EXAMINING THE IMPACT OF VOLUNTARY RESTRICTED DISTRIBUTION SYSTEMS IN THE PHARMACEUTICAL SUPPLY CHAIN

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTHCARE, BENEFITS, AND ADMINISTRATIVE RULES

OF THE

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED FIFTEENTH CONGRESS

FIRST SESSION

MARCH 22, 2017

Serial No. 115–33

Printed for the use of the Committee on Oversight and Government Reform

Available via the World Wide Web: http://www.fdsys.gov
http://oversight.house.gov

U.S. GOVERNMENT PUBLISHING OFFICE

27–116 PDF WASHINGTON : 2017

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

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

Jason Chaffetz, Utah, *Chairman*

John J. Duncan, Jr., Tennessee
Darrell E. Issa, California
Jim Jordan, Ohio
Mark Sanford, South Carolina
Justin Amash, Michigan
Paul A. Gosar, Arizona
Scott DesJarlais, Tennessee
Trey Gowdy, South Carolina
Blake Farenthold, Texas
Virginia Foxx, North Carolina
Thomas Massie, Kentucky
Mark Meadows, North Carolina
Ron DeSantis, Florida
Dennis A. Ross, Florida
Mark Walker, North Carolina
Rod Blum, Iowa
Jody B. Hice, Georgia
Steve Russell, Oklahoma
Glenn Grothman, Wisconsin
Will Hurd, Texas
Gary J. Palmer, Alabama
James Comer, Kentucky
Paul Mitchell, Michigan

Elijah E. Cummings, Maryland, *Ranking Minority Member*
Carolyn B. Maloney, New York
Eleanor Holmes Norton, District of Columbia
Wm. Lacy Clay, Missouri
Stephen F. Lynch, Massachusetts
Jim Cooper, Tennessee
Gerald E. Connolly, Virginia
Robin L. Kelly, Illinois
Brenda L. Lawrence, Michigan
Bonnie Watson Coleman, New Jersey
Stacey E. Plaskett, Virgin Islands
Val Butler Demings, Florida
Raja Krishnamoorthi, Illinois
Jamie Raskin, Maryland
Peter Welch, Vermont
Matt Cartwright, Pennsylvania
Mark DeSaulnier, California
John Sarbanes, Maryland

Jonathan Skladany, *Staff Director*
Rebecca Edgar, *Deputy Staff Director*
William McKenna, *General Counsel*
Natalie Turner, *Counsel*
Kiley Bidelman, *Clerk*
David Rapallo, *Minority Staff Director*

SUBCOMMITTEE ON HEALTHCARE, BENEFITS, AND ADMINISTRATIVE RULES

Jim Jordan, Ohio, *Chairman*

Mark Walker, North Carolina, *Vice Chair*
Darrell E. Issa, California
Mark Sanford, South Carolina
Scott DesJarlais, Tennessee
Mark Meadows, North Carolina
Glenn Grothman, Wisconsin
Paul Mitchell, Michigan

Raja Krishnamoorthi, Illinois, *Ranking Minority Member*
Jim Cooper, Tennessee
Eleanor Holmes Norton, District of Columbia
Robin L. Kelly, Illinois
Bonnie Watson Coleman, New Jersey
Stacey E. Plaskett, Virgin Islands

CONTENTS

EXAMINING THE IMPACT OF VOLUNTARY RESTRICTED DISTRIBUTION SYSTEMS IN THE PHARMACEUTICAL SUPPLY CHAIN

Wednesday, March 22, 2017

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH CARE, BENEFITS, AND ADMINISTRATIVE RULES
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM,
Washington, D.C.

The subcommittee met, pursuant to call, at 2:00 p.m., in Room 2154, Rayburn House Office Building, Hon. Jim Jordan [chairman of the subcommittee] presiding.

Present: Representatives Jordan, Walker, Grothman, Mitchell, Krishnamoorthi, Kelly, Watson Coleman, and Plaskett.

Also Present: Representatives Cummings and Welch.

Mr. JORDAN. The Subcommittee on Health Care, Benefits, and Administrative Rules will come to order.

And without objection, the chair is authorized to declare recess at any time.

And I ask unanimous consent that all members of the Committee on Oversight and Government Reform be allowed to participate in today's hearing.

Without objection, so ordered.

I want to do a brief opening statement and then our ranking member will do his opening comments as well, and then we'll get right to it.

I do want to thank our witnesses for being here, especially the FDA. I know you've testified a number of times in a very short period of time. So we do appreciate, Doctor, you being with us, and all of our witnesses being with us today.

The nature of this week is kind of hectic around here, so we will try to get your testimony and maybe a few questions. But it's an important subject and I don't want to shortchange it, but I just want to kind of give you some context as you all know what's going on here on Capitol Hill this week.

The subject of today's hearing affects Americans across the country: The rising costs of all patent drugs that lack generic competition. To facilitate competition in the pharmaceutical market, the Hatch-Waxman Act created an accelerated pathway for approving generics, while maintaining incentives for companies to invest in developing new innovative products. Hatch-Waxman continues to promote the development of low-cost generics.

According to a recent report, generics are only 27 percent of the total drug costs in the United States, yet fill 89 percent of prescriptions. Last year, however, we saw that there are some medicines with increasing prices, and even though those medicines are not protected by remaining patent life or regulatory exclusivity, they lack lower-cost generic equivalents. The big one, of course, was Turing Pharmaceuticals.

Turing acquired the drug Daraprim and quickly increased the price about 5,000 percent from $13 a pill to over $750. Even though the FDA approved Daraprim in 1953, over 60 years ago, there remains no cheap generics for competition of this particular pharmaceutical. What is not as well known as the exorbitant price is the manipulation of the regulatory framework. Not only did Turing increase the price of Daraprim, but the company also adopted a strategy to block generic competition, thereby frustrating the intent of the law.

Strategy is simple. Generic manufacturers are generally not required to submit full clinical trial data to establish safety and efficacy, they instead rely on FDA's previous finding of safety and effectiveness for the approved medicine.

For the generic applications, generic manufacturers obtains samples of the approved medicine and demonstrates their product as bioequivalent to that approved product. Simple enough. But then enter bad actors. Turing thwarted the generic competition by blocking generic companies access to samples of Turing's pricey product, inhibiting generic manufacturers from conducting the bioequivalence testing for the generic application. Indeed, Turing testified—Turing testified admitting to this blocking strategy to try and block the generic competitor for at least 3 years.

Companies should not be able to use the system to block generic competition. Such abuse is leading to debilitating drug costs. At the same time, however, distribution restrictions oftentimes serve important purposes, such as ensuring the safe use and distribution of medicines with heightened safety concerns.

In 2007, Congress gave the FDA authority to order risk evaluation and mitigation strategies, programs for medicines with heightened safety concerns. REMS, this REMS program ensured that the benefits of medicine with a known or potential safety concern outweigh the risk of the medicine. FDA can mandate that certain distribution restrictions are part of the REMS program.

This hearing will distinguish between the good actors and those companies like Turing that self-imposed restricted distributions for medicines with no apparent reason other than to block the competition.

The panelists today will help us examine the scope of the misuse of this restricted distribution system to block generic competition and help to identify solutions. This Congress needs to find a way to help the FDA spur the interest of generic competition into the market. This hearing is designed to help us move towards that goal.

Finally, I'd like to thank our ranking member for his interest in this issue. There's a good chance that we aren't going to agree always on what may be the solution, but I am pleased that our staffs have been able to work together on this issue so well.

And with that, I would like to recognize Mr. Krishnamoorthi for his opening statements.

Mr. KRISHNAMOORTHI. Thank you, Mr. Chairman, for holding this very important hearing today. And thank you to our witnesses for taking time out of your precious schedules to be here as well.

The topic of today's hearing is restricted distribution systems in the prescription drug market. This is a very important issue. When drug companies use restricted distribution systems and other anti-competitive practices to prevent potential generic competitors from coming onto the market, they drive up prices and impose added costs on our healthcare system.

Even more importantly, these anticompetitive practices harm patients. One such patient is here to testify today. David Mitchell has multiple myeloma, an incurable blood cancer. For over 5 years, Mr. Mitchell took the drug Revlimid, which is made by Celgene. Celgene has come under fire for using a restricted distribution system to prevent generic competitors from getting access to the drug samples they would need to bring a generic version of Revlimid to market.

As Mr. Mitchell will testify, over the 5 years he took Revlimid, his copays increased by 500 percent. During this period, Celgene's revenues from Revlimid also steadily increased, without facing any competition from generics, from $2.5 billion in 2010 to almost $6 billion in 2015. This was an increase of 132 percent.

Given these figures, it's no wonder that some drug companies take extraordinary steps to prevent potential generic competition. But it is important to acknowledge that the challenges we face in the prescription drug market go beyond just restricted distribution systems. For instance, we are seeing incredible price increases for decade's old drugs. Most recently, Kaleo pharmaceuticals increased the price of its autoinjector version of naloxone, a lifesaving drug first approved in 1971 to reverse opioid overdoses, from $690 in 2014 to $4,500.

The opioid epidemic is ravaging my home State of Illinois, as it is many parts of the country. It is wrong for a drug company to raise the price of a lifesaving overdose antidote by more than 500 percent in a span of just 2 years. That's 500 percent in the span of 2 years. And although we absolutely rely on new breakthrough therapies to treat the most challenging diseases, new drugs are being introduced at higher and higher prices that our healthcare system simply cannot support. Some of these drugs are true clinical breakthroughs, but others add little clinical value over drugs that are already on the market.

Lifesaving treatments only save lives when people can afford them. According to a 2014 survey, one in five Americans did not fill a prescription because they could not afford it. Prescription drug prices affect all of our constituents. This is an issue they desperately want us to address. And I am so thankful that Mr. Jordan, Congressman Jordan, has agreed to do this bipartisan hearing on prescription drug pricing.

In fact, a recent Kaiser Family Foundation poll found that 60 percent of Americans, including a majority of Republicans, think lowering prescription drug prices should be a top priority for President Trump and for Congress. And I'm glad President Trump has

actually made this a priority for his administration. According to this poll, more Americans want us to deal with rising prescription drug prices than repeal the ACA.

Of course, we do not want to stifle innovation. We want drug companies to be able to earn a fair profit that allows them to recoup their research and development costs and invest in the next cure. But no company should be able to misuse public safety regulations to stifle competition and secure a monopoly advantage.

I hope today's hearing will allow us to begin a constructive conversation about what we can do legislatively, in a bipartisan way, to a handle on runaway prescription drug prices. Discovering a life-saving drug is complicated, but lowering prescription drug prices is not. We know what the tools are. Among them are promoting generic competition in the market, increasing transparency in the pharmaceutical chain, and letting Medicare negotiate for a better deal on drugs. Congress has only to remove the legal hurdles to lower prices.

I look forward to today's discussion. I hope, with my colleagues on both sides of the aisle, to address this issue on behalf of our constituents.

Mr. Chairman, I just want to do one last thing, which is I would like to allow Mr. Welch on my side 1 minute to talk about a bipartisan bill that is directly relevant to today's hearing.

Mr. JORDAN. Only for the gentleman from Vermont would we make such—no, we're glad to do that. We're glad to do that.

Mr. KRISHNAMOORTHI. Okay. Thank you, Mr. Chairman.

Mr. WELCH. Well, thank you very much. And I really want to associate myself with your statement. And, Mr. Jordan, it's great you're doing this hearing.

If we can bring down the cost of prescription drugs, we've got to do it. I've got a REMS bill with Steve Stivers, and I think that's going to help in one of the areas that would allow us to make certain that we're not abusing a review process for the advantage of higher prices at the expense of consumers.

I also had a chance to meet with President Trump with Elijah Cummings. And it was very clear to me that he gets it that Americans are paying more than we should be paying. And it's not about getting in the way of research and development. You know, drug companies do good things. They create life-extending and pain-relieving drugs. That is a good, good thing, but they can't kill us with the cost.

And there are a lot of market failures, I think we get specific on this REMS being one of them, and work together to get the benefit of fair and accessible drug prices for all of our constituents. That's the goal.

So thank you both for allowing me to wave on to this hearing, and I look forward to working with you to get some things done.

Mr. JORDAN. Without objection, we'll let Mr. Welch be a part of the hearing. And I want to thank the ranking member and Mr. Welch for their statements.

Let's get right to our witnesses. The committee will hold open the record for 5 legislative days for any other members who would like to submit a written statement.

We want to recognize our witnesses. First, we have Dr. Janet Woodcock from the FDA. We appreciate you being here. As I said, I know you've testified several times in the last few days.

Mr. Bruce Leicher.

Mr. LEICHER. Leicher.

Mr. JORDAN. I appreciate you being here. Senior vice president and general counsel for Momenta Pharmaceuticals, testifying on behalf of the Association for Accessible Medicines.

And we have Dr. Anderson, director of the Center for Hospital and Finance and Management, as well as professor at Johns Hopkins Bloomberg School of Public Health. And Mr. David Mitchell, president and founder of Patients for Affordable Drugs.

Welcome again to you all. And pursuant to committee rules, we actually swear you in. So if you stand up and raise your right hand.

Do you solemnly swear or affirm that the testimony you're about to give will be the truth, the whole truth, and nothing but the truth, so help you God?

All right. Let the record show that everyone answered in the affirmative.

And we will start with the gentlelady on my left. Dr. Woodcock, you're recognized.

WITNESS STATEMENTS

STATEMENT OF JANET WOODCOCK, M.D.

Dr. WOODCOCK. Thank you very much, Mr. Chairman and members. I'm really pleased to testify at this hearing on a very important issue.

But first, I'd like to note for the record that appearing on this panel does not waive the Administration's policy of not appearing concurrent with nongovernment witness, nor the Administration's policy of not appearing with less than 2 week's prior notice. I am appearing in the spirit of accommodation and comity.

Mr. JORDAN. Thank you.

Ms. WOODCOCK. Yes. So to move to the topic at hand, the generic drug program that we operate at FDA has been highly successful. Its estimated savings to consumers has been about $1.5 trillion in a decade. And as you said, about 90 percent of prescriptions in the United States now are generic, at much lower cost obviously than the innovators. However, sometimes the benefits to patients are delayed beyond the legal constraints of patent or exclusivity.

Innovators may use various routes or maneuvers to delay availability of a competitor generic. And among these, although there are many others, but among these is the use of REMS or a voluntary restricted program that is set up by the manufacturer, not required by FDA, to keep competitors from getting access to the drug.

Specifically, most generic applicants need a relatively small quantity of brand drug to use as a comparator when they do what's called bioequivalence testing to make sure the generic is absorbed into the body the same way that the brand drug is. And, of course, anyone who gets filled a generic instead of the brand they prescribed, we're guaranteeing to them it's going to have the same ef-

fects. So we want them tested to make sure they're absorbed correctly. And some innovators have been refusing to provide drug for this bioequivalence testing.

For REMS, which certain restricted distribution requirements set up by the FDA for safety reasons, what FDA has done to try and mitigate this is have procedures to review the generic drug bioequivalence protocol and notify the innovator drug in writing that we believe it is adequate and that the REMS restriction does not apply. So to remove that barrier and get us out of the way. Of course, that doesn't really occur for the voluntary restricted programs because there is no barrier to simply providing that in the open market. In that case, no letter is needed.

Nevertheless, sponsors do continue to withhold products. We've had around 150 inquiries from generic firms about difficulties that they have had obtaining product for bioequivalence testing. And I really would be happy to answer any questions you might have about this.

[Prepared statement of Dr. Woodcock follows:]

Restricted Distribution Systems in the Pharmaceutical Supply Chain

Testimony of Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research

Before the
United States House
Committee on Oversight and Government Reform
Subcommittee on Health Care, Benefits, and Administrative Rules

March 22, 2017

U.S. Department of Health and Human Services
U.S. Food and Drug Administration
www.fda.gov

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman and Members of the Committee, I am Dr. Janet Woodcock, director of the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to be here today to discuss restricted (referred herein as "limited") distribution systems in the pharmaceutical supply chain. This is an important topic that has implications for increasing generic competition and patients' access to affordable medicines.

Reference Listed Drug ("RLD") Access and Limited Distribution Systems

In order to get approval for a generic drug, the generic company needs to show (among other things) that its version of the product is bioequivalent to the brand drug (also known as the "reference listed drug" or "RLD")[1]. This usually requires the generic company to do bioequivalence studies comparing their product to the RLD. In general terms, bioequivalence testing is designed to show that the proposed generic drug reaches the site of action at a rate and to an extent not significantly different from the RLD. Bioequivalence testing typically involves a relatively small number of human subjects and a small number of doses (often only one dose) and, therefore, a lower level of risk than other types of clinical testing during the drug development process. The regulatory regime applicable to bioequivalence testing – including the exemption of most bioequivalence testing from the investigational new drug (IND) requirements – reflects the lower level of risk associated with bioequivalence testing when compared with other kinds of clinical testing that occur during the drug development process. In addition, FDA

[1] For purposes of this testimony, we are using the term RLD to refer to the listed drug identified by FDA as the drug product upon which the applicant relies in seeking approval of its generic product or the drug product selected by FDA that an applicant seeking approval of a generic product must use in conducting a bioequivalence study.

regulations (at 21 CFR Part 56) require that before bioequivalence testing can begin, it must be approved by an Institutional Review Board (IRB) to ensure that risks are minimized.

To do these kinds of bioequivalence studies, the generic company needs to get access to a small quantity of the RLD. Typically, generic companies are able to get these RLD samples through normal drug distribution channels – i.e., via wholesalers. Sometimes, however, samples of the RLD are not available through normal distribution channels. This might happen because the brand company limits the distribution of the drug on its own initiative for a variety of legitimate business reasons (for example, by selling it through a central or small group of pharmacies). In other cases, a risk evaluation and mitigation strategy (REMS) program with elements to assure safe use (ETASU) might impact the way the product is distributed. The Food and Drug Administration Amendments Act of 2007 authorized REMS to ensure that a drug's benefits outweigh its risks. These risk management programs may be used for particularly risky drugs, and can include ETASU that, for example, limit where or how the drug can be dispensed, impose patient monitoring requirements, or impose prescriber or pharmacist training or certification.

A subset of REMS programs have features that may impact product distribution. For example, a pharmacy certification requirement might limit the pharmacies to which the product is distributed. The purpose of a requirement of this kind is to ensure that the pharmacist is aware of the specific safe use measures required for the particular drug and helps ensure that they have been followed before the product is dispensed. These kinds of REMS programs allow products that could not otherwise be approved because of safety issues to be approved and available to patients.

We understand that some brand companies that sell products under limited distribution have refused to sell the RLD to generic companies for testing or have included provisions in their contracts with pharmacies/third parties that prohibit the sale of the RLD to generic companies for testing purposes. This is a problem that affects both REMS and non-REMS products. FDA has received more than one hundred and fifty inquiries from generic companies that want to develop generic drugs but tell us they are unable to because they cannot get access to supplies of the RLD to do testing. We have referred such matters that have been brought to our attention to the Federal Trade Commission (FTC) and encouraged generic companies to also raise these matters with the FTC. We have taken a number of additional steps as well.

Because some brand companies have argued that their product's REMS prohibits them from selling RLD supplies to generic companies for testing, we have developed a process, where appropriate, for informing the brand company in writing that FDA will not consider provision of the RLD for these purposes to be a violation of the REMS. This process is described in our 2014 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 https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm425662.pdf. As described in that guidance, when requested to do so, we review the bioequivalence study protocols of companies that want to develop generic versions of these REMS drugs to assess whether they contain safety protections comparable to those in the applicable REMS. If we determine that that they do, we send a letter to the brand company stating so and informing them that selling the RLD to the generic company for testing and development will not be considered a violation of the REMS. While FDA developed this

process to help facilitate access to RLD samples for generic companies, it is important to note that the protections in the REMS program are designed to mitigate risks that occur during real world, every day use by patients, and that safety concerns are likely to be lower in the more tightly-controlled context and limited scope of bioequivalence testing. We note that while the letters provided pursuant to the Protocols Guidance make clear that such sales will not subject the brand company to REMS-related enforcement action, some brand companies have argued that they have independent business reasons for not selling the RLD to the generic firm that are unrelated to their REMS and/or that they have no obligation to do so.

We have also received a significant number of RLD access inquiries about products that are not subject to a REMS for which the brand company has voluntarily limited their distribution. Because there is no REMS in place in such cases, there is, of course, no call for us to review bioequivalence study protocols to ensure they have safety protections comparable to a REMS. When generic companies contact us because they are experiencing difficulty getting access to brand products that are not subject to a REMS, we often confirm that the distribution restrictions they are describing are not required by FDA, and encourage the generic companies to raise the matter with the FTC.

CONCLUSION

We hope you found this information about how some limited distribution systems in the pharmaceutical supply chain can affect generic competition to be helpful.

Mr. JORDAN. Thank you, Dr. Woodcock.
We go now to Mr. Leicher.

STATEMENT OF BRUCE LEICHER

Mr. LEICHER. Good afternoon, Chairman Jordan and Ranking Member Krishnamoorthi. Thank you for the opportunity to participate in this important hearing. I'm Bruce Leicher, senior vice president and general counsel of Momenta Pharmaceuticals, and chair of the board of the Biosimilars Council, a division of the Association for Accessible Medicines. We commend you for holding today's hearing.

Increasingly, patient access to affordable medicines is prevented by certain brand drug manufacturers' use of restricted distribution programs, including FDA-mandated risk evaluation mitigation strategies, REMS, to limit generic and biosimilar development. Having worked in the biotechnology industry for over 25 years and the biosimilars industry since its inception, I'm concerned. These anticompetitive practices are contrary to the careful balance of the Hatch-Waxman and biosimilar laws and threaten generic competition from the emerging biosimilars market.

For over 30 years, generic companies have safely purchased branded drugs on the free market to conduct testing necessary for FDA approval. But in recent years, certain brands have used restricted distribution schemes, including REMS, to block such purchase and testing. If brand products cannot be purchased, then affordable generic drugs and biosimilars cannot be developed.

Momenta and the generic and biosimilar industry are committed to ensuring that Americans have access to safe, effective, and affordable medicine. We do not support policies that would endanger patients. We comply with the same rules administered by the FDA.

Generic medicines are almost 90 percent of prescriptions dispensed in this country, yet account for less than 30 percent of drug spending. Generic drugs save hundreds of billions of dollars annually, $1.46 trillion in the last decade alone. And biosimilars present the same opportunity.

Consider that branded specialty medicines are only 1 percent of all prescriptions, but more than 30 percent of total pharmaceutical spending. Their utilization is only expected to increase, making the competition promised by biosimilars even more important to patients and to taxpayers. The high price of many new biologics will only incentivize further abuse of these arrangements, if they continue, and create excessive spending for the healthcare system.

The FDA recently reported that over 64 biosimilar programs are under review for over 23 different brand biologics. Momenta alone has seven biosimilar development programs, and that's required us to more than double the size of our workforce. Various studies estimate savings for American taxpayers and patients between $42 billion to as much as $250 billion over the first 10 years following biosimilar market formation. But if we're not able to access the product for development, this can't happen.

These brand restrictions take the form of self-imposed restricted distribution schemes with wholesalers or specialty pharmacies that mimic FDA REMS programs, hiding behind the veneer of patient safety. For instance, when we've sought to purchase brand products

from customary wholesalers in the supply chain, we're now asked if we're conducting generic or biosimilar studies. On multiple occasions, they inform us that their contract prohibits them from selling the brand product to us for that purpose. Ironically, when we attempt to purchase the same product for use in a comparative novel drug development program, where far less is known about product safety, we don't encounter these refusals.

It's clear that this has nothing to do with safety, but everything to do with preventing competition. As a result, in our company's development decision-making process, we're now forced to consider how difficult it will be to obtain the brand product. In cases where access is restricted, we have not initiated some programs.

Uncertain litigation is often the only remedy available, and some large companies with the necessary resources have been suing over access for years. However, litigation is too costly and time consuming for companies like Momenta.

The bottom line is simple: A generic or biosimilar manufacturer is prevented from obtaining the brand drug, is unable to perform the required FDA testing, and patients will miss out on generic and biosimilars savings and access. These barriers to competition need to be removed and customary access restored.

Mr. Chairman, the House is currently considering legislation that would study these abuses further, but I believe there's no need for further study. My written statement mentions law firms promoting the use of these programs as a tool for profitability. Almost 5 years ago, the Senate passed legislation that included language, at FDA's request, to address REMS abuse and it was removed in conference. The House has considered similar legislation, Mr. Welch's legislation, in the 113th and 114th Congress; will again this year.

The FDA has testified about the problem repeatedly, most recently just yesterday before the Senate Health Committee, and Dr. Woodcock is here today, I can say now. Committees in both the House and Senate have discussed these abuses on numerous occasions. Some may tell you that this is too small of a problem to address legislatively, but the numbers and this hearing say otherwise.

The Congressional Budget Office has estimated various reform proposals for saving billions of dollars for taxpayers. Experts and patient advocates have called for fixes to these abuses. A study will only further delay competition. It's time to act on legislation.

And I would be pleased to answer any questions after the statements. Thank you.

[Prepared statement of Mr. Leicher follows:]

TESTIMONY OF BRUCE A. LEICHER

SENIOR VICE PRESIDENT AND GENERAL COUNSEL

MOMENTA PHARMACEUTICALS, INC.

BOARD CHAIR, BIOSIMILARS COUNCIL, A DIVISION OF THE ASSOCIATION FOR ACCESSIBLE MEDICINES

SUBCOMMITTEE ON HEALTH CARE, BENEFITS, AND ADMINISTRATIVE RULES OF THE COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

MARCH 22, 2017

Good morning Chairman Chaffetz, Chairman Jordan, Ranking Member Cummings, Ranking Member Krishnamoorthi and Members of the Subcommittee. Thank you for the opportunity to participate in this timely and important hearing.

I am Bruce Leicher, Senior Vice President and General Counsel at Momenta Pharmaceuticals, and Chair of the Biosimilars Council Board of Directors. The Council is a division of the Association for Accessible Medicines (AAM), formerly GPhA.

AAM and the Biosimilars Council commend you for holding today's hearing to discuss a problem that limits patient access to affordable medicines: certain brand pharmaceutical manufacturers' use of restricted distribution programs, including Food and Drug Administration (FDA)-mandated Risk Evaluation and Mitigation Strategies (REMS), to limit market access and generic development of their product.

Having worked in the biotechnology industry for over 25 years and in the biosimilars industry since its inception, I've seen firsthand how these strategies prevent or delay competition. Congress has encouraged generic and biosimilar competition through a delicate balance between innovation and competition established by The Drug Price Competition and Patent Term Restoration Act (P.L. 98-417; 21 U.S.C. §355,) commonly referred to as Hatch-Waxman, and the Biologics Price Competition and Innovation Act (BPCIA) (P.L. 114-38, 42 U.S.C. § 262). Alarmingly, anticompetitive practices threaten to undermine the success achieved through generic competition and to strangle an emerging biosimilars market.

For over 30 years, generic companies have safely and effectively purchased branded drugs on the free market so that they could conduct the testing necessary to file applications for marketing approval at the FDA. But in recent years, certain brand pharmaceuticals have used restricted distribution schemes, including REMS, to block such purchase and testing. If brand products cannot be purchased, then generic drugs and biosimilars cannot be developed. Without such development, the competition envisioned by Hatch-Waxman and the BPCIA will not occur and patients will not have access to safe, effective and more affordable life-saving medicines.

Momenta, and the larger generic and biosimilar industry, are committed to ensuring that all Americans have access to safe, effective and affordable drugs. We have supported the proper use of FDA REMS programs since their inception nearly a decade ago. These programs allow for the safe distribution and use of certain pharmaceuticals that have a higher risk profile. This industry does not support any policies that would endanger patients. Nor do we want to contribute to drug shortages or add unnecessary overhead costs to already low-margin products. Our members comply with the same rules and regulations administered by the FDA for testing of medicine. Any discussion or insinuation to the contrary is simply an effort to distract from the real issue at hand: addressing the use of REMS or other non-FDA mandated restrictions on drug supply to block or delay lower cost generics and biosimilars from coming to market.

I. COMPETITION WORKS

Hatch-Waxman is the foundation on which the nation's generic drug industry was built. For more than 32 years, it has proven to be a tremendous success. Generic medicines are almost 90% of the prescriptions dispensed in this country, yet account for less than 30% of drug spending[1]. On average, generics are 80-85% less expensive than brand drugs[2]. By bringing drugs to the market at a lower price point, generics help drive down costs to patients, as well as the greater U.S. healthcare system, including private health insurance plans and public programs. Generic drug savings provide the healthcare system with the ability to invest in new medications and save hundreds of billions of dollars annually. In fact, generic competition has expanded patient choice and lowered healthcare costs, saving $1.46 trillion in the last decade alone[3]. To underscore the success of our sector, consider that while generic drug utilization continues to

[1] *Generic Drug Savings and Access in the United States* report. Generic Pharmaceutical Association. October 2016 http://www.gphaonline.org/media/generic-drug-savings-2016/index.html

[2] *Understanding Recent Trends in Generic Drug Prices.* HHS Office of the Assistant Secretary for Planning and Evaluation. January 2016. https://aspe.hhs.gov/pdf-report/understanding-recent-trends-generic-drug-prices

[3] *Generic Drug Savings and Access in the United States* report. Generic Pharmaceutical Association. October 2016 http://www.gphaonline.org/media/generic-drug-savings-2016/index.html

increase, the share of pharmaceutical spending attributed to generics is decreasing[4]. More prescription drugs are being dispensed to patients, while the cost of generic medicines declines.

Looking forward, biosimilars present the same opportunity – competition for high-cost specialty biologic medicines. To contextualize the promise of biosimilars, consider that branded specialty medicines are only 1% of all prescriptions, but account for more than 30% of total pharmaceutical spending[5]. Utilization of these costly drugs is only expected to increase in the coming years. Experts anticipate that specialty products will account for nearly half of all pharmaceutical costs in the next three to five years[6]. As more conditions are treated with these more effective but higher cost biologics instead of traditional small molecule drugs, total spending is expected to increase. This is why the competition promised by biosimilars is so important to patients and taxpayers.

Thanks to the bipartisan work of Congress to enact the BPCIA, opportunities for greater access to lower-cost and high-quality biosimilar medicines are on the horizon. Today we have a growing and thriving biosimilars industry – creating good jobs and leading the world with our innovative science – particularly in the science of more fully understanding our biologic products. In fact, the FDA reported that over 64 biosimilar programs were under review for development of 23 different biologic products.[7] Momenta alone has seven biosimilar development programs which has required us to more than double the size of our workforce. These are American jobs, paying good wages that enhance the economic and innovative dynamism of the U.S economy. Various economic impact studies estimate projected savings for American taxpayers and patients between $42 billion[8] to as much as $250 billion[9] over the first 10 years of biosimilar market formation. But if we are not able to access comparator brand product to conduct development in a timely and routine manner, this will not happen.

---

[4] *Understanding Recent Trends in Generic Drug Prices.* HHS Office of the Assistant Secretary for Planning and Evaluation. January 2016. https://aspe.hhs.gov/pdf-report/understanding-recent-trends-generic-drug-prices

[5] *Generic Drug Savings and Access in the United States* report. Generic Pharmaceutical Association. October 2016 http://www.gphaonline.org/media/generic-drug-savings-2016/index.html

[6] 2015 ExpressScripts Drug Trend Report, available at https://lab.express-scripts.com/lab/~/media/e2c9d19240e94fcf893b706e13068750.ashx

[7] Testimony of Dr. Janet Woodcock Testimony "Examining FDA's Generic Drug and Biosimilar User Fee Programs." House Energy and Commerce Committee. March 2, 2017. https://energycommerce.house.gov/hearings-and-votes/hearings/examining-fda-s-generic-drug-and-biosimilar-user-fee-programs

[8] *"The Cost Savings Potential of Biosimilar Drugs in the United States"* RAND Corporation. 2014. https://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf

[9] *"The $250 Billion Potential of Biosimilars"* Express Scripts. April 2013. http://lab.express-scripts.com/lab/insights/industry-updates/the-$250-billion-potential-of-biosimilars

Generics, and the patient access and savings they produce, are an American success story. A robust biosimilar market is becoming more of a reality every day. However, we are leaving savings on the table. We need to boost competition and reduce regulatory burdens to ensure this dynamic thrives. One of the surest ways to accomplish that goal is to address restricted distribution schemes and abuses of FDA REMS programs that limit generic and biosimilar development and competition.

II. RESTRICTED DISTRIBUTION ABUSES BLOCK GENERIC DRUG ENTRY

Our efforts to lower costs and improve access to medicines are often frustrated by brand tactics designed to block or delay the generic and biosimilar drug development process. These tactics take the form of novel self-imposed restricted distribution schemes with wholesalers or specialty pharmacies that mimic FDA REMS programs, or hide behind the veneer of patient safety and FDA mandates.

This refusal to sell samples may be direct, or may take the form of the brand restricting the supplier from selling the product for research purposes or through unreasonable contract terms. In any case, it has nothing to do with safety and they are rarely designed to manage costs or prevent a shortage. These samples are used solely for FDA-required testing, following FDA's review and approval of the competitor's safety protocols. Ultimately, the brand's actions to keep generic and biosimilar firms from receiving samples makes it impossible for prospective competitors even to submit an application for FDA approval – indefinitely preventing patients from accessing affordable treatment options.

For instance, in the past few years, when we have sought to purchase brand products from customary wholesalers in the supply chain, we are now asked if we are conducting generic or biosimilar studies. On multiple occasions, they inform us that their contract prohibits them from selling the brand product for that purpose. No REMS program was involved; it was simply a self-justified refusal to sell to a generic or biosimilar competitor.

On another occasion, we were told we could not purchase a product because it was subject to a REMS program that restricted distribution to patients only on a named basis. We looked up the product and it was not subject to a REMS. We then informed the wholesaler, who then informed us they could not sell the product to us for biosimilar development.

Ironically, when we attempt to purchase the same product for use in comparative novel development programs that are not designed to develop competitive products, we do not encounter these refusals. It is clear that this dichotomy has nothing to do with safety but everything to do with preventing lower-cost generic or biosimilar competition.

As a result, we are now forced to consider how difficult it will be to obtain the brand product when selecting generic or biosimilar development programs. In cases where access is restricted, we have not initiated some programs. Uncertain litigation is often the only option to gain access, and that is too costly and time-consuming for companies like Momenta. Some of the larger companies that have the resources to sustain such litigation have been suing over access to individual products for years.

Other AAM members report similar experiences: a REMS or self-imposed restricted distribution program limits sale of a drug and acts to preclude timely development of follow-on products. The bottom line is simple: a generic or biosimilar manufacturer is prevented from obtaining the brand drug, is unable to perform the testing required for FDA review and approval, and patients miss out on the savings that would be available through generic competition. These barriers need to be removed and customary access restored.

III. FEDERAL REGULATORS HAVE RECOGNIZED THESE ABUSES

These abuses have real costs: a 2014 study concluded the abuse of REMS and REMS-like limited distribution strategies cost the U.S. healthcare system $5.4 billion annually - $1.8 billion to the federal government[10]. But these abuses affect more than just payers – they have a direct impact on the costs borne by patients. The Federal Trade Commission (FTC) has weighed in on cases currently pending in federal court. In one, the FTC noted "a troubling phenomenon: the possibility that procedures intended to ensure the safe distribution of certain prescription drugs may be exploited by brand drug companies to thwart generic competition.[11]"

In a 2010 presentation to ACI's REMS Conference, a prominent Washington, D.C. law firm highlighted how REMS programs could be used as a "tool for profitability.[12]" They went on to make a nod to Stanley Kubrick's 1964 film *Dr. Strangelove*, subheading the title of their presentation, "How to learn to stop worrying and love REMS" because of the potential the program had to forestall competition[13].

---

[10] Brill, Alex, Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry, Matrix Global Advisors, July, 2014.

[11] Brief for the Federal Trade Commission as Amici Curiae, Mylan Pharmaceuticals, Inc. v. Celgene Corporation, (No. 2:14-CV-2094-ES-MAH) Available: https://www.ftc.gov/policy/advocacy/amicus-briefs/2014/06/mylan-pharmaceuticals-inc-v-celgene-corporation

[12] Powerpoint Presentation contained in Congressional Record of Senate Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights hearing titled, "The CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition" https://www.judiciary.senate.gov/meetings/the-creates-act-ending-regulatory-abuse-protecting-consumers-and-ensuring-drug-price-competition

[13] *Id.*

In addition to the FTC's activity, senior officials at the FDA have repeatedly spoken of the challenge. Dr. John Jenkins, M.D., then Director of the FDA's Office of New Drugs previously stated that, "the problem is the use of REMS blocking generic competition. [14]" He went on to say that "innovators have really become very aggressive in using that strategy [and] hiring the best lawyers to back up that strategy.[15]" The Director of the FDA Center of Drug Evaluation and Research, Janet Woodcock, M.D., testified only a few weeks ago that these abuses are "a problem we struggle with a lot[16]" and went on to note that they have "delayed [the] availability of generics.[17]"

But access to the brand drug is only part of the problem. Another common ploy is to use the law's shared-REMS requirement to prevent launch of a filed and otherwise ready to be approved generic competitor. This involves the statutory requirement that, unless waived, the brand and follow-on products must enter into a single, shared safety protocol[18]. It has become yet another opportunity for brands to game the system.

For example, a product to treat irritable bowel syndrome was able to continue to repeatedly increase prices through abuse of the FDA administered shared REMS system since 2008[19]. While a generic competitor ultimately entered the market, this occurred only after prolonged refusal by the brand to negotiate a shared-REMS which FDA noted took more than three years to conclude. The Agency characterized the brand's repeated delays as "pre-textual appeals to safety as a means to delay that competition.[20]" Unfortunately, FDA has only limited authority to allow generic manufacturers to implement their own REMS programs, even when the agency has confirmed the generic company's ability to satisfactorily implement the necessary precautions.

---

[14] Gingery, Derrick. REMS That Block Generics Are 'Major' Problem For FDA, Jenkins Says. "The Pink Sheet" Daily. January 8, 2015.

[15] *Id.*

[16] Testimony of Dr. Janet Woodcock Testimony "Examining FDA's Generic Drug and Biosimilar User Fee Programs." House Energy and Commerce Committee. March 2, 2017. https://energycommerce.house.gov/hearings-and-votes/hearings/examining-fda-s-generic-drug-and-biosimilar-user-fee-programs

[17] *Id.*

[18] Federal Food, Drug and Cosmetic Act § 505-1(i)(1)(B), 21 U.S.C. 355–1 (i)(1)(B)

[19] AAM Analysis of AWP Data from Truven Health Analytics, Micromedex Solutions. RED BOOK Online. Alosetron. Oral. 0.5 mg. 30s ea.

[20] Brief of Defendant Sylvia Matthews Burwell, et al. on Plaintiff's motion for a Temporary Restraining Order, Prometheus Laboratories, Inc. v. Sylvia Matthews Burwell, et al. (2015) (No. 1:15-CV-00742 (JEB)). Available at: http://www.fdalawblog.net/LOTRONEX%20-%20Roxane%20TRO-PI%20Opp.pdf

Even after FDA provided a waiver for the generic manufacturers to operate an equivalent REMS program, the brand sued the Agency in an attempt to force the generics back into the stalled negotiations. In the time period between expiration of the brand exclusivity and the FDA waiver, the brand raised its price over 50%, much more rapidly than it had prior to the threat of generic competition[21].

These abuses keep important products off the market indefinitely, even after the FDA has determined that the company's follow-on product is just as safe and just as effective as the brand product, and even when the brand product's patent protection has expired. The FDA needs more explicit authority to authorize generic and biosimilar companies to implement safe REMS programs of their own under FDA regulation.

IV. THESE ABUSES ARE NOT NEW AND SHOW NO SIGNS OF SLOWING

This is not a new problem. Almost five years ago, the Senate passed legislation that included language – at FDA's request – to address it. In 2012, the Senate passed that language as part of the prescription drug user fee reauthorization[22]. Unfortunately, the language fell out when the bill went to conference with the House of Representatives. Since then, FDA has frequently called for legislation to address REMS abuse. Dr. Woodcock has repeatedly addressed the point head-on in testimony to Congress, calling for a legislative fix. Last year, when asked why brand companies are abusing the REMS program she stated, "innovator companies feel it is their duty to their stockholders to delay completion as long as possible.[23]" These products bring in billions of dollars in revenue to the brand so, as Dr. Woodcock noted, market manipulations are viewed merely as a cost of doing business.

There were further legislative discussions last year, as legislation was introduced in the House and Senate, and as part of the 21st Century Cures process. We are encouraged by the continued attention, and hope that Congress will complete work on a solution to this issue this year.

---

[21] AAM Analysis of AWP Data from Truven Health Analytics, Micromedex Solutions. RED BOOK Online. Alosetron. Oral. 0.5 mg. 30s ea.

[22] Food and Drug Administration Safety and Innovation Act, S. 3187, 112th Congress (As passed by Senate May 24, 2012)

[23] *Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs. Before S. Comm. on Health, Education, Labor and Pensions*, 114th Congress (2016) (Comments by Janet Woodcock, MD, Director of Center for Drug Evaluation and Research at FDA). Available at: http://www.help.senate.gov/hearings/generic-drug-user-fee-amendments-accelerating-patient-access-to-generic-drugs

The potential for abuses is only growing. Increasingly, new FDA approvals are subject to REMS, and the percentage of REMS programs that require distribution restrictions referred to as Elements to Assure Safe Use (ETASU) has increased dramatically in the last several years. In 2009, roughly 75% of REMS programs only required medication guides – but now over 50% of REMS programs include limits on distribution[24]. Some manufacturers have even requested FDA to impose these restrictions despite FDA's conclusion that they are not necessary to protect patient safety[25]. In the context of biologic products – drugs that tend to have extremely high list prices – 34% of all biologics approved are subject to a REMS program[26]. As more biologics lose underlying patents and market exclusivities, the profit incentives for brand manufacturers to delay biosimilar development will become even more pronounced than they already are.

V. RESTRICTED DISTRIBUTION ABUSES ARE NOT LIMITED TO PRODUCTS WITH REMS

There is also growing use of self-imposed restricted distribution programs. While most attention has focused on high-profile examples, these are by no means outliers. AAM has surveyed their membership about products they have encountered where restricted distribution agreements prevent a generic or biosimilar drug developer from purchasing samples. There are dozens of products on that list in addition to the 78 FDA REMS programs. Many self-imposed restricted-distribution programs are designed – often explicitly – to block generic entry.

For example, in an investor presentation, the pharmaceutical manufacturer Retrophin discussed how limiting distribution of the drugs Thiola® and Chenodal® to a single specialty pharmacy would block a lower-cost alternative from coming to market and serve to protect their product from competition[27]. I'll also note this Committee's previous investigation of Turing Pharmaceuticals' pricing practices around the drug Daraprim®. Turing used a closed distribution system as an effective block on generic competition. John Hass, the company's director of patient access, said so explicitly, noting that generics wishing to buy samples of the drug would not be welcome. Hass said:

---

[24] Individual REMS programs listed at: https://www.accessdata.fda.gov/scripts/cder/rems/

[25] Letter from FDA to Jennifer Ekelund at pg 3. February 2015. http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/021196Orig1s015ltr.pdf

[26] Individual REMS programs listed at: https://www.accessdata.fda.gov/scripts/cder/rems/

[27] Retrophin: Manchester Pharmaceuticals Acquisition February 13, 2014. Available at: https://web.archive.org/web/20150226002409/http://www.retrophin.com/pdf/ManchesterAcquisitionAgreementConferenceCall.pdf

> *"Most likely I would block [a generic purchase]...We spent a lot of money for this drug. We would like to do our best to avoid generic competition. It's inevitable. They seem to figure out a way [to manufacture a generic alternative] no matter what. But I'm certainly not going to make it easier for them*[28]*."*

These programs do not stand on any FDA safety requirements. Rather, the manufacturers choose to adopt REMS-like protocols because they know how effective a tool they can be in blocking lower-cost alternatives from coming to market.

Your colleagues on the Senate Aging Committee have also examined market restrictions absent any FDA-mandate. Summarizing their investigations of abuses by drug companies like Turing, Retrophin, and Valeant, they noted that:

> *"In the cases of Turing and Retrophin, placing the drug into restricted distribution was a way for the companies to control who could buy their drugs. Mr. Shkreli blocked any purchase that looked like an attempt by a potential generic entrant to obtain the [brand product]. To the extent that drugs travelled through less-typical channels (such as 340B institutional distribution), the same rules applied—sales via that channel were carefully regulated and quantity limited to ensure that drugs were not sold to a potential generic entrant.*[29]*"*

The Committee also noted testimony from Dr. Woodcock on the challenge posed by non-FDA-mandated restricted distribution schemes. She explained:

> *"[T]he companies on their own behalf have restricted programs that we do not really understand, but they are not related to REMS. We have had over 100 inquiries from generic companies who cannot get a hold of the innovator drug to compare their drug to. We have done everything we can to—we have written a letter saying, you know, that REMS does not require this, you can give it out for this purpose, and so forth, and we also refer these to [the Federal Trade Commission], okay? But we still continue to get*

---

[28] Ed Silverman, *How Martin Shkreli prevents generic versions of his pricey pill*, Pharmalot, October 5, 2015. Available: http://pharmalot.com/how-martin-shkreli-prevents-generic-versions-of-his-pricey-pill/

[29] Special Committee on Aging United States Senate, *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System.* December 2016.

complaints from generic companies that they cannot get a hold of the drug to make the comparison they need to do.[30]"

So while many opponents of reform have argued that there are only a small number of products that are subject to REMS with ETASU, they ignore two very important facts: first, more and more products approved are subject to a REMS requirement, just setting the system up for further abuse; second, there is no public record of what companies are already using restricted distribution networks to restrict access to specific drug samples. Most troubling, the FDA cannot prevent those contractual arrangements and the FTC has yet to bring an enforcement action against one.

VI. RESTRICTED DISTRIBUTION ABUSES POSE A PARTICULARLY GRAVE THREAT TO THE DEVELOPMENT OF BIOSIMILARS

I have made clear the harm that these abuses are already causing today. But the danger is even more pronounced as we look to the future. As the biosimilars market develops, the high price of many new biologics will only incentivize further abuse of these types of arrangements, and create incredibly excessive spending for the healthcare system through the loss of potential savings.

As we increasingly shift from use of small-molecule drugs to biologic products, the development of biosimilar medicines will be critical to reducing the cost of prescription drugs. But such products are much more complex and difficult to develop. The foundation of biosimilar development is demonstrating that a biosimilar is highly similar to the brand product. This requires thorough characterization of multiple lots of the brand product over time. If access to brand lot variability is blocked by restricted access to brand product, then biosimilar development will be blocked.

In addition, unlike most small molecule generic drugs, the development of biosimilars is more likely to involve clinical trials and require far greater quantities of samples of the original product. For instance, clinical studies blind the medicine from the physician to avoid bias and ensure the validity of the data. This requires the purchase and re-labeling of the product to conduct the study. Moreover, the quantities are large and require purchases over a longer period

[30] Testimony of Dr. Janet Woodcock, "Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs" January 28, 2016 HELP Hearing, Trans. at 51:4–14 https://www.help.senate.gov/hearings/generic-drug-user-fee-amendments-accelerating-patient-access-to-generic-drugs

of time than generic development. Restricted access at any point in the development cycle could cause a study to fail, thereby slowing or preventing the entry of lower-cost biosimilar medicines.

Perhaps what is most interesting is a review of ClinicalTrials.gov – the website listing clinical studies in the United States – showing over 90 comparative clinical trials underway by brand companies that use comparative or combined use of brand products that appear to be freely purchased without any of these restrictions[31]. This makes clear that the motivation of the restrictions is to protect profits, not patients.

To be clear, the use of restricted distribution schemes, whether tied to a REMS or self-imposed, poses a severe threat to the billions in savings expected in the next ten years through biosimilar competition.

Some may tell you that this is "too small" of a problem to address legislatively. But the numbers say otherwise. The Congressional Budget Office has estimated various reform proposals as saving billions of dollars for taxpayers. Experts at the FDA and FTC have called for fixes to these abuses. Anything less merely continues the opportunity for further abuse.

I would be happy to address any questions from the Subcommittee.

[31] Individual studies available at https://clinicaltrials.gov/.

Mr. WALKER. [presiding.] Thank you, Mr. Leicher.
Dr. Anderson.

STATEMENT OF GERARD ANDERSON

Mr. ANDERSON. Thank you. Members of the committee, thank you for inviting me today. Today I'm presenting, and it's not as a member of the Johns Hopkins University, but as a faculty member of Johns Hopkins. So I'm not the corporate representative for Johns Hopkins.

I'm working on the issue of drug pricing with a team of faculty at Johns Hopkins with funding from the Arnold Foundation from The Commonwealth Fund, and a variety of other entities. I don't receive any funding from the pharmaceutical industry, wholesalers, insurance companies, or any other entities involved in the pharmaceutical supply chain.

Last December, I had the opportunity to testify at the Senate Aging Committee about the rapid increases in off-patent drugs. Your committee had similar hearings with Martin Shkreli and others. I made a number of very specific suggestions on how to deal with the issue of rapid increases and the prices of off-patent drugs. These ideas are in my written testimony, but they are basically expedited FDA reviews on allowing compounding importation in very, very restricted circumstances.

At the time of our testimony, we really didn't understand exactly how Martin Shkreli and others were able to use limited distribution chains to stifle competition. It was only after the investigations of several congressional committees that we learned all the details of what they were able to do.

Now, just a little bit of background. What happens in most cases is that the wholesaler takes the drugs from the manufacturer and brings them to the pharmacy or the hospital and they're given to patients. The wholesalers compete against each other, and as a result, the cost of distributing drugs is very low.

As Dr. Woodcock said, the FDA created the REMS programs, which required pharmacies, wholesalers to take special precautions in—for very specific drugs. Now, this is totally appropriate and very good medical practice. Drugs are put into these limited distribution networks for safety reasons. In contrast, what we're hearing about today is companies that have put these drugs in limited distribution networks to stifle competition and raise drug prices. Safety is not their concern; it's profits.

As we've already noted, a problem is that they prevent generic drug companies from creating the bioequivalents. Without access to the drugs, a competing drug company just cannot submit an application to the FDA to manufacture the drug. There are other concerns as well. The fact is that putting it into a limited distribution chain allows the drug company to find out very detailed information about who's taking that specific drug. Because there's only one distributor, it's possible to track every single patient using that drug. So patient confidentiality is very much compromised.

There's other problems as well. Working at a hospital, what I know is for most drugs you can get the drugs 24/7. All the wholesalers make them available. But when there's a limited distribution

chain, that may not be true because they may not be working 24/7.

There is the lack of Federal guidance on when drugs can be put into one of these limited networks, if the decision is left to the pharmaceutical company, if it's not part of REMS. And they're doing it for financial, not safety reasons as in most cases.

We at Johns Hopkins are assembling an inventory of drugs that are being dispensed in these limited distribution chains and the characteristics of them. We're looking at whether or not the price increases when they're put into a limited distribution network. And hopefully, in a couple of weeks, we'll be able to provide the committee some more information.

So we have three policy recommendations for the committee to consider: The first one is what Congressman Welch essentially has proposed, which is to limit the drugs placed in limited distribution networks to only the REMS drugs. If the Congress doesn't think that this is appropriate, a second alternative is to require drug companies to sell their products to all competitors. And the third one is to have it announced when they're putting it into a REM—into a limited distribution network when they put an application into the FDA.

For me, the main problem, besides the issue of access, is the issue of confidentiality.

We're also looking at another alternative, and that's creating a nonprofit drug company to compete against these activities. So they would only focus on drugs where there are no competition, and they would only focus on where there's been very rapid price increases. The hospitals, everybody's getting clobbered by this, and we need an alternative.

I'm happy to answer any questions.

[Prepared statement of Mr. Anderson follows:]

JOHNS HOPKINS

The Center for Hospital Finance and Management
624 North Broadway,Room 304
Baltimore MD 21205
410-955-3241 / Fax 410-955-2301

March 22, 2017

Members of the Committee, thank you for inviting me here today. My name is Gerard Anderson and I am a professor at Johns Hopkins University Schools of Public Health and Medicine. I am not here representing Johns Hopkins University, but testifying in my role as a Professor.

Currently, I am working on the issue of drug pricing with a team of faculty from Johns Hopkins as part of a grant from the Arnold Foundation and the Commonwealth Fund. I have not received any funding from pharmaceutical companies, drug wholesalers, health insurance companies or any other entities involved in the pharmaceutical supply chain.

Last December, I had the opportunity to testify at the Senate Aging Committee on how certain off - patent drug companies were raising their prices when there were no competitors. Your committee had Martin Shkreli and others testify on similar issues.
http://www.aging.senate.gov/imo/media/doc/SCA_Anderson_12_9_15.pdf

In my testimony at the Senate Aging Committee, I focused on three approaches that would create more competition in the generic industry. The overall goal of these three approaches was to deter pharmaceutical companies, such as Turing Pharmaceuticals (Martin Shkreli) from dramatically raising the prices on their drugs.

Since it is the absence of competition in the market place for a particular drug that enables a drug company to get away with exorbitant price increases, my first recommendation was to promote additional competition by allowing the FDA to offer an expedited review process for generic drug companies. My first recommendation was to allow companies seeking to enter the market to get an expedited review path at the FDA, making it more likely that the generic company would indeed enter the market. It would reduce the amount of time that any given company could maintain a monopoly position.

The second recommendation was to allow the original branded company that received the original FDA approval to import the drug into the US. This applies if the original banded company is still making the drug overseas. For example, GlaxoSmithKline (GSK), the original patent holder of the Turing Pharmaceutical drug, daraprim, manufactures the drug in the UK and sells it in the UK for only a few dollars.

My third recommendation is to allow compounding, but only for off-patent drugs that do not have any competitors. However, this only applies in situations where there is no competition and is done by reputable compounders approved by the FDA.

Along with two of my colleagues at Johns Hopkins, Jeremy Greene and Joshua Sharfstein, I published an article in JAMA providing more detail about these recommendations. Greene, Jeremy A., Gerard Anderson, and Joshua M. Sharfstein. "Role of the FDA in affordability of off-patent pharmaceuticals." *JAMA* 315.5 (2016): 461-462.

Senators Collins and McCaskill have adopted some of the recommendations in proposed legislation and the FDA has issued a policy statement stating that they will use expedited review in certain cases (http://www.congress.gov/bill/114th-congress/senate-bill/2615/text).

In preparing my Senate testimony, I became aware of the problems created by off-patent drug companies using limited distribution networks as a way to keep generic companies from copying their drugs and competing with them. However, it was necessary for the Congress to discover additional information using their investigative powers before the seriousness of this issue became apparent.

The Senate Aging Committee released a report that summarizes how certain off-patent drug companies have used limited distribution networks to stifle competition. https://www.aging.senate.gov/press-releases/collins-mccaskill-release-committee-report-of-bipartisan-drug-pricing-investigation. As a result of this report, we began looking into how limited distribution networks are corrupting the distribution process.

Limited distribution networks

Nearly all drugs are sold to patients through retail or nail order pharmacies, hospitals. Large wholesalers like McKesson, Cardinal and Amerisource Bergen distribute these drugs. They compete against each other and, as a result, the actual cost of distributing the drugs is very low. In contrast, specialty distributors are the sole source for certain drugs. They distribute a small, but rapidly increasing, number of drugs. This creates several problems.

In conducting our investigations, the first thing that we learned is that there is very little data on which drugs are distributed by these limited distribution networks. The FDA created the first limited distribution networks to protect patients. However, this original intent has been abused and safety is not the primary objective when some off- patent drug companies now use limited distribution networks.

The Food and Drug Administration Amendments Act of 2007 gave the Food and Drug Administration (FDA) the authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers in very certain circumstances. REMS is an approach to manage a drug or biological product with a known or potential serious risk in order to ensure that the benefits of the drug or biological product outweigh its risks. In short, REMS is a "safety strategy" to manage known or potential risks. This makes good clinical sense since some drugs can be dangerous without proper handling.

Each Risk Evaluation and Mitigation Strategy is unique and targets a particular drug or drug class. The FDA may determine that a REMS program is necessary at any time, including before or after a drug is approved. All REMS are required to have a timetable for submission of assessments that evaluate the REMS' effectiveness. In addition to the timetable of assessments, the REMS may contain any

combination of four other components: a medication guide or patient package insert, a communication plan, elements to assure safe use, and an implementation system.

FDA maintains on its website a list of drugs that are required to have a REMS.
http://www.accessdata.fda.gov/scripts/cder/rems/.

The FDA places these drugs on the REMS list for very specific reasons. Many biologics (drugs that mimic the compounds used in the body) are placed on the REMS list because they are often living cells or other compounds that can degrade quickly. Some of them require special handling because, for example, they are heat sensitive or susceptible to microbial contamination. All of this makes clinical sense and the FDA REMS program should be continued.

The problem is that some drug companies have used the REMS concept for their own benefit when they created limited distribution networks. The objective was not safety but profit.

Abuse of the REMS System

A few drug manufacturers quickly learned that selling drugs through limited distribution networks has advantages. In response, wholesalers saw the market opportunity and created limited distribution networks. Many of the large wholesale companies also offer limited distribution networks as subsidiaries.

One of the most visible examples is the way that Martin Shkreli and Turing Pharmaceuticals used specialty distribution networks to keep other companies from copying and manufacturing darapriam, a drug that had been off- patent for over 50 years. A second very visible example is Valeant Pharmaceuticals. Valeant created its own exclusive relationship with the online specialty pharmacy, Philidor, which has been the subject of considerable investigation by Congress.

Examples of other drugs that are less well known, but have seen rapid price increases and also use limited distribution networks are H.P. Acthar Gel (corticotropin injection) and Emflaza (deflazacort).

H.P. Acthar Gel was approved for use in treatment of multiple sclerosis and infantile spasms. It has been off- patent since 1952. There was a drug shortage issue due to manufacturing and stability in the late 90's. Questcor used this shortage to raise the price from $1,650 to $23,000 overnight in 2007 when they purchased the drug from another company. They stated the reason for increase was 'really, our only principle market is infantile spasms."
http://www.nytimes.com/2012/12/30/business/questcor-finds-profit-for-acthar-drug-at-28000-a-vial.html?ref=health
The drug was later purchased by Mallinckrodt, and now the wholesale acquisition cost is over $40,000 per vial.
http://www.fiercepharma.com/special-report/h-p-acthar-gel-questcor-mallinckrodt

The D FDA does not require a REMS for H.P. Acthar Gel. The limited distribution network was selecIted by the company and is only available through limited distribution networks (Acthar Support and Access Program (A.S.A.P.)) and not through traditional distribution wholesalers. After treatment is initiated, prescriptions must be submitted to the Acthar Support and Access Program in order to ensure an uninterrupted supply of the medication.
https://www.pparx.org/prescription_assistance_programs/hp_acthar_gel_patient_assistance_program

The FDA recently approved Marathon Pharmaceutical's steroid deflazacort (brand name Emflaza) with orphan drug designation for treatment of Duchenne muscular dystrophy.

Patients had been importing this drug from the UK for approximately $1,500-$2,000 annually for many years. Marathon planned to launch the drug with a list price of $89,000 annually, defending its price by pointing to the prices of other orphan drugs that often exceed several hundred thousand dollars annually.

The distributor for deflazacort is expected to be LGM Pharma, another specialty distribution network.
http://lgmpharma.com/product/deflazacort/
The drug has not been distributed in the US yet because Marathon delayed the launch of deflazacort after widespread outrage over their pricing plan, including two Senate requests for justification of the exorbitant list price.

Details on this relationship can be found in these WSJ articles:
https://www.wsj.com/articles/marathon-pharmaceuticals-to-charge-89-000-for-muscular-dystrophy-drug-1486738267

https://www.wsj.com/articles/lawmakers-probing-firms-decision-to-charge-89-000-for-muscular-dystrophy-drug-1487006652

Problems Created by the Limited Distribution Networks

Perhaps the biggest problem is that some drug companies have used limited distribution networks to prevent generic drug companies from getting access to the drug and developing another generic version to increase competition. Essentially, they accomplish this by allowing only one wholesaler to distribute the drug. The wholesaler then makes sure that competing companies do not have access to the drug and so they cannot copy it. As a result, they are unable to submit an abbreviated new drug application (ANDA) to the FDA.

There are other concerns with limited distribution networks. One is access to patient information by the drug company. Placing a drug on a limited distribution network provides the drug company additional information about each patient taking the drug. Because there is only one distributor, it is possible to track every single patient using this drug and find out detailed information about that specific patient. Patient privacy is compromised since the drug company can have access to personal information about a specific patient. With multiple wholesalers, this is not possible.

The limited distribution network does allow the drug company to help patients who cannot afford the drug to receive financial assistance. The advantage of this is that the patient with limited financial means can more easily obtain financial assistance. The problem, however, is that financial assistance programs can steer patients to more expensive or less effective drugs. This undermines the efforts of PBMs, health plans, and corporations to steer patients to the most effective and least costly drugs.

There are other problems created by these limited distribution networks. For most drugs, there are a multitude of wholesalers that can provide the drugs 24/7. For hospitals and physicians immediate access to certain drugs is essential to the health and safety of the patient. However, many of these limited distribution networks do not operate 24/7 and so there is a lag in obtaining access to these drugs that

can have devastating implications for patients.

In addition, placing these drugs in a limited distribution network prevents competition, since there is only one supplier. Suppliers and PBMs compete against each other to get the lowest prices, but when there is only one limited distribution network, there is no competition. The drugs placed on limited distribution networks typically have higher distribution costs.

Government programs and limited distribution networks

The Medicare program contains certain provisions that limit the ability of drug companies to exploit limited distribution networks. Part D plans may not restrict access to Part D drugs to only specialty pharmacies in such a manner that restricts access. Part D plans are permitted to use restrict distribution networks when it is necessary to meet FDA limited distribution requirements or ensure the appropriate dispensing of Part D drugs (i.e., when the drug requires extraordinary special handling, provider coordination, or patient education, or when such extraordinary requirements cannot be met by a network pharmacy). If the drug is part of a limited distribution network in the 340B program operated by the Public Health Service, then the Public Health Service needs to be told about this in writing.

Challenges To Overcome

There is a lack of federal guidance regarding which medications can be a part of a limited distribution network; the decision is primarily at the discretion of the pharmaceutical company. Aside from the drugs that are part of the REMS program there is no federal guidance on which drugs can be placed into limited distribution networks. The problem is that some drug companies are placing drugs into limited distribution networks to maximize profits not to maximize safety.

We simply do not have all the data we need to identify all of the problems that limited distribution networks are creating. There is little empirical data on how many drugs are affected by limited distribution networks because this data is not routinely collected. We do not know how much this adds to the price of the drugs. However, we can see from the few examples with Turing Pharmaceuticals, Valeant, Mallinckrodt and Marathon that the magnitude of the price increases is significant.

As part of our research we are assembling an inventory of drugs that are dispensed in limited distribution networks and the characteristics of these medications. We are examining whether prices increase when the drug is placed in a limited distribution network. Finally, we are examining the restrictions that are imposed on limited distribution drugs and how they affect other generic drug companies, hospitals, physicians and ultimately patients. Hopefully we will be able to provide the Committee more information at a later date.

Policy Options For the Committee to Consider

We have three policy recommendations for the Committee to consider:

1. The most restrictive is to limit the drugs placed on limited distribution networks to REMS drugs.

2. A less restrictive alternative is to require drug companies using limited distribution networks to sell their product to all competitors
3. The least restrictive alternative is to require drug companies using limited distribution networks to announce this when they submit the new drug applications to the FDA

We are also looking at different alternatives. One possibility is to create a non-profit drug company that would manufacture off- patent drugs that did not have any competitors. We are working with a group of large hospitals and managed care plans to set up a non-profit drug company to manufacture a limited set of drugs. The non-profit company would specialize in manufacturing off-patent drugs without any competitors where there have been unjustified large price hikes.

I am happy to answer any questions

Mr. WALKER. Thank you, Dr. Anderson.
Mr. Mitchell, we recognize you now for 5 minutes.

STATEMENT OF DAVID MITCHELL

Mr. MITCHELL. Mr. Chairman, members of the committee, thank you very much for inviting me here today. I'm David Mitchell. I'm founder of Patients for Affordable Drugs. We're a national organization focused exclusively on policies to lower prescription drug prices. To maintain our independence, we don't accept funding from any organizations that profit from the development and distribution of prescription drugs. We're about patients first, last, and always.

More importantly, for the committee, I'm a relapsed cancer patient with multiple myeloma. It's an incurable blood disease. Drugs are keeping me alive, and because my cancer finds its way around drugs, I'm going to need new ones. So the importance of innovative, affordable drugs is not theoretical for me; it's literally life and death.

I hope to watch my youngest son graduate from high school in 3 years, and to have one of my older kids give me a grandchild one day. I'm very grateful for the drugs produced by the science and research sector in our country. But lifesaving drugs have to come at prices that'll bankrupt patients and ruin the lives of people who are struggling to maintain their health.

Yesterday, I sat in an infusion room for almost 5 hours and I received a two-drug combination that costs more than $26,000 a month. Prior to this drug regime, I took Revlimid, made by Celgene, for 5–1/5 years, and I participated in a risk evaluation and mitigation program.

I obtain my drugs only from specific specialty pharmacies. And each month, I received counseling on the dangers of this drug and I participated in a survey designed to remind me of those dangers. The counseling consisted of a nurse reading a list of cautions to me. The survey was an automated phone call, press 1 for yes, 2 for no, and the whole process took 5 to 10 minutes. It could easily have been duplicated by any generic manufacturer. It wasn't rocket science.

Of course, during the same period, Celgene was doing its best to delay generic versions of the drug by hiding behind its restricted distribution system and REMS, refusing to give samples to generic drugmakers. Here's what that meant for me: My out-of-pocket cost for Revlimid went from $42 a month in 2011 to $250 a month by the time I had to stop taking it last year because of side effects. As you can see from this invoice, the retail price for one 4-week cycle of Revlimid is $10,691, more than $500 per capsule. Now, I'm lucky. At the time, I had good employer-provided insurance. I'm on Medicare now. But Medicare beneficiaries aren't always so fortunate. They're paying thousands of dollars out of pocket every year. It is the most expensive out-of-pocket Medicare drug.

Members of the committee, that's the impact of REMS abuse for real people, and it's a part of the problem with drug prices in America. Patients are foregoing their medications, they're spending their retirement funds and their kid's college savings when a generic competitor sits right around the corner.

In 2016, Revlimid accounted for 62 percent of Celgene's revenue. Revlimid is key to propping up its stock price. It's clear to me that Celgene is gaming our system, or as the chairman said in his opening remarks, manipulating the regulatory framework. It's using bogus pretext of risk evaluation mitigation to unlawfully deny samples to generic manufacturers in order to prevent them from developing a cheaper alternative. It's blocking market competition. We need to reform the law and stop these abuses.

But speeding generics to market will only address a fraction of the problem of high drug prices. The problem is that instead of a competitive free market for prescription drugs, we have a system of monopoly pricing by the drug companies through government policy. We have pharmacy benefit manager middlemen who process billions in drugs each year but who keep all their deals secret.

As President Trump has said, and 82 percent of Americans agree, it's time to allow Medicare to negotiate prices for drugs on an open market instead of allowing drug companies to act as monopolies. I also believe that requiring transparency into PBMs and into prices set when a drug is invented using taxpayer funding would go a long way to making drugs more affordable. And we should set prices based on the value they deliver to patients.

I'm extremely encouraged that members on both sides of the aisle are focusing on drug prices. In my experience, the most enduring legislative successes in our country have come with bipartisan action.

Thank you for your attention.

[Prepared statement of Mr. Mitchell follows:]

PATIENTS FOR AFFORDABLE DRUGS™

Statement of David E. Mitchell

Founder, Patients For Affordable Drugs

before the

U.S. House of Representatives Committee on Oversight and Government Reform, Subcommittee on Health Care, Benefits, and Administrative Rules

on

"Examining the Impact of Voluntary Restricted Distribution Systems in the Pharmaceutical Supply Chain"

March 22, 2017

Mr. Chairman, Members of the Committee, thank you for inviting me here today.

I am David Mitchell. I am the founder of Patients For Affordable Drugs, a national patient organization focused exclusively on policies to lower prescription drug prices. To maintain our independence, we do not accept funding from any organizations that profit from the development or distribution of prescription drugs. We are about patients first, last, and always.

My wife is a cancer survivor. She and I contributed seed money to the effort. And we received a grant from the Laura and John Arnold Foundation. I retired to devote myself to this cause, and I work for free.

More importantly for the committee, I am a relapsed cancer patient with multiple myeloma—an incurable blood disease. Drugs are keeping me alive. And because my cancer finds its way around drugs, I need new ones. So the importance of innovative, affordable drugs is not theoretical for me—it's life and death.

I hope to watch my youngest son graduate from high school in three years and to have one of my older kids give me a grandchild one day. I am *very grateful* for the drugs produced by the science and research sector in our country. But life-saving drugs must come at prices that don't bankrupt patients and ruin the lives of people struggling to maintain their health.

Yesterday, I sat in an infusion room for almost five hours receiving a two drug combination that costs more than $26,000 per month.

Prior to this drug regime, I was on Revlimid for five-and-a-half years, and I participated in Celgene's Risk Evaluation and Mitigation program. I obtained my drugs only from specific

specialty pharmacies. Each month, I received counseling on the risks of the drug, and I participated in a survey designed to remind me of those risks—the most dangerous is birth defects if I impregnated a woman while taking Revlimid.

The counseling under the program consisted of a nurse reading a list of cautions to me. The survey was an automated phone call—press one for yes and two for no. The whole process took 5-10 minutes. It could have been easily duplicated by any generic manufacturer. It wasn't rocket science.

Of course, during this same period, Celgene was doing its best to delay generic versions of the drug by hiding behind its restricted distribution system and REMS—refusing to give samples to generic drug makers. Here's what that meant for me: My out-of-pocket cost for Revlimid went from $42 a month in 2011 to $250 a month by the time I had to stop taking it last year because of side effects. As you can see from the attached bill, the retail price for one four-week cycle of Revlimid is $10,691—more than $500 per capsule.

I am lucky. I had good employer-provided insurance. But Medicare beneficiaries aren't always so fortunate. The median out-of-pocket cost for a Medicare beneficiary taking Revlimid is $11,500 per year. It is the most expensive Medicare drug.

Members of the committee, that's the impact of REMS abuse, and it's part of the problem with drug prices in America. Patients are forgoing their medications—they are spending their retirement funds and emptying their kids' college savings to afford drugs when a generic competitor sits around the corner.

In 2015, Celgene reported $1.6 billion in profits. Revlimid accounted for 63 percent of its revenue. Revlimid is key to propping up its stock price.

It's clear to me that Celgene is gaming our system. It is using the bogus pretext of Risk Evaluation and Mitigation to unlawfully deny samples to generic manufacturers in order to prevent them from developing a cheaper alternative. It is ripping off patients and taxpayers while blocking market competition.

Let me make the comparison more stark: The median income of a Medicare beneficiary is about $24,000 per year. The median out-of-pocket cost for Revlimid is $11,500 per year. But the CEO of Celgene—Robert Hugin—was paid almost $100 million dollars over three years. That is like a direct income transfer from the patient on Medicare to Mr. Hugin. It is just plain wrong. But they promoted him to Executive Chairman. Job well done.

We need to reform the law to stop these abuses. But speeding generics to market will only address a fraction of the problem of high drug prices.

The problem is that instead of a competitive free market for prescription drugs, we have a system of monopoly pricing by the drug companies enforced through government policy. We have pharmacy benefit manager middlemen who process $323 billion in drugs each year—but who keep all their deals secret.

As President Trump has said–and 82% of Americans agree[1]–it is time to allow Medicare to negotiate prices for drugs on an open market instead of allowing drug companies to act as monopolies. I also believe that requiring transparency into PBMs and into prices set when a drug is invented using taxpayer funding would go a long way toward making drugs more affordable. And we should set prices based on the value drugs deliver to patients.

Finally, as a patient completely dependent on innovation and new drugs for my survival, I know we can have innovation and new drugs while reducing prices. Drug corporations try to scare patients by saying that they must have high profits or they will stop investing in research. But independent analyses show that while drug companies spend at best a few pennies of every dollar of revenue on basic research, they spend 20-40 cents on marketing and advertising[2,3]. The pharmaceutical industry is among the most profitable in the U.S. And health care and drug company executives are the highest compensated in the U.S. More than half of new drugs that come to market are based on breakthroughs in science paid for by taxpayers through NIH and academic medical centers.

Drug corporations can lower prices, pay for research and development and still provide a healthy return to shareholders. But it won't happen until we break the government enforced monopoly pricing power of the pharmaceutical industry, gain transparency on the part of PBMs, and restore competition in a free market that benefits patients, consumers and taxpayers.

I am extremely encouraged that members on both sides of the aisle are focused on drug prices. In my experience, the most enduring legislative successes in our country have come with bipartisan action. Thank you for your attention.

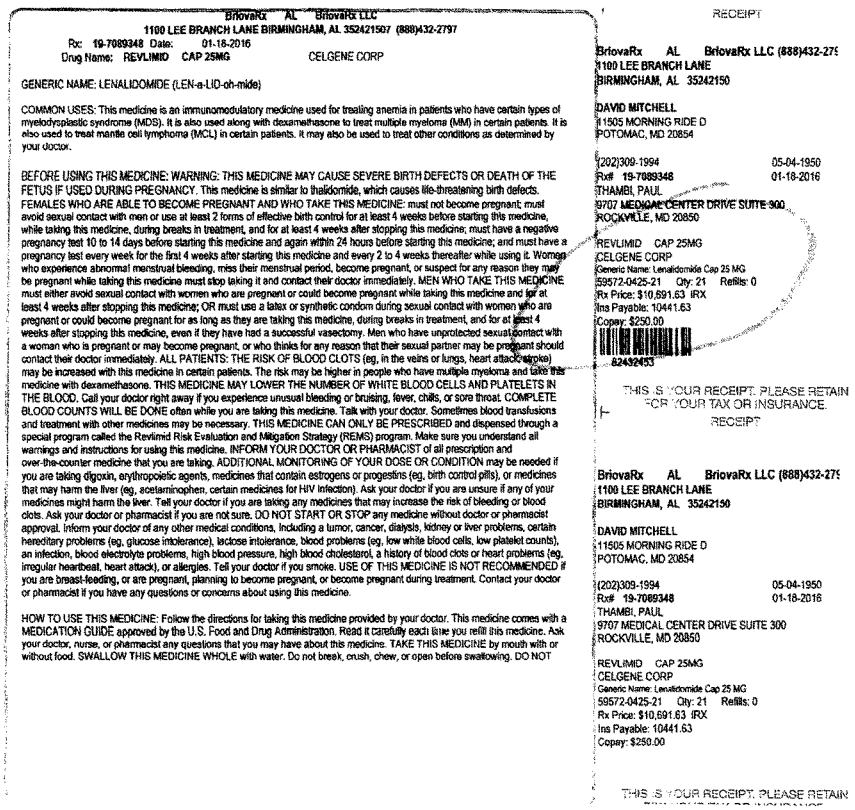
---

[1] Cubanski, Juliette, and Tricia Neuman. "Searching for Savings in Medicare Drug Price Negotiations." Kaiser Family Foundation, 23, Jan. 2017. Web. 20 Mar. 2017.

[2] Kantarjian, Hagop, and Vivian Ho. "The Harm of High Drug Prices." U.S. News & World Report, 12 Dec. 2016. Web. 20 Mar. 2017.

[3] Yu, Nancy, Zachary Helms, and Peter Bach. "R&D Costs For Pharmaceutical Companies Do Not Explain Elevated US Drug Prices." Health Affairs. N.p., 7 Mar. 2017. Web. 20 Mar. 2017.

Attachment 1:



BrivaRx AL BrivaRx LLC
1100 LEE BRANCH LANE BIRMINGHAM, AL 352421507 (888)432-2797
Rx: 19-7089348 Date: 01-18-2016
Drug Name: REVLIMID CAP 25MG CELGENE CORP

GENERIC NAME: LENALIDOMIDE (LEN-a-LID-oh-mide)

COMMON USES: This medicine is an immunomodulatory medicine used for treating anemia in patients who have certain types of myelodysplastic syndrome (MDS). It is also used along with dexamethasone to treat multiple myeloma (MM) in certain patients. It is also used to treat mantle cell lymphoma (MCL) in certain patients. It may also be used to treat other conditions as determined by your doctor.

BEFORE USING THIS MEDICINE: WARNING: THIS MEDICINE MAY CAUSE SEVERE BIRTH DEFECTS OR DEATH OF THE FETUS IF USED DURING PREGNANCY. This medicine is similar to thalidomide, which causes life-threatening birth defects. FEMALES WHO ARE ABLE TO BECOME PREGNANT AND WHO TAKE THIS MEDICINE: must not become pregnant; must avoid sexual contact with men or use at least 2 forms of effective birth control for at least 4 weeks before starting this medicine, while taking this medicine, during breaks in treatment, and for at least 4 weeks after stopping this medicine; must have a negative pregnancy test 10 to 14 days before starting this medicine and again within 24 hours before starting this medicine; and must have a pregnancy test every week for the first 4 weeks after starting this medicine and every 2 to 4 weeks thereafter while using it. Women who experience abnormal menstrual bleeding, miss their menstrual period, become pregnant, or suspect for any reason they may be pregnant while taking this medicine must stop taking it and contact their doctor immediately. MEN WHO TAKE THIS MEDICINE must either avoid sexual contact with women who are pregnant or could become pregnant while taking this medicine and for at least 4 weeks after stopping this medicine; OR must use a latex or synthetic condom during sexual contact with women who are pregnant or could become pregnant for as long as they are taking this medicine, during breaks in treatment, and for at least 4 weeks after stopping this medicine, even if they have had a successful vasectomy. Men who have unprotected sexual contact with a woman who is pregnant or may become pregnant, or who thinks for any reason that their sexual partner may be pregnant should contact their doctor immediately. ALL PATIENTS: THE RISK OF BLOOD CLOTS (eg, in the veins or lungs, heart attack, stroke) may be increased with this medicine in certain patients. The risk may be higher in people who have multiple myeloma and take this medicine with dexamethasone. THIS MEDICINE MAY LOWER THE NUMBER OF WHITE BLOOD CELLS AND PLATELETS IN THE BLOOD. Call your doctor right away if you experience unusual bleeding or bruising, fever, chills, or sore throat. COMPLETE BLOOD COUNTS WILL BE DONE often while you are taking this medicine. Talk with your doctor. Sometimes blood transfusions and treatment with other medicines may be necessary. THIS MEDICINE CAN ONLY BE PRESCRIBED and dispensed through a special program called the Revlimid Risk Evaluation and Mitigation Strategy (REMS) program. Make sure you understand all warnings and instructions for using this medicine. INFORM YOUR DOCTOR OR PHARMACIST of all prescription and over-the-counter medicine that you are taking. ADDITIONAL MONITORING OF YOUR DOSE OR CONDITION may be needed if you are taking digoxin, erythropoietic agents, medicines that contain estrogens or progestins (eg, birth control pills), or medicines that may harm the liver (eg, acetaminophen, certain medicines for HIV infection). Ask your doctor if you are unsure if any of your medicines might harm the liver. Tell your doctor if you are taking any medicines that may increase the risk of bleeding or blood clots. Ask your doctor or pharmacist if you are not sure. DO NOT START OR STOP any medicine without doctor or pharmacist approval. Inform your doctor of any other medical conditions, including a tumor, cancer, dialysis, kidney or liver problems, certain hereditary problems (eg, glucose intolerance), lactose intolerance, blood problems (eg, low white blood cells, low platelet counts), an infection, blood electrolyte problems, high blood pressure, high blood cholesterol, a history of blood clots or heart problems (eg, irregular heartbeat, heart attack), or allergies. Tell your doctor if you smoke. USE OF THIS MEDICINE IS NOT RECOMMENDED if you are breast-feeding, or are pregnant, planning to become pregnant, or become pregnant during treatment. Contact your doctor or pharmacist if you have any questions or concerns about using this medicine.

HOW TO USE THIS MEDICINE: Follow the directions for taking this medicine provided by your doctor. This medicine comes with a MEDICATION GUIDE approved by the U.S. Food and Drug Administration. Read it carefully each time you refill this medicine. Ask your doctor, nurse, or pharmacist any questions that you may have about this medicine. TAKE THIS MEDICINE by mouth with or without food. SWALLOW THIS MEDICINE WHOLE with water. Do not break, crush, chew, or open before swallowing. DO NOT

RECEIPT

BrivaRx AL BrivaRx LLC (888)432-27
1100 LEE BRANCH LANE
BIRMINGHAM, AL 35242150

DAVID MITCHELL
11505 MORNING RIDE D
POTOMAC, MD 20854

(202)309-1994 05-04-1950
Rx# 19-7089348 01-18-2016
THAMBI, PAUL
9707 MEDICAL CENTER DRIVE SUITE 300
ROCKVILLE, MD 20850

REVLIMID CAP 25MG
CELGENE CORP
Generic Name: Lenalidomide Cap 25 MG
59572-0425-21 Qty: 21 Refills: 0
Rx Price: $10,691.63 IRX
Ins Payable: 10441.63
Copay: $250.00

82432453

THIS IS YOUR RECEIPT. PLEASE RETAIN FOR YOUR TAX OR INSURANCE.

RECEIPT

BrivaRx AL BrivaRx LLC (888)432-27
1100 LEE BRANCH LANE
BIRMINGHAM, AL 35242150

DAVID MITCHELL
11505 MORNING RIDE D
POTOMAC, MD 20854

(202)309-1994 05-04-1950
Rx# 19-7089348 01-18-2016
THAMBI, PAUL
9707 MEDICAL CENTER DRIVE SUITE 300
ROCKVILLE, MD 20850

REVLIMID CAP 25MG
CELGENE CORP
Generic Name: Lenalidomide Cap 25 MG
59572-0425-21 Qty: 21 Refills: 0
Rx Price: $10,691.63 IRX
Ins Payable: 10441.63
Copay: $250.00

THIS IS YOUR RECEIPT. PLEASE RETAIN

Mr. WALKER. Thank you, Mr. Mitchell.

Thank you all on the panel for being here today.

I will at this time recognize myself for 5 minutes. I'd like to start with Mr.—is it Leicher? Is it the long A?

Mr. LEICHER. It's Leicher.

Mr. WALKER. Leicher. Okay. All right. I missed it in two areas then.

Mr. Leicher, in 2014, the trade association representing generic manufacturers commissioned a study showing that the annual cost of misuse of restricted distribution systems to delay generic market entry was about $5.4 billion annually. The estimated cost to the Federal Government was $1.8 billion.

In the past few years, has Momenta Pharmaceuticals encountered more difficulty accessing samples or have they encountered less difficulty? Could you answer that, please?

Mr. LEICHER. So we've encountered more difficulty accessing samples, because what I think has happened is companies have found that the law is not being enforced that exists today, and that the litigation that's been brought against them for engaging in these activities has been able to delay access.

Mr. WALKER. In your testimony, you said that at times when you have tried to purchase samples from wholesalers, they ask you if you are conducting generic or biosimilar studies. And when you respond yes, they tell you their contract prohibits them from selling samples to you. Do you then go to the manufacturer or try to obtain samples? And if so, how do they respond? Would you break that down, first?

Mr. LEICHER. Yes, I'd be happy to. So we would go to a wholesaler typically to buy the product. And for many products, we're able to buy the product, because there's just certain companies that are engaging in these practices. We have chosen to go and develop other products in cases where we haven't been able to purchase from the wholesaler, just because we had other options for development available given our size.

It would be—we don't believe that we would have—we believe we would have ended up in protracted negotiations if we had gone to the manufacturer, based on our experience with talking to other companies.

Mr. WALKER. Just a couple more questions. Are these expensive products that have been off patent for a while?

Mr. LEICHER. These are all products that we designed in the development program to launch when the patents expire. That's the intent of the biosimilar law in Hatch-Waxman. You access the product near the end of the patent life to do the development, and then you prepare to launch at the time the patents are over.

Mr. WALKER. Okay. Well, I think it's pretty clear. I appreciate your articulation. I guess my last question would be how do we fix the problem?

Mr. LEICHER. Well, we think the best way to fix the problem is to—and there are proposals in terms of the FAST Generics Act and the CREATES Act in the Senate—is to recognize more explicitly that a condition of an FDA approval is a recognition that products will be sold on commercially reasonable terms to generic and bio-

similar companies so that we can fulfill the promise of Hatch-Waxman and the promise of the biosimilar law.

Mr. WALKER. Thank you, Mr. Leicher.

At this time, I'm going to yield 5 minutes to Mr. Krishnamoorthi. Are we getting closer? I know we're still working on that.

Mr. KRISHNAMOORTHI. Pretty close.

Mr. WALKER. Okay.

Mr. KRISHNAMOORTHI. Call me Raja.

Mr. Mitchell, thank you again for appearing before the subcommittee and sharing your very personal experience with us. As we heard in your testimony, you've experienced rising prescription drug prices in a deeply personal way through your battle with cancer. You described your experience with one drug in particular, Revlimid, which is made by the drug company Celgene. Celgene has been accused of improperly using its restricted distribution systems to prevent would-be generic competitors from getting access to samples of Revlimid which they need to eventually get FDA approval.

In fact, the FTC warned, in a 2014 amicus brief filed in a lawsuit against Celgene, quote, "If a brand firm can effectively block generic firms from accessing brand product for bioequivalence testing, it may be able to continue to prevent generic competition, even after its patents on these products expire."

So we're really talking about a time period after the patents expire. The FTC also warned that this practice could, quote, "undermine the core principle of the patent system that patents have a limited duration."

Mr. Mitchell, what does the prospect of generic competition mean to you as a patient?

Mr. MITCHELL. It means lower prices for drugs that will work just as well as the brand name drugs that are being given to me and other patients.

Sticking with Revlimid, the Kaiser Family Foundation reports that the median out-of-pocket cost for a Medicare part D beneficiary on Revlimid is $11,500 a year. This is from a company that runs profits in the high 20s and paid its CEO almost $100 million over the last 3 years. So there's room there to lower the price and continue investment in R&D, produce a good return for investors, but lower the cost for patients for a drug that will work equally well.

Mr. KRISHNAMOORTHI. Well, the interesting thing about what you said is that your out-of-pocket expenses are almost $12,000 a year. Think of what it's costing Medicare to provide these drugs to yourself. I mean, this is why Medicare is going to go bankrupt if we don't get control of these prescription drug prices.

Mr. MITCHELL. Well, and it's not only Medicare; it's employers——

Mr. KRISHNAMOORTHI. Right.

Mr. MITCHELL. —who are trying to provide good health benefits to their employees. When they're confronted with rising costs like this, it becomes increasingly difficult to provide the benefits that people need at prices that they can afford.

Mr. KRISHNAMOORTHI. Absolutely, you're right. It's going to bankrupt, you know, our healthcare system, these prescription drug prices rising as fast as they are.

Dr. Anderson, I know you researched restricted distribution systems in-depth. In addition to blocking generic competition, how are these restricted distribution systems harmful to the drug market as a whole?

Mr. ANDERSON. Well, essentially what they do for a patient perspective is that they gather all sorts of information about you when it's on one of these restricted—so they know exactly what Mr. Mitchell's circumstances are. So they have all the information they want to know about him. And you might think that is fine; I am actually very concerned about the privacy type of issues that are involved with this.

And as a hospital, it's very difficult sometimes to access these drugs. Most drugs are available very easily when you need them. And, you know, Cardinal is coming to Johns Hopkins, one of the big wholesalers, every day with truckloads of drugs. But when you're on a limited distribution chain, you might not get it for several days. And if you need that drug on a Saturday, you might not get it. So there are patient safety issues in these concerns as well.

Mr. KRISHNAMOORTHI. Dr. Anderson, can you estimate or do you have an idea, a ballpark estimate, of how many drugs are, you know, in this kind of bucket of drugs that are basically being—flowed through the restricted distribution systems in this kind of what I believe to be an anticompetitive fashion?

Mr. ANDERSON. We don't know an exact number, but we think it's somewhere in the 150 to 250 range. And what we know is that the investment bankers know exactly who it is, and that's where the Martin Shkrelis and other people are looking for these kinds of things where there are no, in fact, competitors and they're going out and buying those particular activities. So it's a market opportunity for the investment banking community.

Mr. KRISHNAMOORTHI. Thank you, sir. Thank you very much.

Mr. Chairman, I yield back.

Mr. WALKER. Thank you very much.

We usually would rotate back to the gentleman from Wisconsin. Mr. Grothman, would you be okay if I yielded time to our overall ranking member on the committee? We'll come back to you after that and put you back into sequence.

Mr. GROTHMAN. Well, it depends who the overall ranking member is.

Mr. WALKER. It would be Mr. Elijah Cummings.

Mr. GROTHMAN. Well, sure.

Mr. WALKER. Mr. Cummings, you're recognized for 5 minutes.

Mr. CUMMINGS. Thank you very much, Mr. Chairman.

Mr. Chairman, the issue—and I want to thank the ranking member and you, Mr. Chairman, for this hearing.

The issue of drug prices has been one of my top priorities for the past several years. As a matter of fact, just last week, Congressman Welch and I, along with the president of Johns Hopkins Hospital met with President Trump on this issue. And I appreciate that Chairman Chaffetz has worked with me in a bipartisan man-

ner at the full committee level to address this issue, which affects all of our constituents.

We all agree that innovation is key, especially when it comes to prescription drugs that save lives. We rely on drugs to help us fight disease, and we want pharmaceutical companies to develop the next cure. We also want them to make a reasonable profit. We also expect drug companies to make a profit. In fact, the pharmaceutical industry has been one of the most profitable industries in America.

Mr. Mitchell, I thank you for your testimony. And I'm going to make sure that President Trump hears your testimony, because you're right. I mean, he gets it, he really does. And I think your testimony is jarring, because there are a lot of people that are going through what you're going through. And I thank God that you take your pain, turned it into a passion to do your purpose. To do your purpose. And I appreciate it. And I really mean that.

But what have we seen year after year, investigation after investigation? Are drug companies exploiting the system and taking advantage of consumers like Mr. Mitchell, while making obscene profits at their expense? We've seen drug companies swoop into the market to buy old drugs and then jack up the price.

Mr. Mitchell, Shkreli sat where you sat, where you're sitting right now, and he basically called us imbeciles because we wanted to make sure that the American people could afford drugs that would keep them alive, keep them healthy. And then he took the Fifth and then, you know, sashayed out of here.

So going back, no R&D, no commitment to patients, just a cold, pricing strategy, designed to take advantage of a temporary monopoly. But one of the things that, I guess, bothers me with all of this, and when I look at you Mr. Mitchell, I—it bothers me that our country and certain industries, certain folks in the pharmaceutical industry don't mind something called collateral damage. In other words, people are unable to afford the drugs that they need. Why? Because of, in many instances, greed.

Shkreli is a perfect example. I know everybody is not like Shkreli. I know that. But there are a lot of Mr. Mitchells. There are a lot of you. As a mater of fact, I just met some ladies getting off the elevator who had been in my office who told me that for a certain disease, they were here lobbying, they said for a certain disease, I can't remember which one, she said 3 years ago it cost $8,000 a year, now it's $85,000 a year. Come on now. We are a country that is better than that.

And so we've obtained internal documents that exposes business strategy, and we have called drug company CEOs to come before the committee to justify their actions. But they never—this is the thing that gets me, Mr. Mitchell. You know what? They come, they do a song and a dance, they do the rope-a-dope, they talk about all these drug programs that they have for discounts, they sashay their way out of here, get on their planes, and they never lower the prices. Collateral damage. People left to get sicker. People left to die.

So we've seen this time and time again. And then they get upset when the stock prices go down. Oh, the stock prices—they make millions, while people are sitting right now, watching us, with chemo dripping through their veins, trying to figure out how

they're going to survive—not only how they're going to survive, but how are they going to do their daily chores. So, again, I hope that we don't just come, have a hearing, and then move on, because there's too much at stake.

With that, Mr. Chairman, I thank you for your indulgence, and I yield back.

Mr. WALKER. Thank you to the ranking member, Mr. Cummings.

With that, we'll yield 5 minutes to the gentleman from Wisconsin, Mr. Glenn Grothman.

Mr. GROTHMAN. Thank you.

I'm not sure which one I'll lead with. Maybe Mr. Leicher. I don't know if I got that right. Just in general, you know, there's a general perception out there, and I'm sure the government wouldn't do a very good job if they had to come up with these new drugs, but a general perception that, to me, both sometimes drugs are overprescribed and sometimes you wonder about the price.

I don't think you guys have looked at financial statements, but, obviously, a drug company, like any company, has expenses. Some of those expenses are the literal production of the drug. Some of those expenses are the research and approval of the drug. Some of those expenses are sales and promotion of the drug.

If somebody spends 10 bucks on a drug, do one of you folks give us a ballpark as to how much of that 10 bucks went into research, how much went into sales and marketing, how much went into administration, that sort of thing?

Mr. ANDERSON. So if you were talking about a brand company, not a generic company, then it's about 17—$1.70 for what goes into R&D and about $2.50 that would go into marketing, about $2.50 would be profit. Very little would actually be manufacturing, and the rest would be a variety of other things.

Mr. GROTHMAN. You still have 33 percent to go. Do you want to take a crack at the other 33 percent?

Mr. ANDERSON. Essentially—I'd have to come back to you on that.

Mr. GROTHMAN. Okay. Anybody else have a crack?

Mr. LEICHER. I'm not sure I can give better numbers than that. But what I would add to that is that from a generic and biosimilars business perspective where marketing is not a significant factor, and all the activities associated with commercialization are not a factor, that's what provides the opportunity for, in the generics business, up to an 80 percent reduction in price when there's multiple competitors entering the market when patents expire and, you know, estimates of, you know, initially, a 30 percent and perhaps more reduction of price for biosimilars.

Mr. GROTHMAN. And maybe you guys don't know. You say 25 percent is marketing. Do you know what that is compared to, say, the cell phone industry or the automotive industry? It doesn't have to be this high, but is it high?

Mr. ANDERSON. It is higher than most other industries, but I couldn't give you an exact number for all of those.

Mr. GROTHMAN. Okay. We'll fire away with some of the other more expected questions.

Dr. Anderson, what lessons have you learned from examining drug shortages that could be used to help address egregious situations like Turing?

Mr. ANDERSON. So, essentially, what you see is generally a two-pronged approach. One is a shortage occurs and it's very hard to get access to a drug. And then following that, what you see is a fairly steep price increase. So they take advantage of when there's a shortage. Often, it is when there are two companies that are manufacturing a drug and one of them stops manufacturing that drug, either because it's not profitable for them to do so anymore or they run into some production problem, and therefore they can't manufacture it. And what we're seeing is a lot of mergers in the generic space. And those things are cutting down the amount of competition. And so you're seeing that as a third problem.

Mr. GROTHMAN. Okay. What can we do to encourage more competition among generics?

Mr. ANDERSON. Well, essentially, what you need to do is to try to get them to—you've got to stop the mergers, is the first thing. And the second thing is to make it easier for them to—when there is no competition, to enter the market. And so that's why I proposed the expedited review by the FDA, which the FDA is starting to do now. So make it easier for a competitor to enter the market.

Mr. GROTHMAN. You said stop the mergers.

Mr. ANDERSON. Yep.

Mr. GROTHMAN. It does—in all industries, compared to when I was a child, it seems like everything is mergered into a few industries, but how many major drug manufacturers are operating now in the United States? Like if there should be a market for a new pharmaceutical, how many drug companies are out there who have the ability to develop the generic and market it?

Mr. ANDERSON. There are still a number, but what we saw last year is the number one generic firm acquired the number three generic firm in the United States. So we're seeing some mergers of very large generic companies occurring.

Mr. GROTHMAN. And when number one swallows number three, or vice versa, do you notice an increase in price?

Mr. ANDERSON. Well, you don't notice an increase in where there are not competitive drugs.

Mr. GROTHMAN. I mean, what I'm saying is I assume sometimes if one swallows three, that there now is no competition. I guess that's what I'm trying to get at.

Mr. ANDERSON. That's what I'm saying. You know, the generic industry works incredibly well when there are three, four competitors in the market. It looks less well when there are two, and it doesn't work at all when there's none.

Mr. GROTHMAN. Okay. I guess I'm well past my time. So thank you for the indulgence, Mr. Chairman.

Mr. WALKER. Thank you, Mr. Grothman.

At this time the chair yields 5 minutes to Ms. Kelly.

Ms. KELLY. Thank you, Mr. Chair and ranking member.

Mr. Mitchell, thank you so much for joining us today and for your testimony. You represent the voice of many of our constituents on both sides of the aisle, that they are the financial burden that is the consequence of companies' anticompetitive behavior. And in

your testimony, you stated that your prescription went up nearly 600 percent, in essence, doubled since 2011 when you stopped taking it due to side effects. And the company that manufactures Revlimid, Celgene, reported $1.6 billion in 2015, which accounted for 62 percent of that revenue Revlimid did.

Mr., and I'm going to say, is it Leicher?

Mr. LEICHER. Leicher.

Ms. KELLY. Leicher. Okay. Are you aware of any companies that have benefited in such a great manner from anticompetitive behavior, and how common is the practice?

Mr. LEICHER. I'm not sure we're experts on how common that practice is because it's not something we seek to engage in, certainly at my company. But we're aware of the scenarios that you've described, the Daraprim scenario, and the fact that they were using restricted access programs as a way to prevent competition. Those are largely what was just described, efforts by companies to purchase what may even be an old generic drug in a shortage situation rebranded and launched it as a branded product with a very high price often when the patents have expired.

And what we see as the real solution here is to reduce the barriers to entry. And one of the big barriers to entry is what this hearing is all about, is if we can't obtain reference product from a brand company to test and develop a generic, we won't have generic or biosimilars to compete and actually use the most effective tool available, which is competitive competition to bring the prices down.

Ms. KELLY. It's just amazing to me. Do they think that, you know, people aren't going to notice or not say anything? I know you're not a psychiatrist, I don't think you are, but I don't get it.

Mr. LEICHER. You know, it's amazing to me too, because what they're doing is they're waiting to see if they're going to lose the litigation. The larger companies—you know, that's what I mean by a barrier entry. We can't afford to litigate for 3 years to purchase some samples at a fair market value from a company and then start development 3 years from now. So they're using that delay of litigation to prevent us from entering that business.

And, you know, it answers the question that was asked earlier, you know, what about all the mergers? Well, Momenta is an example. We're not the only one. We're an example of a company that's a new entrant into this business in the last 10 years. We're providing very significant competition. We developed generic enoxaparin, which was a very significant cost reduction in the country. We developed a generic version of Copaxone. We're working on seven biosimilar programs. But if we can't access the referenced product, none of that can happen.

Ms. KELLY. So you see that as the main——

Mr. LEICHER. We see that as—I've put that as number one on our list of barriers.

Ms. KELLY. And what's two and three? And if anybody wants to join in.

Mr. LEICHER. Two and three?

Ms. KELLY. If you have a two and three.

Mr. MITCHELL. Barriers to generic drugs or barriers to lowering prices?

Ms. KELLY. Well, barriers to assess, and what are the barriers to lowering the prices? What can we do? What are best practices we can implement? What can we do to change this?

Mr. ANDERSON. So, I mean, I guess we need a little more help from you in terms of we can do it in brand space, we can do it in the generic space. Those are very different spaces so——

Ms. KELLY. Well, I guess what can Congress do to help you?

Mr. ANDERSON. Right. So one of the things about Revlimid and others is the whole issue of negotiation. What you heard was $11,000 in out-of-pocket expenditures for a Medicare beneficiary. If you're making $22,000 on Social Security, $11,000 is just prohibitive.

What you've got to recognize is who's paying most of that cost. Eighty percent of the cost is paid for by the Medicare program. Medicare cannot negotiate those prices one little bit when it's paying 80 percent of the cost in the Medicare catastrophic amount.

I helped design the Medicare Catastrophic bill. We did not anticipate drugs that cost $75,000 on it. It was designed to help the person who had multiple chronic conditions that was taking a lot of very inexpensive drugs, but a lot of them, and they would enter the catastrophic amount. The drug companies looked at this and said, oh, if I charge $80,000 for a drug that a Medicare beneficiary might take, Medicare is going to pay $64,000 of that. And the beneficiary will end up paying a fair amount too, and the PDP, the Medicare drug plan only pays 15 percent.

So it wasn't designed for what's happening today. And this is something, you know, now 14 years later, we need to revise.

Ms. KELLY. Thank you. I know my time has run out.

Mr. WALKER. Thank you, Ms. Kelly.

At this time, we'll recognize Mr. Mitchell for 5 minutes.

Mr. MITCHELL OF MICHIGAN. Thank you, Mr. Chair.

Dr. Woodcock, can you please help me understand a few things here. Can you explain the role that the FDA currently plays in ensuring timely and full access to generic medications?

Dr. WOODCOCK. FDA—what FDA does is approve—try to approve those generics at the time all patents expire and exclusivity expires. So as is already explained, the way the system is set up, people can file before that——

Mr. MITCHELL OF MICHIGAN. Right.

Dr. WOODCOCK. —or do their development—not file an application, but do their development process, and then they can file and then they can get approved right at the time or even tentatively approved prior to, a little bit prior to, so they know they have a path to market.

Mr. MITCHELL OF MICHIGAN. In the last year or two, can you share with the committee how many complaints you've received from generic manufacturers that they aren't able to access approved medications in order to proceed with research and production?

Dr. WOODCOCK. Well, overall, we've received over 150 inquiries. And we don't—about their inability to access the reference listed drug, and that's in the generic space. We have not—we don't have it nailed down in the biosimilar space, which is a new program where——

Mr. MITCHELL OF MICHIGAN. What's your distinction between an inquiry and a complaint?

Dr. WOODCOCK. Oh, okay.

Mr. MITCHELL OF MICHIGAN. I come from a very simple world here.

Dr. WOODCOCK. Well, we wouldn't call—we hear about them, all right. And obviously, they're complaining. They inquire if we can get the drug somehow or something like that, and I've explained what we do. If there is a real FDA-imposed REMS program that actually restricts the drug, we have a way we go. We send a letter—after reviewing the protocol, we send a letter to the reference listed drug holder saying that it's safe to provide that drug and that the REMS doesn't apply. But that doesn't mean they're going to go and give the drug.

Mr. MITCHELL OF MICHIGAN. Why does it not mean they're going to give the drug?

Dr. WOODCOCK. Because we don't have the authority to order them to do that. We simply are telling them that the REMS restrictions, which means they can't just give the drug out to anyone because of safety——

Mr. MITCHELL OF MICHIGAN. I understood that.

Dr. WOODCOCK. —doesn't apply in this situation, and that we have actually reviewed the generic protocol to make sure that it doesn't make any safety risks.

Mr. MITCHELL OF MICHIGAN. So the FDA's position currently is, well, we'll waive REMS or—but if you—if the manufacturer of the brand name drug doesn't want to provide access, they're left to litigate. Is that the best answer that they have?

Dr. WOODCOCK. We also have referred all these circumstances to the FTC.

Mr. MITCHELL OF MICHIGAN. And what's happened at the FTC, for entertainment purposes?

Dr. WOODCOCK. I do not know the answer to that. We can get back to you.

Mr. MITCHELL OF MICHIGAN. I think the committee would be interested in that.

Mr. Chair, can we request that information? Is that feasible?

Anybody else want to weigh in on this question? It seems to me that we send them a letter, say, gee, it would be nice if you sent the medication. If they choose not to, you can, you know, gain yourself—bring on some attorneys and sue.

Mr. MITCHELL. I do know from preparing for the hearing, Mr. Mitchell, that the FTC has filed amicus briefs in cases, including the case involving Celgene and Revlimid, saying that Revlimid—Celgene's behavior is anticompetitive and arguing that the REMS' excuse is just that, a pretext.

Mr. MITCHELL OF MICHIGAN. And how long has that—as an example, how long has that case been going on?

Mr. MITCHELL. I believe that case has been going on since 2014.

Mr. MITCHELL OF MICHIGAN. Any solutions side on that that you've seen, or we're still in appeals process?

Mr. MITCHELL. No, sir. I'm not a lawyer.

Mr. MITCHELL OF MICHIGAN. Well, neither am I, sir.

Mr. LEICHER. What I could add to that is the FDA has done an effective job in documenting that generic and biosimilar companies have the safety capability to handle these products when asked. But the FDA does not have authority to regulate competition among competitors, and that's really where the issue is.

And that's where some of the statutes, you know, Mr. Welch's bill is directed, which is—goes to the core of what Hatch-Waxman said and what the biosimilars law said, which was that you need to have access to the reference product commercially. They don't give us samples. It's described as samples. We purchase them at full price.

Mr. MITCHELL OF MICHIGAN. Well, see, I don't see it as regulating the competitions. It's, in effect, allowing the sale of the drug that they would to any other party.

Mr. LEICHER. Exactly.

Mr. MITCHELL OF MICHIGAN. It's not like they're trying to just provide the drug at the same retail price anybody else pays.

Mr. LEICHER. I stated it backwards. It's regulating the anticompetitive prevention.

Mr. MITCHELL OF MICHIGAN. Okay. Maybe that—okay.

I'll yield back. Thank you very much, Mr. Chair.

Mr. WALKER. Thank you, Mr. Mitchell.

Mr. Welch, looks like they have called votes, but I believe we have time, not normally on the subcommittee, but we yield you 5 minutes for your questions. Thank you.

Mr. WELCH. Thank you very much.

First of all, I want to thank Mr. Mitchell for his questions, because I think they really do go to the heart of the issue. It's not a safety issue; it's an anticompetitive issue. And ideally, we would have the drug made available for research and then the patent holder of the drug has the full benefit of that legal patent for the period of time of protection.

So the patent holder here—and tell me if you disagree—is basically trying to extend the life of the patent, i.e., the monopoly beyond the legally protected timeframe. Is that correct?

Mr. MITCHELL. Yes.

Mr. ANDERSON. Yes.

Mr. LEICHER. Yes.

Mr. WELCH. Well, that doesn't sound right. So, I mean, this is where there's some, I think, reason why there's some bipartisan support here, because I think most of us up here support competition, and we also oppose gaming the system. I mean, it's a very significant legal benefit to an owner of intellectual property, whether it's a patent—whether it's a pharmaceutical drug or something else, to get something that can only be given by law, and that is a period of exclusivity where, essentially, they have market dominance and are able to then profit on that company. And none of us here in this legislation are suggesting an attack on that scheme. But I think all of us in support of this legislation are opposed to gaming that.

Mr. Mitchell, I want to just say, I agree with Elijah Cummings. And I want to say to all the witnesses, you don't know what a breath of fresh air it is to have folks coming in here that aren't asking for some special advantage and are trying to help us on a

bipartisan basis understand what we can do public policywise to help a lot of Americans who just want to live their lives, but do need medication along the way. So this is like unusual for us, okay. And thank you.

Dr. Anderson, could you just go through just the specifics again, because I think it's helpful for all of us to hear about it, about how the obstacles are put in the way of the generic companies to get the sample that they need in order to do the research required to then have Momenta put a generic drug on the market.

Mr. ANDERSON. So it's pretty simple. You basically create, and most of these companies are creating their own specially distribution networks or they're working with some existing thing to do it, and then they're very much restricting access to these drugs.

It's true both in the brand side, which Mr. Leicher has been talking about mostly, but it also turns in the off-patent activities as well, where this drug has been around for 50 years. But only in the case of Turing Pharmaceuticals, there's only about 5,000 of those drugs that are being distributed every year.

So the company knows exactly who's buying it and can say, you know, Mr. Welch, you don't have that disease, you're not entitled to that drug, because then you can't give it to Mr. Leicher for him to make it. So, essentially, what they're doing is keeping that access to that drug and then they can't apply to Janet Woodcock.

Mr. WELCH. Okay. You mentioned the legislation. I'm a cosponsor with Mr. Stivers on the Republican side. Would that address, in your view, the issue that you're speaking about?

Mr. ANDERSON. No, I think it very much would. I mean, it's a great piece of legislation, and I totally—I can't endorse it as a faculty member, but I think it makes complete sense.

Mr. WELCH. And I'll just ask you this: Congressman Cummings was talking to his new best friend, President Trump—I can't say that. But I was sitting there when President Trump was very enthusiastic about price negotiation. And the concern that I've heard from some opponents of negotiation authority for Medicare is that that would be the equivalent of price setting. And can you give me your reaction to that.

Mr. ANDERSON. Well, essentially what you have, and especially in the Medicare program for these very expensive drugs, is Medicare is a silent partner paying 80 percent of the cost. So that makes absolutely no sense to me.

So if I were to start in the price negotiation activity, it would be where Medicare is paying 80 percent of the cost and has no negotiating ability at all. You know, I think you could do broader than that, but I think if I had to start somewhere where I think there should be some level of bipartisan agreement on it, it should be where Medicare is paying 80 percent of the cost.

Mr. WELCH. Okay. I thank you, all.

And I yield back.

Mr. WALKER. Thank you very much.

With that, I'd like to thank certainly the FDA for showing up today, some last minute things, but we're grateful. In fact, Dr. Woodcock, Mr. Leicher, Dr. Anderson, especially you, Mr. Mitchell, for having the courage today to come and share your story. That's an honor for us to be part of listening to you and hearing you out,

really the importance of why this is so much—important, really for all of us. So thank you all.

I would ask unanimous consent that members have 5 legislative days to submit questions for the record.

Without objection, so ordered.

If there is no further business, without objection, the subcommittee stands adjourned.

[Whereupon, at 3:13 p.m., the subcommittee was adjourned.]

APPENDIX

MATERIAL SUBMITTED FOR THE HEARING RECORD

No response received to the questions below:

QUESTIONS FOR THE RECORD

Submitted by Representative Stacey Plaskett
For Dr. Janet Woodcock, Director of Center for Drug Evaluation and Research
Hearing on "Examining the Impact of Voluntary Restricted Distribution Systems in the Pharmaceutical Supply Chain"
Committee on Oversight and Government Reform
U.S. House of Representatives
March 22, 2017

1. Is it true that current law bars brand pharmaceutical companies from using REMS restrictions to block generic competition?

2. Does the FDA take into consideration finding a balance between REMS patient safety objectives and also facilitating the availability of generic medicines?

No response received to the questions below:

QUESTIONS FOR THE RECORD

Submitted by Representative Peter Welch
For Dr. Janet Woodcock, Director of Center for Drug Evaluation and Research
Hearing on "Examining the Impact of Voluntary Restricted Distribution Systems in the Pharmaceutical Supply Chain"
Committee on Oversight and Government Reform
U.S. House of Representatives
March 22, 2017

1. Is it the case that generic development can be delayed because restricted distribution systems prevent generic companies from obtaining drug samples needed to conduct studies to support approval?

2. Is it the case that generic approvals can be delayed because of lengthy negotiations between generic and brand sponsors on shared REMS?

3. Does the agency believe that generic development could be expedited if restricted distribution systems did not prevent generic companies from obtaining drug samples to conduct studies?

4. Does the agency believe that generic approvals could be expedited if brand sponsors were required to make product available to generic sponsors for bioequivalence testing?

5. Does the agency believe that generic approvals could be expedited if brand sponsors were required to allow generics to piggyback on the brand REMS?

6. Does the agency believe that generic approvals could be expedited if generic sponsors were allowed to use a foreign reference product (and a bridging study if needed) to show equivalence to the U.S. product, in the case when a restricted distribution system is preventing generic companies from obtaining drug samples needed to conduct studies to support approval?

7. Do you believe that brand companies use Citizen Petitions as a means of stalling approval of complex generics? What measures can FDA or Congress put in place to reduce or mitigate these stall tactics?

8. I'm concerned about the impact some drugs covered by an FDA REMS program can have on patient health. Do you have any concerns that generic and biosimilar drug manufacturers can handle these products safely and bring an equally safe and effective product to market?

9. Do generic and biosimilar drug developers typically conduct clinical trials when bringing competitive products to market?

10. If so, what additional protocols are in place to ensure patient health is protected?

11. Are generic and biosimilar developers held to an equally rigorous safety standard as brand manufacturers?

12. Does FDA take note of companies that have a pattern of using voluntarily restricted distribution for more than one drug?

13. Could FDA take any steps outside the REMS program to discourage brand name companies from maliciously using voluntary restricted distribution systems to block generic market entry?

14. What is FDA doing to ensure that Americans have affordable access to as many generic alternatives to expensive brand-name drugs as possible?