, when a hospital merger happens, the hospitals can't squeeze your wages or your working conditions too much. If you are an OR nurse, where else are you going to go? You may be able to go elsewhere, but it won't be as good a job.

Mrs. DEMINGS. Finally, Dr. Morton, would you just, again, please describe for me what is the connection between a lack of competition and the rising cost of healthcare?

Ms. SCOTT MORTON. Lack of competition means that providers of various kinds of drugs, devices, hospitals, and doctors don't have to compete with one another for the business of patients, and competition generates both lower prices and also more innovation and more quality, more choice for all the consumers of healthcare.

When we don't have competition we have higher prices and lower quality and that just hurts everybody, both the patients and the taxpayers.

Mrs. DEMINGS. Thank you.

Mr. Chair, I yield back.

Mr. CICILLINE. I thank the gentlelady for yielding back.

I now recognize the gentleman from North Dakota, Mr. Armstrong, for five minutes.

Mr. ARMSTRONG. Thank you, Mr. Chair.

I guess my first question is for Dr. Gaynor. So, we have—and North Dakota has been a little different since 2010. We have had an actual boom in our economy. So, prior to that, we were suffering the same type of problems the rest of rural America was facing.

We have noticed a lack of workforce shortage. We probably have—if not the best one of the best rural hospitals in the country, because it is brand new and it is fantastic, but we are having trouble staffing it and so when we are talking about these consolidations in rural areas, we have seen it.

They move into the—yes, we have urban areas in North Dakota—the more urban areas. These aren't all motivated by anticompetitive behavior. Factors such as worker shortage, nurse shortage, provider shortage, resources, and financing are part of this equation, aren't they?

Mr. GAYNOR. So, as I said, there are multiple motives for mergers and acquisition. I don't know that labor market issues are a primary driver. I haven't heard that.

There can be—incentives usually happen more in acquisitions than in mergers where a smaller hospital wants to be acquired by a larger hospital that has more resources, particularly if that hospital is struggling.

Then you can certainly see that. I am not aware of labor market issues as being a motive driving these mergers and acquisitions.

Mr. ARMSTRONG. Maybe it is just unique to our geography.

Well, part of that we have talked about licensing and State licensing and states are all very good at putting up their own White picket fences and ensuring that a nursing degree or a nursing license in Minnesota doesn't apply in North Dakota and we work on those at the State level a lot and a lot of different states are starting to see that the world is becoming a much smaller place.

So, when these consolidations happen, whether they happen for—make economic sense, are there any policies here—and I guess, this question would be for everyone—what can we do at the federal level that promotes access, whether it is urgent care centers or things in rural areas?

I know they are starting to do strep tests at pharmacies in rural areas in our district and before we get into crossing pharmacists with doctors or nurses but, just to continue to provide some semblance of access in rural America?

Mr. GAYNOR. Well, yeah. There are a number of things. One I mentioned previously is making sure that licensing is tailored very specifically to the purpose of protecting the public and doesn't overstep those bounds so that nurses and pharmacists, for example, are permitted to do the things that they have been trained to do and qualified to do and that creates more access right off the board.

So, that is a principle. Now, that is State level. The Federal Government can try to work with states, try and provide information and support to states in this area, and that can actually make an important difference.

Mr. ARMSTRONG. Does anybody else have any? Yes, ma'am.

Ms. SCOTT MORTON. I would agree. I think occupational licensing is often used as a barrier by incumbent licensed people to keep out others and if you have a shortage of a certain medical worker it is not like human bodies are different between North Dakota and South Dakota and any other state.

So, it might be reasonable to imagine that the requirements for being a nurse or a doctor are the same across states and if we had fewer differences workers could move more easily.

Mr. ARMSTRONG. Yes, sir?

Mr. GARTHWAITE. Yeah. I also know that we are seeing private firms start to address this as well. So, some of the motivation behind some of the vertical integration we are seeing in healthcare and this Committee had a nice hearing on CVS–Aetna as a merger.

Some of the motivation behind that is about finding new sites of care, maybe finding ways we can treat chronic conditions at retail settings, be it a CVS. Wal-Mart is thinking about these things as well.

Those will provide more access for care in places that aren't the traditional general acute care hospital or a doctor's office, which can often struggle to be a standalone business in a rural area, given the lack of demand.

Mr. ARMSTRONG. Thank you, and that is important because the economies of scale—it is not unique to the medical profession. We are seeing more and more of this happen in rural areas as we continue to move on.

Mr. GAYNOR. Just one last thought, and this has already been addressed in part by Congress, and that is what are called site-neutral payments for Medicare. I think you are familiar with those.

The payment for the same kind of service delivered by the same kind of professional can be many multiples if it is dubbed in a hospital and that creates some distortions that may favor those things and then actually end up penalizing people in rural areas.

Mr. ARMSTRONG. Thank you. I yield back my negative 15 seconds.

Mr. CICILLINE. I thank you, and I now recognize the gentlelady from Florida, Ms. Scanlon.

Ms. SCANLON. Pennsylvania.

Mr. CICILLINE. Pennsylvania.

Ms. SCANLON. That is a big move. Yes.

Mr. CICILLINE. There is a lot of Florida down on that end. My apologies. Pennsylvania—for five minutes.

Ms. SCANLON. Thank you.

So, there are a few questions that came up or a few topics that came up more frequently when I was running last fall then about affordable healthcare and in that sector the biggest question I kept getting is what can we do about prescription drugs prices, over and over.

It is a priority for my constituents and therefore a priority for me. In addition to being very worried about this, they are also really smart. So, they fed me specific questions.

Professor Scott Morton, the question of evergreening of patents—as I understand, that is tweaking patents to extend the amount of time that there is proprietary rights. Can you speak to that and how that impacts the prices of drugs?

Ms. SCOTT MORTON. Yes. This is a tactic whereby—let us say there is a drug that is administered twice-a-day and the manufacturer invents a once-a-day version and patents that, or maybe even takes 50 milligrams and makes a 60 milligram tablet and patents that and then releases that new product on the market and, in some cases, removes the old product that is about to be generic and therefore much less expensive.

This situation could be really helped with a couple of policies. So, one is generally strengthening the antitrust laws and allowing the FTC to go after behavior that it feels is anticompetitive.

Another one is reforming the incentives of the PBM. The PBM should want everybody to take that generic drug because it is cheaper and not steer them to the more expensive one, and when we have perverse incentives that latter thing can happen.

In general, however, we don't want to get into the business of saying, is this innovation good or not but, rather, subject it to the market test. Once-a-day could be a super valuable innovation and if it has to compete head to head with twice-a-day we will find out.

If, however, the launch of the once-a-day is accompanied by the pulling away of the twice-a-day, we don't have head to head competition anymore. That is a situation where it looks like the manu-

facturer didn't think their once-a-day was going to win and that is why they took away the twice-a-day.

Ms. SCANLON. Okay. Thank you for that.

Mr. Kades, in 2013 the Supreme Court held in *FTC* v. *Actavis* that "pay for delay" settlements, which occur when a branded drug company pays a potential generic competitor to delay entering the market with a lower cost generic, likely violates the antitrust laws absent a justification.

Can you comment on whether that decision is sufficient or insufficient to address the "pay for delay" settlements and is there something we can do about that?

Mr. KADES. Yes. Thank you for the question, Representative Scanlon.

So, at one level, the Supreme Court decision was good because until that time courts were taking the position that a patent holder could pay any amount of money to secure the agreement of the generic not to manufacture its drug, and because the brand makes so much more than the generic these were very common.

Once the court said you can do this, agreements went up. Supreme Court—in principle, the Rule makes sense. The problem is that the lines aren't clear and there has been lots of litigation. I said in my opening statement there was a case that settled just last year and it was filed back in 2006.

So, what you are having to happen is that the government is spending lots of resources to prove that paying your potential competitor not to compete is a problem, and we live in a world of limited resources.

As other people have talked about other things, whether it be the rebates and the PBMs or other things, the product hopping, the government can't even get to those cases because they are basically left having to prove these basic ideas that we all should agree are anticompetitive.

Ms. SCANLON. I know one suggestion to address this is to establish a presumption that these "pay for delay" settlements are anticompetitive. Do you think that is a good idea or are there other legislative fixes that you would suggest?

Mr. KADES. I think that is an excellent idea. When you look at both the economic theory behind what happens in a "pay for delay" settlement and we actually have evidence that they—empirical evidence that these types of agreements delay entry, then you should start with the proposition that if someone is paying a potential competitor in a settlement we should presume it is harmful and make them come forward if it is not.

Instead, we have it the reverse, which makes no sense, given what we know about theory and the empirics.

Ms. SCANLON. Any other suggestions in that "pay for delay" arena for legislative fixes?

Mr. KADES. So, I think part of this is making sure it is sort of complementary. These are incredibly enticing deals. So, in one of the cases I worked on the company paid $60 million and managed to protect close to a billion dollars.

In another one, after the company paid off four generic competitors, they boasted, "We got six years and $4 billion that nobody expected."

So, you have to have a really strong penalty provision. If all the government can do is say, oh, you broke the law—promise us you won't do it again, that is not going to be effective and there is going to be no reason for companies to settle. You have to be able—the government has to be able to go in and say, no, no, no, you don't get to keep the money because you earned it by breaking the law.

Ms. SCANLON. Thank you.

Mr. CICILLINE. The time of the gentlelady has expired.

I now recognize the gentleman from Colorado, Mr. Neguse, for five minutes.

Mr. NEGUSE. Thank you, Mr. Chair.

I want to thank the panel for being here with us today for your testimony. I also want to thank my colleague from Wisconsin for raising the important issue regarding rural areas in particular where this is very pernicious—certainly, in my district.

I represent a variety of counties—Summit County, Eagle County, mountain communities more rural in nature where this is a big problem and the effect is very pronounced.

I want to—so, Dr. Gaynor, I want to call out one particular finding, which I think is fairly intuitive but your data certainly supports it. From your written testimony here I will quote, "One of our key findings is that hospitals that have fewer potential competitors nearby have substantially higher prices.

For example, monopoly hospitals prices are, on average, 12 percent higher than hospitals with three or more potential competitors nearby."

That is a very important fact worth repeating and one of the recommendations you make, and Dr. Morton makes as well, that I believe is particularly compelling is around nonprofit hospitals, which is a big part of this discussion that often gets left out and I think part of it is because there is a misperception about the nature of nonprofit hospital entities, in some cases.

I am sure Members of the panel serve on nonprofit boards. Dr. Gaynor, you have created the Healthcare Cost Institute. I am curious. I imagine that the CEO of the Healthcare Cost Institute does not have a private jet. Would I be right in saying that?

Mr. GAYNOR. Well, I am no longer on the board.

Mr. NEGUSE. Oh, okay.

Mr. GAYNOR. I would be extraordinarily chagrined were that the case.

Mr. NEGUSE. All right. They are not making tens of millions of dollars, right?

Mr. GAYNOR. No.

Mr. NEGUSE. Dr. Kades—I hope I pronounced that right, Kades—is that correct?

Mr. KADES. Kades, yes.

Mr. NEGUSE. Kades. Yes, sir. You, of course, are the director of a nonprofit entity, the Washington Center for Equitable Growth. Is that right?

Mr. KADES. Actually, I am the director of the Competition Policy. The Washington Center for Equitable Growth is a much bigger organization.

Mr. NEGUSE. Okay. Well, I trust that the director of that entity is probably not flying around on a private jet and making tens of millions of dollars either.

Mr. KADES. I think that is a fair assumption.

Mr. NEGUSE. All right. So, here is my point. All right.

Wall Street Journal—this is relatively recent, the last two years—as of December 13th–December 30th, 2016, tax filings as of that date prepared kind of a summary and you have a variety of hospital executives at various large nonprofit hospital systems.

Ascension in St. Louis, $17 million in annual compensation. Northwell Health, $10 million. Highmark Health, $9.8 million. Mercy Health in Wisconsin, $8 million compensation package.

A variety, right? You can encourage folks who are watching to just Google, nonprofit health CEO and private jet, or private chef or any variety of other compensation packages that are attached to folks who are working in those industries.

I think what we have kind of lost sight of there, right, is the charity aspect and obligation that a nonprofit hospital has, right, embedded in its purpose as an entity.

The FTC, in 1999—there is a report. Go onto the website. I was 15 years old in 1999. This is a long time ago. There is a report titled "Competitive Effects of Not for Profit Hospital Mergers," and I will quote from it. It says, "Mergers involving not-for-profit hospitals are a legitimate focus on antitrust concerns." Yet, here we sit 20 years later and the FTC has no power to, essentially, engage in this important area.

So, I would like to give Dr. Gaynor and Dr. Morton perhaps an opportunity to talk about this, because it is a pretty simple change in the law that we could make—that Congress could make—that would really open this up.

Again, a lot of not-for-profit hospitals are doing incredible work—good work. There is a case to be made for the FTC to have expanded authority in this regard.

Care to comment?

Mr. GAYNOR. Yes. Thank you, Representative. So, I agree 100 percent. Just to be clear, the FTC does have the authority to pursue mergers under the Clayton Act. What they do not currently have the authority to do is pursue anticompetitive conduct by nonprofits under the FTC Act.

So, I agree. I think that needs to be revisited and revised so that both our antitrust enforcement agencies are using all the tools in the antitrust arsenal to address the pressing issues in this sector.

Let me say again, yes, most hospitals in the U.S. are technically nonprofit but the numbers you gave out are eloquent testimony to the fact that this is big business.

Once upon a time they were charities but that was a long time ago. When healthcare is one-fifth of our entire economy, when UPMC is a $10 billion revenue company, the largest private employer in the State of Pennsylvania—and that is replicated over and over and over again—they are no longer charities. They are big businesses.

Mr. CICILLINE. The time of the gentleman has expired. I thank you.

I now recognize the gentlelady from Georgia, Mrs. McBath, for five minutes.

Mrs. MCBATH. Thank you, Mr. Chair, and once again to reiterate, as many of my colleagues have today, I just want to thank each of you for coming and sharing your testimony with us today, and I would just like to thank you for being here because this is—this is something that is extremely important to me because it has touched me personally.

I am a two-time breast cancer survivor and I understand what it is like to have your life completely turned upside down overnight. Having that diagnosis once was, I can tell you, you go into a crisis mode.

To have it a second time wreaks even more havoc than it did the first time and the stress of the financial burdens that follow are just—weigh so heavily not only on the individual that has been diagnosed but also the entire family.

Now, I had the benefit of being in a breast cancer study that allowed me to have discounted treatment as well as pharmaceuticals. So, I realize that I was very fortunate in that regard.

Even though I was fortunate to have very good health insurance—I worked for a major corporation, major company. I worked for Delta Airlines. I was under a really good group health insurance program. I still worried about my medical bills and my needs and how would my family be so adversely affected by this health crisis.

So, even though I had good benefits, I could not even imagine what it would be like for a family that didn't have the ability to have the kind of healthcare that I had the fortune of having.

Now, I want to say that my story is absolutely not unique. It is stories like this that we hear every single day from Americans across the country, and just this week I heard from a family—a woman within my own district in Georgia—who told me that she spends $1,500 a month on diabetic supplies for her daughter, who has type 1 diabetes, and that is more than her monthly mortgage.

So, Dr. Scott Morton and Mr. Kades, could you speak very candidly to what should be done to bring down prescription drug prices, those costs, while also supporting innovation and research, which is so sorely needed?

Ms. SCOTT MORTON. I would say that, in my written testimony, I describe a way that you could cap out-of-pocket prices, which is the most harmful thing that consumers and patients are experiencing now and combine that with a ban on kickbacks by the pharmaceutical company in the form of coupons, financial aid, wraparound services, and so on.

This would leave patients protected and then enable competition because without being able to incentivize the patient the manufacturer would have to sell its drug to the PBM and then it would have to compete with other drugs in order to sell its drug to the PBM.

So, the key in restraining prices that patients pay out-of-pocket is to do it in a way that enables as much competition as possible so that you keep the prices paid by the insurer low because, of course, we all pay premiums.

So, that is the other way in which this is very expensive, not just out-of-pocket costs. So, the two sides need to go together.

Mrs. MCBATH. Thank you.

Mr. KADES. So, I am going to come at this from my experience as an antitrust lawyer and what can we do—what is wrong with this marketplace in terms of anticompetitive conduct, and the issue here is a branded company makes a pile of revenue, money, and they are insulated from price competition generally until there is a generic—just having the generic totally changes and prices go down, they lose most of their sales, and so there is a real incentive to do anything possible to delay that date.

So, that can be you pay your competitor not to compete, which we were talking about. It can be the product-hopping stuff conduct that Fiona was talking about. Right now, the antitrust laws have been so weakened that we can't stop this conduct.

The good news is if we strengthen those laws or pass things like the CREATES Act it will make it harder to prevent competition, but it really shouldn't have any impact on innovation because these are all types of strategies that are just about obtaining anti-competitive rents. It is not about innovation.

So, this is a really—injecting competition into the marketplace gets you the benefit of lower cost without undermining incentives to innovate.

Mrs. MCBATH. Thank you so much.

I yield back the balance of my time.

Mr. CICILLINE. I thank the gentlelady. I now recognize myself for five minutes. Thank you to the witnesses.

I want to begin by broadly talking about competition. I am very concerned about the rising tide of economic concentration throughout our economy and the really crippling effects on economic opportunity, innovation, and equality.

Earlier this week, Professor John Kwoka of Northeastern University testified before the Senate Antitrust Subcommittee and said concentration has been steadily rising and competition declining in a great many sectors of the economy, raising legitimate concerns about increasing market power in large swaths of the U.S. economy.

Robert Reisch, the former secretary of labor in the Clinton Administration, similarly noted, and I quote, "America has a monopoly problem. America used to have antitrust laws that stopped corporations from monopolizing markets and often broke up the biggest culprits. Antitrust has faded. The results have been hidden upward redistributions of money and power from the majority of Americans to corporate executives of and major investors in huge concentrations of economic power," end quote.

Dr. Scott Morton, I would like to start with you. In your written testimony you identified a lack of competition as a reason why U.S. healthcare costs are rising so fast and that antitrust enforcement has been weakened in the United States for a variety of reasons.

What are, in your view, the primary reasons that enforcement has so weakened?

Ms. SCOTT MORTON. The primary long-run reason is that we were all influenced by the Chicago School in the '70s that believe

things like monopolies are inherently transitory and oligopolies will price at marginal cost and courts make bad decisions.

These kinds of presumptions we now know, after 40 years of studying the economics literature, are false. They weren't true to begin with and we now are much more sure of that.

In addition, we also see the evidence in front of us, which is rising markups, lower labor share, higher profit share, all the different evidence that you pointed to.

So, it is clear that the pendulum has swung past the ideal point by quite a bit and we need to turn it around. Because courts now interpret the antitrust laws in this way, it is up to Congress to instruct the courts that actually Congress would like it done a different way.

Mr. CICILLINE. Thank you, Doctor, and that leads to my next question to Mr. Kades, who in the end of your testimony just a moment ago you talked about the weakening of the antitrust enforcement and wondering whether you have suggestions of the kind of legislation we should be contemplating that would really strengthen antitrust enforcement.

Mr. KADES. Thank you, Chair, for the question.

Yes. One of the sort of subtleties about why antitrust is weak is we have made it just hard and expensive for—to prove an antitrust case, whether it be a government or private plaintiff.

So, we know how to fix that. The way to fix that is to create presumptions where we are confident that the conduct is likely to be anticompetitive and there is lots of economic evidence about certain types of mergers that we can be comfortable are likely to be anticompetitive, certain types of conduct.

In many ways, the CREATES Act is not an antitrust law, but it takes that idea that where you have conduct that you are confident is not justified, you need to make it easy to prove.

So, that is what I would say. More presumptions to address based on the empirical evidence of where we know things are likely to be problematic.

Mr. CICILLINE. Thank you.

Dr. Gaynor, do we have or do the antitrust agencies have enough resources to do the work that we expect them to do and, if not, what would you recommend in terms of additional resources? Are there other things that you would recommend that would help improve merger and antimonopoly enforcement?

Mr. GAYNOR. Chair Cicilline, thanks for your question.

First, I just want to say I agree with my colleagues, Dr. Scott Morton and Mr. Kades, and I think those are important issues to be addressed. You turn to the other side, rightly so—suppose we do the kinds of things that my colleagues have suggested, which I agree with 100 percent, the agencies will need more resources to do more. It is that simple. Over the past seven to 10 years or so merger filings have risen by about 57 percent and appropriations in inflation-adjusted terms have fallen by 12 percent.

The number of staff is either constant or declining in the Bureau of Competition—Bureau of Economics at the Federal Trade Commission.

As a consequence, what happens is the agencies are faced with an extraordinarily difficult choice between how much to do based

on what is coming in over the transom, which is coming out of a power hose, given the rise in merger activity, and trying to stay abreast of new developments. They desperately need the resources—additional resources to do that.

Mr. CICILLINE. I am just going to squeeze in one last question.

Over the past several years, Sarah Kliff, a reporter for Vox, has documented the outrageous practice of surprise billing in hospitals and she has reported the price of ordinary drugs that could be cheaply purchased at a local pharmacy such as generic eye drops or pregnancy tests often cost hundreds of dollars and, additionally, patients often painstakingly choose to receive care in hospitals that are covered by their insurance only to find out that an emergency room doctor who treated them was not covered by their insurance. As a result, they receive surprise bills that can cost tens of thousands of dollars.

Just wondering, starting with you, Dr. Gaynor, obviously, this is further evidence that our current system is fundamentally broken. I would also like Dr. Scott Morton to reflect on that.

Mr. GAYNOR. Right. A hundred percent. I mean, this is unacceptable and can't be allowed to continue and, moreover, this sort of thing undermines markets.

People think they are making a responsible choice by going to an in-network hospital and then they get socked with this astronomical bill they had no way to prevent.

Why should they shop? Why should they buy insurance policies that ask them to do that? So, it is going to undermine the market and there are some relatively simple remedies for that.

Fiona Scott Morton and Zack Cooper have proposed one. So, I will yield to her because she is the one who can talk about it.

Mr. CICILLINE. I am thanking my Ranking Member for indulgence me one minute. I don't want to abuse my power in my first hearing.

If it is okay, Dr. Scott Morton, if you could just—

Ms. SCOTT MORTON. Yes. So, this is a really bad problem and—

Mr. CICILLINE. Thank you.

Ms. SCOTT MORTON. —it just comes from the fact that we have quite a regulated system and sometimes there is a loophole and then financial players can go in there and say, look, there is a business model. I insert these doctors into a hospital, pull them out of network, and double the charges or triple them.

So, our proposed solution is that hospitals need to sell the bundle. They need to sell all the care you get in the emergency department.

The hospital can go out and organize the doctors. They could employ them. They could contract with a group. Then at least when you arrive at the in-network hospital everything you are getting in the ED is in-network.

Mr. CICILLINE. Terrific.

Thank you again to our witnesses. This concludes today's hearing.

Without objection, all Members will have five legislative days to submit additional written questions for the witnesses or additional materials for the record.

The hearing is adjourned.

[Whereupon, at 3:38 p.m., the Subcommittee was adjourned.]

APPENDIX

American Hospital Association™
Advancing Health in America

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Statement of the
American Hospital Association
for the
Committee on the Judiciary
Subcommittee on Antitrust, Commercial and Administrative Law
of the
U.S. House of Representatives
"Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets"
March 7, 2019

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to submit for the record our comments for the hearing on the effects of consolidation and anticompetitive conduct in health care markets.

During the past decade, there have been significant changes in the health care landscape, and perhaps none has been more profound than the shift to value-based payment by the government and private payers. This shift – combined with numerous technological advances and new, highly-capitalized market entrants – already has altered the way in which every hospital and health system delivers health care to the communities they serve and promises to do so even more in the future.

Three things to appreciate about the changes occurring in the hospital and health system field are:

1. The purpose is to build sustainable, coordinated networks of care with the scale and scope to allow them to innovate while benefiting patients and communities.
2. They will enable hospitals and health systems to try to compete with highly-capitalized tech giants and other large companies often without roots in, or obligations to, the communities served.

3. They are essential to building a platform to advance efforts to improve quality and access through innovation and strategy that can reduce costs and enhance convenience for the entire community.

While some critics and academics have suggested this is about leverage, their studies typically are seriously flawed, for example, lacking data on the largest health insurance companies in virtually every market. The studies appear to be largely academic exercises with little probative value for policymakers at every level, which routinely fail to examine the impact of widespread consolidation in health insurance markets and the impact of dominant commercial health insurers on prices and innovation.

However, the real story is that hospital and health system transactions are about organizations responding to the rapidly changing health care landscape by coming together to drive high-value and high-performing health care. While various forms of affiliation are being pursued, mergers and acquisitions can be an effective means for making progress toward meeting the aims of value-based population health. This realignment is a direct response to the changing needs of communities for more convenient care, continuous financial pressures to reduce costs and the ever-present drive to improve quality for patients.

BUILDING COORDINATED NETWORKS OF CARE TO BENEFIT PATIENTS AND COMMUNITIES

Patients deserve a high-value, high-performing health care system. The key to transforming health care delivery is increased efficiency and quality. In some communities and for certain hospitals, consolidation may be necessary – not only to meet the current health needs of patients and communities – but also to provide a stable foundation upon which to build the health care system of the future.

An analysis released in 2017 by economists at Charles River Associates found that mergers can result in efficiencies that unleash savings, innovation and quality improvement essential to transforming health care delivery. Importantly, the data also showed that mergers do not lead to a spike in revenues that some claim are the motivation for mergers.

Among the study's other key findings:

- Mergers decrease costs due to economies of scale, reduced costs of capital and clinical standardization, among other efficiencies. An empirical analysis showed a 2.5 percent reduction – equating to $5.8 million – in annual operating expenses at acquired hospitals.
- Mergers have the potential to drive quality improvements through standardization of clinical protocols and investments to upgrade facilities and services at acquired hospitals.

- Mergers typically expand the scope of services available to patients, and build upon existing organizational strengths to provide more comprehensive and efficient care.

In addition, the study found that mergers were associated with a decline in revenues per patient admission, which runs counter to some research linking higher hospital concentration with higher prices.

Meanwhile, an updated analysis from Charles River Associates in 2018 found that hospital mergers result in even greater efficiencies and savings when the acquired hospitals are in close proximity. They found that mergers of hospitals within 30 miles resulted in greater cost savings, equating to more than $6.6 million (or a 2.8 percent reduction) in annual operating expenses at acquired hospitals. They also found a statistically significant decline in revenue per admissions for mergers of nearby hospitals, as well as those located further apart, and evidence of improved quality measured by reduced readmission rates.

ENABLING HOSPITALS AND HEALTH SYSTEMS TO COMPETE WITH TECH GIANTS

The realignment in the hospital field also is fueled by the need to be competitive in a rapidly changing environment. More established technology companies, including those about which this Committee has raised market power concerns, have capitalization beyond the means of any hospital system. They also have ambitions to fundamentally disrupt how and where health care is delivered. Many of these outside companies lack roots in or any obligations to the communities they seek to serve, including those who are most vulnerable.

During the last few years, some of the nation's largest companies have entered the health care arena or expanded their footprint into new areas formerly the province of hospitals or health systems. CVS, Walmart, Walgreens, Amazon and others clearly are positioning themselves to be viewed as patients' front door to health care. Huge corporations like Berkshire Hathaway, Apple and Google, among other tech companies, have made health care a focus area for their businesses.

Hospitals and health systems' missions are to provide the highest quality of care in a coordinated manner, and also keep people well. They are leading efforts to transform care to make it more accessible, affordable and convenient … all focused on improving the patient care experience. Mergers and acquisitions are one way hospitals and health systems can create coordinated networks of care with the level of scope necessary to provide high-quality care to all patients in their communities.

For example, access to capital and other resources are essential to ensure hospitals and health systems can provide access to affordable, high-quality care. Without the injection of financial resources that only a full-fledged merger makes possible, some organizations would not be able to underwrite the transformative, value-driven and

patient-centric initiatives that patients deserve, or even maintain a meaningful presence in the community.

A study by the Deloitte Center for Health Solutions and the Healthcare Financial Management Association of hospital acquisitions between 2008 and 2014 found that nearly 80 percent of the acquiring organizations made significant capital investments in the acquired facilities soon after the transaction, and nearly 40 percent used the capital to upgrade or implement clinical information systems, the top-reported use of capital. The study also found that care quality improved after an acquisition.

Hospitals and health systems are leading their own efforts to transform the way in which health care is delivered. For example, more than 40 hospital systems around the nation have established their own centers for innovation focusing both on tools and technology as well as new ideas, workflows and training techniques.

All of these developments suggest that hospitals operate in a competitive landscape that will continue to transform as more innovations hit the market. This changing landscape makes achieving scale increasingly important in order to remain competitive and deliver value to patients efficiently and effectively.

HIGHLY CONCENTRATED HEALTH INSURANCE MARKETS HAVE SPAWNED GROWTH IN HEALTH INSURANCE PREMIUMS THAT IS MORE THAN DOUBLE THE GROWTH IN HOSPITAL PRICES

Currently, the growth in health insurance premium prices is more than double that of the price growth for hospital care services – 4.5 percent compared to 1.8 percent from 2017 to 2018. Prescription drug prices grew 4.1 percent during the same period.

The fact is, hospitals' share of total health expenditures has decreased gradually over time as a percentage of total national health expenditures – declining from 42.7 percent in 1980 to 34 percent in 2016.

The numbers are inconsistent with suggestions that hospital and health system mergers and acquisitions are about increased leverage with dominant health insurers. But they are consistent with recent findings from a Health Affairs study that said "insurer monopoly is the most important predictor of premium levels and growth rates."

The numbers should not come as a surprise as 73 percent of U.S. health insurance markets are highly concentrated, based on guidelines used by the Department of Justice (DOJ) and Federal Trade Commission (FTC) to assess market competition, according to a study released in December by the American Medical Association. In 91 percent of the 380 metropolitan statistical areas (MSA) studied, at least one insurer had a commercial market share of 30 percent or more, and in 46 percent of MSAs a single insurer's share was at least 50 percent.

Recent studies have found that health insurer concentration is responsible for premium increases. For example, a recent study found that marketplace premiums were 50 percent higher, on average, in ratings areas with monopolist insurers.

These findings suggest that federal oversight of commercial health insurance companies is very sporadic, particularly in comparison to oversight of hospital merger and acquisition activity. Since 2012, the FTC has filed complaints against eight proposed hospital mergers, and investigated numerous others. At the same time, despite blocking two high-profile proposed mergers in 2017, the DOJ's Antitrust Division has not moved to alter the trend toward consolidated insurance markets.

ACADEMIC STUDIES ON HOSPITAL TRANSACTIONS ARE UNRELIABLE

A number of academic studies examining hospital transactions draw incorrect conclusions for a variety of reasons. For example, the first "The Price Ain't Right" report on the relationship between hospital prices and market structure in 2015, raised a number of questions and concerns about how the study's authors reached their conclusions. The authors released a revised version of that study last year, and it was greeted with similar concerns – and new ones – from economists who have worked on dozens of hospital transactions.

Findings from the most recent report are based on old and limited data, none of which include the payer with the biggest share in most markets, and with highly uneven geographic representation. Among the most obvious flaws is that its conclusions rely on a database that lacks Blue Cross Blue Shield information on contracts and prices. Recognizing that, the authors attempt to compensate without any success. In fact, their data show that "in markets with high Blue Cross Blue Shield share, hospital mergers are not associated with any significant change in hospital prices for Aetna, Humana, and UnitedHealth post-merger."

Other flaws include findings inconsistent with the way in which hospitals' contracts with insurers are actually negotiated. Moreover, by focusing on a single service – MRIs – instead of an entire bundle of services to evaluate prices, the authors once again fail to appreciate the dynamics involved in real-world negotiations and so their conclusions come up short once again.

CONCLUSION

Health care is changing, and hospitals and health systems are transforming to meet the evolving needs of their patients and communities. They are working to build coordinated and convenient care beyond their four walls – care that is more responsive to patient preferences and community needs than ever before, all with a focus on keeping people well so that they reach their highest potential for health. For health care to flourish in today's environment and in the future, the type of efficiencies that hospital and health system mergers and acquisitions provide are necessary to obtain meaningful cost and quality benefits and ensure that there will be community organizations able to serve

patients with a full range of services, regardless of the composition of that community or its needs.

Responses to Questions for the Record submitted by Representative Ken Buck, U.S. House Committee on the Judiciary, March 7, 2019

Hearing - Antitrust, Commercial, and Administrative Law Subcommittee Hearing
"The Effects of Consolidation and Anticompetitive Conduct in Health Care Markets"

Martin Gaynor
E.J. Barone University Professor of Economics and Public Policy
Heinz College
Carnegie Mellon University

1. Background: When Congress passed the Biologics Price Competition and Innovation Act (BPCIA), it was intended to increase competition in the biologic market by creating a pathway for approval for interchangeable biologics and biosimilars. Unfortunately, while FDA has now approved 17 biosimilars, only 7 of them are on the market. The others remain tied up in patent disputes between the brand and biosimilar manufacturers. These patent disputes occur even when the brand's exclusivity period has long since expired.
   Question: FDA has now approved 17 biosimilars, but most of them aren't on the market due to patent disputes. Why is this happening, even when the branded drug's market exclusivity has expired?

   I am not well informed enough on this issue to express an opinion.

2. Hospitals have been eagerly using their purchasing power to acquire community cancer clinics, dramatically shifting cancer care into more expensive hospital settings over the past decade. A 2016 report indicated a 172% increase in the consolidation of community oncology practices into hospitals since 2008, and 2018 numbers show an 11.3% increase in the number of community cancer clinic closings and an 8% increase in the number of consolidations into the hospital setting. In January 2018, a New England Journal of Medicine study concluded that the 340B program is associated with hospital-physician consolidation in hematology-oncology. It is important to identify and study drivers like 340B to ensure that other Part B infusion drugs do not follow the same trend, thereby increasing patient costs and limiting access to community care even further. This is particularly a problem in rural areas that already face barriers to access. What impact does this consolidation of the cancer care system from community settings into hospitals have on costs to the health care system? On cancer patients and their individual cost burden? On taxpayers?

   This is an inportant issue. It seems likely that this shift in the site of care is leading to higher costs. A study assessing the phenomenon, the overall impacts, and impacts on patients and on taxpayers is important to provide relevant information to policy makers.

3. A 2015 study by Berkeley Research Group found that (disproportionate share hospitals - DSH) hospitals have been driving consolidation of oncology practices and on average more than doubled their oncology services. The result of this consolidation has led Part B reimbursement on oncology products to increase by 123% for 340B hospitals while non-340B hospitals had a 31% increase and physician groups suffered a 5% decrease. With no signs of a slowdown in program growth, will this site of care shift from lower-cost providers like community practices to higher-cost providers like 340B hospitals be sustainable in the long run? Do we know how much this consolidation is costing the system?

   I do not know how much this is costing the health care system. Consolidation like this is a concern both because it represents a shift from lower cost to higher cost providers, but also because it may lead to a reduction in competition, thereby compounding problems with cost and also possibly leading to problems with quality and accessibility.

4. We have seen data documenting the consolidation of community outpatient settings into hospitals and how that is driving up healthcare costs generally, but this also impacts prescription drugs. In 2015, the GAO reported that per beneficiary Medicare Part B drug spending was substantially higher at 340B (DSH) hospitals ($144) than at non-340B hospitals ($60).

   (a) As companies' exposure under the program continues to rise, in some cases into the $3-4 billion, is it reasonable to expect that costs are shifting to other non-340B sites of care?

   I do not know.

   (b) The New England Journal of Medicine stated in 2018 that while, the program is intended to expand resources for underserved populations but provides no incentives for hospitals to use financial gains to enhance care of low-income patients. In Part B, beneficiaries must pay 20 percent of the cost of the benefit provided, but there is no requirement to pass along direct savings from the 340B discount. With reimbursement rates higher in the hospital, doesn't that increase patients out-of-pocket? Shouldnt we ensure patient co-pays are based on the prices hospitals pay to acquire drugs or at the very least not subject patients to increased out-of-pockets through this shift in site of care?

   There is need for reform of this program. In my opinion, the discount should be with the patient, not the site of care. I think this would help address the issue you're raising.

   (c) Would it make sense to look at reforms to the 340B program in the context of drug pricing to address market distortions that may be shifting costs and increasing the financial burdens onto patients?

   Yes, I think this is important. I suggested one reform above – having the discount be with the patient, not the provider, and not specific to the site of care.

5. Questions to the Panel on PBMs: Three Performance Benefit Managers (PBMs) control 80% of the PBM market. In theory, this should give them leverage to negotiate lower drug prices. But my understanding is that PBMs profits are at least partially tied to the manufacturer's list price. Doesn't that actually create an incentive for PBMs to see prices increase? One of the three PBMs, OptumRx, recently told drug companies they couldnt lower prices unless they gave almost two years notice and paid the PBM the same amount of money, despite the lower price. (https://www.beckershospitalreview.com/pharmacy/optumrx-sets-demands-for-drugmaker-price-reductions.html) Why would a drug manufacturer ever lower its price if a PBM is just going to take more of its profit?

   This is a problem. One of the key functions of PBMs is negotiating discounts ("rebates") from pharmaceutical manufacturers. PBMs obtaining discounts from manufacturers is a good thing. However, there are concerns that too little of the discount ends up in the hands of PBM customers, or that because the focus is on the discount, there are incentives for both manufacturers and PBMs to have a higher list price.

   Competition is the key to concerns about buyers getting a proper share of discounts and about perverse incentives for higher list prices. If there is sufficient competition in the PBM market, then PBMs will have to provide attractive terms to their customers - thus competition will address these problems. There has been substantial consolidation among PBMs. At present three firms have 80 percent market share. While this is certainly a highly concentrated market, high concentration doesn't necessarily preclude tough competition. A question that needs to be addressed is if there is sufficient competition in the PBM market. Evidence on this issue is needed.

   Craig Garthwaite and Fiona Scott Morton have proposed a policy that will likely help the PBM market to function better, independent of market structure.[1] *Their proposal is that all payments between the manufacturer and the PBM go to the PBM's customer first, and are then subsequently split as agreed upon between the PBM and its customer. In this way, the PBM's customers will know exactly the amounts of rebates or others payments betweent the manufacturer and the PBM (as opposed to the PBM being able to hide them if it receives them directly from the manufacturer) and will thus be able to negotiate efficiently with the PBM.*

[1] Garthwaite, Craig and Fiona Scott Morton. 2017. "Perverse Market Incentives Encourage High Prescription Drug Price,." ProMarket Blog. November 1. https://promarket.org/perverse-market-incentives-encourage-high-prescription-drug-prices/.

Responses to Questions for the Record from Ranking Member Doug Collins, U.S. House Committee on the Judiciary, March 7, 2019

Hearing - Antitrust, Commercial, and Administrative Law Subcommittee Hearing
"The Effects of Consolidation and Anticompetitive Conduct in Health Care Markets"

Martin Gaynor
E.J. Barone University Professor of Economics and Public Policy
Heinz College
Carnegie Mellon University

1. Your written testimony suggests that what we see in more concentrated hospital and physician markets is exactly what antitrust theory predicts higher prices and worse patient outcomes in the absence of competition. What tools of antitrust law and competition policy would be best to try to reverse that trend?

   There are multiple tools to address these issues. I have addressed this in detail with a set of practical, implementable policy proposals with Farzad Mostashari and Paul Ginsburg[1] *and in my testimony before this committee.*[2]

   These proposals fall in three categories:

   - *Change policies that unintentionally incentivize consolidation.*
   - *Change policies that prevent or deter entry or expansion of competitors.*
   - *Strengthen antitrust enforcement.*

   Some examples of these recommendations are as follows.

   - *Change policies that unintentionally incentivize consolidation.*
     - *CMS and other payers should stop paying more for the same service when it is performed in a hospital outpatient department as opposed to an independent physician's office.*
     - *CMS should tie 340B drug discounts to eligible patients rather than the site of service.*
   - *Change policies that prevent or deter entry or expansion of competitors.*

[1] Gaynor, Martin, Mostashari, Farzad and Paul B. Ginsburg. 2017. "Making Health Care Markets Work: Competition Policy for Health Care". https://www.brookings.edu/research/making-health-care-markets-work-competition-policy-for-health-care/.

[2] Testimony of Martin Gaynor, Ph.D. Before the House Judiciary Committee Subcommittee on Regulatory Reform, Commercial, and Antitrust Law On "Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets." March 7, 2019. pp. 17-20.

- *States should repeal Certificate of Need (CON) laws because they restrict provider entry.*
- *States should repeal Any Willing Provider (AWP) laws because they prevent payers from promoting competition via selective contracting.*
- *States should stop using Certificates of Public Advantage (COPAs) that shield entities from antitrust.*
- *States should update scope of practice laws to reflect current knowledge about non-physician practitioners ability to safely provide services traditionally provided by physicians.*
- *State licensing boards should encourage provider competition through facilitating practices such as telehealth, and more generally state licensing boards should narrowly focus on licensing that protects the public and does not restrict competition.*

• *Strengthen antitrust enforcement.*

- *Federal and state enforcement agencies should maintain their scrutiny and enforcement of horizontal mergers between hospitals, physician practices, health insurers, etc.*
- *Many mergers of physician practices escape antitrust scrutiny because they are too small to fall under the Hart Scott Rodino (HSR) merger reporting requirements. This can be addressed by requiring that mergers that fall below the HSR reporting criteria be reported, but with a simple, short form.*[3]
- *Federal and state agencies should pursue and prevent practices that are intended to limit competition. For example, anti-tiering, anti-steering, and gag clauses prevent insurers from providing information to enrollees about more or less expensive (or better or worse) providers, or from providing incentives to enrollees to go to less expensive or better providers. The federal antitrust enforcement agencies and state attorneys general can pursue these and other anticompetitive practices. In addition, state insurance commissioners can review contracts between insurers and providers and scrutinize them for clauses that harm competition and consumers. Legislative bodies can consider enacting legislation that bans or limits the use of such clauses in provider-insurer contracts. While there is anecdotal evidence about such practices, systematic knowledge is lacking. This is an area that needs further study and development of antitrust theories and evidence.*

[3]Testimony of Fiona M. Scott Morton, Ph.D. Before the House Judiciary Committee Subcommittee on Regulatory Reform, Commercial, and Antitrust Law On "Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets." March 7, 2019. pp. 10, 11; Testimony of Martin Gaynor, Ph.D. Before the House Judiciary Committee Subcommittee on Regulatory Reform, Commercial, and Antitrust Law On "Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets." March 7, 2019. p. 20.

- *There is a great deal of "vertical" consolidation in health care in the form of hospitals acquiring physician practices. To date these acquisitions have been pursued by enforcement agencies as horizontal mergers.*[4] *Vertical cases are more difficult, however, the enforcement agencies should to consider vertical approaches to such acquisitions, and the necessary antitrust theory and evidence.*
- *The antitrust enforcement agencies need more resources in order to increase their efforts. The demands on the agencies have risen, while their inflation adjusted appropriations have declined. The decline in resources relative to demands not only makes it hard for the agencies to address antitrust issues as they arise, it makes it extremely difficult for them to allocate the necessary resources to proactively invest in important new and developing areas.*
- *At present the FTC is prohibited from enforcing against anticompetitive conduct by not-for-profit firms (FTC Act, Section 45(a)(2), Section 44) and is not permitted to study the insurance industry under its Section 6b authority without an explicit request from Congress (Section 5(a) of the Federal Trade Commission Improvements Act of 1980). Removing these restrictions on the FTC will enable it to function to the full extent of its capabilities to protect competition and consumers in health care markets.*
- *Legislation to strengthen antitrust should be considered, specifically altering the standard for competitive harm and changing the criteria under which mergers or conduct would be presumptively illegal (thereby shifting the burden to defendants to establish that they are not). If this comes to pass it would strengthen the antitrust enforcment agencies' positions in dealing with health care mergers they judge to be harmful, as well as mergers in general.*

2. You list in your written testimony urban areas where increasing hospital consolidation has been most problematic. Can you tell us in which states or regions rural hospital consolidation has been the most problematic?

   I do not have the information to tell you in which states or regions rural hospital consolidation has been the most problematic. I agree this is an important problem affecting our country. I think a study should be done which is focused on the issue of rural hospital consolidation and its impacts on these communities in order to provide the information we need on this issue. Such a study could be done by a federal government agency, or commissioned to be undertaken externally.

3. You cite extensive reports of health systems blocking the flow of patient information to these systems direct competitors, even after patients request to change providers.

[4] When a health system acquistion of a physician practice involves combining competing practices (Federal Trade Commission and State of Idaho v. St. Luke's Health System, Ltd, and Saltzer Medical Group, P.A., https://www.ftc.gov/enforcement/cases-proceedings/121-0069/st-lukes-health-system-ltd-saltzer-medical-group-pa).

What are the best ways to address this issue and promote competition?

Much more needs to be known about these practices, the form they take, how extensive they are, and harms to competition versus efficiencies flowing from these practices. A careful study focused on these issues should be done to obtain the information necessary to understand these practices, assess their impacts, and consider appropriate policies.

Nonetheless, reforming data rights so patients are in control of their own data, as opposed to health care providers, seems appropriate and sensible. When patients control their data they will be able to specify who has access to all of their data, regardless of where they are receiving service, eliminating (or greatly reducing) the possibility of data blocking. However, the costs of recording, storing, and processing data have to be adequately covered.

Responses to Questions for the Record from U.S. Congressman Mike Johnson, U.S. House Committee on the Judiciary, March 13, 2019

Hearing - Antitrust, Commercial, and Administrative Law Subcommittee Hearing
"The Effects of Consolidation and Anticompetitive Conduct in Health Care Markets"

Martin Gaynor
E.J. Barone University Professor of Economics and Public Policy
Heinz College
Carnegie Mellon University

1. Drawing upon your considerable experience in the health care field, what specific policy solutions do you believe to be essential in any proposed legislation aimed at increasing accountability for PBMs and lowering costs at the counter?

   One of the key functions of PBMs is negotiating discounts ("rebates") from pharmaceutical manufacturers. PBMs obtaining discounts from manufacturers is a good thing. However, there are concerns that too little of the discount ends up in the hands of PBM customers, or that because the focus is on the discount, there are incentives for both manufacturers and PBMs to have a higher list price. There are also concerns about consumer cost sharing based on the list price, as opposed to the final negotiated price (i.e., list price net of the rebate).

   Competition is the key to concerns about buyers getting a proper share of discounts and about perverse incentives for higher list prices. If there is sufficient competition in the PBM market, then PBMs will have to provide attractive terms to their customers - thus competition will address these problems. There has been substantial consolidation among PBMs. At present three firms have 80 percent market share. While this is certainly a highly concentrated market, high concentration doesn't necessarily preclude tough competition. A question that needs to be addressed is if there is sufficient competition in the PBM market. Evidence on this issue is needed.

   Craig Garthwaite and Fiona Scott Morton have proposed a policy that will likely help the PBM market to function better, independent of market structure.[1] *Their proposal is that all payments between the manufacturer and the PBM go to the PBM's customer first, and are then subsequently split as agreed upon between the PBM and its customer. In this way, the PBM's customers will know exactly the amounts of rebates or others payments betweent the manufacturer and the PBM (as opposed to the PBM being able to hide them if it receives them directly from the manufacturer) and will thus be able to negotiate efficiently with the PBM.*

[1] Garthwaite, Craig and Fiona Scott Morton. 2017. "Perverse Market Incentives Encourage High Prescription Drug Price,." ProMarket Blog. November 1. https://promarket.org/perverse-market-incentives-encourage-high-prescription-drug-prices/.

It's also important to point out the beneficial role played by keeping the amounts of rebates private between manufacturers and PBMs. Having these terms private permits PBMs to negotiate greater discounts than they could if the rebates were made public. The privacy of rebate agreements isn't the problem - it's how much gets passed on to buyers and what the terms are for consumer cost sharing.

Regarding consumer cost sharing, it is a problem that consumers' cost sharing is based on drugs' list prices, not the list price net of the rebate. This needs to be addressed. One way to do this is to base consumer cost sharing on a drug's list price net of the average discount across PBMs, or the average net price for drugs in that therapeutic class, or the lowest price paid in the market.[2]

2. Do you believe that the clawing back, or retroactive assessment of DIR fees, have or could have a negative impact on our pharmacies who serve Medicare Part D beneficiaries?

   I am not well informed enough on this phenomenon to have an opinion. However, in general (not specific to pharmaceutical markets or this practice), for markets to work well, all participants have to know the terms of exchange and understand them in advance. If that is not the case with this practice then it is likely to cause a problem with the functioning of the market.

   (a) If so, what would be your recommendation for resolving this?
   I am not well informed enough about this phenomenon to have a recommendation.

3. In your view, how do you accurately verify pricing to the federal government, beginning with the beneficiary through the rest of the claim accountability process?

   I am not well informed enough about the phenomenon to have an opinion.

   (a) Do you believe increased transparency for clawbacks could more accurately track value and ensure the best financial result for beneficiaries and taxpayers?
   I am not well informed enough about this phenomenon to have a recommendation.

[2]Testimony of Craig L. Garthwaite, Ph.D. Before the House Judiciary Committee Subcommittee of Regulatory Reform, Commercial, and Antitrust Law on "Diagnosing the Problem: Exploring the Effectrs of Consolidation and Anticompetitive Conduct in Health Care Markets." p. 13.

Michael Kades
Response to Questions for the Record
Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Health Markets

Question from Ranking Member Collins

Question: Post Actavis there has been a precipitous decline in the number of settlements that the Federal Trade Commission has raised anti-competitive concerns with. Based on this, what would be the comparative advantages of letting the judicial system continue to deal with the residual element of the problem, as opposed to legislating restrictions on freedom of contract and the ability of litigants to manage litigation between them?

This is an important question. In thinking about the trade-off between passing legislation or relying on the status quo, two key principles stand out. First, pay-for-delay deals are very profitable, so there is a natural and strong incentive for the settling parties to find loopholes or exploit complications to reach such deals. Second, there is little evidence that bright-line rules would limit the litigants' flexibility to settle.

Although the Supreme Court's decision in *FTC v. Actavis* has had an impact in deterring anticompetitive pay-for-delay patent settlements, failing to legislate raises significant risks of consumer harm and unnecessarily requires the FTC to expend resources. In contrast, passing narrowly tailored legislation, such as the Preserve Access to Affordable Generic and Biosimilars Act eliminates this risk without imposing more than a negligible burden on the litigating parties.

Congress previously faced this choice in 2004. Congress considered addressing the issue of reverse-payment patent settlements through legislation in the Medicare Modernization Act, or MMA. At the time, industry argued that the practice had stopped, which it had, and that the antitrust laws were sufficient, so all Congress needed to do was require parties to file the agreements with the Federal Trade Commission. Congress followed this approach.

That approach failed. A few weeks after the MMA was enacted, the 11th Circuit issued its decision in *Valley Drug Company v. Geneva Pharmaceutical, Inc.* beginning the trend toward the scope of the patent test (adopted and expanded by *FTC v. Schering, In re Tamoxifen*, and *In re Ciprofloxacin*, and the Eleventh Circuit's decision in *FTC v. Actavis)*, which made pay-for-delay agreements per se legal as long as generic entry occurred by the expiration of the patent, the patent litigation was a sham, or the patent was obtained by fraud. The lenient legal rule altered industry behavior dramatically as the number of potential pay-for-delay deals increased from zero in 2004 to 40 in 2012 (see Figure 1 below).

Although the Supreme Court's decision in *FTC v. Actavis* has dramatically reduced the number of agreements so far, there are three risks in not legislating. First, it is unclear how the case law would apply to biologics. Because, as of yet, no follow-on biologics are interchangeable with their branded counterparts, proof of market power may be more difficult to discern even though pay-for-delay agreements in the biologic sphere, because of the cost of the drugs, could dramatically increase prescription drug costs.

Second, at least one court has already significantly undermined the *Actavis* decision. The Third Circuit in *In re Wellbutrin XI Antitrust Litig. Indirect Purchaser Class* suggests that if the patent holder is risk averse or thinks the generic has overestimated its chances, then there is no inference to be drawn from the payment. 863 F.3d 132, 168 (3rd Cir. 2017).

Third, companies have shown creativity in hiding payments through the use of a side deal. For example, a generic company agrees to delay its entry. Instead of simply paying the generic company, the branded company licenses the rights to a product in development. Because the value of such assets is difficult to determine, it is easy for the branded company to over pay and hard for a court or the Federal Trade Commission to determine the value of the overpayment. *See* C. Scott Hemphill, "An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Competition," 109 Colum. L. Rev. 629, 663-670 (2009).

At the same time, limiting the use of payments in pharmaceutical patent settlements will not limit the parties' flexibility to settle litigation. The number of patent settlements without payments reached record highs in each of the first two fiscal years after the *Actavis* decision. See Federal Trade Commission Staff, "Overview of Agreements Filed in Fiscal Year 2015: A Report By the Bureau of Competition," at 4 ("FTC 2015 Report) https://www.ftc.gov/news-events/press-releases/2017/11/ftc-staff-issues-fy-2015-report-branded-drug-firms-patent

The Preserve Access to Affordable Generics and Biosimilars Act addresses all three risks. It explicitly applies to settlements involving biological products. It eliminates the danger of courts intentionally or unintentionally adopting interpretations that weaken the law. Finally, by requiring defendants to establish their justification by clear and convincing evidence, the bill strongly discourages attempts to find a loophole or hide a payment.

At the same time, the bill provides significant flexibility to parties settling litigation. It clearly identifies the types of competition, including a de minimis payment for saved litigation expenses, that do not trigger the bill's presumption. The bill also allows companies to rebut the presumption if they have a clear justification. Past history underscores the flexibility the bill would provide. In fiscal years 2014 and 2015, only 19 of the 330 pharmaceutical patent settlements could have triggered the presumption. FTC 2015 Report at 4.[1]

[1] This reflects the total of potential pay for delay settlements that exceeded attorneys' fees, which would be exempted under the proposed legislation.

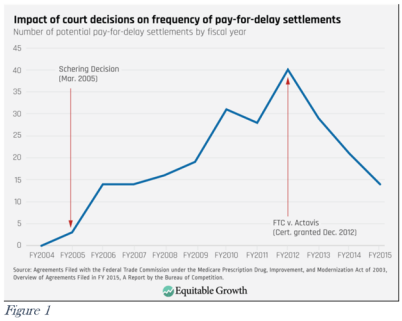

Figure 1

Question from Chairman Cicilline

Christine Varney, the former Assistant Attorney General of the Antitrust Division, previously testified in 2009 that "the McCarran-Ferguson Act antitrust exemption is very expansive with regard to anything that can be said to fall within the business of insurance, including premium pricing and market allocations. As a result, the most egregiously anticompetitive claims, such as naked agreements fixing price or reducing coverage, are virtually always found immune."

Do you agree that when health insurance companies engage in bid rigging, price fixing, or market allocation their conduct should not be exempt from the antitrust statutes?

Yes. There is no reason to immunize insurers from nakedly anticompetitive activity such as bid-rigging price fixing, or market allocation. Such conduct will increase prices and reduce quality. Whatever justification may have existed for the McCarran-Ferguson Act, the act is an artifact and no longer necessary. As then Assistant Attorney for Antitrust Varney explained, antitrust law is sufficiently flexible to allow procompetitive conduct. See Statement of Christine Varney, Assistant Attorney General Antitrust Division, U.S. Department of Justice Before the Committee on the Judiciary, United States Senate, "Prohibiting Price Fixing and Other Anticompetitive Conduct in the Health Insurance Industry (October 14 2009) at 4 https://www.justice.gov/archive/atr/public/testimony/250917.pdf.

Further, the McCarran-Ferguson Act may unintentionally protect anticompetitive conduct that increases the cost of insurance. Multiple studies support limiting or eliminating this exemption, including a 1977 Justice Department study, a 1979 National Commission for the Review of Antitrust and Procedures, a 1989 American Bar Association Commission to Improve Liability Insurance System report, and the 2007 Antitrust Modernization Commission report.[2]

[2] *Id.* At 2.

Questions from Representative Buck

Background: When Congress passed the Biologics Price Competition and Innovation Act (BPCIA), it was intended to increase competition in the biologic market by creating a pathway for approval for interchangeable biologics and biosimilars. Unfortunately, while FDA has now approved 17 biosimilars, only 7 of them are on the market. The others remain tied up in patent disputes between the brand and biosimilar manufacturers. These patent disputes occur even when the brand's exclusivity period has long since expired.

Question: FDA has now approved 17 biosimilars, but most of them aren't on the market due to patent disputes. Why?

This is an important question as there are concerns that some companies may be abusing the patent system by creating patent thickets. To be clear, patents and intellectual property rights play an important role in drug development. When products infringe patents, then patent holders have every right to assert their patents and protect their inventions.

But patent thickets are an abuse of the system that inappropriately delays biosimilar competition. Professor Carl Shapiro defines patent thickets as "a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology." The shear number of patents, regardless of each patent's strength, can deter competition, or the time of litigating on all of the patents in the thicket can delay competition. Former Food and Drug Commissioner Scott Gottlieb pointed to thickets and the litigation they spawn as the cause of "anemic" biosimilar competition: "It's anemic because litigation has delayed market access for biosimilar products that are, or shortly will be, available in markets outside the U.S. several years before they'll be available to patients here."[3] Congress should examine whether abuse of the patent system by some companies is stifling biosimilar competition.

[3] Scott Gottlieb, Remarks as prepared for delivery at the Brookings Institution on the release of the FDA's Biosimilar Action Plan," (July 18, 2018, available at, https://www.fda.gov/news-events/press-announcements/remarks-fda-commissioner-scott-gottlieb-md-prepared-delivery-brookings-institution-release-fdas

Questions to the Panel on PBMs

Three Performance Benefit Mangers (PBMs) control 80% of the PBM market. In theory, this should give them leverage to negotiate lower drug prices. But my understanding is that PBM's profits are at least partially tied to the manufacturer's list price.

- *Doesn't that actually create an incentive for PBMs to see prices increase?*

One of the three PBMs, OptumRx, recently told drug companies they couldn't lower prices unless they gave almost two years notice and paid the PBM the same amount of money, despite the lower price. (https://www.beckershospitalreview.com/pharmacy/optumrx-sets-demands-for-drugmaker-price-reductions.html)

- *Why would a drug manufacturer ever lower its price if a PBM is just going to take more of its profit?*

Both of these questions emphasize the importance of the Prescription Pricing for the People Act of 2019. The answer to both questions depends on whether PBMs have market power. If a PBM has market power, then it could exploit that power by negotiation higher list prices to increase its commission. And there would be little reason for a branded drug manufacturer to lower its list price and pay the PBM the same amount.

In contrast, if the PBM faces competition, then if it seeks higher prices to increase its revenue it will lose business to other PBMs that provide a better value to insurers. And in a competitive market, a drug manufacturer could lower its list price and still pay the PBM the same amount if the PBM is able to increase the volume of sales on the drug.

The Prescription Pricing for the People Act of 2019 requires the Federal Trade Commission to study the PBM market and assess how competitive it is. Its report should help understand whether there is a competition problem in the PBM industry and, if so, how significant that problem is.

20 May 2019

Dear Members of the House Judiciary Antitrust Subcommittee:

I apologize for the tardiness of these answers. Exam grading and other tasks at the end of the semester and another antitrust policy commitment took up my time. I have answers for you below.

Sincerely yours,

Fiona Scott Morton

Questions from Representative Buck

Your first question to me concerns biologic drugs and lack of competition from biosimilars. I agree entirely with the sentiment that purchases ultimately paid for by HHS (the taxpayer) should benefit from competition in the market, which they currently do not do. It is imperative that HHS find a way to choose a price for biologics that generates price competition between branded biologics and biosimilars. One j-code for all biosimilars and their reference innovator would likely lower prices considerably.

Requiring that commercial insurers include the biosimilar on the formulary might prevent innovator biologics from requiring exclusive contracts to keep biosimilars off the formulary. However, the ability of pharmaceutical manufacturers to design sophisticated contracts makes this approach uncertain. As I mentioned in my testimony, I think a more productive direction would be to empower the FTC to pursue any exclusionary conduct by brands against biosimilars as antitrust violations.

Your second question asks about cost sharing for seniors. I believe that if a product is sold as insurance, it needs to protect the enrollee from large financial shocks; that is what insurance does. A specialty tier for a drug that could cost $100,000 with some percent cost-sharing, such as 30% or 20% really does not constitute meaningful "insurance" as people understand the term. Thus I generally agree with policies that require insurers to limit out of pocket payments by enrollees. I further agree with you that Part D should incentivize the use of biosimilar products as they can be much cheaper. But importantly, if there is one biosimilar on the market, and one brand, and the law requires the plan to buy the biosimilar, the law would be endowing the biosimilar with market power -- and that may be no better in terms of the final price. Rather, the law must create price competition between the all biosimilars and the reference product. This can be done by making it clear that any biosimilar or innovator may be placed on the formulary and the others excluded, and by making sure plans bear the cost of biologics (perhaps by increasing the plan share in the catastrophic region) so that they have an incentive to search for, and buy, a low cost biologic.

The short answer to the question for the panel on the lack of biosimilar entry is patent exploitation. The innovator can continue filing patents long after the drug is launched, thereby creating a window of patent protection that is many decades long. Professor Robin Feldman has proposed policy solutions for this problem. One simple solution described in my original statement is to freeze the intellectual

property of the innovator at launch. All hurdles for biosimilar entry are with respect to this portfolio and not any patent filed later.

The question for the panel on PBMs: The PBM's incentive is not necessarily tied to list price. If a higher list price allows a higher rebate and PBMs can capture that rebate because employers are not paying attention, then yes, the PBM benefits from higher list. But if 100% of the higher rebate went directly to the end client, there would be no profit gain to the PBM from a higher list price. So the extent to which this strategy works depends on whether clients are informed, have audit rights, and can take their business to a competitor in the event that the PBM captures more profit. To the extent a PBM runs a Part D plan and gains from high list prices that push enrollees into the catastrophic region, that can be another mechanism for it to gain. The Optum statement is a puzzle and I have no answer for you on that; perhaps they can explain it directly.

Questions from Ranking Member Doug Collins

Your second question asks about how to preserve a generic firm's incentive to file an ANDA. If pay for delay is prohibited, then generic entrants will hope to be approved, to overcome any remaining branded IP, and to sell to the whole market. Should the brand and generic have a dispute over patent infringement, they may settle based on an entry date rather than money and be safe from liability. Such a settlement delivers competition quicker when IP is weaker, which is efficient. The incentive to enter under these rules is strong because generic markets are large and buyers typically switch immediately to the first entrant. Whereas when the brand can pay the generic to stay out of the market beyond the time justified by the patent strength, consumers are harmed. If you are asking whether the generic is made worse off financially because it is no longer allowed to extend the brand's monopoly and therefore cannot share financially in monopoly profit, the answer is yes. But the antitrust laws are designed to protect consumers and make corporations earn their revenue by offering quality and low prices, not by prolonging monopolies.

Your first question asks for more detail as to how PBM consolidation could encourage manufacturers to raise list prices. The main insight is that consolidation creates market power and reduces the choices available to clients. Therefore, when a PBM's product gets more expensive, the client is not always able to leave and this means the client is exposed to higher prices. The details of how this leads to an effect on list prices is contained in piece Craig Garthwaite and I wrote about 2 years ago, and reproduced here:

Economists often describe the adverse consequences that result from consolidation of market power in the hands of either sellers or buyers. In the case of the pharmaceutical market, we argue that the recent consolidation of the middlemen market, i.e., the PBMs, combined with opaque pricing is one cause of higher prices. When only a few PBMs exist, it is all too easy for them to stop functioning as brokers that increase market efficiency, and start looking for win-win arrangements in which consumers are the ultimate losers. The first step in disrupting this dynamic is understanding it.

Net prices for on-patent drugs are determined as follows. A final payer (e.g., an employer or insurer) contracts with a PBM to manage its pharmacy claims, design formularies, and negotiate the prices paid to pharmaceutical manufacturers.

Manufacturers set an initial list price for their products. PBMs then negotiate with manufacturers over a rebate (i.e., discount) from the publicly known list price. A PBM can stimulate price competition where an individual consumer cannot because the PBM acts on behalf of a group of consumers and can shift those consumers between competing, substitute drugs. If there are two good blood pressure medications, the PBM can place the one that offers more favorable terms on the lower cost tier and encourage consumption by its enrollees. The higher-cost competitor then loses market share, which induces both drug manufacturers to offer discounts. If PBMs can credibly shift many consumers across rival products, they have more bargaining power and can earn larger rebates. To "move share," PBMs invest in tools like differential out-of-pocket payments, prior authorization, and step therapy.

For many good reasons, the magnitude of the rebates made by manufacturers to PBMs is kept confidential. This lack of transparency is not inherently problematic and in fact has many benefits. However, the tradeoff for these benefits is that payers cannot fully observe what is at stake in their PBM negotiations.

Even when rebates are confidential, an important question to ask is who ultimately gets the rebate: the PBM or the final payer (i.e., the employer)? The contract between the employer or insurer and the PBM is complex. The contract may allow for sharing of the rebates between the PBM and final payer, per-member-per-month charges, administrative fees, consulting fees, and a proportion of the list price of the medication that the final payer pays. The share of the rebate kept by the PBM can take the form of a flat fee per prescription or a percentage of the rebate paid. The ultimate terms of this contract depend on both the relative bargaining power of payers and PBMs and the information each has about the amount of economic surplus that is available.

In a well-functioning competitive market, the combination of this contract structure and lack of rebate transparency shouldn't matter to the final price. In such a market, PBMs would compete by offering payers a package of total costs and quality and payers would pick the PBM with the most attractive options. In an attempt to win the payer contract, a PBM in a competitive market would compete with lower prices until the total package of payments just covers its costs. In other words, effectively, the entire rebate would be transferred to the payer. However, any lack of competition in a more concentrated market decreases the incentive to lower price. Raising price by increasing the per-member-per-month fee is transparent and salient for consumers. But if the PBM chooses a contract type that allows it to keep a share of the rebate, and then goes on to create contracts with manufacturers featuring higher prices and larger rebates, net prices rise in a way that is hard for the final payer to see. Note that a spate of recent PBM mergers has resulted in the top three firms controlling nearly 80 percent of all prescriptions.

Contracts with shrouded rebates in a concentrated market can result in higher manufacturer prices and increased profits for PBMs. This situation is illustrated by the following simple example. Suppose the manufacturer raises its list price by $10 and its rebate by $9. The result is a $1 higher net price so the manufacturer is better off. If a

lack of competition allows a PBM to return $8 to the payer instead of the full $9, the PBM is better off by $1 also. The PBM has little reason to bargain with manufacturers to keep prices from increasing in the first place; indeed their incentive is to encourage higher prices and higher rebates. Meanwhile, the payer's drug costs increase by $2. In a competitive PBM market, we would expect another PBM to approach the payer and offer to give it $8.50 of the rebate, and another would approach offering $8.75, and eventually all of the rebate would be returned to the payers.

In a truly competitive market we would expect the PBM to attempt to win the payer's contract by also negotiating with the manufacturer to increase the rebate to $10 and return that full rebate to the payer. These patterns, however, depend on the existence of multiple PBMs actively competing for the payer's business—something unlikely to emerge in a market with few PBM participants and large barriers to entry, including barriers like contract terms created by the PBM. The situation becomes even less competitive should the small number of existing PBMs begin to realize that such price competition would decrease everyone's profits.