S. HRG. 116–267

DRUG PRICING IN AMERICA: A PRESCRIPTION FOR CHANGE, PART I

HEARING

BEFORE THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED SIXTEENTH CONGRESS

FIRST SESSION

JANUARY 29, 2019

Printed for the use of the Committee on Finance

U.S. GOVERNMENT PUBLISHING OFFICE

41–359—PDF WASHINGTON : 2020

COMMITTEE ON FINANCE

CHUCK GRASSLEY, Iowa, *Chairman*

MIKE CRAPO, Idaho
PAT ROBERTS, Kansas
MICHAEL B. ENZI, Wyoming
JOHN CORNYN, Texas
JOHN THUNE, South Dakota
RICHARD BURR, North Carolina
JOHNNY ISAKSON, Georgia
ROB PORTMAN, Ohio
PATRICK J. TOOMEY, Pennsylvania
TIM SCOTT, South Carolina
BILL CASSIDY, Louisiana
JAMES LANKFORD, Oklahoma
STEVE DAINES, Montana
TODD YOUNG, Indiana

RON WYDEN, Oregon
DEBBIE STABENOW, Michigan
MARIA CANTWELL, Washington
ROBERT MENENDEZ, New Jersey
THOMAS R. CARPER, Delaware
BENJAMIN L. CARDIN, Maryland
SHERROD BROWN, Ohio
MICHAEL F. BENNET, Colorado
ROBERT P. CASEY, JR., Pennsylvania
MARK R. WARNER, Virginia
SHELDON WHITEHOUSE, Rhode Island
MAGGIE HASSAN, New Hampshire
CATHERINE CORTEZ MASTO, Nevada

KOLAN DAVIS, *Staff Director and Chief Counsel*
JOSHUA SHEINKMAN, *Democratic Staff Director*

CONTENTS

OPENING STATEMENTS

WITNESSES

ALPHABETICAL LISTING AND APPENDIX MATERIAL

COMMUNICATIONS

DRUG PRICING IN AMERICA: A PRESCRIPTION FOR CHANGE, PART I

TUESDAY, JANUARY 29, 2019

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:15 a.m., in room SD–215, Dirksen Senate Office Building, Hon. Chuck Grassley (chairman of the committee) presiding.

Present: Senators Crapo, Roberts, Enzi, Cornyn, Thune, Burr, Isakson, Portman, Toomey, Scott, Cassidy, Lankford, Daines, Young, Wyden, Stabenow, Cantwell, Menendez, Carper, Cardin, Casey, Hassan, and Cortez Masto.

Also present: Republican staff: Jeffrey Wrase, Deputy Staff Director and Chief Economist; Brett Baker, Health Policy Advisor; Maddie Davidson, Professional Staff Member; Evelyn Fortier, General Counsel for Health and Special Projects; Stuart Portman, Health Policy Advisor; and Karen Summar, Chief Health Policy Advisor. Democratic staff: Joshua Sheinkman, Staff Director; Sal Christ, APSA Fellow; Anne Dwyer, Health Counsel; Peter Gartrell, Investigator; Matt Kazan, Health Policy Advisor; and Kristen Lunde, Winston Fellow.

OPENING STATEMENT OF HON. CHUCK GRASSLEY, A U.S. SENATOR FROM IOWA, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. The Senate Finance Committee will convene for this hearing.

Welcome, everybody, to a very important hearing. I would like to say a few words before I make my opening statement about returning here as chairman after the last time in 2007—12 years ago—when I last sat in this chair. We got a lot done. Nearly all of it was bipartisan. I am very eager to pick up where we left off. It may be a bit harder to get bipartisan work done these days, but I hope that we can prove naysayers wrong.

It is also an honor to lead this committee alongside Ranking Member Wyden. We have worked very closely over the years on things in this committee, but also lots of things outside of this committee, particularly his and my belief of encouraging wrongdoing in government to be reported through whistleblowers. And he and I have a caucus of a few members, bipartisan, called the Whistleblower Caucus.

I hope to work with all of you on this committee in good faith. We will surely have disagreements with each other at times, but I hope that we use this Congress as an opportunity to improve the

lives of our constituents. I know that that is what motivates everyone here, whether you are Republican or Democrat. In fact, last Congress I introduced a bipartisan health-care bill, separate bills with each Democratic member of this committee, and I hope to do that again as chairman.

So with that opening, I want to go to welcoming our witnesses and thank them for the hard work that they have to do to prepare for answering our questions. The information they will share will help inform the committee as it addresses the issue of high prescription drug prices.

Millions of Americans woke up this morning and started the day with their dose of prescription medications, including this Senator. For so many of our loved ones who have diabetes, high blood pressure, cystic fibrosis, epilepsy, and many other chronic health conditions, prescription drugs are a basic necessity of life. We need to continue to have a strong research engine to develop new treatments, but we must also have a discussion about the affordability of these drugs.

Today you will hear many numbers describing the costs of those drugs. Those numbers are impressive, but the stories I have heard from patients, doctors, and pharmacists in Iowa have really gotten my attention. I have heard stories from doctors and pharmacists about skyrocketing prices of commonly used generic drugs. Usually generics are a way to keep costs reasonable.

I have also heard from seniors who have seen their prescriptions increase month after month for no apparent reason. And I have heard stories about people reducing their life-saving medicines like insulin to save money. This is unacceptable, and I intend to specifically get to the bottom of the insulin price increase. But other drugs are creating problems as well. That is why tackling high prescription drug costs is one of Senator Wyden's and my first priorities on this committee.

The reasons for these high prices are complex. I plan to hold a series of hearings in order to identify and address these reasons. We will look at all aspects of the prescription drug market and make changes where necessary.

So where do we start? So many of you have heard me talk about transparency and bringing accountability. So it is not very defined when you use that word "transparency," but I think it starts with transparency. When it comes to drug prices, you should not need a Ph.D. in economics to understand how much your prescription costs. I believe it starts with putting the list price of a drug on television ads as one example. I am confident in the ability of Americans to use such information to make their best decision.

Drug advertisers want to tell consumers all the benefits of a drug. They are required to tell you about the side effects. But they do not seem to be very gung ho to share how much the drug costs. The President's blueprint to lower drug prices includes a provision to include list price on TV. The administration has a proposed rule to do just that.

Senator Durbin and I, in a bipartisan way, have been vocal in our support of this proposal. I look forward to the rule being finalized.

Senator Wyden and I introduced the Right Rebate Act last week. When enacted, this bill will close a loophole that allowed the manufacturers of EpiPen to rip off taxpayers and consumers for as much as $1.2 billion dollars.

Speaking of transparency, I want to express my displeasure at the lack of cooperation from the pharmaceutical manufacturers very recently when they were invited here. This committee has a long history of working in a bipartisan manner to solve difficult problems for the American people. So when Senator Wyden and I invited several pharmaceutical companies to come and discuss their ideas to address high drug prices, I was extremely disappointed when only two companies agreed to do that. The companies that declined said that they would be very happy to have discussions with us in private, but not in public. One company said testifying would be a problem because of language barriers. I thought we all spoke English.

So that is not what I mean when I talk about transparency.

[The prepared statement of Chairman Grassley appears in the appendix.]

The CHAIRMAN. Senator Wyden?

OPENING STATEMENT OF HON. RON WYDEN, A U.S. SENATOR FROM OREGON

Senator WYDEN. Thank you very much, Mr. Chairman.

As you noted, Mr. Chairman, I have very much appreciated the chance to work with you on health-care issues in the past, including fighting pharmaceutical price gouging and exposing rip-offs by unscrupulous health-care providers. In my view, there is a big opportunity in this Congress to find common ground on holding down health-care costs.

Now, this is our first hearing, and I also would like to just welcome our new members—I know you have as well—Senator Hassan and Senator Cortez Masto on our side, Senators Lankford, Daines, and Young on the Republican side. I am looking forward to working with them. And, Mr. Chairman, I would also note with the dais creeping further and further into the audience, you and I may have to consider putting up stadium seating here in this room.

Now the chairman noted that we invited the heads of several of the largest drug companies to testify. And obviously they are not exactly tripping over themselves to answer our questions. That ought to tell you something. Even the big tobacco companies were willing to come to Congress and testify, and they made a product that kills people. They all lied to me, but at least they showed up, and the drug makers are going to have to show up as well.

As the chairman noted, this is not a one-off. This is the first in a series of hearings we are going to hold. So nobody is going away. And even if it means using our powers as the chairman noted, on a bipartisan basis, to compel the drug company CEOs to show up, they are going to come before this committee.

The crisis of prescription drugs threatens too many lives and bankrupts too many people for the Congress to tolerate ducking and weaving by the companies. According to a recent report, millions of Americans have skipped doses or declined to fill prescriptions because of their costs. That is intolerable.

Just look at the price of insulin, particularly for type 1 diabetes. Insulin has been saving lives for nearly a century. There have been some improvements, but the real breakthrough came back in the 1920s. There has been no recent "aha" moment in a lab to explain why the list price of Eli Lilly's main insulin drug Humalog went from $21 a vial in 1996 to the current list price of $275. That is a 13-fold increase. Humalog is not 13 times as effective as it used to be. A vial does not last 13 times longer than it did in 1996.

Other manufacturers have hiked prices as well. But the problem is not just diabetes. The incredible strain that drug costs put on patients in my State and across the country is in plain view. Thousands and thousands of people at any given moment are turning to fundraising websites and even asking complete strangers to help them cover the cost of their medicine.

Colleagues, it is grotesque. The price-hiking drug makers have turned American patients into beggars.

Now, the chairman and I have a lot of history on this. We recently investigated the drug maker Gilead on its pricing of the hepatitis C drug Sovaldi, which clocked in at $1,000 a pill wholesale according to our bipartisan investigation, and it was based, colleagues, on the company's own documents. The price was not about recovering research and development costs. It was not based on the previous standard of care. The company charged a list price of $1,000 a pill because they knew they could get away with it. And the figure would set a pricing platform, a benchmark to be surpassed by successor drugs.

So there is no shortage of evidence about what the problems are. The companies have unchecked power to set prices on their own, and often it is to meet Wall Street's expectations rather than meet demand in the market.

I am going to close by briefly—as the chairman did—touching on several policy challenges. I am especially troubled by health-care middlemen who skim off enormous sums of money when there is scant evidence that the patients get a better deal. That sure looks like the case with the pharmacy benefit managers, PBMs. They are supposed to negotiate better deals, but it sure seems like they take a big cut and inflate the prices. The three biggest PBMs are among the 25 largest companies in America. So I have appreciated what the chairman has said on this, and we need to pull back the curtain on what is really going on with these pharmacy benefit managers and see who benefits. It does not look to me like it is families or taxpayers.

A word, finally, about Medicare Part D—the chairman was a lead author of the bill that created the Medicare prescription drug benefit in 2003. While it was not the bill that I would have written, I supported that bill because it was a first step to help the seniors pay for their medicine. But colleagues, the pharmaceutical industry looks a lot different than it did back then.

Today we are going to hear from our witnesses that the structure of Part D encourages the manufacturers to set list prices sky-high. We will hear that private Part D plans are incentivized to push these high-priced drugs on seniors. That cannot happen any longer.

More than a decade of evidence shows that Medicare Part D plans often do not do a good enough job negotiating prices down-

ward. So I believe Medicare ought to be able to use its bargaining power of 43 million seniors to get a better deal for the patients and the taxpayers.

The astronomical list price of sole-source drugs, in particular, is a major strain on patients. And with respect to the sole-source drugs, private plans have not been able to correct that problem.

So we need to look at these issues. We ought to recognize also that profits, drug company profits, are often dependent on taxpayer-funded research. I have deep reservations about this whole notion that drug companies can privatize all the gains from this research after socializing the costs of the research.

So, Mr. Chairman, I look forward to working with you. I hope that the administration will join us in this effort. So far, they have been pretty light on details. But as you said, the committee has a real opportunity to take action this year. We have a history of bipartisanship and big ideas.

So what I would like to do, Mr. Chairman, is work with you and all our colleagues on both sides of the aisle so our work on this issue lives up to the tradition of the Finance Committee at its best.

Thank you.

[The prepared statement of Senator Wyden appears in the appendix.]

The CHAIRMAN. I appreciate your opening remarks and your cooperation on setting up this hearing and as we work forward.

You were right from the standpoint—I did not recognize the new members of this committee. And so I have the opportunity of welcoming three new Republicans and I believe two new Democrats to the committee. So welcome—and he named all of you, so I will not bother to mispronounce your names. [Laughter.]

Let us start with Senator Young. I was told that you would take the pleasure of introducing your constituent, our first witness, Ms. Sego.

OPENING STATEMENT OF HON. TODD YOUNG, A U.S. SENATOR FROM INDIANA

Senator YOUNG. Well, thank you. Mr. Chairman, Mr. Ranking Member, it is a pleasure to be a member of this committee, and I am honored to begin my time on this committee by introducing Kathy Sego.

Kathy is a loving mother from Indiana who has agreed to give her personal story on how her family has been affected by high drug costs. Kathy has a 22-year-old son, Hunter, whom I have had the opportunity to meet. And Hunter has type 1 diabetes.

Hunter was not aware of the actual price that his mother and father were paying for his insulin until he attended college. And after entering College, Hunter realized that the price of insulin—a drug that he had been dependent upon his whole life—cost $487 a vial.

Now that translates to roughly $2,000 a month. And Hunter, being a young humble man and not wanting to burden his family, began rationing his insulin in order to save money. This ended up making Hunter very sick, of course. Coaches and professors at his college started to notice Hunter's sickness, and eventually Kathy had to constantly monitor her son in order to make sure he was

taking his correct amount of medication. As a parent, I want to make sure families like the Segos do not have to worry about their children rationing out drugs because costs are too high.

I am glad to say that Hunter is doing much better now, and he is on track to graduate DePaul University this spring. Both Kathy and Hunter have been volunteering for the American Diabetes Association for over a decade now, and I applaud their advocacy on behalf of the diabetes community and the great State of Indiana.

I hope that Kathy's testimony today will inspire others and help bring about needed change to the high costs of life-saving drugs. So please join me in welcoming Kathy here today.

I yield back.

The CHAIRMAN. And we welcome you, Ms. Sego.

Now, I am going to introduce Dr. Douglas Holtz-Eakin, who currently serves as president of the American Action Forum. The doctor has previously served as Chief Economist of the President's Council of Economic Advisers. Dr. Holtz-Eakin also served as Director of the Congressional Budget Office. He earned a bachelor's degree from Denison University and his Ph.D. from Princeton University.

We welcome you once again. You are pretty much a regular here at testifying on Capitol Hill.

Next is Dr. Mark Miller. Dr. Miller currently serves as vice president of health care at the Laura and John Arnold Foundation. He previously served as Executive Director, MedPAC. Dr. Miller also served at the Congressional Budget Office, where he was Assistant Director of the Health and Human Services Division. Dr. Miller has previously served as Deputy Director of Health Plans at CMS. He was Chief of the Health Financing branch of the Office of Management and Budget, and he has a Ph.D. in public policy analysis, State University of New York.

We welcome you, Dr. Miller.

Our final witness, Dr. Peter Bach, currently serves as director of the Center for Health Policy and Outcomes, Memorial Sloan-Kettering Cancer Center. Dr. Bach focuses on health-care policy, particularly as it relates to Medicare. Dr. Bach's work in lung cancer screening has led to the development of several lung cancer screening guidelines. Dr. Bach has also served as Senior Advisor for Cancer Policy at the Centers for Medicare and Medicaid. Dr. Bach earned his bachelor's degree at Harvard and his medical degree at the University of Minnesota.

We thank all of you for joining us. We will start with Ms. Sego.

And remember, if you have a statement longer than 5 minutes, or any longer statement you have, it will be just automatically put in the record for all of you. And I generally do not stop somebody just exactly at 5 minutes, but try to wrap up as soon as you can after the 5-minute light comes on.

STATEMENT OF KATHY SEGO, MOTHER OF A CHILD WITH INSULIN-DEPENDENT DIABETES, MADISON, IN

Ms. SEGO. Good morning. Thank you, Chairman Grassley, Ranking Member Wyden, Senator Young, and distinguished members of the Senate Finance Committee, for inviting me to testify before you today. My name is Kathy Sego. I am a choir teacher from Indiana,

and my husband and I have two children. Our son Hunter has type 1 diabetes.

For millions of Americans with diabetes—including my son—and all individuals with type 1 diabetes, access to insulin is literally a matter of life and death. My son Hunter thrives as a student and college football player at DePaul University.

On the surface, you would never know that he lives with a chronic disease. Hunter was diagnosed with type 1 diabetes on August 23, 2004, 1 month before his eighth birthday. On that date our lives changed forever, and ever since we have been advocates and volunteers with the American Diabetes Association fighting to make sure Hunter and all people with diabetes can stay healthy and have the same rights as people without diabetes.

Four years ago when Hunter was starting college, he offered to go to the pharmacy to pick up his insulin. I thought, "My son is growing up," but for Hunter growing up means understanding the cost of diabetes. The cost that day was $1,700. Hunter panicked. We have insurance. One month's insulin could not possibly be that expensive. But it was.

What happened next brings me to tears. My energetic, athletic, and positive son was not himself. He seemed depressed. His grades were dropping. He looked labored on the football field.

I found out Hunter had decided to purchase one vial of insulin instead of the four vials he needed for the month. Unbeknownst to my husband and myself, Hunter was rationing his insulin. This means he stopped eating to avoid taking insulin. With one-quarter of the insulin, he could eat less than once a day, and he was trying to give his all on the field. He was also starving and making himself sick.

In response, he started eating and not dosing with the necessary insulin to allow oxygen to feed his organs, muscles, and brain cells. He began accumulating ketones, known as ketoacidosis. He lost 20 pounds in 2 weeks. The combination of ketones and lack of oxygen could have ended with him in the morgue.

Thankfully, Hunter is okay today. But insulin rationing can lead to devastating, even deadly complications, which I never want my son to experience. I am heartbroken to know that my son felt he was a financial burden to us. Money over life is not the choice we want him to make.

In everything my family does, we think first of the cost of Hunter's insulin. We do not eat out. I do not turn on the heat in our home. I play a risky game with my utility bills, strategizing how long I can go before paying the past-due fees. Our electricity was turned off because I needed to purchase the medicine that keeps my son alive. Almost every dollar I make goes towards health expenses.

It is not like this everywhere. We hosted an exchange student from Hungary, and her family flew us to their home for a visit. We went to the pharmacy for insulin. It cost $10. The same vial of insulin that cost us $487 out of pocket cost $10 in Hungary. I wanted to stockpile it. I wanted to buy every vial, but I could not.

My son is about to graduate college. And when that happens, it will be one of the proudest moments of my life. However, unlike other parents, that moment fills me with dread. Hunter's life

choices are contingent on his ability to pay for his medicine to keep him alive.

Hunter has these worries too. He wonders can he pay for an apartment, utility bills, his student loans. Will he be able to have a social life, take a girl out on a date?

It comes down to this: Hunter needs insulin to live. But should that need for insulin keep him from living?

Our family is not alone in this struggle. More than 7 million Americans use insulin, and more than 400,000 have signed the American Diabetes Association petition calling for action to make insulin more affordable for all. I am here today on the behalf of each of those families to ask for your help. We do not want a handout or a free ride. We want to keep those 7 million alive without having to do what my son thought was his only option.

The three scientists who discovered insulin sold the patent for $1 each to ensure affordable insulin for all who needed it. Nearly 100 years later, it is my most desperate wish that we make that vision come true.

Again, thank you for the opportunity to testify before the committee today. And this is my son, Hunter.

The CHAIRMAN. Thank you.

[The prepared statement of Ms. Sego appears in the appendix.]

The CHAIRMAN. Dr. Holtz-Eakin?

STATEMENT OF DOUGLAS HOLTZ-EAKIN, Ph.D., PRESIDENT, AMERICAN ACTION FORUM, WASHINGTON, DC

Dr. HOLTZ-EAKIN. Chairman Grassley, Ranking Member Wyden, and members of the committee, I am honored to be invited on a bipartisan basis to discuss this important issue today. You have my written statement. Let me make a few points in the introduction, and then I look forward to your questions.

The first point is that the demand for prescription drugs is high and rising. Over half of Americans take drugs. The population is aging and will have more chronic diseases. Forty percent of Americans have a chronic disease—60 percent have one, 40 percent have two or more.

And so we are seeing an additional need for those therapies. We have substituted drugs for other kinds of medical therapies over time. Scientific advances have allowed new things to be treated with drugs. So there is an enormous amount of demand for drugs.

The supply of drugs is a costly undertaking. It costs about $3 billion to develop a new drug. Only one of every 1,000 drug formulas actually enters clinical testing, and only 8 percent of those are ultimately approved by the FDA. The time from start to finish is about 15 years.

This combination of supply and demand is an economic recipe for high and rising prices. And we need to monitor carefully the effective functioning of those markets to see how well they are doing.

Diagnosis of problems, I think, is complicated by intermixing different concepts. People talk about and interchange the list price of a drug, the stated price of the manufacturer, with the net price of the drug, which is a net of any rebates received, which is different in turn from the out-of-pocket price that someone like Kathy might face when they go to the drug counter.

A lot of people focus on spending. And spending has grown about 5 percent per year for drugs in recent years. But total drug spending is only about 10 percent of national health expenditure, the same as it was in 1960. And per capita spending has only gone up at a rate of about 1 percent.

And so in thinking about policies, I would urge this committee to identify very clearly the problem that they care about and look at those things which can improve the performance of those markets. Most of those ultimately will come down to, can we improve the supply of prescription drugs? Can you lower the costs, shorten the time to test and put drugs on the market? Can you reduce barriers to entry that perhaps could be erected by incumbents in the market? That would be central. How can you increase the number of both branded and generic drugs? There is nothing better than having more than one drug on the market to reduce prices. The poster child for this is the introduction of competitors to Sovaldi, the drug that was mentioned at the outset.

We need to look at the incentives provided by programs like Medicare and Medicaid for effective competition. And we need to make sure that when we get competition, it is reducing overall costs and not simply shifting those costs around in the system.

In looking at the data, it seems to me that what jumps out is not a problem with all drug prices, but instead very particular prices, both of which have come up in the opening remarks by the chairman and the ranking member. We have some very isolated instances of costs associated with off-patent sole-source drugs, and in those circumstances, it appears that firms are able to take advantage of their market power and raise the prices of drugs sharply. This strikes me as a fundamentally anti-competitive act that ought to be investigated and remedied.

The second place where we see things happening is in the specialty drugs, which is oncology drugs right now. These are expensive drugs with small populations to treat. There are going to be more, not fewer of these kinds of drugs in the future, and I think coming to terms with effective strategies on specialty drugs would be another place where the committee would provide a lot of value in this discussion.

So my testimony contains lots and lots of different aspects that have been suggested to address drug prices. I would be happy to talk about those, and I look forward to your questions.

The CHAIRMAN. Thank you.

[The prepared statement of Dr. Holtz-Eakin appears in the appendix.]

The CHAIRMAN. Dr. Miller?

STATEMENT OF MARK MILLER, Ph.D., EXECUTIVE VICE PRESIDENT OF HEALTH CARE, LAURA AND JOHN ARNOLD FOUNDATION, HOUSTON, TX

Dr. MILLER. Chairman Grassley, Ranking Member Wyden, distinguished members of the committee, I am Mark Miller, executive vice president of health care at the Arnold Foundation, and I appreciate you asking us here to testify.

The Arnold Foundation is dedicated to reforming dysfunctional markets and programs to assure a better return on investment for

the people they serve and the people who pay for those programs. We work to develop evidence and ideas to improve public policy in the areas of health care, pensions, education, and criminal justice—just to name a few. We strongly believe in markets, but we also believe in evidence-based intervention when markets fail. Our health objective is to lower costs and increase value for businesses, for governments, and for patients. We focus broadly on these problems: excessive hospital and physician prices, excessive drug prices and spending, reducing inappropriate and unsafe utilization, and finding better ways to care for complex patients.

Today you asked us to discuss possible solutions to control drug spending in Medicare and Medicaid. In all instances, the objective is to protect innovation, but lower the cost for the taxpayer and the patient.

Turning to Medicare Part D, consistent with MedPAC recommendations and proposals included in the last two administrations' budgets, we would suggest that the committee consider a series of reforms to Medicare Part D's payment structure to increase pressure on the plans to more aggressively negotiate drug prices—for example, by requiring the plans to pick up 80 percent rather than 15 percent of catastrophic drug costs. Concurrently, this policy would include enhanced beneficiary protections when they reach the catastrophic cap.

We suggest considering that you increase the transparency of, and examine the rules around, sharing rebates and other fees between the Medicare program and the plans to maximize taxpayer savings. More ambitiously, you could consider whether the rebate compensation model should be changed altogether to a fee-based model.

You should consider changing the "sunshine" legislation to report contributions to patient groups. Where there is no competition and PBMs have little leverage to negotiate lower prices, you should consider new tools such as reference pricing, paying for the clinical value of the drug, or binding arbitration. Authorizing the Medicare program to leverage its marketing power would allow it to address situations where manufacturers have set excessive prices in the absence of competition. These drugs could then return to the usual Part D negotiation process once competitors enter the market.

Turning to Part B, you should consider replacing the percentage reimbursement model with a flat-fee model to eliminate the incentive to prescribe higher-cost drugs. Other options include creating an inflation rebate and empowering physicians to form their own purchasing groups to negotiate prices. Finally, you could consider lowering the payment benchmark altogether in Part B by using an international price index like the one proposed recently by the administration.

Turning to Medicaid, you could legislatively and administratively support State innovation such as Louisiana's subscription model for hep C drugs and New York State's spending cap and negotiation model. At the Federal level, you could allow CMS to have greater authority to assure that drug manufacturers don't misclassify drugs in order to avoid paying higher rebates, and you could increase the statutory cap on the brand rebates in order to capture more taxpayer savings.

One final area of ideas, Mr. Chairman: from your previous work, you know we need to curb the anti-competitive behaviors of manufacturers and inject competition back into the marketplace. Manufacturers benefit from taxpayer-funded NIH research and from government-granted monopolies, and naturally they devote resources to protecting those monopolies. Those monopolies were granted by the government, and the government's responsibility is to intervene on behalf of taxpayers when the market fails.

Although outside the committee's jurisdiction, a comprehensive legislative package would include policies such as CREATES and "pay for delay." They are equally important to controlling expenditures in Medicare and Medicaid and would also control expenditures in the commercial sector.

In closing, there are additional ideas in the testimony, but most importantly the Arnold Foundation and its grantees stand ready to engage with you and your staff to talk about these and any other ideas that you would like to bring to the table. Any change will entail difficult trade-offs between manufacturers, PBMs, taxpayers, and patients, and stiff resistance from the status quo. Sticking with the status quo is always an option, but we know what it will produce: anti-competitive behaviors, high prices, and higher spending for Medicare and Medicaid.

I appreciate your attention and leadership on these issues. I look forward to your questions.

The CHAIRMAN. Thank you, Dr. Miller.

[The prepared statement of Dr. Miller appears in the appendix.]

The CHAIRMAN. Now, Dr. Bach?

STATEMENT OF PETER B. BACH, M.D., DIRECTOR, CENTER FOR HEALTH POLICY AND OUTCOMES, MEMORIAL SLOAN KETTERING CANCER CENTER, NEW YORK, NY

Dr. BACH. Thank you very much. Chairman Grassley, Ranking Member Wyden, and members of the Senate Finance Committee, thank you for the opportunity to share my views on pharmaceutical pricing.

My name is Peter Bach. I am a physician at Memorial Sloan Kettering Cancer Center in New York, where I lead the drug pricing lab, which is funded by the Laura and John Arnold Foundation, Kaiser Permanente, as well as my institution. My views are my own. I should note I have received fees from pharmaceutical and diagnostics corporations, PBMs, insurers, and trade associations, all of which are listed in detail in my testimony.

An organizing theme of the pharmaceutical supply chain is that all participants benefit as both drug prices and total spending rise. Pharmaceutical corporations seek to profit through high prices, but other supply chain participants should serve as a countervailing force, although they often do not.

As just one example, physicians and hospitals make a percentage of Part B drug prices under "buy and bill." The literature is consistent that this incentive increases prescribing of more expensive drugs—340B hospital prescribing shows a similar pattern.

One step we should take is to delink the provider's bottom line from the pharmaceutical corporations' pricing by, for instance, changing the percentage-based markup on Part B drugs to a flat

fee. Another example is, we could claw back Medicare funds expended on discarded leftover Part B drugs.

Inserting more price competition within the Medicare program would also be a good step. I recently outlined ways in which Medicare, for example, could create price competition between CAR-T therapies, applying approaches such as competitive acquisition, or bundling of payments.

As for Part D, my team worked with *The Wall Street Journal* recently and showed that plans may in fact be strategically bidding in a manner that increases their profitability while shifting costs onto the Federal reinsurance portion of the benefit. At this point, I would argue that plans should take on the risk currently borne by Medicare for individual level reinsurance. And we should explore rebates at point of sale so patients can have full benefit of planned negotiated price concessions.

In another example, Mark Trusheim from MIT, Senator Cassidy, and I recently proposed a payment model that we nicknamed Netflix, which aims to solve the affordability problem of expensive hepatitis C therapies. Our subscription model would have State purchasing coalition's pay a flat fee over time in exchange for an unlimited supply of treatments.

Now, some concerns. Value-based pricing has been proposed for new branded drugs that have no competition. The notion is to undo the vicious cycle of rising prices tied to unaffordable co-payments, instead setting a drug's price based on its benefits while mandating favorable formulary placement with low out-of-pocket costs. This constructive and viable idea is different from the outcomes contracts pharmaceutical corporations are promoting, even though they call them value-based. To be clear, refunds when a drug does not work will not guarantee prices are linked to the benefits received when it does work.

Long-term financing for new treatments, many of which are one-time, should be viewed cautiously as well. We cannot solve the affordability problem by pushing costs into future years. That will not make the costs go away. When companies say we need to change the payment system to afford their new high-priced treatments, this framing is entirely backwards. Prices for monopoly goods such as these are determined by the market in which they are sold, not the other way around. Asking you to recast the market to pay more is, of course, in the pharmaceutical corporation's interest. But that does not mean it is good policy.

Please realize that these drugs do not inherently cost $1 million any more than they inherently cost $1. So how should you figure out if you need to find a way to pay these enormous sums, these millions of dollars that companies say they deserve? I would focus on the impact on future innovation and encourage you to remember that we have already seen a large number of amazing one-time treatments come to market. And we hear many more are just over the horizon, and that is, of course, happening under our current payment system.

Likewise, we have seen multi-billion-dollar valuations for companies making these therapies, also under our current system. In other words, our current payment system appears to be providing the incentive to develop these amazing treatments. I would not

rush to solve a problem I am not certain we have. I would especially avoid a solution that carries only one promise, which is that it will increase how much we spend on drugs overall.

Thank you for the opportunity to share my views. I look forward to answering any questions you may have.

[The prepared statement of Dr. Bach appears in the appendix.]

The CHAIRMAN. Before I start asking questions, I would like to inform members of how I, kind of, handle question time, generally 5 minute rounds. The order of Judiciary was one Republican, one Democrat, but I guess the practice of this committee is first come, first served, except at the fall of the gavel. It would be by seniority at the fall of the gavel. Otherwise, you can have two or three Democrats ask questions, or it could be the opposite for Republicans. So I get the list from the clerk on that, and I will go by that list.

Then I usually will—if you start your last question before the 5 minutes has run out, I will let you complete your question. Hopefully you do not take advantage of making a speech with 1 second left to go when you start your question. And I hope that you would not encourage a long answer if you ask a question with 1 second left. But whatever you get started before the red light comes on, complete your question.

And I am willing to listen to anybody who disagrees with what I said. Not now—let us talk privately. But if you want me to consider handling it a different way, then please discuss that with me.

So I am going to start my 5 minutes with Ms. Sego. A very simple question: you already referred to—I think I heard you say in your opening comments that you went to another country to get some product, and it was much cheaper. So we hear so much about people going to Mexico or ordering drugs online. Have you considered Mexico or online?

Ms. SEGO. Yes, but we cannot afford to travel to Mexico or to Canada, or even back to Hungary, so I would—that is why I am here. I am hoping that all of us can come together and create a solution of how we can get the same pricing here in the greatest country.

The CHAIRMAN. Okay. Thank you.

I will now go to each of our three economists. I have consistently said that we need to address high costs of drugs. And still we have to consider preserving innovation.

You have each shared a number of ideas for lowering drug costs in your testimony, but I would ask you to explain what you would consider the one best way to lower the cost of drugs while still realizing the novel treatments we have. So we will just go from left to right here.

Dr. Holtz-Eakin?

Dr. HOLTZ-EAKIN. So I think the first thing to do is to stop having policies that push up drug prices. And one that jumps to mind is the 340B program, which is in need of desperate reform.

It was a well-intentioned program intended to provide drugs at lower cost to needy patients. It is not well-targeted on those patients right now. It is leading to higher drug costs, and I would encourage the committee to take a close look at reforming the 340B program.

The CHAIRMAN. Okay.

Dr. Miller?

Dr. MILLER. The first thing is that I think that you have headroom between the prices that are being charged and paid and how much is being spent on R&D. And I think research that Peter Bach has done shows that there is a fair amount of headroom.

And so I think you can go after prices and go after spending and not immediately threaten innovation. But you should always keep that in your mind. It is an important concern.

If you are forcing me to say just a few things—which is very problematic for me, I might add—I would say restructure the Part D benefit so that you are maximizing the PBMs incentive to negotiate their prices. And then for Medicare—I am focusing only on D, because you are making me do it—is then go outside, and for those sets of drugs that are extremely expensive and do not have competition, consider things like reference pricing or binding arbitration while there are no competitors for those drugs. And then bring them back into the negotiation once you have competitors.

The CHAIRMAN. Okay.

And Dr. Bach?

Dr. BACH. So, a couple things. One is, as I mentioned, the notion of value-based pricing. Taking new branded drugs that have no competition and finding their prices based on the benefits they provide to patients is a much better way to align the incentives in the market for innovation than we currently have. The basic notion of markets is, we should pay more for things that matter more or help more. And the current system has little alignment on that.

The other is—well, that deals with launch prices. We should make more efforts to have time-certain expiration of monopolies amongst branded drugs, and the discussions of generics and biosimilars are versions of that. But we have a number of policy approaches that could end the monopoly period directly and require companies to sell at marginal cost, plus a profit at the end of that exclusivity period. And that would free up a lot of money to pay for new drugs.

The CHAIRMAN. Okay.

This question is for Dr. Miller, but also if Dr. Holtz-Eakin has anything to add, or anything different from it. What do you see, Dr. Miller, as the key issues in the Medicaid drug rebate program? What challenges do you see in achieving the program's twin purpose of making sure Medicaid patients have access to the medicines they need while at the same time ensuring States get the best price available?

Dr. MILLER. So I think the two things that I would say are, first, I think there are changes you can make to the rebate structure where you can capture more savings for the taxpayer. Right now, once you hit a particular cut point, the manufacturer's price, the manufacturer can continue to raise their price and not pay anything more in rebates. And you could make incremental changes and capture more for the taxpayer.

But the second thing which was, sort of, the second half of your question, there are innovative models being thought through in the States, such as the ones that have already been mentioned here today. And setting up clear administrative or legislative pathways

for the States to pursue those, I think, would also help. And I could give some specific examples to your staff or to others.

The CHAIRMAN. Do you have anything to add, Dr. Holtz-Eakin?

Dr. HOLTZ-EAKIN. Keeping in mind your admonition to be brief, I would say three things. First, it has long been established that having the Medicaid best price diminishes the incentives for vigorous competition among firms. And CBO has noted this for a long time. I would worry about that, the very program.

The second is that the increase in the rebates, along with some other things in the Affordable Care Act, added about $100 billion to drug makers costs over the past several years. That has to show up in prices at some point. We should be cognizant that this is not free. It is a trade-off. When you do these rebates, they show up elsewhere in the system.

And then the third is this issue of capping the rebate at 100 percent of the drug's price. There has been some discussion of relaxing that cap. I, at least, would be concerned that that would be counterproductive, that if you raise that cap and actually impose a tax of more than 100 percent of the drug's price to the program, all you will get is an incentive for higher launch prices and lower inflation. And that is counterproductive. We do not need higher launch prices.

The CHAIRMAN. Senator Wyden?

And I think I will step out just a minute, but I will be back before you finish.

Senator WYDEN. Thank you, Mr. Chairman.

Ms. Sego, I heard you say that every decision in your household starts with whether you are going to be able to afford your insulin. I think you heard me say it is up 13-fold since 1996.

Insulin drugs are certainly not 13 times more effective. This is going on because manufacturers have been taking advantage of families like yours, and nobody has been willing to take them on. That is going to end today. And I just so appreciate your being here.

Ms. SEGO. Thank you.

Senator WYDEN. Dr. Miller, let me start with you, and you are a big expert in the field. Let us talk about Medicare Part D. There are almost 43 million seniors on this program. I was one who voted for it. I still have the scars on my back from that. And now, clearly, reform is needed.

So I want to see if I can put in English what is going on, because you have touched on it. Medicare Part D is now set up in a way that if the prices of drugs are high, manufacturers and insurance companies win and seniors lose. For most drugs purchased through Part D, the Part D plan, or sometimes the drug manufacturer, pays a large portion of the cost of the drug. But when a senior on Part D spends a lot on medicine, the government—not the plan or the manufacturer—pays most of the bill.

It does not take a rocket scientist to see that that is a prescription for these powerful companies to take advantage of the situation. Is that the heart, in your view, of what we ought to be looking at as we try to make sure that in the future, Part D does not encourage these high prices?

Dr. MILLER. Fundamentally, yes.

Senator WYDEN. All right; I am going to quit while I am ahead.

Let me—and, Dr. Holtz-Eakin, you touched on this as well, and I appreciated your thoughtful comments as well.

So let me then turn, if I could, to the issue of Medicare negotiations, because every one of us goes to a town meeting, and people say, "Hey, why is Medicare not negotiating? There are 40 million seniors. Why aren't we using their bargaining power?"

So private Part D plans negotiate with drug makers, as I just touched on, and you accepted the reason why it is going to be so important on a bipartisan basis that we work on Part D to take away the incentives for higher prices.

It seems to me that if you are talking about sole-source drugs with no competition, I do not see how Part D as structured today is going to protect the senior and the taxpayer. So if you would, tell me a little bit about Part D, particularly as it relates to those drugs. And I gather those can be cancer drugs and other drugs that are pretty important to people.

Please?

Dr. MILLER. One thing I would say is, what will go back and forth in this debate is, why is the government going to be able to negotiate a better price than a PBM? Okay, and so, just to kind of take you through that a little bit, what I am about to say is predicated on your first set of comments, which is: have you restructured the benefits so that you are extracting maximum negotiation from the PBM for drugs that have competition? Because even for drugs that have competition, sometimes the prices are still going up.

So first, you reform the structure in order to get the PBMs to operate as efficiently as possible. Then the thinking is, there are sets of drugs, just like you said, D was never really designed to deal with, because there is no competition and the PBM does not have an opportunity to leverage.

And there are a couple things I would point out there. Back to Peter's point—I mentioned it as well, but Peter was on it more completely. You could begin to try to price those drugs using a value-based approach to it.

Senator WYDEN. Sole-source drugs.

Dr. MILLER. That is right. And I would even add further it is expensive sole-source drugs, like a drug that when the beneficiary gets it, they are going to hit the catastrophic cap and the government is going to be paying 80 percent of it.

You could narrow the range of drugs that you are focused on and say, it is not everything that starts to be affected this way but drugs that do not have competition and are very expensive.

Senator WYDEN. We are going to want to ask you more about this, and I know in talking with the chairman that he is aware, in particular—I voted for Part D. It was not what I would have written, but clearly now—whether it is the incentives in Part D that jack up the prices, or the sole-source drugs that you have said have not really been the subject of kind of the classic notion of bargaining under Part D—we ought to be looking on a bipartisan basis at trying to make some reforms.

So we are going to be talking to all three of you experts, with the goal being at the end of the day, Ms. Sego, that you and fami-

lies from sea to shining sea see that the days are over when these big companies get a pass, because I think that is the heart of the problem. And the chairman and I saw that in our Sovaldi investigation and a variety of others.

So thank you, Mr. Chairman.

The CHAIRMAN. Senator Stabenow?

Senator STABENOW. Thank you very much, Mr. Chairman. And welcome to the chairmanship. I look forward to working with you. We have worked on many different committees together and issues together, and so I am looking forward to good work from this committee.

And welcome to all of our witnesses today. First, Ms. Sego, if I could just talk with you a moment about your situation, which I wish was rare—and it is not rare. We hear about it all the time. In fact, the price of insulin has nearly tripled over the last 15 years, even though it was developed 100 years ago.

Ms. SEGO. Correct.

Senator STABENOW. So a very similar situation occurred with a mom from Minnesota who spoke at a hearing that I had organized about this—a forum actually—Nicole Smith-Holt from Richfield, MN, and a State employee, a mother of four. Her son Alec—similar situation—but he was diagnosed with type 1 diabetes at age 24.

And when he turned 26, unfortunately, his insurance lapsed. And so when he went in to pick up his supplies, he was told the copay was $1,300. And he did what your son did, which was to ration his insulin. And unfortunately, he had a different outcome. He died.

Ms. SEGO. Yes.

Senator STABENOW. And unfortunately, that is also not a rare occurrence. And I will never forget Nicole and her powerful words for the executives at Eli Lilly who oversaw these outrageous price increases and what she said to them.

So the drug company execs were invited today. They are not here, but if they were here, what would you say to them?

Ms. SEGO. As a mother, I would probably say to them, "I hope you know that there are people who are going without their medication. And because they are going without their medication, they are at risk of dying. And how can you be okay with that?"

I do not know how any person would be okay with knowing that the medication is priced so high that you have to make a decision about life or death. Do you pay for your bills? Do you buy food? That should never be a decision that a person needs to make. And unfortunately, it is.

So I would ask them what is their goal, and how are we going to come together at the table and create change?

Senator STABENOW. Thank you.

Dr. Bach, you have data that shows that the top 15 pharmaceutical companies sell internationally at 40 percent of the price they sell in the U.S. And I can say directly, coming from Michigan—where you can go 10 minutes across an international bridge and drop your cost by 40 percent—that we have Eli Lilly Canada on one side of the bridge and Eli Lilly USA on the other side of the bridge, and Eli Lilly USA would say that what is sold in Canada is not safe. Now I am assuming they do not mean their own company.

But at this point, Mr. Chairman, I want you to know that I continue to be strongly supportive of safe FDA-approved drugs being reimported from Canada, and continue to want to work with you on this, because we have one way to create a different kind of competition, and we have trade on everything else, but we close the border on safe FDA-approved prescription drugs on both sides of the border. So I am very concerned. I think that would be one way to create some change.

Also just—I see I am about out of time. I have many questions, but I am going to instead just do a couple of statements.

First, Dr. Holtz-Eakin, I just want to go on record. I do not want to debate you, but I do not agree that 340B is the primary reason for higher prices. So we can have that debate another time. I think there are a whole lot of other reasons, and that is not the primary reason.

And the other thing that I would say is that, when we look at whether or not negotiation under Medicare makes sense or not, we know it works in the VA. The VA negotiates on behalf of all of the veterans in America. And they pay about 40 percent less, which I am glad they do, but that certainly is another kind of model.

And finally, I would just say—and, Dr. Bach, if you want to comment on this—on value-based pricing, I support value-based purchasing. And in fact, the University of Michigan has been a leader in that, and I have promoted that and got that into the Affordable Care Act.

But if we are saying that if a drug has more value, it should be higher priced because it has more value, that is the problem, right? When somebody really needs it because otherwise they will lose their life, they should pay more as a result of that? I do not see how that, from a public policy standpoint or a health-care standpoint, makes sense.

Dr. BACH. Thank you for your question regarding that. The notion is not that the patient should pay more, and the work at the University of Michigan on value-based insurance design points to that directly. The notion is that the pharmaceutical company should capture a higher price if their drugs work better relative to drugs that work less well.

But under value-based pricing, the central idea is that if the prices are linked to the benefits, then patient co-payment should be low, and therefore there should be access to high-quality drugs. Now, we cannot just make more money. So what this really is is a reallocation away from some drugs whose prices do not make any sense at all. They are vastly too high for the thin benefits they provide, which should free up money to pay for drugs that work well.

Senator STABENOW. Yes, and I understand exactly what you are saying. What happens right now in the real world is that, if somebody needs it more, the price is higher.

The CHAIRMAN. Senator Enzi?

Senator ENZI. Thank you, Mr. Chairman.

I want to thank the panel for all of the information in their testimony as well as what they have provided here.

Ms. Sego, I am going to give you the name of my main diabetes advisor who has a son who has diabetes. He is in his 20s now, but he found a way to work through a foundation to import insulin for

a number of people at lower costs. And I think that you work through a foundation so that it would be legal. And I will share that with you.

Ms. SEGO. Thank you.

Senator ENZI. Getting to a question: Dr. Miller, there has been a lot of interest lately in moving away from rebates and towards some form of up-front discounting and value-based payments. However, it might require some sort of a retrospective price concession that could be made on the basis of clinical outcomes.

If we did move more towards up-front discounting, how could value-based payments still be a part of that system?

Dr. MILLER. I may not understand the question, but if you were to have a value-based price that was the price that was established or negotiated, whichever context we're talking about, whether we are talking about the commercial sector or in the public sector—I am not quite sure where—then that price would be the price that would carry through the supply chain, as opposed to right now where you have a list price, then a rebate price, and then a back-end adjustment.

But I think the idea is that you would establish the price up front in your scenario on a value, and that value would carry through the supply chain—if I follow your question, which I may.

Senator ENZI. I think so.

Dr. MILLER. Okay.

Senator ENZI. Thank you.

Dr. Bach, Medicare beneficiaries reach the catastrophic phase of their Part D benefit this year when they reach $5,100 dollars in true out-of-pocket costs. True out-of-pocket costs include expenses like the annual initial deductible, and co-payments or coinsurance, but also include the 70-percent rebates that manufacturers are required to provide during the coverage gap.

Mathematically, higher list prices mean that the beneficiaries reach the catastrophic phase faster because the percentage-based rebates and coinsurance that are paid by manufacturers and beneficiaries add up more quickly. Can you talk about how this affects the share of the drug spending that is covered by beneficiaries and Medicare, compared to plans and manufacturers?

Dr. BACH. Yes, thank you for summarizing that. The interplay is complex, but the core notion and the core challenge with D is that, exactly as you said, the way the beneficiary moves through the phases of the benefit from deductible all the way to catastrophic indexes off of the list price of the drug, which is what the beneficiary routinely pays at the pharmacy and deductibles as a share of coinsurance.

And because pharmaceutical firms can raise their list prices and make up for them with rebates to the plans, this allows the plans working in concert with the pharmaceutical companies to push patients more quickly into the catastrophic phase where Medicare provides 80 cents on the dollar with no risk corridor or gain-sharing or anything. We are about 12 years into this program; the risk corridors and particularly the reinsurance were put in place so that plans would have confidence when they cautiously stepped into D to provide it in 2006.

They have now mastered the structure. So we should probably put that tail-end risk back on them, either as MedPAC recommended at the 80-percent level, or I would propose probably just putting that risk on top of them at this point, because they have clearly figured out how to bid in a way where they end up gainsharing with excess profits on the risk corridor and capturing additional reinsurance from the Federal Government on the back end.

Senator ENZI. Thank you.

Dr. MILLER. May I say just one thing on that?

Senator ENZI. Sure.

Dr. MILLER. So you were sort of saying how much of the impact—5 years ago those people hitting the catastrophic cap were about 40 percent of the spend. Now they are 58 percent spend; more people are hitting the cap. We are up to about, I think, 8–9 percent of beneficiaries at this point. And most of them—and Doug made this point—there are different experiences in D, and some of the patients are dealing with more expensive drugs, being driven into the catastrophic cap, and most of that is driven by the price of the drug. It is more expensive drugs.

The CHAIRMAN. Before I call on Senator Menendez, I stated in my opening statement that we had invited pharmaceutical manufacturers to this hearing, and I also said that they declined, except for a couple small ones. I want to make clear that Senator Wyden and I expect to invite them again, and next time we will be more insistent of their coming.

Senator Menendez?

Senator MENENDEZ. Thank you all for your testimony. Ms. Sego, thank you for sharing your family story. I think there are many families in our Nation in that regard.

And I hope in the future, in addition to the industry, we can speak with administration officials, Mr. Chairman, about some of these proposals and look forward to hearing what they have to say.

For Doctors Bach, Holtz-Eakin, and Miller, would you support a proposal to cap drug price increases in Medicare to CPI and not medical inflation?

Dr. HOLTZ-EAKIN. A blanket cap of that type, I think, might have some unexpected bad consequences. It gives an incentive for a very high introductory price, no inflation thereafter, but the problem is, prices are already too high. And so I would prefer mechanisms that actually got lower introductory prices and provided enough competition to keep prices from rising.

Dr. MILLER. And I would agree with that. As part of a solution, there might be something of an inflation cap. But if you are not dealing with the launch price problem—and that might involve things outside of Medicare, you know—the anti-competitive behavior that leads to the high launch prices, you would want to consider it in a broader context.

I would not reject it out of hand. But as a single solution, to Doug's point, I agree: not on its own.

Dr. BACH. I would say in the absence of—I agree on all the list price or the launch price points. In the absence of the company producing compelling new data that their drug is more effective, for example, I would think that we should not see price inflation. But I think we should be open to the possibility that a company—for

example, for a new indication with greater effectiveness or a better regimen with less toxicity—should be able to price their drugs based on the benefits they provide.

That is not happening currently whatsoever. So it would require a shift to that kind of approach.

Senator MENENDEZ. Well then, let me ask you, Dr. Bach, about drug coupons. Manufacturer coupons, many suggest, distort spending, and insurance companies are cracking down on how the coupons affect enrollees' deductibles and out-of-pocket maximums. Many companies tout patient assistance programs as a way they help with drug costs, but access in that regard is not universal.

I have seen the commercials on TV where, at the end, a drug company says, if you can't afford your medications, they may be able to help you. And often they provide coupons to help patients afford their medications.

It sounds great, but I wonder if patients really save with these coupons. Is there a way to improve transparency and track use so that we know what role these coupons play in the drug marketplace? Who is winning with these coupons, because I often think it's possible that companies are actually getting sales that they would not otherwise get. And at the end of the day, they are making more than they would but for the coupons.

Dr. BACH. Thank you for your question.

I can assure you we know who is winning, and it is the people who are printing the coupons. And the problem is that we should be acutely concerned that patients can afford drugs they need, as we have already talked about all morning.

And so it is very difficult to be critical when coupons step in and make drugs instantly affordable. But the reality is, they are artificial price supports. And insurers tack on high co-payments and coinsurance and put in utilization management to try to counteract pharmaceutical corporations' desire to charge high prices. And that is the dynamic in the market.

And what is challenging now is that patients are entirely caught in the middle of that. So when coupons are used, they are used specifically to undo what the insurers are trying to do to counteract the higher prices of drugs. It is a lose-lose situation in the long run, but it is—like I said—very difficult to say we should not have coupons because we have to be concerned about the patient in front of us.

Senator MENENDEZ. One final question, Dr. Miller, on generic price collusion. There are reports generic companies work together to split the U.S. into territories and not compete against each other. I was a co-sponsor of the chairman's CREATES Act last Congress, and I plan to support the legislation again in this Congress.

So I am concerned by the growing reports of anti-competitive behavior by generic manufacturers. What can be done to prevent the alleged anticompetitive practices that drive up prices for everyone?

Dr. MILLER. And I also think that this practice is not exclusive to the generic drug market. I mean, the practices that you are talking about—dividing markets up—that happens in the brand-name sector as well.

So what you want to do is be able—and many people have already commented on this. You want to open pathways so that other

competitors get in, create the "pay-for-delay," which is also focused on these anti-competitive practices, and these agreements are a step in that direction.

Senator MENENDEZ. Thank you, Mr. Chairman.

Dr. MILLER. Could I say one thing on the coupons? Everything stands that he said. There are other things that you could do. Say, if you enter with a coupon for the patient, you do not drop the patient off when they hit their catastrophic cap. You have to keep paying once they hit the catastrophic cap. In other words, if you are in, you are in. You support that patient. You could also change the tax treatment of that coupon and say, if you are really into this, then do it out of your revenues, not a tax-subsidized revenue.

Senator MENENDEZ. Thank you.

The CHAIRMAN. Senator Cardin?

Senator CARDIN. Well, thank you, Mr. Chairman, and I welcome your leadership on this committee.

The CHAIRMAN. Thank you.

Senator CARDIN. And welcome to our five new members. And let me thank all of our witnesses for our first hearing. Drug pricing is certainly one of the top challenges we have in this Congress.

Ms. Sego, again, many of us very much appreciate you putting a face on the issue. We hear the numbers, but it is important to see that each one of those numbers is a family that is struggling because of our inability to get proper control over drug pricing here in America.

So I want to just try to simplify this a little bit. I really appreciate the nuances that have been mentioned here about our programs and how pharmaceutical companies can manipulate pricing in order to take advantage of our current system, and I certainly recognize that there could be unintended consequences to whatever we would do here. And we certainly want to make sure that we maintain access to the latest drugs here in America.

But for drugs that are competitive, I am having a hard time understanding why we would not want to put in competitive pricing here in America, as other countries have by formularies, and have the largest possible purchasing power. I know we are restricted here on Medicare, but if you take all government purchases, it gives you the largest market share in the world, I believe.

And therefore, for drugs that are competitive, we should be able to negotiate rather competitive international pricing, rather than having to go to Canada to buy discounted drugs. And I very much support what Senator Menendez and others have said about anti-competitive activities. We have to fight them aggressively and make sure that there are not steps being taken to compromise competition.

In regards to those drugs that are not competitive, and that is the high-cost drugs, I fully understand that. I get that. I want to make sure they are available. But we should have some way of having either mandatory arbitration or value-based pricing in order to be able to get a handle on these drugs as they come into market. And remember, one day they will be competitive, and if we have a competitive model in place for competitive drugs, their costs will come down sooner, rather than later, as under the current structure we have in this country.

Now, I will start with Dr. Miller and anyone else who wants to comment. Does this make sense? Would this bring down pricing?

Dr. MILLER. I mean, I think—okay. A couple of things. When your question started with competitive drugs, you said: "Why doesn't the government broadly negotiate or intervene there?" You could take that path, but you also have to think about the administrative burden and complexity of negotiating the range of drugs that are out there with competition and ask yourself whether having a private intermediary might be a more efficient way to get there.

Senator CARDIN. I am not wedded to the government doing it. I do not mind an intermediary, but let them have the full complement.

Dr. MILLER. I mean, some people talk about that. They have an agent on behalf of the government doing the negotiations.

So you could do that, but you still have to think about the administrative complexity of how many drugs you are talking about negotiating. Definitely in my comments, I was pointing you towards, particularly in Medicare, the ones where there's little competition and saying that that may be a more manageable basket of drugs to think about with value-based pricing or a binding arbitration approach that the government could approach.

This assumes that the negotiation inside D is working well, which it is not right at the moment. If that is not going to get fixed, I think then we do have to talk about the kinds of things you are talking about.

Senator CARDIN. Dr. Bach?

Dr. BACH. If I can add to that—Mark talked about D. If I can talk about Part B drugs, the issues of competition I mentioned in my opening remarks, there are some in my testimony, for example, about CAR-T therapies. There are a couple of CAR-T therapies aimed at the same part of the cell for lymphoma that Medicare will not treat as competitive products, but it could.

And Medicare has tools at its disposal to cause price competition between these products, although it might need some help, if you will, to have the authority in some cases, such as putting the drugs in the same billing code so that, as the manufacturers compete over price, the average price would be lowered.

They have had this ability to use least-costly alternatives as well just so that product competition in the same disease area with the same mechanisms could have drugs competing, even if they do not fall into the classic multi-source product category.

Senator CARDIN. Dr. Holtz-Eakin?

Dr. HOLTZ-EAKIN. So let me reemphasize what I said at the outset, which is, I do not think you want to look for a one-size-fits-all solution. Not all drug prices are a problem. There are some that are. There are some off-patent, sole-source drugs that are priced exorbitantly. And I have been confused for a long time as to why the FTC does not go after these folks. I have asked the staff as to why the legal foundation is not there to really take on what I think is anti-competitive, abusive pricing. And I would encourage you to look into that.

The second thing is, there are these very high price specialty drugs, and those are the hardest thing to think about. And in

terms of Part D and Part B, I would just want to echo everything that has been said. The Part D program has been enormously successful, but it could be reformed not using any single lever, but broadly with the catastrophic maximum, realigning incentives for the PBMs to negotiate effectively, and getting everything you can out of that program. That is a good thing. And on Part B, certainly separate out the physician reimbursement from the drug price. That makes perfect sense.

I would be nervous about, for example, the administration's proposal on the international price index for the following simple reason: if you look at the study they base this on, it is based on 27 drugs that are available in the U.S. Only 11 of those drugs are available in the rest of the countries.

And so you get what you pay for. And one of the things we get in the United States is access to the best therapies. And what they are not getting in those other countries is access to all the best therapies, and I would be careful there.

The CHAIRMAN. Senator Hassan?

Senator HASSAN. Well, thank you very much, Mr. Chairman. And I want to thank you and the ranking member for welcoming me to the committee. I am so pleased to be here, and I hope to work with you and Ranking Member Wyden and all the members of the committee on the full range of issues under the committee's jurisdiction, including on efforts to strengthen Medicare, Medicaid, and access to affordable, quality health care.

Obviously, lowering prescription drug prices is a big part of this. So I am very pleased we are having this hearing, and I want to thank all the witnesses for being here today.

To Ms. Sego in particular, I know from personal experience how difficult it is to talk about one's children in public, especially when they need particular medical care or help. So thank you for being willing to do that, because you are giving voice to an awful lot of people, and we really need to understand your experience and the experiences of people with chronic illness all around our country. So thank you for being willing to do that.

Dr. Miller, I wanted to start with a question to you, really to follow up on something that you said in your testimony. We have seen a lot of bad actors gaming the system over the years, really to pad their pockets. There are countless ways drug companies take advantage of loopholes, and taxpayers end up footing the bill. I certainly saw that as a former Governor. I know how hard it can be on States, especially when it comes to Medicaid.

One way drug makers play games is with the Medicaid rebate program and the way they calculate rebates for what are known as authorized generic drugs, generic versions of brand drugs that the brand manufacturer itself produces and sells which are typically less expensive than the brand drug. When this was first explained to me, it really made my head spin, and it still kind of does.

Drug makers can take advantage of a loophole in the law that lets them include the less expensive authorized generics in the calculations of how much they need to provide in discounts for brand drugs under Medicaid. And oftentimes they do this by selling their authorized generics at a lower price to their own corporate subsidiaries. Including these authorized generics in the calculation then

lowers the amount in discounts a manufacturer needs to provide to Medicaid, meaning that the government ultimately is not getting the full discounts they should from the manufacturers, and neither are taxpayers.

MACPAC has unanimously recommended that Congress fix this loophole. Now I know, Dr. Miller, that your expertise tends to focus on the Medicare area, but I am interested to hear your thoughts here. Do you think it is important that we prevent manufacturers from gaming the system, including fixing this specific issue?

Dr. MILLER. I agree. Your head is spinning—mine is too on these behaviors.

I do agree. I tried to address it in my testimony. It may not have come across clearly. But yes, that misclassification of drugs is something that should be addressed, and I believe there is draft legislation floating around.

Senator HASSAN. Right.

Dr. MILLER. And that should be a step that is taken.

Senator HASSAN. Well, I thank you for that response. And speaking of Medicaid rebates, I certainly know that the chairman and ranking member have both been champions of fixing this classification. So I will be pleased to work on legislation around this issue and look forward to the committee's work to get it over the finish line.

Dr. Miller, I also share another priority on drug pricing and health-care costs more generally, that I know both the chairman and ranking member have also worked on, and that is the need for more transparency, and everybody has talked about that here today.

Well, we know that transparency alone is inadequate to address high drug prices and other health-care costs. We know that it can certainly play an important role. For example, we know that drug companies pay billions of dollars to physicians. Data gathered because of the Physician Payment Sunshine Act shows that in 2016 alone, drug and device companies paid more than $8 billion to doctors. These payments are in gifts and meals and travel, and speaking fees.

Dr. Miller, I would like to know what you think about these drug company payments and how they influence prescribing and ultimately how they might influence patients?

Dr. MILLER. So I think we are talking about the "Sunshine" or what is referred to as the "Sunshine" legislation. Back in the day when I was the Executive Director at MedPAC, we strongly recommended that and endorsed it, developed the design behind it that we put in front of the Congress. So we think that there should be line of sight for drug and device companies, their contributions to physicians, and other actors in the system.

The one thing I would draw your attention to is, payments to patient groups are not tracked as part of that and should be added.

Senator HASSAN. I thank you for that point, and I look forward to following up on it with you.

Thank you, Mr. Chairman.

The CHAIRMAN. Yes.

Senator Isakson, Senator Cornyn returned, so I have to call on Senator Cornyn first here.

Senator CORNYN. Can anybody on the panel explain to me why we have a general prohibition against kickbacks, call them rebates, under the Social Security Act, but we nevertheless allow them for prescription drug pricing? What is the sound public policy reason for excluding prescription drug pricing from the anti-kickback rule under Federal law?

Dr. HOLTZ-EAKIN. I cannot explain that and will not pretend to.

Senator CORNYN. I thought I was the only one who did not understand the wisdom of that.

Well obviously, it is not a transparent arrangement. And it does produce upward pressure on drug prices, and obviously the negotiations between the PBM and pharma in terms of actually what the net cost is are not transparent nor do they deliver to the consumer. Dr. Miller? Dr. Bach?

Dr. BACH. It is delivered to the consumer indirectly through the reduction of the total cost of the benefit, but it is not delivered to the actual consumer using the drug. And that is a disassociation that is a problem, because it essentially reverses the structure of insurance, lowering the total cost for people who use it the least and raising the cost for people who use it the most relative to what would be the case if you allowed the rebate to be used at the point of sale, including all discounts.

Senator CORNYN. So in Ms. Sego's situation, if the pharmacy benefit manager pays a certain price but then negotiates a kickback or a rebate, that is not delivered to Ms. Sego or to her son as a cost savings for the insulin she has to buy; correct?

Dr. HOLTZ-EAKIN. That is correct. And I want to emphasize something about that situation. If we had the negotiation be about the up-front price, instead of a high list price and a rebate, you just negotiate a lower price. That would be the price that Ms. Sego would face. And insurance companies would look at that and say, "Okay, she is not paying as much as she used to. We are going to have to make up that money somewhere else," and they might raise premiums.

That means that people who do not have extreme insulin drug costs would pay a little bit more in a premium every month, and people who have extremely devastating medical conditions and high health-care costs would get less cost. That is exactly what insurance is supposed to do.

And so this rebate system is more than giving strange incentives on pricing. It is undercutting the purpose of insurance in general.

Dr. MILLER. Keeping in mind that if it transfers to the premium, it is possible that the premium goes up. But remember, that is how the insurance company is marketing its product to the public. And so there is downward pressure on that premium.

Senator CORNYN. Well, explain this to me. I thought the reason why we granted patents in this country to develop new drugs and new things, the reason why we gave people exclusivity when it comes to selling it, was based on the sunk cost they put in research and development, so they could recoup that back in the generic drug space. Once that patent expires, then the benefit is no longer exclusive, and so that means that, for example, the blood pressure medication I take, I think I pay $9 for a three-month supply. It is very inexpensive.

But those same benefits do not flow in the case of biosimilars like insulin, so it strikes me as bizarre that 100 years after insulin basically was started to be used to treat diabetes, we still have a system which guarantees an inflated price even though the cost of the research and development, which I thought was the rationale in the first place, is inapplicable.

So what am I missing? Dr. Bach? Dr. Miller?

Dr. BACH. I do not think you are missing anything. And I think the issue is, we provide the monopoly protection and the exclusivity as a way for companies that successfully innovate to recoup their risk—you know, risk-adjusted return, which includes the money they sunk into research and development. And it is supposed to be for a time-limited period.

And what you have focused on is that, in the space of biologic drugs, that period, which is supposed to be 12 years, is not 12 years for these biologic drugs. They maintain their monopolies well after it. Most analysts expect that smaller-market biologic drugs with less than, let us say, a billion dollars a year in revenue, which is a lot of money, but still a smaller market, those drugs are very unlikely to face biosimilar competition ever.

And so, if you believe in the structure that the party ends at the end of exclusivity, the monopoly pricing ends, that is the reward period, you may want to examine taking a more aggressive stance on the prices of biologics when that period ends or when the patent period ends, and directly intervening on that price. And that would reconstitute the reward structure we have for innovative medicines.

I think if you wait for this biosimilar process to play out, you will be perpetually unsatisfied by what it achieves. Even for large market drugs, we will not see the kind of price declines we could if we drove those prices down to marginal costs, which is the goal of competition.

Senator CORNYN. Thank you.

The CHAIRMAN. Senator Isakson?

Senator ISAKSON. Thank you very much, Mr. Chairman.

Ms. Sego, I have a question for you. And congratulations on being a wonderful mother and willing to come here and testify and tell us your story. When you can put a face on a story, it helps more than any professional degree that Dr. Bach or anyone else has. Although, I am sure he is extremely talented, and I am going to find out in just a second.

Ms. Sego, did you ever have the manufacturer of your insulin drugs for your son—did you ever qualify for any program because of income level to get a benefit?

Ms. SEGO. No. We kind of fall within this window; we make either $100 too much or $500 too much. So we do not fall into any programs and we cannot use the coupons, the rebates everyone seems to be talking about. We cannot use those because we have employer-based insurance.

I have had one success with that, and we got $25 off the vial of insulin.

Senator ISAKSON. I asked that question because, when I first got elected to Congress 20 years ago, one of the first calls I got for constituent help was to get some help to get insulin for somebody who could not afford to get it.

Ms. SEGO. Yes.

Senator ISAKSON. And I did my research as a new member of Congress to try to find a way to solve the problem and found out there were companies offering insulin at a deeply discounted price if the people qualified for it based on need.

Ms. SEGO. Yes.

Senator ISAKSON. And that still goes on, does it not? Pharmaceutical manufacturers still create some availability of drugs for people who have that need and cannot afford it? Is that true or is that not true? I do not know.

Dr. MILLER. I cannot speak specifically to insulin, but as a general proposition—and some of this was taken up in the coupon questions—yes. Drug companies provide coupons to help, and they also have patient assistance programs that they use to try to help.

Senator ISAKSON. It makes sense that they ought to, because they have done it in the past, I know. And people like Ms. Sego ought to be able to benefit from that.

Yes, sir?

Dr. MILLER. Well, but there is this trade-off that I think Peter went through fairly thoroughly, which is, it does help the patient at that moment, but it allows the drug company to maintain the high price, and then that price is kind of baked into the system more broadly.

Senator ISAKSON. The next question I want to ask deals with an experience I had about 2 weeks ago. My gastroenterologist is not Dr. Cassidy, but Dr. Cassidy is at the dais here, so he can correct something that I say if it is not correct.

But I have a hiatal hernia. I have had that problem for some time, and I have a gastroenterologist who treats it. When it flares up from time to time, I have to go to him, and recently that took place. He gave me a prescription and I cannot believe I cannot remember it, but it is a 40-milligram yellow and round tab capsule. And Dr. Cassidy will think of what that might be. It is omeprazole, or——

Senator CASSIDY. Nexium? Prilosec?

Senator ISAKSON. Prilosec—no. Omeprazole. No, not Nexium. [Laughter.] Anyway, that is not the point. The point is this. I was leaving town the next day. I had an appointment with the doctor, a follow-up. And he gave me—he said, "I need you to stay on this for 30 more days. I am going to give you a prescription for 30 days."

And I said, "Well, I have to go out of town." And he said, "Well, you can go by the drug store on the way home and they will get it, and we will call them." I said, "Okay."

And so I gave them my cell phone number, because it was going to be about 30 minutes before I could come back by and pick up the written prescription. When I did he said, "I cannot—your price is $309 for 90 days. That is all that your insurance coverage will allow it to be done."

I said, "Well, that is crazy, because last time I think I paid $30 or $20 or something like that." He said, "Well, it is a part of this negotiation stuff," and it was after January 1st, so it all changed from last year's benefit program.

In the end—what I wanted to make a point of is—he said, "Well, there are lots of different things. Let me see what I can do," and this is the pharmacist.

A half hour later, he called me back and said, "Well, I got you $7.50 for 30 capsules. I got the $309 that you had before, and then there were 3 other offers in between those numbers."

And there are different reasons for them, but is there that much difference that goes on between the pharmaceutical manufacturers or the PBMs or whomever it is and the insurance company and the patient? Is that an odd example, or does that happen all the time? I just do not know.

Dr. BACH. I think my various graduate degrees allow me to answer that question, and the——

Senator ISAKSON. I would not know the right answer from the wrong, but I know it is a problem for me, and I want to try to find out what the answer is.

Dr. BACH. No; I apologize for being light-hearted.

Senator ISAKSON. No, that is good.

Dr. BACH. The issue is highly complex, and it is not just with the pharmaceutical manufacturer. But there are many transactions behind the one that you just discussed, including that the pharmacy is buying medicine through different means. Some are reconciled through the pharmacy benefit managers, others are not.

And so in one way, it is very pleasing to hear that you had the price transparency you did at the counter to have some options. But the reality is that it is not ideal that patients, many of whom are on many medications, have to deal with this very complicated shopping which makes buying an airline ticket seem simple.

Senator ISAKSON. I respect that answer and I understand that answer, but I do think—my time is up. It is so complicated. I am not a really smart guy anyway. It is beyond me.

And I know that for a lot of the people—the constituents I have—it is way beyond them, so complex. When we have these hearings, we talk about things we might do. When I go back the next night and try to remember what was said, I cannot remember what Doug said to beat myself—so it is mind boggling. We can simplify it in some ways and get the consumer involved.

It seems like we would have more price pressure, favorable price pressure, than anything else. But I appreciate the time.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Cortez Masto?

Senator CORTEZ MASTO. Thank you, Chairman Grassley and Ranking Member Wyden. Thank you for the welcome. I also look forward to working with you and all of my colleagues and so appreciate the hearing today.

So thank you to all of the panelists. This has been very, very informative.

Let me—Dr. Bach, I have only got about 5 minutes. Let me talk to you a little bit about Medicare Part B.

In 2014, the Obama administration proposed a demonstration project to test changes to Medicare Part B drug reimbursements in an effort to diminish incentives that drive doctors toward high-cost drugs. At the time, stakeholders—and many of my colleagues—ex-

pressed concerns that the proposal would negatively impact patients' access to critical therapies.

This administration has made another attempt to test changes in Part B. That proposal has also been met with concerns about patient access. Both real and perceived threats to beneficiary access are one of the most fundamental challenges that we face in enacting meaningful policies to combat high drug costs.

So, Dr. Bach, you have advocated for such models to move forward. What makes you confident that we can keep beneficiaries safe in the process, and are there guard rails or beneficiary protections that we should be considering?

Dr. BACH. So, thank you for your question. There are two different proposals, the one that came in the Obama administration, and the more recent one. But let me say about Part B drugs that one of the core distortions is that physicians and hospitals are paid a percentage markup in reimbursement above the average cost of acquiring the drug.

And that creates the reality that if you use an inexpensive drug, your markup or your profit is a smaller total number than a drug that is very expensive. And you could say these are small effects, but every study—and I have included links in my testimony to this—that has looked at this has shown that prescribers are, in fact, influenced by this and tend towards the more expensive drug.

Now even that you could say might be okay if they are equivalent, but it creates actually a problem, because then the manufacturers have a way of building market share by raising their prices. So you have an upside-down system where, ideally, the users are incentivized to use lower-price products and pull down prices, and the sellers are always, of course, trying to raise prices. We now, instead, have alignment that will raise prices.

What was proposed in the prior administration that is shared with the current proposal is that we should dispense with, or at least get a hybrid version of that markup, which is either a smaller percent, plus a flat—if you will—handling fee, or entirely go to a handling fee so that at least that proportional profit incentive disappears or is attenuated enough.

In my testimony, I walk through why it actually makes sense to have a very small percentage markup having to do with financing and bad debt risk.

What has also been proposed—and it was part 2 of the Obama proposal and is in this proposal—is the idea of actually pulling the ownership away for expensive drugs from the doctors and hospitals entirely so that a vendor, another party, would send drugs. When the doctor had got them, they could use them, but they would never own them. They would never bill for them. They would be completely separated from the economics.

That is a very attractive idea. It was originally in the 2003 Medicare Modernization Act under competitive acquisition. And what is appealing about it is that it would allow purchasing entities that were much bigger to negotiate aggressively.

They could do sophisticated things like have indication-specific pricing. And they would allow doctors to do what they are best at, which is practice medicine, and not get involved in the finances of these often hundreds of thousands of dollars of drugs.

Senator CORTEZ MASTO. Okay.

But is there some concern about patient access? That is what I was hearing. And I do not disagree with what you just said. I am concerned with patient access as well.

Dr. BACH. I apologize. I managed to talk for 3 minutes without answering your question.

Senator CORTEZ MASTO. That is all right.

Dr. BACH. The concerns about patient access are marched out every time there is an attempt to reform Part B and take away the proportional profit. We have some research on our website I can send you as well. We have examined the various claims, such as, if you decrease the proportional markup, doctors will leave Medicare or they will shift patients to the hospital outpatient department.

Because of sequestration in 2013, I believe, we actually have a natural experiment. There was a shock to reimbursement. It fell by 2 percent, unanticipated. None of the concerns that were raised with doctors dropping from the program or shifting their patients to the outpatient department in hospitals or anything actually occurred. So I would be fairly confident now that we have that data to say that going to a more rational system is very unlikely to impede access.

Senator CORTEZ MASTO. Thank you.

Dr. MILLER. One thing very quickly.

If you lower the price in many of the ways that Peter said, the beneficiary's co-payment goes down.

Senator CORTEZ MASTO. Okay. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Yes. Thank you.

Senator Toomey?

Senator TOOMEY. Thank you, Mr. Chairman.

And thank you very much to the witnesses. This is a really, really important and useful conversation, certainly for me.

I want to just briefly follow up on this discussion. We have had several iterations of this, and it seems to me on Medicare Part B, if we used the markup rather than the percentage approach we use now, if we had a mostly flat amount or an entirely flat amount, you could set that at a level that would be equivalent to what we pay now. And from a government accounting point of view, the score would be the same in terms of that direct payment, but having changed incentives, presumably over time, there would be a savings.

Does anybody on the panel disagree with moving Part B drug reimbursements in the direction of a mostly flat fee?

No? Well, I think that is an idea whose time may have come.

I did want to also step back for a second, though, and make sure that we are all looking at this the same way, if that is possible. Specifically I am talking about the—it is indisputable that prescription drugs are enormously expensive and can be enormously problematic for many families. We heard a very compelling case from Ms. Sego.

But when I have looked at this compared to other countries, it is not clear that this is a problem specific and unique to the United

States. Let me just show you a couple of charts that I think are interesting.

This is an illustration—this is from the OECD, and it is a chart that shows the percentage of overall health-care spending that is constituted by retail pharmaceuticals. And if you look at that, the United States is the red bar. We are actually towards the lower half compared to OECD countries. Gold countries are G7. The blue are OECD. And as you can see, most of these countries have a higher pharmaceutical spending rate relative to overall health-care spending. I was surprised to see this.

There is another chart that I want to take a quick look at here. Because the more important fact for most of my constituents is, what is their out-of-pocket cost? And if you look at out-of-pocket spending, it is actually a similar story. This data comes right from the OECD website. As a percentage of overall health-care spending, the U.S. has the second lowest out-of-pocket spending among all OECD countries.

There is no question we have very high spending, but it is much lower than most of the rest of the modern developed world, which just tells me that we must have enormously high costs across the board, right? We must have high hospital costs, we must have high physician costs; we have high costs everywhere.

And as it happens, as a percentage of everything we are paying, the pharmaceutical problem is actually not as big as it is in most of the rest of the world. So just briefly, I do have another question. Does anybody—am I missing something? Do you disagree with this? Is there—Dr. Miller?

Dr. MILLER. I would qualify some of it. First of all, the statement of 10 percent or what you were looking at originally as a percentage of spend, if you use national health expenditures, which is what feeds into that OECD, I believe, then you are missing a significant portion of the spending that occurs in physicians' offices, and in hospitals and other settings. So it is only part of the total spend.

Senator TOOMEY. Right. But the methodology, that is true for the U.S. and for the OECD countries.

Dr. MILLER. I would be careful about doing those cross comparisons. I am not expert enough to tell you that that is a comparable number. And then the other thing I would say is, you are looking at percentages—and I think you made this point at the end of your comment—that I would track on very carefully. Yes, but total spending—and it not just drugs. It is hospitals, physicians, everything else. We pay top dollar for everything in this country. You are definitely right on that point.

Senator TOOMEY. Dr. Bach, did you——

Dr. BACH. This is why I emphasized we do not have a broad-based drug pricing problem. There are places we have it. It is largely these inpatient Part D reimbursed drugs. Those are the things to focus on.

Senator TOOMEY. Yes.

Dr. BACH. I was just going to add, a better number for total pharmaceutical spending is about 14 percent of total health-care spending. That incorporates the numbers that Mark was just men-

tioning: inpatient and medical benefit drug. So it is 50-percent higher than on that chart.

Senator TOOMEY. Right, but it might also be for the other OECD countries. That is my only point.

So look, this is not to suggest that we do not have a problem here. But I think it is something we ought to be thinking about, especially if we are thinking about some radical change.

Last point—I suppose I am not supposed to do this, Mr. Chairman, so I will leave it at that, but I would like to follow up with some of you on some Medicare Part D issues.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Lankford is next.

Senator LANKFORD. Mr. Chairman, thank you. And for all of you here and the research you have done, and for what you have already done for your son and your family, I thank you for being a part of this dialogue today.

Oklahoma is currently in the process of doing a values-based pricing model. And it is something we have experimented with, started that process, got the waiver to be able to do it, and we are to start reimbursing for drugs based on how well they work. And if they are not working, they get a lower cut on it.

So it will be an interesting model. We will come back and try to give you more data, as I hope we can interact on this in the days ahead based on what we are doing in our State with the Medicaid program.

Dr. Holtz-Eakin, you mentioned earlier about 340B being what you thought was a driver of an increase in cost overall, then did not have a chance to be able to fill in the gaps. Why? Why do you think the 340B is a perverse incentive there?

Dr. HOLTZ-EAKIN. Well, it has just grown enormously. And when you evaluate the program it should be, do the benefits of lower cost, do the discounts that are provided by drug companies in the 340B program, flow through to lower-income Americans who need the help?

The answer is "no." There is nothing about that that flows the benefits through. So you have this program which has large amounts of discounting, which is helpful to the hospitals and others who are benefiting from it, but it forces drug companies to raise prices elsewhere and feeds the general upward pressure in other parts of the sector. It is a classic example of how we are shifting costs around, not dealing with the underlying costs.

Senator LANKFORD. Okay.

Back to the previous comments we have had about rebates. If you are going to participate in the Medicaid program, you have to give a rebate. You have to give rebates as a part of that formulary.

What is a better way to handle this, or for us, is it just a matter of stepping in and saying rebates were an experiment that has been done for decades and needs to go away?

Dr. HOLTZ-EAKIN. As I said in my other remarks, I think there is a real problem with the Medicaid best price formulation to begin with. It really does inhibit the incentives of firms to compete aggressively because, if they do that, they then have to pass that along to the Medicaid population as well.

I think you do not think about the rebate in isolation. You have to think about what kind of competitive pressures you want to build into these systems. And we do not have good competition.

Senator LANKFORD. But then you have to have a situation like what we have in Oklahoma where we compete—Medicaid actually competes to be able to get a drug discount. We do not do PBMs. Other States have PBMs for Medicaid. We do it as a State to be able to do that and be able to compete for a better price, and actually beat the price for a lot of PBMs.

Dr. HOLTZ-EAKIN. And if the State is willing to say "no" to some, and "yes" to others, and not have to honor every drug on the market, then you can do that effectively. You can actually negotiate.

Senator LANKFORD. Right.

Thoughts from Dr. Miller on rebates?

Dr. MILLER. Yes, so I guess a couple things that I would say on the rebate as it relates to Medicaid, keeping in mind that this is a public program and a taxpayer dollar. I think the motivation in requiring a rebate from the manufacturer is to try to get a good spend on the taxpayer dollar.

And the only thing I would say is, if you are going to abandon the rebate, which will double your costs as a budget expenditure, then you need to have a very aggressive structure to make sure that the prices coming into that program are not as high as they currently are. And I am not quite sure how to advise you on that.

Senator LANKFORD. And we have talked a lot about how we actually get the rebates to the actual consumer who is most affected by them. And I think that is part of this long-term getting out of the Medicaid portion of it, getting over to the private side of it.

Dr. MILLER. Yes, that——

Senator LANKFORD. That is a different issue. But this has become extremely complicated.

Several of you have brought up—and several of us have brought up—this issue about a flat fee, basically, for doing a prescription rather than a percentage. That is currently in the Medicaid program right now for the pharmacist.

The pharmacist does not get a higher amount based on the cost of the prescription. They get a flat fee as a pharmacist regardless of what the cost of the prescription is, just to do the dispensing.

It seems odd that the physician is not in that same spot that the pharmacist is in, that somehow we think flat fees are okay with pharmacists, but flat fees are not okay for the person actually writing the script on it. Does that seem odd?

Dr. BACH. I think we have all agreed that the physicians getting a percentage of the drug's price is not good policy.

Senator LANKFORD. Okay.

Dr. Miller, you made a comment in your written testimony as well trying to dispel this argument that the high cost of drugs is based on R&D. You made the statement that between 2013–2017, the five largest U.S.-based drug companies spent substantially more on marketing and administrative costs than on research and development.

Dr. MILLER. That is right.

Senator LANKFORD. What do you include in the administrative cost there?

Dr. MILLER. I am not sure I can book this through for you right here. But we are talking about things like marketing costs, advertising costs. Those are included in the number that we were putting together.

I can come back to you and give you the detail on what we put in. I just cannot do it off the top——

Senator LANKFORD. Sure. That is fine.

But are you trying to push back on the issue of everyone who says the drug cost going up is because of R&D actually is not comparable, because administrative costs and marketing costs are as high as their R&D costs?

Dr. MILLER. I am trying to say a couple things, and I appreciate the opportunity to spell it out.

Senator LANKFORD. Sure.

Dr. MILLER. The first thing that I would say to you—and again, this draws on Peter's research—the revenues that come out of the United States exceed R&D revenues by something like 70–75 percent, somewhere in that range. So the first point is, when people say R&D is driving these prices, there is a big disconnect in that.

The second point we are trying to make with that is, we looked at specific companies and said, how does your R&D look relative to other expenditures in your company? And we found many companies in which they are spending much more on advertising, marketing, and other administrative expenses than they are on R&D.

Senator LANKFORD. Okay. Thank you.

The CHAIRMAN. Senator Thune?

Senator THUNE. Thank you, Mr. Chairman, for holding the hearing and all of you for being here today.

This is an issue that we all hear about from folks back home. It is a front and top of mind issue for a lot of our constituents.

The President has expressed his interest in tackling this issue, and I hope that we will have Senators on both sides of the aisle who are interested in finding solutions that promote competition, ensure access to needed medicines, and reduce costs for patients.

Dr. Miller and Dr. Bach, you each referred to the possibility of shifting incentives in the current supply chain in such a way that patients recognize a greater benefit at the pharmacy counter. Would you elaborate a little bit further on how that could work and what implications there would be elsewhere in the supply chain? And maybe particularly too, how does it impact competition in Part D?

Dr. BACH. Thank you for your question. The area that was being discussed was particularly that patients in Medicare Part D pay the price that is negotiated by the Part D plan. So let me explain what that is.

As has been mentioned several times today, the majority of the price concession that Part D plans get from pharmaceutical manufacturers comes in the form of a rebate given back to the plan after the prescription is dispensed. But the way the beneficiary experiences the price is essentially list price. It is slightly different than that, but for argument's sake, it is a list price.

So when they earn their deductible and they are paying every dollar of that price, if they are taking a drug that has, let us say,

a 50-percent rebate, they are paying a dollar even though the plan has achieved a price of 50 cents.

The notion of point-of-sale rebates is that instead, when the beneficiary comes to get their medicine, that 50 cents the plan is eventually going to get back is subtracted from the cost that the patient pays. Now the the issue is, that 50 cents has to go somewhere. And it will go back to the plan, which means it will go back to Medicare. And Medicare pays, you know, the majority of the Part D plan costs, about 75 percent or so.

So it means shifting the burden of those costs. But as Doug mentioned, right now the system is structured—because of high list and high rebate prices—to push more than, if you will, the fair share of prices on to patients who take expensive drugs and take a lot of them. And they are paying more than that negotiated price. They are ending up paying more than the share that the program was originally designed to put upon them.

And the beneficiaries, whose major expenditure is premiums, are each getting the savings as well as the taxpayers more generally. But from a proportional perspective, it is very expensive for the few who really need the benefit, and the savings to those who do not need it as much are really quite slight.

Senator THUNE. Anything to add, Dr. Miller?

Dr. MILLER. The only thing I would add is, you could turn this around in some of the ways all of us have mentioned, I believe, which is start with a discounted price, and then you do not have—because you are figuring out how to deal with this rebate and distribute it differently.

The other way is to start with a discounted price as it moves through the supply chain, so that the person who faces that at the counter is paying that discount price, the PBM is working with the discount price, the program, the manufacturer—it is one discounted price throughout. It is not all this back-end action.

Senator THUNE. Yes, it seems like—what we are talking about, obviously, is just shifting around, redistributing where the costs in the whole system are. And I guess the question is, how does that actually lower drug prices to the consumer?

I mean, it would for some, obviously. But you would be shifting it on the backs of others.

Dr. Holtz-Eakin?

Dr. HOLTZ-EAKIN. In the Part D program, though, I think all of us have emphasized you could take the standard arrangement where there is a catastrophic maximum—and right now, above that, the taxpayer is on the hook for 80 percent of it. And the plan itself is on the hook for very little. You could change those incentives so they put the plans on the hook for those very high costs, and the contribution that the drug companies are currently making, which is in the coverage gap, put that in the catastrophic region. Now, both of those actors have incentives to keep the drug prices lower.

And that would be a beneficial change that just in the moment would rearrange—and I am sympathetic to your observation you do not just want to rearrange costs, but it would improve the incentives over time. And that is a good idea.

Senator THUNE. That is how you lower it. Okay.

I am running out of time here quickly. But very quickly, Dr. Miller, I would like to hear a little bit more about how the Foundation thinks that this concept of greater transparency in pricing and producing alternatives to older medicines that have become costly due to the lack of competition actually will work to disrupt the markets, and if there is anything we might be able to learn that is applicable to the broader drug pricing discussion.

Dr. MILLER. Well, so is this a transparency question, or is this a——

Senator THUNE. Yes; I mean, it is kind of what your organization is trying to do——

Dr. MILLER. Okay.

Senator THUNE [continuing]. The Arnold Foundation, along with other health systems that have committed to financial support, for example, Civica Rx, the not-for-profit generic drug company's focus on producing affordable generic medications that oftentimes are in short supply at hospitals.

Dr. MILLER. Okay. There could be a few things happening here. Let me hit a couple of them.

So one is that, in terms of transparency, I think the way we think about it—and a couple of things have already been touched on, certainly keeping track of contributions to providers and to patients; we think that is relevant. We also think having greater line of sight on the part of the program, think of Part D in particular, of the fees and rebates in the supply chain and how those are allocated back to the government, is another place where you could have line of sight.

But then the Civica Rx point was, we were trying to support a group of health systems to enter the—particularly, the shortage generic market, become a manufacturer in and of themselves and be able to sell to their members to overcome some of the shortage drugs in that particular place.

And we saw that as disruptive to the generic market, where it had come down to a very few manufacturers, and prices were rising.

Senator THUNE. Thank you.

Dr. MILLER. That was some of it anyway.

The CHAIRMAN. Senator Young?

Senator YOUNG. Thank you, Mr. Chairman.

Once again, I want to acknowledge Ms. Sego. Thanks for your advocacy here today and for putting a real human face on this topic. It reminds us all why we are here. So thank you. You are doing the Hoosier State proud.

Dr. Holtz-Eakin, in your testimony you discuss the drivers of drug spending. And one point of emphasis is the key factor of utilization, increasing utilization. And you note that Americans are getting older, we are living longer. Those are good things, but they can also lead to an increased burden of utilization, especially since so many of our elderly have chronic conditions.

In fact, you note that, as of this year, 60 percent of the United States adult population had been diagnosed with at least one chronic health condition and 40 percent had two or more chronic conditions. Managing these conditions—you go on to emphasize—has been primarily done through the use of pharmaceuticals.

So, since 75 percent of overall health-care spending can be attributed to treatment of chronic diseases, what strategies might be employed to address this upstream issue, this preventive issue? Obviously, increased public investment in research comes to mind, public education campaigns about the impacts of various social and environmental determinants of health. Are there other things that we are not doing as policymakers that you think we ought to be doing?

Dr. HOLTZ-EAKIN. So I think that the public education on the impact of lifestyle on the incidence of chronic disease is an important aspect of this. You can go further in some circumstances. We see employers do this who are in the employer-sponsored market, using carrots and sticks to have people stay on that adherence to medications once they are on them, have smoking cessation programs, other things like that, to avoid getting into that position. Some go as far as to do monitoring of fitness and other things to give you incentive.

So there are a lot of things which, on various small scales, people have tried, and with some evidence of success. I do not think we have yet the definitive body of research knowledge to be able to tell you in any sort of honest way what could a Federal, State, or local government do on these sorts of social determinants of health that would be broadly effective over long periods of time.

But that is certainly something that is important and on the agenda for learning more about.

Senator YOUNG. Right. Perhaps to lay a predicate for that, we should make sure there is an adequate financial incentive for people to go out and figure this out as well. Okay.

Do you think a market incentive exists to crack this? The difficult challenge is, to the extent one can address, you know, drivers of increased utilization and the acquisition of chronic conditions—if you are incented to come up with new ways and grow a body of research around this, then we are going to save taxpayers a lot of money and improve the human condition substantially moving forward, right?

Dr. HOLTZ-EAKIN. So, I want to make sure I answer this carefully because——

Senator YOUNG. That is fine.

Dr. HOLTZ-EAKIN [continuing]. There are a bunch of different possibilities. One are things that—incentives—you could give me for the way I conduct my life, allow me to make myself healthier over the course of a lifetime. Those are certainly things where I think economists would believe that you can generate such incentives.

Insurance companies, if for example, they had contracts over long periods of time as employers often do—they have employees for a long period of time—you have an incentive then to sort of do that.

There is a second set of issues which are genuinely social in nature, and environmental in their character. And it is very difficult for an individual set of incentives to address those. Those require some sort of governmental intervention, collective intervention. The Arnold Foundation can figure it out, something like that.

And then there is the third, which is the research enterprise. And I think we have lots and lots of evidence that the research

world is healthy and investigating these things, and I do not think there is any additional need there.

Senator YOUNG. Please.

Dr. MILLER. Two quick things I would say.

One, a lot of our payment systems in the public programs do not encourage thinking across medical, pharmaceutical, social types of services. And you could think of payment structures there that at least allow some more of that to happen.

And the other thing is, and this is a little more philosophical, and I will be very short. This does raise this whole question of trade-offs in the environment like, do you want to put your spending here in drugs or would spending in a social context on some of the issues that you raised be a better investment for society?

The CHAIRMAN. Senator Daines?

Senator DAINES. Thank you, Mr. Chairman, and thank you for your attention and commitment to this issue so important to Montanans and Americans across the country.

I am very pleased that the first hearing of the 116th Congress is focused on examining prescription drug prices. I spent 13 years working for Procter and Gamble. That was once somewhat of a pharma company, and they got out of pharmaceuticals for a lot of different reasons.

The high cost of prescription drugs is an issue that folks back in Montana call me about frequently and write to me about a lot. In fact, an elderly couple recently told me the cost of one of their medications that they rely on increased 300 percent just over the last 2 years.

Mr. Chairman, I look forward to working with you and members of this committee to find out how we can make sure the consumers can afford the medications that they depend on.

I recently had the opportunity to meet with Secretary Azar and discuss President Trump's drug pricing blueprint. I am encouraged that this administration has put forth ideas and received stakeholder input on ways to lower costs for American patients. I do want to ensure, like I think every member of this committee does, that we protect access to critical medications and continue to support the innovation that we want to see to develop the next generation of new and life-saving medicines.

Ms. Sego, thank you for being here as well. The stories help a lot to put a face and some background here to what sometimes can become very much of a "boil the ocean" kind of challenge we have here finding ways to lower the cost of prescription drugs.

Dr. Holtz-Eakin, I want to come back to your testimony. I think you were asked what were the number-one priorities you would focus on here that might have the greatest impact on lowering drug costs that we can move forward with on a bipartisan basis.

You mentioned the 340B reforms as one of those items.

Dr. HOLTZ-EAKIN. So I want to be clear. I do not think I want to say that it is going to be the biggest driver of costs or anything like that. But it is a program under your jurisdiction. It is not a program that is meeting its objectives, in my view, very well, and it tends to raise prices.

So you ought to first start with things which are artificially raising prices, fix them, and then worry about what you can do to——

Senator DAINES. So if you are thinking of one or two things that are artificially raising prices, where would you tell this committee to look?

Dr. HOLTZ-EAKIN. I started with 340B. I am worried about the structure of the Medicaid best price provision and the things that have been—you know, 340B came about because of Medicaid best price. There used to be genuine charity on the part of pharmaceutical companies. They would give the drugs to hospitals for low-income individuals. Once you passed Medicaid best price, that best price is now zero if you make a charitable donation. Charitable donations dried up—unintended consequence.

So now you created the 340B program. The 340B program is growing like mad, and it hardly looks like something that would be low-cost charity to deserving individuals. And so I worry about government programs with unintended consequences taking a situation where demand is growing, supply is expensive, and making it worse.

So my suggestion first is in the spirit of, do not make it worse. And then try to do other things to make it better: reform the Part D program, do not pay physicians——

Senator DAINES. That sounded like, to Congress, do not make it worse. That is wisdom.

Dr. HOLTZ-EAKIN. It's what I do.

Senator DAINES. So Senator Angus King, he once said in one of our committee hearings on the resources side, he said oftentimes there is no such thing as a silver bullet, but it is silver buckshot. And the thing is, as we look at this situation, it is going to be a number of different items we can work on here, versus the one single thing.

I was struck, Dr. Bach, in your written testimony here, that 1 percent of total prescriptions, specialty drugs, account for about 40 percent of the total spending. One percent is 40 percent.

So that tells me as we think about trying to solve this problem around—it cannot be some kind of a blanket approach. We have to take a look at specifics here.

And I guess I am looking for direction in terms of what we tell this committee—what are the three or four, perhaps, drugs that are widely prescribed? Insulin is a great example here as one, perhaps, but what others are widely prescribed that we should look at, which should be case studies around what we can do here to put better policy forward at a lower cost?

Dr. BACH. Yes; thank you for your question.

What that statistic illustrates is exactly what you have just pointed out, that we do not want to go boil the ocean when we can use focused policy to deal with certain categories of drugs that are really driving spending and actually account for very few prescriptions relative to the rest, if you will.

I do think diabetes and the medications for diabetes are not only a case study but a problem of substance in and of themselves, not only for Ms. Sego and for specific patients, but at a general spending level as well. And so I think it is a category large enough that it is worthy of specific solutions.

I feel the same way about the treatments for hepatitis C, which is why I brought up earlier our subscription-based model that we

nicknamed Netflix, because it is a condition worthy of a bespoke solution.

But I do think this issue of single sole-source drugs having essentially no downward pressure on their prices—and for many of the things we listed, actually things within the system that drive up their list prices and increase market share as a result—is a good place to start.

I want to say one other thing. I hesitate to disagree with Doug, so to be clear, he and I are in complete alignment that the 340B system is problematic on multiple fronts. My concern is how it distorts the commercial market. And because it increases the arbitrage for hospitals to buy physician practices, they then pass on their higher insurance rates that are negotiated onto those doctor's services, and that is inflationary on the commercial side.

I do not believe—although I do not have an advanced degree in economics—that the bigger discounts given in 340B drive up drug prices outside of 340B. The profit maximization is local to them. It is true about Medicaid best price, but not 340B.

The CHAIRMAN. Senator Cassidy?

Senator CASSIDY. Ms. Sego, I am a doctor. I took care of the uninsured for many years. Thanks for putting a human face on that which otherwise could be abstract.

Ms. SEGO. Thank you.

Senator CASSIDY. Secondly, rarely do I enjoy being the very last of a long series of questions, but I learned from all. So I appreciate that.

Peter, great to work with you on the Netflix model. It is a silver buckshot. It is a piece of buckshot that hopefully will help.

Several things; Dr. Holtz-Eakin, obviously you have a problem with the international reference pricing. I actually put that on my website about 8 months ago suggesting it, and I was amazed that the administration brought it up, because it seems so aggressive. So I am going to explore that a little bit with you.

Peter Bach, just before he disagreed with you, made the point that the issue is sole-source drugs for which there is no competitor and there is no ability for the PBM to leverage a rebate. So what do we do about those? If it is that subgroup of international reference pricing for which there is a rich wealthy country which has it—and I accept the limitations that you point out. We also have Croatia, for example, Slovenia.

But if we just took Italy, Germany, Great Britain, France, and Canada, why should we be paying so much more than just those countries for example? And if not, what is the alternative mechanism to lower the price?

And by the way, secondly, I was intrigued by what Dr. Miller said, maybe baseball-style negotiation for those which are not also in other countries. But your thoughts, because I respect you so much, I would appreciate that.

Dr. HOLTZ-EAKIN. So I think you read the testimony very carefully, and so there are reservations about sort of how that actual index was constructed in the proposal and some of the countries we end up referencing against being much poorer and probably not good——

Senator CASSIDY. But if we just exclude those?

Dr. HOLTZ-EAKIN. If we did what you did—I hear you on that—then you get to the second step of this, which is just a decision people are going to have to make, right?

The target is to get prices 30 percent below where they are now. That is what the indication would be. And the data is that, of the 27 drugs they looked at, 11 of them, only 11, are available in all those countries.

Senator CASSIDY. But if we took out those 11—so we say for those 11, we shall apply. But for the others, we shall have a different mechanism. Again, I think baseball-style negotiation is intriguing. I have not—this is the first time I have heard about it.

Dr. HOLTZ-EAKIN. So I am not opposed. I actually think—let me back up and just say, I thought it was an interesting proposal. And I think the reflexive condemnation of it by some people on the grounds that it was intervening in the market and not free market and all that is a mistake. We do not have a free market that works really well in drugs. So let us look at different mechanisms.

I am not a big fan of this one for some of these reasons. I do think there is a general problem in being concerned about access to medicines. The United States has a tradition and values access to the most recent therapies. These other countries have very different traditions, and there is not access.

Senator CASSIDY. On the other hand, we would still pay more than other countries.

Dr. HOLTZ-EAKIN. We are paying more than other countries, and we are footing the globe's bill for R&D. And that is not okay. I get that.

Senator CASSIDY. So let me just toss out something else to you all. A drug that really bugs me is Duexis. Okay, it is $40; if I went to the pharmacy, bought $40 worth of ibuprofen and a Pepcid, combined them, and then sold them for $2,400, which is what happens with Duexis—I do not know what share of that goes to the PBM, but I think that kind of exposes the problem with the rebate system, because it may be only $40 going to the pharmaceutical company, but we are paying $2,400 a month for $40 worth of drugs.

Now to me, that particular drug seems to be drafting in on the protection we give for innovation. Now one thing that intrigues me is the Australian model, where there is some third party which does an assessment as to the relative value of a drug. If you want to pay more than that, you can, but you are only going to get compensated this much. You want to charge more, then the patient shall pay more—not to do that for the truly innovative, because, Dr. Miller, you pointed out we want to continue to incentivize the truly innovative, but for that which is just drafting in on regulations designed to promote innovation.

Any thoughts about that idea?

Dr. HOLTZ-EAKIN. So I think this is out of the category of alternatives that people are interested in where you are actually going to reward on value, and there is little value in the combination of these two drugs. And so the issue becomes, how do you identify value and reimburse on it?

There are these outcome-based models where the outcomes can be no better than $40 worth of drugs, or there are these others

where you have third-party validators and identify value at the point of launch. Peter has mentioned some of those.

Those are different alternative mechanisms that are worth thinking about in this space, because we do have to figure out what to do in those situations where there does not appear to be any value in there. There is not a lot of competition.

Senator CASSIDY. Gentlemen, any other thoughts? Actually, let me hold off on that, because I have just a second more to go.

Now Senator Cornyn asked about why we have rebates. I read a nice article by Scott Gottlieb that once pointed out we have rebates because there was a lawsuit by independent pharmacies that suggested that the chains were getting a better deal, and so the way they worked around the lawsuit was to give rebates on the back end.

But as I mentioned, there is no reason for a PBM which is getting a large rebate from the makers of Duexis not to carry Duexis, even though the value of Duexis is at best marginal relative to $40 worth of medicine.

So let me ask you this, on the rebate issue: what if we limited rebates to 10 to 20 percent? And others will suggest we lose leverage on the part of the plans. So what if you limited the rebates to 10 or 20 percent, or pick a number, some percent, and the rebate could not be over that which would still give a margin for the plan to negotiate a lower price based upon volume? But it would not give this situation of insulin where we might have a drug which at net price to the manufacturer is still $100, for example, but the price to the patient is $400, and $300 is going into a rebate system.

Dr. HOLTZ,-EAKIN. So let us just focus on the issue. The issue is, is there value to having an entity, currently called a PBM, that collects covered lives and negotiates on their collective behalf to get better deals? Yes, and those entities have delivered a lot of value in the system.

How do you reward them for that value? Well, the current system, with the after-the-fact rebates, rewards them for that value, but you could reward them in other ways. You could write them checks at the beginning of the year and say, "Go negotiate. We have 900,000 people. Go negotiate."

Senator CASSIDY. So you are suggesting we just outlaw them, but I just say——

Dr. HOLTZ-EAKIN. No, no. I am not outlawing the PBMs. I am saying——

Senator CASSIDY. I think PBMs have an important function.

Dr. HOLTZ-EAKIN. Yes.

Senator CASSIDY. But I will tell you, Mark McClellan, I think, has told me personally—if I can quote Mark—that rebates are important. And he would be reluctant to get rid of them.

So what if we limit them?

Dr. MILLER. I mean, my reaction to the limiting is that you are moving more to a fee-based system, and you could have a performance-based fee. And to Doug's point, you are looking at overall spend and saying, here is your fee, but if you lower my overall spend by X, then you will get a bump up in your fee. But it is not tied to the specific distribution of individual drugs, and you get the kind of circumstances that you are speaking to.

Sort of agreeing and just taking it a little bit to a different—and I am stopping.

Senator CASSIDY. I am sorry. We have one more person. The chairman has been forbearing.

I apologize. Thank you, gentleman, very much. Thank you, ma'am.

The CHAIRMAN. Senator Cantwell?

Senator CANTWELL. Thank you, Mr. Chairman. And I thank you and the witnesses for this hearing.

I think there has been a lot of unpacking of issues here today, but I think we need to continue to do more unpacking.

The CHAIRMAN. We are going to have more.

Senator CANTWELL. Good. I worked with you, Mr. Chairman, in 2009 on provisions for PBMs to report confidential information to the Department of Justice, and they have been doing that. And so I do think that that holds some opportunities for us to continue to look at PBMs.

Obviously, you play a key role in both of these committees. And I think that would be of interest.

Although I do think, Dr. Holtz-Eakin, you brought up the larger picture, or at least I have read your testimony more closely; maybe the others did as well. But there are so many issues here. By that I mean, cause and effect even. Me, personally, I would take the PBM issue and put that more towards some other market functions.

I think, Dr. Miller, you talked about Medicaid as that function of driving benefits. And in the State of New York, they have been able to do a basic health plan and also drive down costs to those individuals.

So to me the issue is this larger point about capital formation, of how long it takes to develop a drug. Having worked in software, I can tell you, you build and ship something in 6 months. And here you have an industry that tries to build something over a longer period of time of getting capital, maybe for as many as 15 years.

But it is these other organizations afterwards that are letting them try to recoup those costs and benefits at very high extremes. So to me, that is why we should look for more market functions that give as much of those benefits to the consumers with what I call a Costco model.

Like, if you buy in bulk, if you are the Veterans Administration, or you are Medicaid, or you are something like the basic health plan, you should be able to get a discount by buying in bulk. Why should we not look at that as more of a market mechanism?

Dr. HOLTZ-EAKIN. For which program? I am sorry. I want to make sure I know where this is targeted.

Senator CANTWELL. Well——

Dr. HOLTZ-EAKIN. Because we have a lot of that now.

I mean, certainly there is the Veterans Administration, many Medicaid programs where you can buy and not buy, importantly, some manufacturer's drugs and drive a good bargain as a result. And we have those incentives in the Part D program with the prescription drug plans. I think we agree we could strengthen them, but you want to do that.

So I am not sure where else you would want to put that in.

Senator CANTWELL. Well, Medicare; you could do it more in health care, you could broaden the——

Dr. HOLTZ-EAKIN. Beyond drugs?

Senator CANTWELL. No. No, broaden the ability to negotiate. In this case, the State of New York and Minnesota are given the ability to negotiate on price. The State of Washington used to do a similar thing and thereby created an environment in which those kinds of discounts are given directly to the beneficiaries, as opposed to the PBMs that are in a business model of advantaging from that.

Dr. HOLTZ-EAKIN. So going back to the inception of the Part D program, when I was the CBO Director, there have been numerous inquiries from Congress on the capacity of the Secretary of HHS to negotiate on behalf of the prescription drug plans. And the basic answer has always been that that is going to offer very little in the way of savings, with the likely exception being perhaps some sole-source drugs, particularly new and innovative ones.

And the reason for that has been the inability of Medicare to have a formulary, to actually say "no, we are not going to let America's seniors have some drugs." And so, if you cannot bring that leverage to the negotiation, you do not have any particular advantage over our prescription drug plans.

They have large numbers of seniors. If they combine and use the PBM, they have even greater covered lives, and they have formularies which can be used to drive preferred placement and thus, get discounts. And HHS does not have that.

And it would be a sea change for the U.S. Government to decide to exclude access to some prescription drugs for its seniors.

Dr. MILLER. I just want to add something to that and disagree just a little bit here.

I think a lot of people approach the negotiation question exactly that way, which is you have to say, "I am going to offer this drug or I am not," and that is your negotiation leverage. And by and large, that is a very true statement, and that is a lot of what goes on inside PBMs in Part D, and in the commercial market all the time.

But the thing I was trying to drive at is Medicare's posture could be, we do cover this drug. We want to reach a fair price for the beneficiary and the taxpayer, and try to work through either a value-based pricing strategy like Peter was saying, or a binding arbitration strategy might be a different way.

But it is true that in the end, if the manufacturer says, "I do not like this price," they could walk away as opposed to Medicare saying, "I am not willing to cover it." But remember, the U.S. and the elderly are a gigantic market, and they get a lot of revenue out of that.

And so that would be a bit of the game of chicken that would be——

Senator CANTWELL. I just think—Mr. Chairman, thank you. I know I am over my time, and I am pretty sure everybody wants to get to their next focus.

I think we should be spending more time right on that question. And what are the tools by which government—I would look at these States that have been able to use this tool. Yes, they have

had to make some hard decisions, and we should look at the success of how States have done that, because they are pretty big entities. And I am sure they have data where they have made some choices, and they probably have details on that.

But I am more for us looking at that, and making sure that PBMs are not taking unfair advantage, because I just think these are the market forces that are going to drive the most savings into the cost, into the hands of consumers.

And I think, Dr. Holtz-Eakin, you have done a really good job of painting in your testimony the other end of the picture. We have a bow wave of seniors coming at us. Okay, that bow wave is caused by the baby boomers retiring and people living longer.

And we have to get better strategies. And so to me, drilling down on how some of these States have been able to peel back the layers of this and actually get those negotiations on price, on prescription drugs, could be a telling example of how you could—even if you just took some drugs and started that way at the Federal level—could give us some data and information.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Carper?

Senator CARPER. I would like to say we save the best for last, but that is probably not true. [Laughter.]

My mom used to say, Mr. Chairman, the third time is a charm. This is the third time we have been here, and so you are worth coming back for three times.

I just want to ask you to approach my responsibilities here as a recovering Governor of Delaware. And one of the things I did as Governor was, we won a lawsuit with 49 other States against the tobacco industry.

Other States did different things with the money. We put the money, and still do, in a prescription assistance program for seniors. And later on, I had the opportunity here as a fairly new Senator to support the Medicare Part D program, which I thought then, and I still think, is a good idea and a good plan.

We have a number of companies in our State that are in the pharmaceutical business. So I could come at this from a lot of different directions.

What a wonderful panel, what a diverse panel with different ideas and good ideas. And what I want to ask each of you to do is, at the end of this hearing, to reflect on where you think there is consensus among you in ways that would give us some direction and guidance as we proceed in this field?

And I am going to ask you, ma'am, if you would go first. Where do you think there is some consensus that actually might inform a path forward for us?

Ms. SEGO. Well, I think there have been a lot of great ideas, but as a mom and an educator, I am really going to rely on the expertise of the gentlemen beside me and mostly for the committee to come up with a plan that is viable for all of us who are living and trying to survive with the high cost of prescription drugs.

Senator CARPER. Fair enough. Thank you.

We are delighted that you were able to come and share your story with us, your son's story with us. Thank you.

Ms. SEGO. Thank you.

Dr. HOLTZ-EAKIN. I think there have been——

Senator CARPER. Doctor, how are you?

Dr. HOLTZ-EAKIN. I am doing well, sir. How are you?

Senator CARPER. Good to see you.

This guy has been before us many times, ma'am. He always wears different hats, but he has always had a pretty good hat to wear.

Dr. HOLTZ-EAKIN. Thank you, Senator.

I think there are three places where there is broad agreement. One is that it would be valuable to reform the Part D program to maximize the incentives for sharp negotiations. That has come up in all the remarks.

The second is that the current system of back-end rebates may not serve the beneficiary, the consumer, as well as an alternative set of economic arrangements that has the same math, but actually lowers the price at the counter. And that is worth thinking about.

And then the third would be that a particularly vexing problem is figuring out the value of new specialty drugs and determining a way to reimburse on that value.

Senator CARPER. Okay. Good. Those are three good ones. Thank you.

Dr. Miller?

Dr. MILLER. I agree on Part D benefit redesign that we have talked about. I think there is agreement on changing the percentage add-on in Part B.

I think there is agreement to reexamine the rebate scheme. I think, even though we did not talk about it a lot, there is general agreement on going after the anti-competitive behaviors before the market launches.

There is some agreement on certain parts of transparency, although I will just be a little careful in saying that and see if anybody objects. And even though I am kind of where Peter is, I think there is agreement on 340B, not as the top priority, but there are issues there that need to be addressed.

I think where there is more disagreement is in the negotiation issues that Doug has raised.

Senator CARPER. All right; thank you.

Dr. Bach?

Dr. BACH. Well, this reflects our agreement. Everything I had written down has already now been said.

Senator CARPER. Do you want to say it again?

Dr. BACH. Oh sure. That is right. That is the rule.

Senator CARPER. No, you do not have to do that.

Okay, keep in mind there is more agreement here than I had even hoped for.

The administration last year put forth a number of ideas about bringing down prescription drug prices for consumers, for taxpayers as well. And I described it as a lot of singles, some doubles, and maybe a triple or a home run or two. But I am told by my staff, by Lynn Sha, sitting right behind me, that so far no one has asked this question, so I am going to ask it to close, if I could.

In your opinion, which administration proposals do you find the most promising, and why? And which proposals will not work or cause unintended consequences? So, which of the proposals do you

find most promising and why? Which one would you say, nope, that is not going to work, has unintended consequences? Any thoughts?

Dr. HOLTZ-EAKIN. I think, given that there are 14 seconds left, I am going to get back to you in writing with that.

Senator CARPER. I think that would be fine. Yes, that would be good.

Dr. MILLER. And I had a list of the things that the administration did, and I cannot find it, but the couple things that I am remembering off the top of my head—I just want to say this carefully.

I think we should examine the international price index issue. I think there are pros and cons, and I think there are things that have to be worked out, but we should look at it.

The administration has raised some issues on protected classes in Part D. I think those ideas should be looked at.

That is all I can think of off the top of my head.

Senator CARPER. All right. Thank you, sir.

Dr. Bach, do you want to get the last word? You can give us a benediction.

Dr. BACH. Okay.

Two things. So the administration implemented ASP minus 22.5 percent for the 340B hospitals. I believe that is either caught up in court or is not going to proceed now. But that is a fundamentally good idea, to take away the spread that the hospitals were earning from those drugs.

The other is, with relation to the international price index, we may have some disagreement about the role of using negotiated prices that the companies have agreed to in other countries, but there is another element within this, which is the use of competitive acquisition or the third-party vendor for the distribution of the drugs that removes the economics from the doctors and hospitals, which I think is a fundamentally good stand-alone idea as well.

I am hoping that they will at least propose the rule. It is only an announcement of a proposed rule at this point.

Senator CARPER. All right. Good; thanks.

Mr. Chairman, thanks for giving me a chance to get the answers to that quick last question.

And thanks to the panelists for being here, all of you, all four of you.

The CHAIRMAN. Thank you.

Before we have one last question from Senator Wyden, sometimes I forget to thank you folks who work so hard to get ready for this and participate in it. So I want to thank you. And then, any member of the committee, either members who have been here or members who were not here, have till Tuesday, February the 12th to submit questions for the record. And we would ask that the panel would respond as quickly as you can.

With that, go ahead.

Senator WYDEN. Mr. Chairman, I am going to be very brief, but I also want to note as we wrap up this first hearing, I think you have pulled together, on both sides of the aisle today, a real opportunity for finding common ground, for Democrats and Republicans to fight price gouging. With respect to reforming Part D, there were a lot of ideas taken on the middlemen, the PBMs. So I want to

thank you for it. I just have a quick question, and it is on something Dr. Miller's been talking about.

But before we close, you and I have sat through a lot of healthcare hearings over the last few years where we did not have this kind of opportunity for bipartisanship. So I think that is leaving it on a positive note.

The CHAIRMAN. I agree with you because, in my work on the Judiciary Committee, I was able to sponsor or co-sponsor several bills with Democrats on that committee. And one of those bills even got out of committee, the CREATES Act, and I think we will pursue those two over there and do here what we can.

Senator WYDEN. Good. My quick question, Mr. Chairman.

Dr. Miller, you have talked a little bit about scientific research. And of course the American taxpayer puts up billions of dollars in terms of funds for basic scientific research each year. And practically every member goes to a town hall meeting at home and someone says, "Hey, we taxpayers are putting up all this money for the research, and then when it comes to Medicare and Medicaid, we cannot afford the medicines that we did a lot of the heavy lifting for."

So obviously, taxpayers do not want to be taken advantage of twice, and you have thought creatively about some ideas, some alternatives, to fund the development of new drugs so that tomorrow's cures are not being held hostage by drug manufacturers today.

Can you just close and give us a little bit of your thinking on some of these alternative ideas?

Dr. MILLER. Yes. I appreciate you saying that I thought creatively about it. I think what is more accurate is that the Foundation has put some money out recently to bring smart people to the table to start thinking about this. And there are a couple of ways that they are starting to think about it, but we are very early on in this. Okay, if we fund a lot of basic science in NIH and then that turns into a monetized drug that is developed by a pharmaceutical company, let's revisit how that actually could come back to the taxpayer, whether there is some participation in the patent and a return in that particular case.

There are ideas, like prize monies targeted to parts of the drug markets where the revenue model does not drive companies to look at those types of changes, like the next generation of antibiotics, where you are creating a drug that you do not want people to take in a sense.

There are also targeted tax incentives that could be thought about that could also sort of draw out different kinds of innovation.

We have work coming up on this. We have a couple of public forums that are going to pull people together to discuss it. I am not as deep as you characterize me. I appreciate it, but we are bringing people to the table who are.

Senator WYDEN. The chairman has been here a long time and been very patient. Why don't you just get us what you have for the record on this, because I am interested in looking at it.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you all. Adjourned.

[Whereupon, at 12:55 p.m., the hearing was concluded.]

APPENDIX

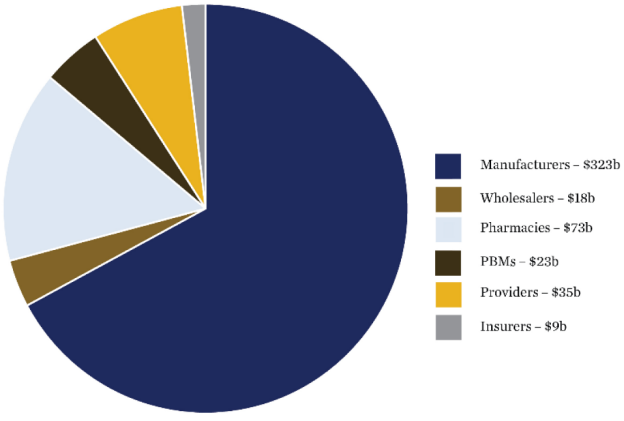
ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF PETER B. BACH, M.D., DIRECTOR, CENTER FOR HEALTH POLICY AND OUTCOMES, MEMORIAL SLOAN KETTERING CANCER CENTER

Chairman Grassley, Ranking Member Wyden, and members of the Senate Finance Committee, thank you for the opportunity to testify before you regarding the important and pressing topic of pharmaceutical prices and affordability. My name is Peter Bach. I am a physician at Memorial Sloan Kettering Cancer Center in New York where I lead the Drug Pricing Lab, which is funded by the Laura and John Arnold Foundation, Kaiser Permanente, and my institution. I have received speaking fees from pharmaceutical companies, PBMs, insurers, and trade associations. Each of these is listed at the bottom of this testimony.

OVERVIEW OF THE PHARMACEUTICAL SUPPLY CHAIN

Although the lion's share of pharmaceutical product revenues goes to their manufacturers, the distribution and payment system for pharmaceuticals does capture a meaningful share of total spending, which was approximately $500 billion in 2018. Our group looked at the net retained revenues across the supply chain associated with all pharmaceutical sales based on a collection of different inputs and found that the pharmaceutical corporations capture around two-thirds of all dollars spent on drugs, seen below. It is worth noting that although PBMs are frequently blamed for capturing a large share of total spending in the form of rebates, in fact they capture around 5 percent of total spending. We cannot tell from this analysis whether the net savings PBMs achieve through negotiation are greater than or less than this amount.[1]



[1] Yu N, Atteberry P, Bach PB. "Spending on Prescription Drugs in the U.S.: Where Does All The Money Go?" *Health Affairs Blog*. 2018 July 31. doi: 10.1377/hblog20180726.670593. Accessed from *https://www.healthaffairs.org/do/10.1377/hblog20180726.670593/full/*.

Inflationary Distortions in the Supply Chain

I would like to review some of the inflationary distortions in the current system of pharmaceutical distribution and payment, in particular for specialty drugs, that now comprise 39.6 percent of spending even as they are fewer than 2 percent of total prescriptions.[2, 3, 4] An organizing theme of the pharmaceutical supply chain is that all participants benefit as both drug prices and total spending rise. Pharmaceutical corporations logically seek to profit by charging high prices, but ideally the other parties in the supply chain would serve as a countervailing force to push prices down. They often do not. Rather, most of the participants in this system benefit over the long term from rising spending and prices. While in any particular period one participant or another may seek to lower costs, in general terms, all make a profit that is linked to the underlying cost of the drugs that they handle.

Pharmaceutical products are often marked up in percentage terms as they pass through the supply chain. This means that more expensive drugs on average bring larger profits. This pattern applies to wholesalers and pharmacies. It also applies to physicians and hospitals when they use expensive infused drugs covered by Medicare Part B. This is because the reimbursement formula for Part B drugs includes a markup over the average acquisition price of the drug. The formula is often referred to as "ASP+6." Due to the percentage-based markup, profits are larger for those drugs that are more expensive. We recently reviewed studies that examine whether or not the profit potential for various Part B drugs influences prescribing; across the studies we examined, the conclusion was consistent that they do. On the margin physicians will prescribe the more profitable of drugs when there are options to choose from.[5] Aaron Mitchell and colleagues published a review of this topic as well. That authors graded the quality of the literature along with summarizing its findings, and arrived at the same conclusion. Physicians systematically select more profitable drugs to prescribe when they are able to choose among clinically substitutable options.[6]

---

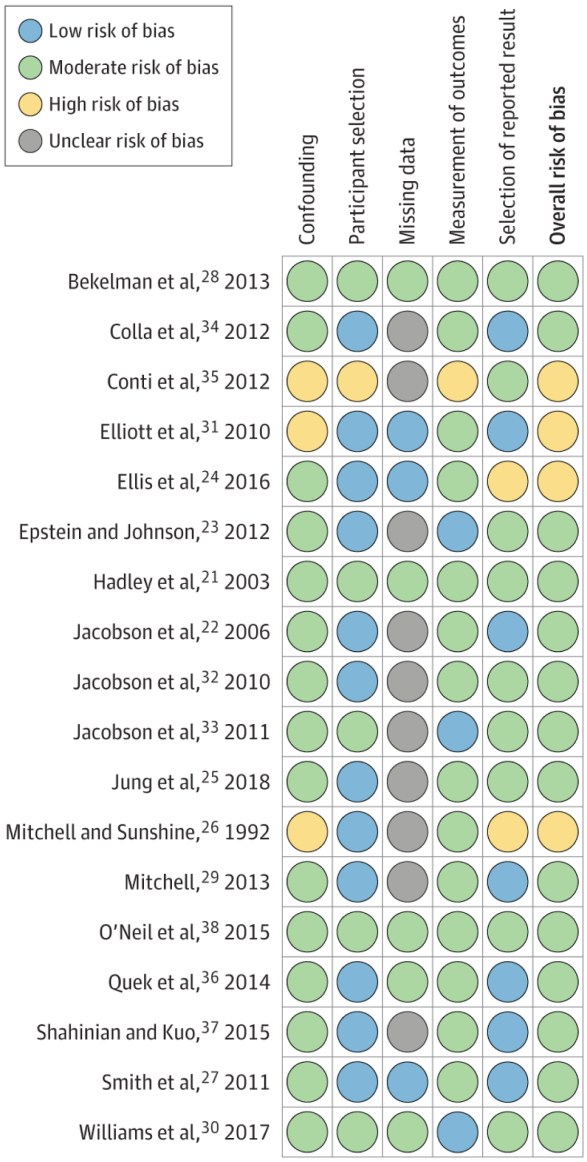
[2] IQVIA. *Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021,* IQVIA. Published 2017. Accessed at *https://www.iqvia.com/institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2016.*

[3] Hirsch BR, Balu S, and Schulman KA. "The Impact of Specialty Pharmaceuticals as Drivers of Health Care Costs," *Health Affairs* 2014; 33(10), p. 1714–1720.

[4] IMS Institute for Healthcare Informatics (IMS Institute). *Medicine use and shifting costs of healthcare: A review of the use of medicines in the United States in 2013,* IMS Institute for Healthcare Informatics. Published 2014. Accessed from *http://www.imshealth.com/cds/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Secure/IIHI_US_Use_of_Meds_for_2013.pdf.*

[5] Bach PB, Ohn J. "Does the 6% in Medicare Part B drug reimbursement affect prescribing?" *Drug Pricing Lab. https://drugpricinglab.org/wp-content/uploads/2018/05/Part-B-Reimbursement-and-Prescribing.pdf.* Published May 9, 2018. Accessed January 27, 2019.

[6] Mitchell AP, Rotter JS, Patel E, Richardson D, Wheeler SB, Basch E, Goldstein DA. "Association Between Reimbursement Incentives and Physician Practice in Oncology: A Systematic Review." *JAMA Oncology* 2019 January 3rd [Epub ahead of print]. Accessed from *https://jamanetwork.com/journals/jamaoncology/fullarticle/10.1001/jamaoncol.2018.6196.*



Source: Mitchell et al., 2019

The phenomenon does not appear to be unique to physician offices. Preference for more expensive drugs has been observed in prescribing in hospital outpatient departments. The most dramatic example of this pattern was in a report from the GAO, that found a strong shift to more expensive drugs in hospitals after they entered the 340B drug discount program.[7] There are not many analyses that compare the relative impact of these incentives on prescribing between physician offices and hospital outpatient departments. The effects could be of similar magnitude, but alternatively one might anticipate physician practices to be more susceptible to them given that physicians in offices are often owners or otherwise directly participate in profit sharing, while hospital based physicians do not. My team conducted an analysis that showed that among treatments in oncology that are not recommended and that involve expensive Part B drugs, the likelihood that these treatments were administered was higher in physician offices than hospital outpatient departments across all the clinical scenarios we examined, a finding that was robust to clinical severity risk adjustment.[8]

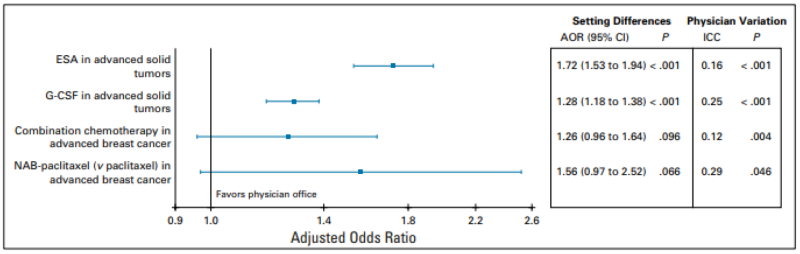


FIG 1. Impact of oncology practice setting on the use of drugs. AOR, adjusted odds ratio; ESA, erythropoiesis-stimulating agent; G-CSF, granulocyte colony stimulating factor; ICC, intraclass correlation; NAB, nanoparticle albumin-bound.

Possible Policy Options

Subscription-based payment for HCV treatment ("Netflix model"). The subscription model for hepatitis C virus treatment that Mark Trusheim from MIT, Senator Bill Cassidy, and I nick-named "Netflix" solves a problem specific to the hepatitis C market. The profit maximizing price for treatments is unaffordable for many State Medicaid programs and prison systems.[9] The unique situation with hepatitis C infection is defined by a number of features. First, there are highly effective treatments that have prices far higher than most States can afford; second, HCV infection is essentially a one time problem that would be amenable to a single elimination effort that would decrease prevalence very sizably and thus reduce infection rates; the market for the products has seen discounting but also collapsing volumes of sales, and as a result the long run prospects for revenues generated by sales of these treatments in relatively poor States are not good and the expectation is that even over the next decade the number of infected individuals who will be treated will be low. That phenomenon can be seen here.

---

[7] U.S. Government Accountability Office. "Drug Discount Program: Characteristics of Hospitals Participating and Not Participating in the 340B Program." Washington, DC: Committee on Energy and Commerce. GAO–18–521R. Accessed from *https://www.gao.gov/assets/700/692587.pdf.*

[8] Lipitz-Snyderman A, Sima CS, Atoria CL, Elkin EB, Anderson C, Blinder V, Tsai CJ, Panageas KS, Bach PB. "Physician-driven variation in nonrecommended services among older adults diagnosed with cancer." *JAMA Internal Medicine.* 2016 October 1;176(10):1541–8.

[9] Trusheim MR, Cassidy WM, Bach PB. "Alternative State-Level Financing for Hepatitis C Treatment—The 'Netflix Model.'" *JAMA.* Published online October 29, 2018. doi:10.1001/jama.2018.15782. Accessed from *https://jamanetwork.com/journals/jama/article-abstract/2712366.*

eTable. Example of Possible Projections of HCV Prevalence, 10-Year Treatment Rates, 10-Year Annual and Net Present Value of Gilead Pharmaceuticals Anti-HCV Regimen Sales

State	HCV Prevalence[a]	10-Year Projections											
		Anticipated Treatment Overall Under Current Model, No. (%)[b]	Gilead Pharmaceuticals' HCV Revenues by State (in the millions), $[c]										
			Net Present Value, ($mm, 2019–2028)[d]	2018[e]	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
Arkansas	37,500	7,875 (21)	60	16	12	11	10	9	9	8	7	6	6	5
Louisiana	73,000	17,247 (23.6)	130	34	27	24	21	20	19	17	15	14	12	11
Oklahoma	94,200	16,811 (17.8)	126	33	27	23	21	19	19	17	15	13	12	11
New Mexico	45,000	8,949 (19.9)	67	18	14	12	11	10	10	9	8	7	6	6
Tennessee	122,500	32,665 (26.7)	244	64	52	45	41	38	37	33	29	26	23	21

Abbreviation: HCV, hepatitis C virus.

[a] Data from Rosenberg et al.[10] or State Department of Health figures if available.

[b] Based on consensus estimates of HCV sales for both Gilead and AbbVie (including price declines and market share shifts).

[c] Proportional revenues based on State's percentage of HCV prescriptions for HCB for 2017 and HCV prevalence as percent of U.S. prevalence.

[d] Net Present Value of 10-year HCV revenue projections for Gilead (2019–2028, using an 8-percent rate); Net Present Value was calculated as follows: NPV = Annual Cash Flow/$(1 + \text{Interest})^n$.

[e] Estimated annual HCV revenues for Gilead attributable to each State.

eReference

1. Rosenberg ES, Hall EW, Sullivan PS, Sanchez TH, Workowski KA, Ward JW, Holtzman D. "Estimation of state-level prevalence of hepatitis C virus infection, U.S. States and the District of Columbia," 2010. *Clinical Infectious Diseases* 2017;64(11):1573–81. doi: 10.1093/cid/cox202.

Under our proposal, a purchasing coalition within a State would run an auction to obtain a market-based price for flat subscription payments for a set number of years during which time the coalition would work with the winning manufacturer to eliminate HCV infection in the State. This idea has begun to take shape in several States, and in the past months two States—Louisiana and then Washington—posted solicitations for manufacturers to participate in a subscription-based payment model to treat HCV-infected residents.[10,11,12]

Reform Part D: My team recently worked with reporters at *The Wall Street Journal* and showed that Part D plans appear to be bidding in a strategic manner to increase their profitability while shifting costs onto the Federal reinsurance portion of the benefit. One solution to this problem is that at this point, a dozen years after the commencement of the program, plans could take over the risk (or at least the lion's share) that is currently borne by Medicare through individual level reinsurance. From the perspective that these protections were put in place at the time Part D launched to ease the transition and lessen the risk of plans entering this new market, our analysis suggests that the plans have matured to the point that they are not only comfortable with the program, but actually able to take advantage of the protections to increase their profitability. We should explore rebates at point of sale so patients can have full benefit of plan negotiated price concessions. This will ensure that when a plan selects a drug with a high list price and a large rebate, the beneficiary pays the net price after the rebate when they are paying coinsurance or in their deductible. A preliminary assessment from the CMS actuary suggested that adding point of sale rebates to Part D would increase total Medicare spending under current rules.[13, 14]

Insert competition where possible for high-priced therapies: In the category of high-priced therapies, Medicare currently has an open National Coverage Decision on CAR–T therapies, the expensive one-time treatments for various cancers. One option for Medicare would be to consider ways to use its coverage authority (particularly Coverage under Evidence Development) in conjunction with CMMI authority to test alternative payment approaches, with the objective of inserting price competition between CAR-T treatments. I outlined this approach recently in *The New England Journal of Medicine.*[15] The agency should be seeking to create competition based on price when it has opportunities between products with similar effectiveness. The article included a decision matrix that CMS could use to consider its options based on its conclusions along several dimensions of its analysis.

---

[10] Louisiana Department of Health. Request for information on subscription payment models. August 24, 2018. Accessed from *http://www.ldh.la.gov/assets/docs/SPM*_RFI.pdf.

[11] Washington State Health Care Authority. "HCA issues request for proposals from drug manufacturers for hepatitis C treatment and services." January 23, 2019. Accessed from *https://www.hca.wa.gov/about-hca/hca-issues-request-proposals-drug-manufacturers-hepatitis-c-treatment-and-services.*

[12] State of Washington, Office of the Governor. "Directive of the Governor: Eliminating Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach." September 28, 2018. Accessed from *https://www.governor.wa.gov/sites/default/files/18-13%20-%20Hepatitis%20C%20Elimination.pdf.*

[13] *https://www.cms.gov/newsroom/fact-sheets/cms-proposes-policy-changes-and-updates-medicare-advantage-and-prescription-drug-benefit-program.*

[14] Dusetzina SB, Conti RM, Yu NL, Bach PB. "Association of Prescription Drug Price Rebates in Medicare Part D With Patient Out-of-Pocket and Federal Spending." *JAMA Internal Medicine.* May 2017;177(8):1185–1188. doi:10.1001.jamainternmed.2017.1885.

[15] Bach PB. "National Coverage Analysis of CAR-T Therapies—Policy, Evidence, and Payment." *New England Journal of Medicine.* 2018 Aug 15; 379(15):1396–8. doi: 10.1056/NEJMp1807382. Accessed from *https://www.nejm.org/doi/full/10.1056/NEJMp1807382.*

Strategy for CMS's Evaluation of Potential Coverage and Payment for the Various CAR-T Therapies.*

Key Question and Level of Confidence	Are the ancillary service costs similar?	
	Adequate level of confidence in answer	Uncertain level of confidence in answer
Are the net benefits similar?		
Adequate level of confidence in answer	Competitive bidding Competitive acquisition Consolidated payment code	Case-rate payment Bundled payment Gain sharing†
Uncertain level of confidence in answer	RCT: compare net benefits (and other outcomes)	RCT: compare net benefits (and other outcomes), gather detailed resource-utilization data

* This strategy applies to the overlapping indications for axicabtagene ciloleucel are relapsed or refractory large B-cell lymphoma in an adult who has received two or more lines of systemic therapy. RCT denotes randomized, controlled trial.

† These approaches would bridge payment between inpatient and outpatient settings, incorporating the prospective inpatient (i.e., diagnosis-related group) payment.

Recapture funds spent on discarded drugs: My team identified a pervasive problem in Medicare Part B, which was that it spends enormous sums on discarded leftover drug in vials. This problem primarily plagues those drugs that are dosed based on individual patients' body size, but these types of drugs are common in conditions such as cancer.[16] The reason for this is that in many situations the vials containing drugs are "single dose," meaning that once the vial is accessed, if there is more drug than is needed to treat the patient in it, the leftover is discarded. Medicare, under buy and bill, pays for all of the drug in the vial when any portion is administered. The article reporting these findings includes an interactive graphic displaying each of the drugs that we examined, seen here: *https://www.bmj.com/content/352/bmj.i788.* In 2017 Medicare instituted mandatory use of the JW modifier for portions of drug billed to Medicare that was in fact leftover and discarded as waste. Our understanding is that the OIG has investigated how much drug is coded as discarded and found it to be hundreds of millions in 2017. With this mandatory code now designating what part of each billed vial was discarded, CMS could, with appropriate authority, "claw back" from the manufacturer those funds expended on discarded drugs recorded as billed with the JW modifier.

Move to Flat Fee Reimbursement for Part B Drugs

As noted above, the proportional markup model for Part B drugs tends on the margin to favor the prescribing of more expensive drugs. This is problematic on two fronts. (1) It leads to higher program spending (and beneficiary out of pocket spending for those without secondary coverage). (2) It creates an environment where pharmaceutical corporations can actually increase market share in part by charging higher prices, the reverse pattern of a typical competitive market. Changing to a flat fee add-on above ASP is a more rational policy. This flat fee should be calibrated to the complexity of handling, storing, and preparing the product for administration, rather than having a markup that is based entirely on the cost of the underlying drug. A hybrid fee, with the majority being made up of the "handling" component, and a small percentage markup, would be a reasonable middle ground.

[16] Bach PB, Conti RM, Muller RJ, Schnorr GC, Saltz LB. "Overspending driven by oversized single dose vials of cancer drugs." *BMJ.* 2016 February 29;352:i788. doi: 10.1136/bmj.i788. Accessed from *https://www.bmj.com/content/352/bmj.i788.*

There is a plausible argument that two parts of the cost of drugs are related to their underlying cost. It costs more to finance the purchase of more expensive drugs, and when coinsurance is uncollected the amount lost is larger when the drug costs more.

DEFINITIONAL ISSUES RELATED TO "VALUE-BASED PRICING"

"Value-based pricing" has been proposed by a number of analysts for new branded drugs with no competition. Today we often end up with drugs priced at levels well beyond what their benefits justify. We then see payers attempt to counteract these high prices. Payers insert barriers to access including shifting costs to out of pocket, delaying access through utilization management, and generally thinning the quality of the insurance benefit for patients who most need insurance. This push-pull makes all parties worse off. The core notion of value-based pricing is that in exchange for drug prices being based on their measurable benefits, payers would provide favorable formulary placement and low out of pocket costs coverage for eligible patients. It is important to note that this approach is distinct from several other approaches that have been suggested which at times include the word "value" in their moniker. We recently reviewed these alternative approaches, the key table is included below.[17]

Outcomes-based contracts, which provide the payer with refunds when a drug does not work, is an example. This approach does not guarantee that prices are value-based, because it leaves untouched how much a drug costs when it does work. Most proposals and agreements in place with outcomes based arrangements have this basic flaw. One such example was outlined in the *Annals of Internal Medicine,*[18] in which my colleagues and I wrote an editorial explaining that these outcomes arrangements may be an attempt to distract from the underlying question of how much a drug should cost when it does work.

Long-term financing for one-time treatments should be viewed cautiously as well. This approach has been proposed by pharmaceutical corporations as a way to push through multi-million-dollar prices for their products, and embraced by some commercial payers as a means to help smooth expenditures and pass through costs into future premiums. It is important to note that we can't solve the affordability problem by pushing costs into future years. Financing does not reduce total spending, it just changes current obligations. It is also relevant to appreciate that, whether for student loans or home mortgages, long-term payment arrangements are inflationary.

Table. Comparison of Value-Based Pricing and Adjacent Concepts

Concept	Definition	Rests on Existing Evidence of Benefit	Aligns Price With Benefit and Market Entry	Examples
Value-based pricing	Price of a drug set on the magnitude of its benefit	Yes	Yes	Pricing of dupilumab according to ICER value-based price
Indication-specific pricing	Drug price specific to each of its uses	Yes	Yes	Tisagenlecleucel sold at two different prices for two different cancer indications
Outcomes-based contracts	Manufacturer refunds or rebates payer when an agreed-upon outcome is unmet	No	No	Amgen agreement with Harvard Pilgrim to refund cost of evolocumab for treated patients who have a myocardial infarction while taking the drug

[17] Kaltenboeck A, Bach PB. "Value-Based Pricing for Drugs: Themes and Variations." *JAMA.* 2018;319(21):2165–2166. doi:10.1001/jama.2018.4871. Accessed from *https://jamanetwork.com/journals/jama/fullarticle/2680422.*

[18] Mailankody S, Bach PB. "Money-Back Guarantees for Expensive Drugs: Wolf's Clothing but a Sheep Underneath." *Annals of Internal Medicine.* 2018;168:888–889. doi: 10.7326/M18–0539.

Table. Comparison of Value-Based Pricing and Adjacent Concepts—Continued

Concept	Definition	Rests on Existing Evidence of Benefit	Aligns Price With Benefit and Market Entry	Examples
Mortgage pricing	Commits a payer to pay for expensive treatments over time	No	No	No known examples
Value-based insurance design	A health benefit design that reduces out-of-pocket expense for high-value medial care and treatments	Yes	No	Prime Therapeutics program to reduce copayment and increase amount dispensed for insulins; Pitney Bowes's initiative to reduce or eliminate cost sharing for statins and clopidogrel

Abbreviation: ICER, Institute for Clinical and Economic Review.

Lastly, when companies say we need to change our payment system to afford their new high-priced treatments, they are framing the issue backwards. Prices for monopoly goods are dictated primarily by what payers are willing to pay for them, as the companies do not face traditional market competition that would put downward pressure on their prices. So, when companies call for long term financing to pay them for their treatments, they are inventing a means by which the market can pay them more than they would get without such a system. But in viewing this proposal, it is important to keep in mind that these drugs do not inherently cost $1 million or $2 million dollars. Rather, it is policy choices that will dictate what they cost, policy should not configure to what the corporations want them to cost.

Other arguments advanced to justify mortgage type financing for one time treatments is that our system does not have a way to pay for cures. This seems like an odd assertion in that many types of one time curative treatments have been available for many years and are paid for without difficulty, including courses of antibiotics and radiotherapy of local cancer. The notion that one time treatments are special and thus need to be paid for at many multiples of other drugs is also problematic. In truth many new expensive drugs on the market are only taken for a short period by each person who receives them. New cancer drugs are a prime example. A single dose versus a handful of doses over a few weeks or months before the patient goes on to some other treatment seems more similar than different. In either case there is a brief period of payment for each unique patient where the drug corporation receives its reward for successful innovation. We can safely conclude that our system pays adequately for the latter scenario, as evidenced by the continued development of new treatments that meet this definition. In fact the current incentive system has led to the creation of a spectacular number of new cancer drugs that are rewarded in this type of treatment horizon.

Lastly, I urge the committee to remember that the purpose of paying high prices for drugs when they are approved is to provide an incentive for companies to undertake the risks of trying to create new treatments that can help the sick. In this context, without any change in the payment system, we are already seeing a large number of spectacular one time treatments come to market. While companies logically will seek to loosen the payment system to accommodate even higher prices, please remember that the treatments they are discussing charging such high prices for actually emerged under current payment approaches. This would suggest that investors eyed the prospects under current payment rules as favorable enough to take the risks to develop them. Those investors have successfully earned their rewards for taking these risks, companies that specialize or solely focus on one-time treatments have achieved multi-billion-dollar valuations prior to having any marketed products in multiple cases. If anything, since the launch of these early "one-time treatment" companies, the technology and science of making gene therapies for instance has advanced considerably. New companies entering this domain will face lower risks and higher success rates. This would mean that if anything the rewards can be downsized while maintaining the current level of innovation.

International Pricing

A number of discussions have been undertaken around benchmarking U.S. prices to those in other western countries. In general terms, prices for most drugs are higher in the U.S., sometimes twice as high or even more. My research team has examined some claims with regards to this observation, including the oft-cited argument that U.S. taxpayers fund the world's research and development in the pharmaceutical sector. When we examined the claim, we looked at whether the additional revenues companies earned from higher prices charged to U.S. patients compared to if they charged prices similar to those in Europe. We then compared that spread with benchmark prices in several European countries. We found that typically a pharmaceutical corporation captured 1.7 times their global research and development spending from charging higher prices to U.S. patients, taxpayers, and insurers.[19]

The 15 Pharmaceutical Companies Responsible for the World's 20 Top-Selling Products in 2015

Company	International price/U.S. price	U.S. premium price percent	U.S. sales (2015, $mm)	Revenue from U.S. premium ($mm)	Revenues from U.S. premium as percent of global research and development
AbbVie	48%	52%	$13,561	$7,092	166%
Amgen	43%	57%	$16,523	$9,355	239%
AstraZeneca	36%	64%	$9,474	$6,078	101%
Biogen	25%	75%	$6,546	$4,934	245%
Bristol-Myers Squibb	45%	55%	$8,188	$4,516	76%
Celgene	45%	55%	$5,525	$3,020	148%
Roche (pharma division)	45%	55%	$17,782	$9,759	119%
Gilead	75%	25%	$21,200	$5,200	173%
GlaxoSmithKline (ex consumer)	48%	52%	$10,188	$5,300	114%
JNJ (just pharma division)	39%	61%	$18,300	$11,127	163%
Merck	39%	61%	$17,519	$10,649	159%
Novartis	52%	48%	$18,079	$8,678	97%
Pfizer (ex consumer)	21%	79%	$19,906	$15,735	219%
Sanofi	28%	72%	$12,625	$9,123	163%
Teva (specialty meds)	22%	78%	$6,442	$5,018	263%
Average	**41%**				**163%**

Thank you for the opportunity to share my views. I look forward to answering any questions you may have.

[19] Yu N, Helms Z, Bach PB. "R&D Costs for Pharmaceutical Companies Do Not Explain Elevated U.S. Drug Prices." *Health Affairs.* Published March 7, 2017. doi: 10.1377/hblog20170307.059036. Accessed from *https://www.patientsforaffordabledrugs.org/2017/03/08/health-affairs-blog-rd-costs-for-pharmaceutical-companies-do-not-explain-elevated-us-drug-prices/*.

Disclosures

Full list of disclosures from last 3 years—

Funding: Laura and John Arnold Foundation, Kaiser Permanente, Memorial Sloan Kettering Cancer Center institutional support.

Speaking fees: American Society for Health-System Pharmacy, Gilead Pharmaceuticals, WebMD, Goldman Sachs, Defined Health, Vizient, Anthem, Excellus Health Plan, Hematology Oncology Pharmacy Association, Novartis Pharmaceuticals, Janssen Pharmaceuticals, Third Rock Ventures, JMP Securities, Genentech.

Consulting fees: Foundation Medicine, Grail.

PREPARED STATEMENT OF HON. CHUCK GRASSLEY,
A U.S. SENATOR FROM IOWA

I want to welcome the witnesses and thank them. The information they will share will help inform the committee as it addresses the issue of high prescription drug prices.

Millions of Americans woke up this morning and started the day with their dose of prescription medication.

For so many of our loved ones who have diabetes, high blood pressure, cystic fibrosis, epilepsy, or other chronic health conditions, prescription drugs are a basic necessity of life.

We need to continue to have a strong research engine to develop new treatments, but we must also have a discussion about the affordability of these drugs.

Today you will hear many numbers describing the costs of prescription drugs.

Those numbers are impressive, but the stories I have heard from patients, doctors, and pharmacists in Iowa have really gotten my attention.

I have heard stories from doctors and pharmacists about skyrocketing prices of commonly used generic drugs. Usually generics are a way to keep costs reasonable.

I have also heard from seniors who have seen their prescriptions increase month after month for no apparent reason.

And I have heard stories about people reducing their life-saving medicines, like insulin, to save money.

This is unacceptable, and I intend to specifically get to the bottom of the insulin price problem.

But other drugs are creating problems too. That is why tackling high prescription drug costs is one of my first priorities as chairman of the Senate Finance Committee.

The reasons for these high prices are complex. I plan to hold a series of hearings in order to identify and address these reasons.

We will look at all aspects of the prescription drug market and make changes where necessary.

So, where do we start?

I believe we should start with transparency.

When it comes to drug prices, you should not need a Ph.D. in economics to understand how much your prescription costs.

I believe it starts with putting the list price of a drug on television ads.

I am confident in the ability of Americans to use this information to make the best decision for themselves.

Drug advertisers want to tell consumers all of the benefits of the drugs.

They are required to tell you about side effects.

But they aren't as gung-ho to share how much the drugs cost.

The President's blueprint to lower drug prices includes a provision to include the list price on TV ads. The administration has a proposed rule to do just that.

Senator Durbin and I have been vocal in our support of this proposal.

I look forward to the rule being finalized.

Senator Wyden and I introduced the Right Rebate Act last week.

When enacted, this bill will close the loophole that allowed the manufacturer of EpiPen to rip off taxpayers and consumers for as much as $1.27 billion.

Speaking of transparency, I want to express my displeasure at the lack of cooperation from the pharmaceutical manufacturers recently.

The Senate Finance Committee has a long history of working in a bipartisan manner to solve difficult problems for the American people.

So, when Ranking Member Wyden and I invited several pharmaceutical companies to come and discuss their ideas to address high drug prices, I was extremely disappointed when only two companies agreed to do that.

The companies that declined said they would discuss their ideas in private, but not in public.

One company mentioned that testifying before the committee would create a language barrier problem.

That is not what I mean when I talk about transparency.

So, we will extend the opportunity again in the future, but we will be more insistent the next time.

Today, however, I want to extend a welcome to the witnesses. I look forward to their testimony.

PREPARED STATEMENT OF DOUGLAS HOLTZ-EAKIN, PH.D.,
PRESIDENT,* AMERICAN ACTION FORUM

Chairman Grassley, Ranking Member Wyden, and members of the committee, thank you for the opportunity to testify today on the matter of drug prices. I hope to make four basic points:

1. The term "rising drug costs" is riddled with ambiguity; list prices, net prices, out-of-pocket prices, development costs, and total spending on drugs have displayed very different patterns over time.
2. There is rising demand for pharmacological therapies driven by an aging population, chronic disease, and the development of specialty drugs.
3. In the face of rising demand, the only way to reduce prices is to increase supply and heighten competition.
4. In thinking about policy actions, it is important to recognize first existing policies that exacerbate price increases. In addition, many popular proposals are unlikely to be beneficial.

Let me discuss these further.

INTRODUCTION

Over the past several years the public's attention has increasingly been focused on the cost of health care, and specifically the contribution of prescription medications to those costs. With 55 percent of the U.S. population using prescription drugs as of 2017,[1] expensive sticker prices on certain new medications, the pricing revelations at Turing Pharmaceuticals and other companies, and the EpiPen episode have fed these concerns and led policymakers to consider addressing drug prices through legislation and regulation. Policymakers, however, should first clearly identify the actual problem they're trying to address.

IDENTIFYING THE PROBLEM: PATTERNS IN DRUG COSTS

There is little consensus in the term "rising drug costs," making it difficult to determine if there is an actual policy problem, its size, or its scope. The first step in

---

*The views expressed here are my own and not those of the American Action Forum. I thank Christopher Holt and Tara O'Neill Hayes for their assistance.

[1] *https://www.consumerreports.org/media-room/press-releases/2017/08/consumer_reports_examines_do_americans_take_too_many_prescription_medications/*.

identifying whether there is a problem is to differentiate between prices, costs, and spending, which are related but not identical.

For example, "rising drug costs" might refer to a narrow definition focused on the sales prices (or "list price") set by drug developers and manufacturers. Alternatively, the problem might not be with all drugs, but instead the high prices of some drugs. Finally, the problem may be the increasing cost of prescription drugs borne by individuals at the pharmacy counter, which has resulted from an increase in high-deductible health plans.

Rising drug costs could also mean an increase in overall prescription drug expenditures, whether in dollar figures or as a percentage of National Health Expenditures (NHE). Because spending is a function of both price and quantity, this could result from increased utilization due to rising national reliance on prescription drugs or broader access to them.

Pharmaceuticals as a Share of National Health Expenditures

The first important fact to consider is that prescription drug spending as a percent of NHE has remained steady at about 10 percent since 2000, the same percentage it was in 1960. There was a dip in prescription drug spending as a share of NHE in the years between 1960 and 1980, as advances in technology and expanded insurance coverage of hospital visits contributed to a shift in NHE towards hospital stays.[2] In the 1980s, that trend began to reverse as new pharmaceuticals became widely available for the treatment of many of the most prevalent diseases in American society. The availability of advanced pharmacological treatments is highly correlated with reduced expenditures for hospitals and other health professionals.[3] As pharmaceutical growth began to level out to roughly the same levels as the 1960s, so did other NHE categories.[4] Viewed from this national perspective, there appears to be little support for a radical rise in drug spending in the data, although national averages can mask the variance among subpopulations and the most current NHE data is more than a year old.

Drivers of Drug Spending

To the extent that drug expenditures are increasing or will begin to increase in the near future, a key factor is utilization. Annual growth in pharmaceutical spending in November 2018 was 5.1 percent,[5] but annual pharmaceutical price growth was only 0.6 percent.[6] On a per capita basis, real net spending has grown by only 1 percent since 2007 and actually declined by 2.2 percent in 2017.[7]

Still, Americans are getting older, living longer, and are increasingly burdened with chronic disease. As of this year, 60 percent of the United States' adult population had been diagnosed with at least one chronic health condition, and 40 percent had two or more chronic conditions.[8] Managing these chronic conditions is an expensive proposition that relies primarily on medication. Eighty-six percent of all health-care spending is for patients with one or more chronic disease; 98 percent of Medicare and 83 percent of Medicaid spending goes towards providing care for the chronically ill.[9, 10] Specifically, over 75 percent of U.S. health-care spending goes towards treatment of chronic disease.[11] As these trends continue, the financial burden of maintaining a high quality of life with chronic conditions will inevitably disproportionately increase the growth of pharmaceutical health care spending.

Drivers of Drug Prices

Developing new treatments is an expensive prospect in terms of both capital and time. A Tufts University study in 2016 found that the average cost for each drug

---

[2] *https://www.americanactionforum.org/research/understanding-pharmaceutical-drug-costs/.*
[3] *https://www.americanactionforum.org/research/understanding-pharmaceutical-drug-costs/.*
[4] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html.*
[5] *https://altarum.org/sites/default/files/uploaded-publication-files/SHSS-Spending-Brief_January_2019.pdf.*
[6] *https://altarum.org/sites/default/files/uploaded-publication-files/SHSS-Price-Brief_December_2018.pdf.*
[7] *https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022.*
[8] *https://www.cdc.gov/chronicdisease/resources/infographic/chronic-diseases.htm.*
[9] *http://www.partnershipforsolutions.org/DMS/files/chronicbook2004.pdf.*
[10] *http://www.ahrq.gov/sites/default/files/wysiwyg/professionals/prevention-chronic-care/decision/mcc/mccchartbook.pdf.*
[11] *https://www.chronicdisease.org/page/whyweneedph2imphc.*

successfully brought to the market is nearly $2.9 billion.[12] Data from the Organisation for Economic Co-operation and Development also shows that the amount of spending per new drug approved has been growing for decades.[13] It takes an average of 15 years from the time a drug developer first begins testing a new formula until the Food and Drug Administration (FDA) approves it.[14] Only 1 in 1,000 drug formulas will ever enter pre-clinical testing, and of those, roughly 8 percent will ultimately receive FDA approval.[15]

Additionally, the last decade has seen a significant shift towards the use of "specialty drugs." While there is no precise definition of a specialty drug, this term typically refers to drugs with at least one of the following characteristics: requires special handling, must be administered by a doctor, requires patient monitoring or follow-up care, is used to treat complex, chronic conditions.[16] As a result, these drugs tend to be quite expensive. In fact, by 2016, about half of the top 80 most expensive drugs nationally were specialty drugs, and that number is increasing annually.[17] In 2010, the United States spent just over $11.5 billion on the top 25 specialty drugs. By 2017, net spending on specialty medicines reached $151 billion, accounting for 46.5 percent of all expenditures on medicines, despite accounting for just 2 percent of the volume.[18] Because specialty drugs are often more expensive to develop and typically treat small patient populations with very specific and otherwise untreatable diseases, they tend to have higher prices. Over time, the cost of new specialty drugs per patient will likely continue to be higher as the target population for each new drug will grow smaller with the development of treatments for less common diseases.

List Versus Net Prices

An important aspect of the discussion is the difference between list price and net price. List prices for brand-name drugs, on average, have increased between 7 and 13.5 percent over the past 6 years, yet the average net price of these drugs has grown between 1.9 and 4.7 percent, with the trend being downward sloping.[19] In fact, price growth for prescription drugs over the course of 2018 was the lowest growth rate since 2013, and even dipped into negative territory between December 2017 and early 2018.[20] So while the average list price of brand name drugs rose 35 percent between 2013 and 2017, average out-of-pocket (OOP) costs for those drugs remained unchanged at $30.33.[21] Similarly, generic list prices rose 7 percent during this time period, but patient OOP costs declined more than 9 percent as a result of discounts and rebates. The increasing difference between list and net price points to the growing use of discounts and rebates. Understanding the role of these incentives in price determination is an area worthy of careful consideration to ensure resources are being allocated as desired.

Out-of-Pocket Prices

From a patient perspective, many anecdotally report that OOP costs are climbing and the increased frequency of high-deductible health insurance plans is cited as the reason. But the data show that average patient OOP costs at the pharmacy counter have actually declined since 2013. Nearly one-third of all medicines were available in 2017 for zero OOP costs, and 97.5 percent were available for $50 or less, with the average OOP cost equaling $8.69. Only 2.5 percent of prescriptions filled had a co-pay of more than $50. But for the small share of very costly drugs, the expense adds up fast: 3.4 million prescriptions (0.1 percent of all prescriptions filled in 2017) had an OOP cost of more than $500, with an average cost of $1,502; total OOP ex-

---

[12] *https://csdd.tufts.edu/csddnews/2018/3/9/march-2016-tufts-csdd-rd-cost-study.*

[13] *https://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-2015/research-and-development-in-the-pharmaceutical-sector_health_glance-2015-70-en.*

[14] *http://www.fdareview.org/approval_process.shtml.*

[15] *http://www.fdareview.org/approval_process.shtml.*

[16] *https://www.pcmanet.org/pcma-cardstack/what-is-a-specialty-drug/, https://cvshealth.com/thought-leadership/whats-special-about-specialty.*

[17] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/index.html.*

[18] *https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022.*

[19] *https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022#reportcharts.*

[20] *https://altarum.org/sites/default/files/uploaded-publication-files/SHSS-Price-Brief_January_2019.pdf.*

[21] *https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf.*

penditures for these drugs was $5.2 billion.[22] It is likely also true that a number of prescriptions that would have cost at least that much were never filled because the patient simply could not afford it (or chose not to spend the money). The abandonment rate for brand-name drugs reached 21 percent in 2017.[23]

A REVIEW OF POSSIBLE SOLUTIONS

Like the leading principle of the Hippocratic Oath, policymakers should "first, do no harm." The myriad mandatory discount programs and industry taxes collectively result in higher list prices and cost-shifting to the private market as companies look for ways to offset the lost revenue. These programs don't reduce the cost of the drug; rather, they distort the health-care market (beyond just the prescription drug market) and force some to pay more so others can pay less.

Medicaid Drug Rebate Program

The Medicaid Drug Rebate Program (MDRP) requires drug manufacturers to pay a rebate for all drugs dispensed to Medicaid beneficiaries, ultimately ensuring Medicaid receives the best price for prescription drugs. As a consequence, because there was no exception for charitable donations of medicines, such donations ceased, and Congress responded by creating another program: the 340B drug discount program. 340B similarly requires drug manufacturers to provide their drugs at a statutorily determined discounted rate to all eligible entities for qualified patients (though, the program does not require those discounts be passed on to the patient receiving the medicine). The Affordable Care Act (ACA) both expanded the MDRP and increased by 53 percent the mandatory rebate that drug manufacturers must provide for all Medicaid beneficiaries.[24] Consequently, drug manufacturers paid an estimated $80 billion in rebates between 2011 and 2015.[25] The average Medicaid rebate is now greater than 50 percent of a drug's cost. The ACA also dramatically expanded the 340B prescription drug discount program, and the value of drugs subject to the program's mandatory discount nearly doubled from $6.4 billion in 2011 to $12 billion in 2015.[26] Further, the ACA required drug manufacturers to begin rebating 50 percent of the price of all brand-name drugs provided in the Medicare Part D coverage gap. Between 2011 and 2016, these rebates cost the industry $24.6 billion.[27] Finally, the ACA imposed a new tax on all manufacturers and importers of brand-name prescription drugs that cost the industry $14.1 billion over those 5 years.[28] The ACA's provisions cost drug manufacturers more than $100 billion in just 5 years. It should not be surprising that drug prices simultaneously increased.[29]

340B Drug Discount Program

The 340B program is in dire need of reform. While the program was created to resolve an unintended consequence of the Medicaid Drug Rebate Program, it has created its own unintended consequences.[30] The 340B discount incentivizes hospitals to acquire physician practices. This consolidation reduces the number of community practices and consequently drives up the cost of care for all services at those facilities, relative to the cost of the same services provided in non-hospital-owned physician offices. Studies have shown that consolidation among hospitals and other health-care facilities leads to higher costs at hospitals, often by as much as 20 percent and sometimes by as much as 40 percent.[31] Further, the program suffers from a lack of clear guidance and requirements regarding the use of savings generated. One change that could help ensure the program's discounts are passed on to the beneficiaries it is intended to serve is to reduce Medicare reimbursements for such drugs. The Centers for Medicare and Medicaid Services (CMS) implemented such a policy in 2018, through regulation, by changing the reimbursement for Part B drugs

---

[22] *https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf.*

[23] *https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf.*

[24] *https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html.*

[25] *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nationalhealthaccountshistorical.html.*

[26] *https://www.drugchannels.net/2017/05/exclusive-340b-program-hits-162-billion.html.*

[27] *https://www.cms.gov/newsroom/press-releases/nearly-12-million-people-medicare-have-saved-over-26-billion-prescription-drugs-2010.*

[28] *https://www.irs.gov/affordable-care-act/annual-fee-on-branded-prescription-drug-manufacturers-and-importers.*

[29] *https://www.americanactionforum.org/insight/understanding-the-policies-that-influence-the-cost-of-drugs/.*

[30] *https://www.americanactionforum.org/research/340bmarketdistortions/.*

[31] *https://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261.*

obtained through 340B from Average Sales Price (ASP) + 6 percent to ASP − K22.5 percent.[32] Congress could codify such a change by amending the ASP calculation to include discounts obtained through 340B. Congress should reform the 340B program to restore its original intent, ensure program integrity, and eliminate the harmful market distortions caused by it. Without such reforms, the program is unsustainable and the rest of the health care market will continue to suffer.

Medicare Part D

The Part D program is also in need of reform. Though the program has generally been quite successful, recent trends detailed here have highlighted the need for structural reforms. The current program structure—namely the minimal liability on plans for high-cost enrollees (particularly after the changes made by the Bipartisan Budget Agreement of 2018[33]), the coverage gap discount program and the counting of those manufacturer rebates towards a beneficiary's True Out-of-Pocket (TROOP) calculation, and the existence and nature of the risk corridors—does not incentivize plans strongly enough to control the cost of high-cost drugs and even allows plans to shift more costs to the Federal Government beyond what was intended.[34]

Medicare Part D reinsurance expenditures have grown rapidly for the Federal Government over the past several years, primarily because of a significant increase in both the number of beneficiaries reaching catastrophic coverage and the costs that each of them incur. This rapid growth has caused reinsurance expenditures to increase from less than one-third of the Federal Government's overall subsidy of the Part D program in 2007 to more than two-thirds of the subsidy in 2016. Further, a recent investigation by *The Wall Street Journal* found that plan sponsors have leveraged the program's risk corridors to contain their losses and increase their profits, resulting in $9.1 billion in extra subsidies.[35]

One way to realign incentives is a restructuring of the program's benefit design proposed in a recent American Action Forum study: increase insurer liability in the catastrophic phase to roughly 70 percent while simultaneously reducing the government's liability to 20 percent. Move the drug manufacturer rebate program from the coverage gap to the catastrophic phase to cover the remaining costs. These changes will significantly increase the incentive for both insurers and drug manufacturers to control costs. Further, provide beneficiaries with true financial protection by imposing an OOP cap. Plan sponsors and beneficiaries will also benefit from a simplified benefit structure since the coverage gap will be eliminated and beneficiary co-insurance will be held steady at 25 percent above the deductible until reaching the catastrophic threshold. Such reforms should encourage behavioral changes that reduce overall program costs for all stakeholders.

There are a number of proposals that are frequently mentioned as ways to reduce drug prices. A bit of reflection suggests that none is likely to be successful, however.

Government Negotiation

Some have argued that the best way to reduce drug costs, in Part D or otherwise, is to allow government negotiation. Although government negotiation is expressly prohibited in Medicare Part D, the program is rich with price negotiations. In fact, the Part D plan sponsors negotiate directly with drug manufacturers, and this is a cornerstone of the program's success. Part D beneficiaries have access to 27 different plans, on average, enabling individuals to choose a plan that is tailored to their needs.[36]

Government negotiation of drug prices could only be effective if the government were willing and able to impose a drug formulary (like the Part D plan sponsors already do) and to restrict access to medicines for which the price is "too high."[37] Doing so, however, would fundamentally change the Part D program. The government would have to impose a single formulary in order to leverage the negotiating power advocates claim it has, which would eliminate the key differentiator between plans. Suddenly, beneficiaries' choices would drop from 27 plans to 1. Beneficiaries

---

[32] *https://www.americanactionforum.org/insight/cms-moves-toward-much-needed-340b-reforms/*.

[33] *https://www.americanactionforum.org/research/examining-effects-recent-proposed-reforms-medicare-part-d/*.

[34] *https://www.americanactionforum.org/insight/evidence-for-structural-reform-part-d/*.

[35] *https://www.americanactionforum.org/insight/evidence-for-structural-reform-part-d/*.

[36] *https://www.kff.org/medicare/press-release/people-on-medicare-will-be-able-to-choose-among-24-medicare-advantage-plans-and-27-medicare-part-d-drug-plans-on-average-during-the-open-enrollment-period-for-2019-new-analyses-find/*.

[37] *https://www.americanactionforum.org/insight/the-art-of-the-drug-deal/*.

would no longer be able to shop for the plan that's best for them; rather, they would have to simply hope the government was able to negotiate a good deal for the drug(s) they need.

Drug Re-importation

Drug companies don't want their drugs sold for the lower prices available in other countries; of course they often sell at that low price because a low price is better than nothing. They will certainly not sell excess drugs to those countries to allow for a supply to be available for re-importation into the United States. And those countries, not having any excess supply, are going to provide the limited number of drugs they do have to their own people before they allow them to be sold back to the United States. Even if the United States were to allow drug re-importation, the economics make it very unlikely that it would have any impact on the availability of cheaper medicines in the United States. And that's saying nothing of safety concerns, which are legitimate.

International Reference Pricing

The Trump administration recently proposed establishing a demonstration program for drugs covered through Medicare Part B, under which reimbursement would be tied to an International Pricing Index (IPI). While the administration's objective to reduce the cost of drugs and increase Americans' access to necessary medicines is laudable, the solution that has been proposed here is not likely to achieve that objective, and in fact, could result in significant undesirable repercussions. The most likely consequences are restricted access to existing medicines and reduced innovation for future advancements and new medicines; cost-shifting to the private-sector insurance markets; an undermining of the administration's goal to move to value-based payments; and harm to U.S. trade objectives. That said, addressing the reality that the United States spends substantially more on pharmaceuticals, and supports the industry's ability to innovate more than similarly developed economies is worthy of policy experimentation. A key concern with this particular proposal is that it is unlikely to achieve the goals of reducing drug prices and maintaining patient access to innovative treatments.

The 14 countries that CMS has proposed referencing in this IPI model, on average, have access to only 48 percent of the new drugs developed in the past 8 years, and it took an average of 16 months after their initial global launch for those drugs to become available in those 14 countries. The U.S., on the other hand, has gained access to 89 percent of new medicines within 3 months.[38]

Also of concern are the indirect effects and implications of adopting a reference pricing model. Of the 14 countries under consideration for this reference pricing model, 11 use reference pricing themselves to control their prices. Between four and six of these 11 countries reference each of the following countries in determining their own price: Cyprus, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia, and Spain. By referencing the price of drugs in countries that reference the prices in other countries, we would indirectly be referencing the prices of those other countries. The average gross domestic product (GDP) per capita in these countries listed was $18,685 in 2017, while the GDP per capita in the United States was $59,532—more than three times greater. The estimated age-standardized mortality rate for all cancers in these countries is 123.47, compared with a rate of 91 in the United States. The average life expectancy in these countries is nearly a year shorter than that of the United States. It is not appropriate for the United States to reference the prices paid in countries so different than ours.

Adopting the non-market prices of other countries, and thus the punitive and authoritative policies used to obtain those prices, will likely also mean adopting for American patients similar levels of restricted access to new medicines as experienced in other countries. Worse yet, this demo may result in new medicines never being developed in the first place. Americans highly value their access to and choice of new treatment options. The reduced innovation that will likely occur as a consequence of the reduced manufacturer revenues that will result from this model will have significant ramifications. Further, referencing the prices paid for drugs in countries that do not adequately reflect the value of medicines is inconsistent with the administration's goal of adopting a value-based payment system.

Finally, this model will undermine American trade policy which may have repercussions far beyond the pharmaceutical industry. The United States should instead

---

[38] *https://www.americanactionforum.org/comments-for-record/comments-to-cms-on-proposed-international-pricing-index-for-medicare-part-b-drugs/*.

work to strengthen intellectual property rights in other countries and fight compulsory licensing in trade agreements to end the coercive practices that allow countries to force manufacturers to provide their drug for less than it's worth; this is the only way to get other countries to pay more so that we may hopefully pay less without risking reduced innovation.

There are, however some proposals that would be successful in reducing prices.

Competition and Increased Supply

History has proven the best way to reduce the price of a good for which there is growing demand is to increase its supply through competition. For drug pricing, that means bringing generics and biosimilars to market to compete with brand-name drugs.

A now-classic example of this phenomenon is the hepatitis C treatment, Sovaldi, which contributed over $3 billion to 2014 expenditures alone.[39] While the drug was quite expensive, it is important to note two things. First, Sovaldi—and its eventual competitors—provided a cure for what had been up until that point a costly-to-manage chronic disease. Second, as competitors came into the market, the price of Sovaldi was cut in half. Where there is competition, prices come down.

The FDA is doing its part by approving a record number of generic drugs and biosimilars.[40] But other barriers to unlocking robust market competition remain.

Barriers to Entry

Manufacturers of innovator drugs rightly and understandably want to protect their market share as long as possible. As discussed, bringing a drug to market is a rather risky and expensive endeavor, and investors need the promise of a formidable profit to be incentivized to make that investment. And there can be no generic without first having the expensive innovator drug. The needs of the investors to receive a return, however, must be balanced with the needs of the consumers and taxpayers in order for the market system to remain sustainable. There are obvious incentives for brand-name manufacturers to extend the length of their market exclusivity through various means. Congress can scrutinize the opportunity to create entry barriers, such as brand-name manufacturers allegedly abusing the REMS system and, if appropriate, legislate to help even more generics come to market quickly.[41] (One such example is the CREATES Act.)

Legal Enforcement of Competition Policy

Another challenge is the case of single source generics. Often, once a generic drug has been on the market long enough, it acquires enough of the market share that the brand-name manufacturer stops producing its version of the drug. In many cases, the price reaches a low enough point that other generic competitors also exit the market, leaving a sole manufacturer. In some high-profile cases we see what amounts to abuse of monopoly power—that sole manufacturer taking advantage of its position and dramatically increasing its price once there is no more competition and consumers have no choice but to purchase the now high-priced drug. In these cases, it should be treated as the abuse that it is and prosecuted where appropriate.

CONCLUSION

Fundamentally, there is no broad prescription-drug pricing crisis. Indeed, in most instances, things are working just fine. Rather what we face are more nuanced challenges, for example, the price of specialty drugs and biologics, which are expensive to develop and manufacture and frequently treat a limited population. In these instances, particularly with oncology drugs, it is important to make sure that the cost of the treatments correlates to the value. Remember that the goal is not low cost, it is high value. It is easy to have low-cost drugs; they, however, may not do much good. Conversely, it might make sense to spend more for a drug if its therapeutic benefits are high enough.

While the U.S. market has long been an environment where manufacturers are willing to invest in necessary research and development in hopes of a financial return later, more and more government regulations and taxes are reducing that incentive. Programs such as the Medicaid Drug Rebate Program and the 340B drug

---

[39] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/index.html.*

[40] *https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm625627.htm.*

[41] *https://www.biopharmadive.com/news/congress-creates-act-generic-branded-samples/543147/.*

discount program interfere with the market incentives and shift, rather than reduce, the high cost of drug development. A more effective solution to high prices is greater competition in the supply and greater financial incentives on behalf of the payers and manufacturers to keep costs and prices down.

PREPARED STATEMENT OF MARK MILLER, PH.D., EXECUTIVE VICE PRESIDENT OF HEALTH CARE, LAURA AND JOHN ARNOLD FOUNDATION

Chairman Grassley, Ranking Member Wyden, and distinguished members of the committee, my name is Mark Miller, and I am the executive vice president of health care at the Laura and John Arnold Foundation. Until recently, I was privileged to serve this committee and the Congress as a whole for 15 years as Executive Director of the Medicare Payment Advisory Commission (MedPAC) by providing analyses and delivery and payment recommendations. It is a pleasure to be back. I want to thank you for inviting me to testify today on policies designed to address the unsustainable prescription drug cost burdens on the Medicare and Medicaid programs, the populations these programs serve, and the taxpayers who finance them.

The Arnold Foundation is dedicated to reforming dysfunctional programs and systems to ensure a better return on investment for the people they serve and those who finance them. To that end, we work to develop an array of evidence and ideas to improve public policy that can drive reform in the areas of health care, pensions, education, and criminal justice—areas we believe are not serving target populations or taxpayers well. The Arnold Foundation is drawn to issues characterized by a lack of evidence; dysfunctional markets; inefficiently run and/or under-resourced government programs; and by strong interests excessively driven to protect the status quo. We strongly believe in markets, but we also believe in evidence-based intervention when markets are failing and competition is lacking. Within health care, we have seen these market failures cause stress to patients and their families, to Federal and State governments, and to employers and taxpayers.

Our objective in health care is to lower cost growth while maintaining and enhancing access to needed, high-quality care. Across the health-care system, we focus on opportunities to achieve more affordable care while securing better health outcomes. We focus on four areas where we see the greatest problems and opportunities. These four areas are (1) reducing hospital and physician prices and/or costs, (2) rationalizing drug prices and purchasing approaches, (3) identifying and avoiding low-value and/or unsafe care, and (4) improving the care for Americans with complex health conditions and needs.

We know that the issue of health care is top of mind to Americans. Rising health spending in general is squeezing government, business, and household budgets. In fact, the most important issue for American voters in 2018 was health care, and within health care, one of voters' biggest priorities is lowering prescription drug prices and costs.[1] With respect to drugs, our ultimate goal is to strike a fair balance between the industry's incentive to innovate and the affordability of medications that improve, extend, and sometimes literally saves lives.

We believe the science behind new medications is the best it has ever been. Diseases that in the recent past would be debilitating or life threatening can now be managed through medication. The predicted survival of a child born with cystic fibrosis has risen from 29 years in 1986 to 47 years in 2016.[2] A 12-week regimen can now cure hepatitis C. Advanced therapies like CAR-T hold the potential to cure cancer in a single treatment, and there is a growing pipeline of gene therapies on the horizon that hold the promise of treating or curing a variety of once-deadly genetic conditions.

However, we have several concerns. First, these treatments are launching at increasingly unsustainable prices that are not justified by their research and development costs. Life-extending cystic fibrosis treatments cost nearly $300,000 a year.[3] The cost of curing hepatitis C can be tens of thousands of dollars per treatment.[4]

---

[1] *https://www.kff.org/health-reform/poll-finding/kff-election-tracking-poll-health-care-in-the-2018-midterms/*.

[2] *https://www.cff.org/CF-Community-Blog/Posts/2017/Survival-Trending-Upward-but-What-Does-This-Really-Mean/*.

[3] *https://www.statnews.com/pharmalot/2018/05/04/vertex-cystic-fibrosis-drug-prices/*.

[4] *https://www.gilead.com/news-and-press/company-statements/authorized-generics-for-hcv.*

CAR–T therapy can easily top $500,000 and several companies have discussed pricing gene therapies above $2 million dollars.[5, 6, 7] Second, the pipeline is shifting to high-priced specialty drugs, which are expected to comprise nearly half of pharmacy industry revenues by 2022.[8] Third, given the complexity of these drugs and the dysfunction in our current system, they will often face limited competition, which will keep prices high. These drugs only work if patients can afford to take them.

The Arnold Foundation funds research to address high drug prices in a few key areas:

- Identifying the drivers of innovation and developing alternative incentive structures that drive innovation;
- Encouraging competition by reforming our current patent and exclusivity system that grants monopolies to pharmaceutical companies for decades. This includes ending abuses such as pay-for-delay settlements, product hopping, patent thickets, evergreening, and other techniques intended to keep competitors off the market;
- Rethinking the way we pay for drugs to move away from high list prices and spread pricing and move towards alternative methods of payment including reference pricing, paying on the basis of the clinical value of a drug; and
- Increasing transparency throughout the drug delivery and payment system. This includes ensuring accountability to the public for launch prices and price increases; understanding how money flows from manufacturers to pharmacy benefit managers (PBMs) and supply chain middlemen; and clear reporting of payments by manufacturers to providers and patient groups.

We believe America can remain at the vanguard of medical research and innovation while also ensuring the affordability of the fruits of this research.

THE BROKEN AMERICAN PHARMACEUTICAL MARKET

In 2016, the United States spent $471 billion on prescription drugs.[9] That number is expected to rise by nearly a quarter to $584 billion by 2020.[10] This expenditure must be taken in the larger context of spending in America. Federal debt held by the American public currently stands at about 77 percent of GDP and is expected to approach 100 percent by 2028.[11] Spending on health care is about 18 percent of GDP.[12] Both of these numbers are expected to grow in the near future. In fact, the Congressional Budget Office projects that rising health-care costs, along with payments to service the Federal debt, are among the largest drivers of increasing Federal spending in the future.[13] Budget tightening is being felt at the State level as well, and States are being asked to choose between health services and schools, roads, or public safety services.

This spending growth is mirrored in Federal and State programs like Medicare and Medicaid. In Medicare Part D, total net spending on drugs was over $100 billion in 2016.[14] From 2007 through 2016, reinsurance payments to Part D plans, which are financed largely by the taxpayer, rose at a rate of 17.7 percent per year.[15] The program's costs to the taxpayer are rising faster than premiums paid into Part D.[16]

Medicare Part B, which covers physician-administered drugs, experiences similar drug spending growth. Spending on Part B drugs neared $30 billion in 2016, which

---

[5] *https://www.washingtonpost.com/national/health-science/staggering-prices-slow-insurers-coverage-of-car-t-cancer-therapy/2018/07/17/ea7f150c-89a1-11e8-9d59-dccc2c0cabcf_story.html?utm_term=.9a31adc7c1b8.*

[6] *https://www.wsj.com/articles/biotech-proposes-paying-for-pricey-drugs-by-installment-11546952520.*

[7] *https://www.reuters.com/article/novartis-gene-therapy/novartis-says-sma-gene-therapy-is-cost-effective-at-4-5-mln-per-patient-idUSFWN1XG0OD.*

[8] *http://drugchannelsinstitute.com/files/State-of-Specialty-Pharmacy-2018-Fein-Asembia.pdf.*

[9] *https://altarum.org/sites/all/libraries/documents/Projections_of_the_Prescription_Drug_Share_of_National_Health_Expenditures_June_2018.pdf.*

[10] *Ibid.*

[11] *https://www.cbo.gov/system/files?file=115th-congress-2017-2018/reports/53651-outlook.pdf.*

[12] *https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.05085.*

[13] *https://www.cbo.gov/system/files?file=115th-congress-2017-2018/reports/53651-outlook.pdf.*

[14] The Laura and John Arnold Foundation's analysis using the Medicare Part D Prescription Drug Event Data and rebate information in the Medicare Trustees Report published June 2018.

[15] *http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf.*

[16] *Ibid.*

is nearly double the amount spent in 2010.[17] MedPAC notes that price is the largest factor contributing to the growth of Part B drug spending.[18] Together, this is part of the reason that an average Medicare household will spend nearly 15 percent of their total spending on health care.[19]

Medicaid programs are under pressure from rising drug costs as well. Spending on drugs grew nearly 50 percent over the 2011 to 2017 period. In total, the Federal Government and States spent about $30 billion on drugs in 2017 after rebates.[20] This growth, driven by Medicaid expansion and high cost therapies like those that treat hepatitis C and cystic fibrosis, puts unnecessary pressure on taxpayers and has outstripped traditional pharmacy cost containment measures.

Ultimately, drug spending is placing an increasing burden on patients and taxpayers to cover the bill. About one in four Americans chose not to fill a prescription last year because of cost.[21] Specialty medications cost, on average, over $50,000 a year at retail prices and many people with employer sponsored insurance have to pay on average 27 percent of this amount, or nearly $14,000.[22, 23] This is particularly concerning considering that 40 percent of households would find it hard to produce $400 in an emergency.[24]

Government Granted Monopolies Drive-Up Prices

Given these issues, it is not surprising that most Americans, their employers, and even the doctors who prescribe treatments believe our prescription drug market is broken. They cannot explain or understand why we pay as much as three times or more for the same drugs than patients in other developed nations.[25]

The Level of Research and Development Investments Do Not Explain High Prices

A common refrain from the drug industry is that high prices are necessary to drive innovative research and drug development and that making drugs is hard and risky and America subsidizes research for the rest of the world. In fact, revenues generated just from sales in America would fund 176 percent of the global pharmaceutical research and development budgets for these companies.[26] Between 2013 and 2017, the five largest U.S.-based drug companies spent substantially more on marketing and administrative costs than on research and development.[27] Rather than embodying the ideals of competition and choice, the American system, when examined closely, appears to be rife with market failures and perverse incentives.

Manufacturers Engage in Creative Ways to Block Competition

Instead of encouraging research into the next generation of cures, firms with drugs approved by the Food and Drug Administration (FDA) are incentivized to hold on to their monopolies as long as possible and deploy as many anticompetitive tactics as possible to ensure generics or biosimilars are not available. The FDA and the United States patent system were designed to create a virtuous cycle: innovator companies are granted certain exclusivities through the FDA and United States Patent and Trademark Office for their work and when those exclusivities expire, cheaper alternatives like generic drugs or biosimilars become available. Ideally, this would, over time, ensure that there is budgetary room for future products, but this is not happening.

---

[17] *http://www.medpac.gov/docs/default-source/data-book/jun18_databooksec10_sec.pdf?sfvrsn=0.*

[18] *Ibid.*

[19] *https://www.kff.org/report-section/the-financial-burden-of-health-care-spending-larger-for-medicare-households-than-for-non-medicare-households-tables/.*

[20] *https://www.macpac.gov/wp-content/uploads/2015/11/EXHIBIT-28.-Medicaid-Gross-Spending-and-Rebates-for-Drugs-by-Delivery-System-FY-2017.pdf.*

[21] *https://www.kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-august-2015/.*

[22] *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017.*

[23] *https://www.aarp.org/content/dam/aarp/ppi/2017/11/full-report-trends-in-retail-prices-of-specialty-prescription-drugs-widely-used-by-older-americans.pdf.*

[24] *https://www.federalreserve.gov/publications/2018-economic-well-being-of-us-households-in-2017-dealing-with-unexpected-expenses.htm.*

[25] *https://www.scientificamerican.com/article/how-the-u-s-pays-3-times-more-for-drugs/.*

[26] R&D Costs for Pharmaceutical Companies Do Not Explain Elevated U.S. Drug Prices, *Health Affairs Blog,* March 7, 2017. DOI: 10.1377/blog20170307.059036.

[27] Top 5 U.S.-based companies determined by market cap taken 11/12/2018 (JNJ, PFE, MRK, ABBV, AMGN). Annual research and development (R&D) and selling, marketing, and administrative (SG&A) spending reported in annual filings.

Between 2005 and 2015, over 75 percent of drugs associated with new patents were for drugs already on the market.[28] Of the roughly 100 best-selling drugs, nearly 80 percent obtained an additional patent to extend their monopoly period at least once; nearly 50 percent extended it more than once.[29] For the 12 top selling drugs in the United States, manufacturers filed, on average, 125 patent applications and were granted 71.[30] For these same drugs, invoice prices have increased by 68 percent.[31] Manufacturers also engage in pay-for-delay schemes, in which payment is made to generic firms to not compete with a product. Even in cases where the Federal Trade Commission fines a company for these tactics, the profits made from the delay may outstrip the fine, effectively incentivizing illegal behavior.[32]

Pharmaceutical companies will often point out that, despite invoice and list prices increasing at an alarming rate, the net price paid for drugs has been increasing much more slowly. This begs a further question, why is the gulf between list and net prices widening? The answer may often lie in the pharmaceutical supply chain. The rebates paid off list price may end up with the PBMs and wholesalers within the supply chain. In exchange for these rebates, branded drugs are often given favorable treatment on formularies and are sometimes placed preferentially ahead of generic or biosimilar versions. In the end, patients often pay coinsurance based on the higher list price despite the discounts offered to these other players.

POLICY OPTIONS TO LOWER DRUG SPENDING AND INCREASE AFFORDABILITY

It is encouraging that bipartisan support for legislative and regulatory fixes is growing. As evidenced by this hearing, Congress has heard the concerns of American families, businesses, and taxpayers and is interested in finding policy solutions that will balance innovation and affordability. Doing nothing is a policy decision, and it is a decision that we know will lead to ongoing patent abuse and market dysfunction; an opaque supply chain characterized by spread pricing; higher costs of doing business for employers; increasingly unsustainable public programs; and higher out-of-pocket expenditures for families.

And while we recognize that the patent abuses and other anticompetitive behaviors mentioned above are beyond this committee's jurisdiction, they must be addressed in any comprehensive piece of legislation. If they are not, public programs like Medicare and Medicaid will continue to face higher drug prices and expenditures.

During today's hearing, this testimony will largely focus on potential fixes to Medicare and Medicaid. Consistent with the mission of The Arnold Foundation, we offer an array of credible ideas for Congress to consider in crafting a solution to these problems. The status quo represents a series of choices and trade-offs that we believe are unfair to the taxpayer and the patient. Any new policy will also require choices and tradeoffs across patients, taxpayers, PBMs, and manufacturers. These tradeoffs demand careful consideration, but we feel that a balance can be found that more equitably benefits each of these groups.

Medicare Part D

The Medicare Part D program was designed with financial incentives to encourage plan and beneficiary participation to ensure its success. We now have a very robust program. About 44 million of the 60 million people with Medicare have prescription drug coverage under Medicare Part D and each beneficiary has, on average, 40 plan offerings.[33, 34]

Restructuring Part D to Improve Competitive Pricing

The financial structure that seemed necessary in 2006 is now creating incentives that waste taxpayer money. Here are a few examples. (1) *The Wall Street Journal* recently reported that plans generated over $9.1 billion in profit since 2006 by overestimating their expected costs and capitalizing on the Federal payment structure

---

[28] *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3061567.*
[29] *Ibid.*
[30] *http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf.*
[31] *Ibid.*
[32] Robin Feldman and Evan Frondorf, *Drug Wars: How Big Pharma Raises Prices and Keeps Generics Off the Market* (Cambridge 2017).
[33] *http://www.medpac.gov/docs/default-source/default-document-library/status-report-on-part-d_jan-2019.pdf?sfvrsn=0.*
[34] *https://www.kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-prescription-drug-plans-in-2018/.*

of Part D.[35] (2) Part D is required to cover all drugs in six classes, which undercuts plan ability to negotiate rebates. These drugs comprised about 20 percent of Part D spending in 2015, but only 14 percent of prescriptions.[36] (3) Experts believe the benefit structure encourages plans to prefer high cost drugs to move people into the catastrophic region where taxpayers pay 80 percent of the cost.[37] As mentioned previously, reinsurance payments are growing rapidly. Medicare's reinsurance payments to plans are estimated to be seven times the amount they were in 2006, reaching $43 billion in 2019.[38] There are over 3.6 million people in Medicare Part D who had drug spending above the catastrophic coverage threshold. Of the 3.6 million, 1.1 million did not receive a low-income subsidy. That number is more than double what is was in 2010.[39]

MedPAC has recommended a set of policies that restructure Medicare Part D to give plans greater financial incentives and stronger tools to manage the benefit.[40] Both recent republican and democratic administrations have proposed similar policies.[41, 42] Taken together, the following proposals would reduce the amount that taxpayers pay to provide the Part D drug benefit to its 44 million beneficiaries. However, the proposals would also expose some beneficiaries to higher cost sharing. In turn, some consideration could be given to using some of the savings to help people with higher out-of-pocket costs.

Benefit Structure

1. Transition Medicare's individual reinsurance subsidy from 80 percent to 20 percent while maintaining Medicare's overall 74.5 percent subsidy of basic benefits.
2. Exclude manufacturers' discounts in the coverage gap from enrollees' true out-of-pocket spending.
3. Eliminate enrollee cost sharing above the out-of-pocket threshold.
4. Modify copayments for Medicare beneficiaries with incomes at or below 135 percent of poverty to encourage the use of generic drugs, preferred multisource drugs, or biosimilars when available in selected therapeutic classes.

Plan Flexibility

5. Provide plans with additional leverage to lower prices paid for drugs by removing at least the antidepressant and immunosuppressant drug classes from protected status and by considering recent administrative proposals that give plans additional tools to manage the six protected classes.[43] To protect the beneficiary, these policies must be coupled with expeditious, well-functioning exceptions and appeals processes.
6. Streamline the process for formulary changes.
7. Require prescribers to provide supporting justifications with more clinical rigor when applying for exceptions.
8. Permit plan sponsors to use selected tools to manage specialty drug benefits while maintaining appropriate access to needed medications.

In addition to the issues with Part D benefit design and plan flexibility, there are transactions such as rebates, pharmacy fees, and other forms of compensation that occur in the supply chain that pose several issues.

Although rebates put downward pressure on premiums, they give plans incentives to steer beneficiaries to drugs with the highest rebates, which also tend to have high list prices. This leads to higher cost sharing for beneficiaries and could accelerate

---

[35] *https://www.wsj.com/articles/the-9-billion-upcharge-how-insurers-kept-extra-cash-from-medicare-11546617082.*

[36] *https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicares-protected-classes-policy.*

[37] *http://www.medpac.gov/-blog-/factors-increasing-part-d-spending-for-catastrophic-benefits/2017/06/08/factors-increasing-part-d-spending-for-catastrophic-benefits.*

[38] *https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/.*

[39] *http://www.medpac.gov/docs/default-source/default-document-library/status-report-on-part-d_jan-2019.pdf?sfvrsn=0.*

[40] *http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf.*

[41] *https://www.hhs.gov/about/budget/fy2017/budget-in-brief/cms/medicaid/index.html?language=es.*

[42] Table S–6 *https://www.whitehouse.gov/wp-content/uploads/2018/02/budget-fy2019.pdf.*

[43] *http://www.medpac.gov/docs/default-source/comment-letters/01162019_partd_4180_p_medpac_comment-letter_v2_sec.pdf?sfvrsn=0.*

the rate at which a beneficiary reaches the catastrophic portion of the benefit, where taxpayers pick up 80 percent of the cost.

There are several points for consideration. First, may we need to revisit how Part D's financing structure allocates rebates to the taxpayer versus the plan and fix any misalignments. Second, there are other forms of compensation that may not be shared with the program currently. We should be asking whether plans should be permitted to profit from them without the taxpayer directly benefiting. Third, if rebates are creating so many perverse incentives in the program, maybe we should consider moving the entire Part D benefit to one that is paid using claims plus a flat fee. This, perhaps, would be the best way to realign incentives in the program to encourage use of the most appropriate and lowest cost drugs.

Even if the benefit structure were reformed, plans were given more flexibility, and rebate incentives were improved, Part D still has a problem. As mentioned earlier, specialty drugs are filling the pipeline and they tend to face little or no competition. The average net price per prescription of a brand-name specialty drug in Medicare Part D grew at an average annual rate of 22 percent from 2010 to 2015.[44] While less than 1 percent of all Part D claims were for specialty drugs in 2017, they comprised a quarter of Part D spending, up from 6 percent in 2007.[45]

Part D is not well-equipped to address these types of drugs, in part because negotiations are disaggregated across plan sponsors. This disaggregation makes negotiating prices for high cost drugs with limited competition less efficient than if the program were able to negotiate on behalf of all beneficiaries. We need to think through creative solutions to address this issue to ensure the program's fiscal sustainability.

There are two sets of policies that could address this issue:

1. *Reference pricing.* The program could use the following external prices when setting reimbursement rates for certain high cost drugs:
   a. Prices paid by a subset of foreign countries similar to the idea proposed by the administration in its Part B demonstration.
   b. Prices based on the clinical value of the drug to the patient.
   c. Prices based on independently developed research and development costs for a given therapeutic class.
   d. Prices paid for similar drugs with competition or other drugs within a similar therapeutic class.
2. *Negotiation with binding arbitration.* Before Medicare covers certain high-cost drugs, the Secretary of Health and Human Services and pharmaceutical manufacturers would negotiate a price. If the negotiations fail, a neutral arbitrator would set the price of a drug once presented with a full set of information from which to make the pricing decision. In order to drive more reasonable bids, the arbitration would be highly structured such as those used in baseball to negotiate a player's salary. The arbitrator would have to pick one of the bids.

We recognize that there are a number of complex design issues that need to be worked through. As mentioned, this would be restricted to a small subset of drugs with limited competition so it is administratively feasible. The Secretary would have to appoint or create a neutral arbitrator with drug market expertise (*e.g.,* experts associated with the American Arbitration Association). Additionally, the legal issues of having a third party present a decision to the Secretary would have to be addressed. This concept of program-level negotiation may be foreign, but it is important to keep in mind that the Department of Veterans Affairs engages in negotiation for drugs they purchase on behalf of their patients.

You can combine these two ideas and have reference prices built into the negotiation and binding arbitration process in order to guide the bids that are offered.

In both of these policies, once there are a sufficient number of competitors on the market, price negotiation would return to Part D's standard negotiation process.

---

[44] *https://www.cbo.gov/system/files/115th-congress-2017-2018/presentation/53929presentation.pdf.*

[45] *http://www.medpac.gov/docs/default-source/default-document-library/status-report-on-part-d_jan-2019.pdf?sfvrsn=0.*

MEDICARE PART B

In Medicare Part B, drugs and biologics dispensed by physicians are reimbursed using a buy-and-bill system. Under this structure, physicians are paid for the price of a drug plus a set percent, which can encourage providers to use higher cost medications and thus bring in higher revenue.[46] The types of drugs used in Part B can also complicate matters. These physician-administered products are often high-cost specialty drugs or biologics. Of the top 10 drugs by spending in Part B in 2016, nine were high-cost biologics, which typically face limited competition.[47]

A number of payment reforms could move away from incentivizing the use of high cost drugs and instead encourage the use of the most clinically appropriate product, regardless of price, or the use of lower-cost alternatives.

1. *Reduce or reform the average sales price (ASP) add-on payment for physician-administered drug reimbursement.* This could either be calculated as a lower percentage add on (*e.g.,* from 6 percent to 3 percent) or as a flat add-on fee.
2. *Require manufacturers to pay Medicare a rebate when their ASP growth exceeds and inflation benchmark.* This type of inflation penalty is used to control price growth in Medicaid and would reduce both the prices paid for Part B drugs and the associated beneficiary cost sharing.
3. *Require that Medicare use the same billing code for biosimilars and their reference biologic product.* This would be similar to the way generic small molecule drugs are treated. Currently, biosimilars are reimbursed at their own ASP plus a percentage of the reference biologic's ASP. This provides no difference in margin for the administering provider and a weak incentive to use a biosimilar over the higher priced biologic.
4. *Allow physicians to form purchasing groups and negotiate their own formularies for physician-administered drugs.* This would mimic some of the cost-containment techniques already used in the Part D benefit and through private plans and would allow groups to leverage purchasing power and market forces to negotiate for lower prices.

Recently, the administration introduced the International Price Index (IPI) Model, which benchmarks Medicare reimbursement for Part B drugs to an international reference price.[48] We believe models like the IPI are worth examining. They have a chance to reduce costs for beneficiaries and taxpayers significantly while still ensuring access to critical medications.

MEDICAID

The Medicaid rebate program is very successful at driving down average prices paid by the program relative to other payers. However, States are still struggling to afford new, high-cost specialty drugs, where the rebate is less effective in lowering prices. Additionally, since States are essentially required to cover all drugs, they are not getting as good a price as they could if they had additional flexibility.

States are working with the administration to address this issue creatively. Louisiana recently received approval from CMS to operationalize a "Netflix" subscription model to purchase hepatitis C medications and New York instituted a Medicaid drug spending cap.[49, 50] However, it is clear that more needs to be done both administratively and legislatively to provide States with additional flexibility to rein in spending.

1. *Provide States Additional Flexibility to Manage the Drug Benefit.* Currently, States do not have as many tools as the private sector to manage the Medicaid drug benefit. If a manufacturer participates in the Medicaid rebate program, a State must cover all of its drugs. States are permitted to use some utilization management tools like prior authorization and quantity limits. If States were given additional flexibility to exclude from coverage certain drugs, while maintaining access to the statutory rebate, States would be able to lower drug spending. This legislative change would ensure that States like Massachusetts and Arizona could pursue the more flexible benefit designs

[46] *https://www.cms.gov/sites/drupal/files/2018-10/10-25-2018%20CMS-5528-ANPRM.PDF.*
[47] The Laura and John Arnold Foundation's analysis of CMS Part B spending file.
[48] *https://innovation.cms.gov/initiatives/ipi-model/.*
[49] *https://www.washingtonpost.com/health/2019/01/10/louisiana-adopts-netflix-model-pay-hepatitis-c-drugs/?utm_term=.c7a9553d49fd.*
[50] *https://www.health.ny.gov/health_care/medicaid/regulations/global_cap/docs/2018-09-17_medicaid_drug_cap.pdf.*

they proposed to CMS.[51, 52] Obviously, any changes like this would have to be accompanied by a well-designed, rapid appeals process and access to off-formulary drugs when clinically indicated.

2. *Address Misclassified Drugs.* Provide the Centers for Medicare and Medicaid Services the authority to ensure that manufacturers are appropriately classifying their drugs as brands or generics to ensure payment of the appropriate rebate amount to the Medicaid program.
3. *Increase the Statutory Cap on the Brand Rebate.* A unique feature of the Medicaid rebate program is that it has an inflation component. A manufacturer's rebate liability grows if it increases its average manufacturer price (AMP) more than inflation. This inflation-based rebate comprises over half of the average rebate owed on brand drugs.[53] The rest comes from the basic rebate, which for most drugs is 23.1 percent of a drug's AMP or the best price given to certain other payers. Under current law, the total rebate amount owed to Medicaid on a brand drug is capped at 100 percent of its AMP. One important scenario is that once a drug's rebate reaches the cap, a manufacturer can continue to raise its AMP without paying additional rebate dollars to Medicaid. If the rebate cap were increased, States and the Federal Government would receive a larger rebate because of this price increase, making the penalty more reflective of excessive price growth. While this policy would generate savings to the Medicaid program, we recognize that it creates a scenario where some manufacturers would be paying Medicaid to cover their drugs. The cap could be raised by an incremental amount (*e.g.,* 105 percent of AMP) to dampen the effect on manufacturers.
4. *Remove the Statutory Requirement That Manufacturers Blend the AMP of a Brand Drug With its Authorized Generic.* Under current law, the calculation of AMP requires a manufacturer to average the price of its authorized generic product with its branded product. Because the authorized generic is typically much lower in price than its branded counterpart is, this lowers the AMP off which the brand rebate is a calculated. MACPAC proposed changing the calculation to exclude the authorized generic price from the calculation of a brand drug's AMP. This would lower the prices States and the Federal Government pay for certain brand-name drugs in the Medicaid program.[54]

CONCLUSION

Mr. Chairman, on behalf of The Arnold Foundation, I wish to sincerely commend the committee for its leadership in holding today's hearing and for remaining committed to addressing the challenge of ever-rising prescription drug costs and the burden it places on all Americans. Advances in science have given us the ability to manage and even cure diseases that had no treatment even a decade ago. Despite this, the American health-care system must find a way to properly balance scientific discovery and innovation with affordability to patients, employers, and taxpayers.

We believe that the system can deliver affordable treatments while also encouraging the development of the next generation of treatments. All of the ideas we offered you today involve trade-offs. We stand ready to support your work and your commitment to find the best policy approaches to achieve this important balance. Mr. Chairman, Ranking Member Wyden, and members of the committee, thank you for having me testify on this important subject. I would be happy to answer any of your questions.

PREPARED STATEMENT OF KATHY SEGO, MOTHER OF A CHILD WITH INSULIN-DEPENDENT DIABETES

Good morning. Thank you, Chairman Grassley, Ranking Member Wyden, and distinguished members of the Senate Finance Committee, for the opportunity to testify before you today. My name is Kathy Sego. I am a choir teacher from Indiana. My husband and I have two children. Our son Hunter has type 1 diabetes.

More than 30 million Americans have diabetes and approximately 7.4 million of them rely on insulin. For millions of people with diabetes—including my son, and

---

[51] *https://www.mass.gov/files/documents/2018/04/26/masshealth-1115-waiver-hearing-slides.pdf.*
[52] *https://www.azahcccs.gov/shared/Downloads/News/FlexibilitiesLetterFinal_11172017.pdf.*
[53] *https://www.macpac.gov/wp-content/uploads/2018/06/Improving-Operations-of-the-Medicaid-Drug-Rebate-Program.pdf.*
[54] *Ibid.*

all individuals with type 1 diabetes—access to insulin is literally a matter of life and death. There is no medication that can be substituted for insulin, and nobody should ever have to go without it due to prohibitive costs. An American Diabetes Association study estimates that diabetes costs a total of $327 billion a year, but for my family, the true cost cannot be calculated.

My son Hunter thrives as a student and football player at DePauw University. On the surface, you would never know that he lives with a chronic disease. Hunter was diagnosed with type 1 diabetes on August 23, 2004, 1 month before his seventh birthday. On that date, our lives changed. Ever since, I have been an advocate and volunteer with the American Diabetes Association, fighting to make sure Hunter and all people with diabetes can stay healthy and have the same rights as people without diabetes.

Diabetes is an everyday struggle. Every meal, every snack, every workout must be calculated. Hunter checks his blood sugar 10 times a day and doses his insulin accordingly. Any misstep can cause dangerous health problems. For Hunter, and every person who relies on it, insulin is as important as water or oxygen. Imagine if the one thing you relied on to survive was nearly out of reach because it was too expensive. That, for us, is insulin.

Four years ago, when Hunter was starting college, he offered to go to the pharmacy to pick up his insulin. I thought, my son is growing up. I was proud. But for Hunter, growing up means understanding the cost of diabetes. The cost that day was $1,700, and Hunter called me in a panic. We have insurance; it simply could not be that expensive. The price tag was accurate. What made it worse was—it was just for 1 month.

What happens next brings me to tears. My energetic, athletic, and positive son was not himself. He seemed depressed. His grades dropped. He looked labored on the football field. His professors and coaches noticed the change too.

I found out that Hunter had decided to purchase one vial of insulin instead of the four vials he needed for the month. Unbeknownst to me and my husband, Hunter was rationing his insulin.

Rationing meant he didn't eat in order to keep from having to give insulin that metabolizes food. So, armed with 25 percent of the amount of insulin, he averaged eating less than 1 time per day. Daily energy expenditure, for even a non-athlete, requires more fuel. But as Hunter was trying to give his all on the field, he essentially found himself starving and making himself sick. In response, he started eating, but not dosing with the necessary insulin to allow enough oxygen to feed his organs, muscles, and brain cells. All the while, he began accumulating ketones (known as keto-acidosis), which left him 20 pounds lighter in the course of only 2 weeks. The combination of ketones and lack of oxygen could have ended with him in the morgue.

Thankfully for Hunter, we caught wind of this, and he is okay today. But insulin rationing can lead to devastating—even deadly—complications, which I never want my son to experience. I'm heartbroken to know that my son felt he was a financial burden to us. Money over life is not the choice I want him to make, and I agonize over the idea that this could happen again.

In everything my family does, we think first of the cost of Hunter's insulin. It is the root of every decision we make. We don't eat out. I don't turn on the heat in our home. I play a risky game with my utility bills—strategizing how long I can stretch them out before paying the past due fees. Our electricity was turned off because I needed to purchase the medicine that keeps my son alive. Almost every dollar I make goes towards health expenses, yet the increasing cost of medicine and care keep us in an endless cycle of trying to find innovative ways to generate other sources of money to pay for it all. Both my husband and I work 80-plus hours a week.

This doesn't have to be this way. It is not like this everywhere in the world. We hosted an exchange student from Hungary, and her family flew us to their home for a visit. We went to the pharmacy for insulin; it cost $10. The same vial of insulin that costs us $487 out of pocket in the U.S. cost $10 in Hungary. I wanted to stockpile it. I wanted to buy every vial, but they only allowed us to bring home a 1-month supply.

My son is about to graduate college. When that happens, it will be one of the proudest moments of my life. However, unlike other parents, that moment also fills

me with dread. Hunter's life choices are contingent on his ability to pay for the medicine that keeps him alive.

Hunter has these worries too. He wonders—can he pay for an apartment? Utility bills? His student loans? Will he be able to have a social life? Take a girl on a date? The thing is, it really comes down to this: Hunter needs insulin to live, but should that need for insulin keep him from living?

Our family is not alone in this struggle. More than 7 million Americans use insulin, and more than 400,000 have signed the American Diabetes Association's online petition calling for action to make insulin affordable for all who need it. I'm here today on behalf of every family that is impacted by this disease and by these costs to ask for your help in easing this burden. This is not a call for a handout or a way to allow those who live with diabetes to be given a free ride. We just want to keep those 7 million alive without having to do what my son thought was his only option to stay alive.

The scientists who discovered insulin sold the patent to the University of Toronto for $1 each to ensure affordable insulin for all who needed it. Nearly 100 years later, it is my most desperate wish that we make their vision come true.

Again, thank you for the opportunity to testify before the committee.

PREPARED STATEMENT OF HON. JOHN THUNE, A U.S. SENATOR FROM SOUTH DAKOTA, AND HON. ROB PORTMAN, A U.S. SENATOR FROM OHIO

We appreciate the witnesses' testimony and insight into addressing high drug prices. The topic of 340B was raised throughout the hearing, and we would like to state for the record the importance of the program for hospitals in our States and the community benefits 340B enables them to provide. The total discounts from the program equate to about 1 percent of all drug spending in the United States, and while a relatively small amount, the associated savings are important to meeting the needs of our communities.

PREPARED STATEMENT OF HON. RON WYDEN,
A U.S. SENATOR FROM OREGON

Thank you, Senator Grassley. I've appreciated the chance to work with you on health-care issues in the past, including fighting pharmaceutical price-gouging and exposing ripoffs by unscrupulous health-care providers. In my view, there's a big opportunity in this Congress to find common ground on holding down health-care costs.

Since this is the first hearing of this Congress, I also want to welcome our new committee members, Senators Hassan and Cortez-Masto on the Democratic side, and Senators Lankford, Daines, and Young on the Republican side. I'm looking forward to working with all our new members in the months ahead. And I'd note, with the dais creeping farther and farther into the audience, we may need to consider putting up stadium seating in here.

As Chairman Grassley noted in his opening statement, the Finance Committee invited the heads of several of the largest drug companies to testify today. They weren't willing to come answer our questions about why their products cost so much. That ought to tell you something.

A little history. Even the big tobacco CEOs were willing to come to Congress and testify, and they made a product that kills people. They all lied to me, but at least they showed up. The drugmakers won't even do that much.

This hearing is not a one-off. This is the first in a series we will hold on this topic. So nobody is going away, and even if it means using our power to compel the drug company CEOs to show up, they will come before this committee.

The crisis of prescription drug costs threatens too many lives and bankrupts too many people for the Congress to tolerate this ducking and weaving by the companies that caused it. According to a recent report, millions of Americans have skipped doses or declined to fill prescriptions because of their cost. That is intolerable.

Look at the price of insulin. Particularly for type 1 diabetes, insulin has been saving lives for nearly a century. There have been some improvements in insulin treatments over the years, but the real breakthrough came in the 1920s. There has been

no recent "aha" moment in a lab to explain why the list price of Eli Lilly's main insulin drug, Humalog, went from $21 a vial in 1996 to its current list price of $275. A 13-fold increase. Humalog isn't 13 times as effective as it used to be. A vial doesn't last thirteen times longer than it did in 1996.

Other insulin manufacturers have hiked prices as well. But the problem isn't just about diabetes. The incredible strain that drug costs put on patients in Oregon and across the country is in plain view.

Thousands and thousands of people at any given moment are turning to fundraising websites and asking complete strangers for help covering the cost of their prescriptions. It is grotesque that price-hiking drug makers have turned American patients into beggars.

Chairman Grassley and I recently investigated how the drugmaker Gilead came to price its hepatitis C drug Sovaldi at $1,000 a pill, wholesale. According to our investigation—based on the company's own documents and their employees' own words—setting that price was not about recovering R&D costs. It was not based on the previous standard of care. The company charged a list price of $1,000 per pill because they knew they could get away with it. And that figure would set a pricing platform—a benchmark to be surpassed by successor drugs.

So there's no shortage of evidence about what the problems are. Drug makers have unchecked power to set prices on their own—power that's often used to meet Wall Street's expectations rather than meet demand in the market. The system prioritizes quarterly earnings over human lives.

There are several policy challenges to tackle. I'm especially troubled by healthcare middlemen who skim off enormous sums of money, when there's scant evidence they're getting patients a better deal. That sure looks like it's the case with pharmacy benefit managers. Called PBMs, they're supposed to negotiate better deals, but the reality is, they take a big cut and inflate list prices.

The three biggest PBMs are among the 25 largest companies in America. So let's pull back the curtain on what's really going on and see who really benefits from this arrangement. Right now, it's pretty clear to me that it's not families or taxpayers.

Finally, a word about Medicare Part D. Chairman Grassley was a lead author of the bill that created the Medicare prescription drug benefit in 2003. While it was not the bill I would have written, I supported that bill because it was a first step to help seniors pay for their prescriptions. The pharmaceutical industry looks a lot different now than it did back then. Today we will hear from our witnesses that the structure of Part D encourages drug manufacturers to set list prices sky-high. We'll hear that private Part D plans are incentivized to push these high-priced drugs onto seniors. That cannot happen any longer.

More than a decade of evidence shows that private Medicare Part D plans often do not do a good enough job of negotiating drug prices downward. So I believe Medicare ought to be able to use the collective bargaining power of 43 million seniors to get better deals for patients and taxpayers. The astronomical list prices of sole-source drugs is a major strain on patients and health-care budgets, and private plans have proven unable to correct that problem. Let's also recognize that drug company profits are often dependent on taxpayer-funded research. I do not believe drug makers ought to be able to get away with privatizing all the gains after socializing the costs of that essential research.

The administration has often talked about addressing drug prices, but what's been offered is too light on details and destined to come up short. To live up to the President's promises, the administration will need to work with both sides in the Congress to pass meaningful legislation that lowers prices.

The Finance Committee has a real opportunity to take action this year. We have a long tradition of bipartisanship and big ideas. So let's make our work on lowering drug prices live up to that tradition.

COMMUNICATIONS

AMERICAN COLLEGE OF PHYSICIANS
25 Massachusetts Avenue, NW, Suite 700
Washington, DC 20001–7401
202–261–4500, 800–338–2746
www.acponline.org

The American College of Physicians (ACP) would like to express our appreciation to the Senate Finance Committee for hosting a hearing on prescription drug pricing in America. ACP is the largest medical specialty organization and the second largest physician group in the United States. ACP members include 154,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

We understand that this issue is a top priority for Chairman Grassley and Ranking Member Wyden and that the Committee plans a series of hearings concerning this issue. Our physicians see first-hand the choices that patients must make about their health when trying to budget between the cost of their medications and every-day living expenses. Dr. Nitin Damle, a practicing physician in Wakefield, RI, and the founding and managing partner of South County Internal Medicine, related the obstacles encountered by his patients in taking their medications in one day of his practice in his testimony to the Senate Judiciary Committee on June 21, 2016, that examined methods drug companies use to raise prices of medications.

- A 67-year-old patient with diabetes, hypertension and heart disease can no longer afford his medications, as he has fallen into the "doughnut hole" of drug coverage. He must take brand-name drugs due to lack of cheaper generic alternatives to control his diabetes and prevent another heart attack.
- A 40-year-old patient with asthma cannot afford his preventive and rescue inhalers because of the high cost and his high deductible plan. There are again no generic alternatives. His non-compliance with medication will lead to an asthma exacerbation that may lead to an emergency room visit and even admission to the hospital.
- A third patient with rheumatoid arthritis cannot afford the immune modulating medications that are the standard of care due to the cost of the brand name medication with no generic alternatives. The inability to treat early rheumatoid arthritis with these medications will lead to more serious joint problems including joint replacement surgery and other medical complications of the disease.

These examples are just three of many that play out in physicians' offices day in and day out. Advances in medicine have been life-saving but they need to be affordable to society. Non compliance with medication regimens can lead to more serious health complications, more patients suffering from disease and more costs to society. The pharmaceutical industry needs a reasonable return on investment but there needs to be a balance between profits and the service they provide in treating and maintaining the health of our patients.

We look forward to working with members of the Committee in a bipartisan fashion to develop policies to lower the cost of drugs for our patients and share our perspective as internal medicine physicians on how the rising cost of prescription drugs are making medications unaffordable for our patients. As the Committee examines solutions to lower the cost and price of prescription drugs, we urge Senators to consider the enactment of policies that will achieve the following objectives: promote competition in the pharmaceutical industry, increase transparency in the pricing and costs

associated with the development of drugs, implement reforms to Medicare to lower out of pocket costs for seniors, and increase the value of drugs in the marketplace.

Drug Prices Continue to Rise

According to a multitude of studies published over the last several years, drug companies dramatically and repeatedly continue to raise the price of their products to levels that are simply unaffordable to patients.

- A recent study found that between 2002 and 2013, the price of insulin increased dramatically, with the typical cost for patients increasing from approximately $40 a vial to $130. As a result, according to a published report on the new study "a surprisingly large number of people with diabetes are using less insulin than prescribed because of the rising cost of the drug, putting themselves in danger of serious complications. Those are the findings of a small new study by researchers at Yale University, who found that at one clinic in New Haven, CT, one in four patients admitted to cutting back on insulin use because of cost."
- A report by the Senate's Homeland Security and Governmental Affairs Committee found that "The prices of many of the most popular brand-name drugs increased at nearly 10 times the cost of inflation from 2012 to 2017. Prices increased for every brand-name drug of the top 20 most-prescribed brand-name drugs for seniors in the last 5 years. On average, prices for these drugs increased 12 percent every year for the last 5 years—approximately 10 times higher than the average annual rate of inflation. Twelve out of the 20 most commonly prescribed brand-name drugs for seniors had their prices increased by over 50 percent in the 5-year period. Six of the 20 had prices increases of over 100 percent. In one case, the weighted average wholesale acquisition cost for a single drug increased by 477 percent over a 5-year period."
- Generic drugs, which usually are expected to offer a lower-priced competitive alternative to bioequivalent brand name drugs, are also experiencing price increases. A study in the October issue of Health Affairs shows that the portion of generic drugs that at least doubled in price, year-over-year, represents a small but growing share of the market: from 1 percent of all generic drugs in 2007 to 4.39 percent in 2013. "For consumers, this can mean soaring costs to purchase some drugs that are life-savers, sparking public outrage and leading many to question whether the market—which has historically functioned well—is still working."[1]
- According to an article published in the *Journal of Internal General Medicine,* between 2010 and 2015 300 off-patent drugs experienced price increases of 100 percent or more, and some drugs were sold at 5,500 percent higher than in previous years.[2]

Promoting Competition to Lower Drug Prices

As the Senate Finance Committee continues to examine ways to lower drug costs, we encourage the Committee to use its oversight and legislative authority to develop policies to promote competition for brand-name and generic drugs and biologics. ACP provides the following recommendations to the Senate Finance Committee to prevent a number of techniques that brand name drug companies use to block the approval of other drugs to compete with their products in the marketplace including: improving competition for single-source drugs, product hopping, ever greening, and pay for delay tactics.

- **Improving competition for single-source drugs**—Increasingly, the pharmaceutical marketplace is narrowing its focus to highly innovative, biologic, or specialty drugs for which there are few, if any, competitors, creating monopolies and limiting the cost-controlling power of competition. The focus on brand-name drugs and new biologics results in a greater desire for companies to protect the investments in these drugs and keeping them as profitable for as long as possible.
- **Increase oversight of companies that engage in product-hopping or ever greening**—In these practices, companies prevent generic competition from entering the market by making small adjustments to a drug with no real therapeutic value that grant the company longer patent protection, or they re-

[1] *https://news.use.edu/149667/do-price-spikes-on-some-generic-drugs-indicate-problems-in-the-market/.*
[2] *https://link.springer.com/article/10.1007/sl1606-018-4372-3.*

move the drug from market, forcing patients to switch to a reformulated version of the same drug.

- **Enforce restrictions against pay for delay practices**—Pay-for-delay, also known as "reverse payment settlement," is a patent settlement strategy in which a patent holder pays a generic manufacturer to keep a potential generic drug off the market for a certain period. The Congressional Budget Office estimated that enacting legislation restricting pay-for-delay settlements would cut the federal deficit by $4.8 billion over 10 years.

Senators Grassley and Klobuchar have recently introduced legislation S. 64, The Preserve Access to Affordable Generics and Biosimilars Act. This legislation would prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market. ACP calls for robust oversight and enforcement of pay-for delay agreement in order to limit anti-competitive behaviors that keep lower cost alternative off the market and we appreciate that Senators have introduced legislation with the intent to address these harmful tactics.

Improve Access to Generic Drugs

Limited competition—even in the generic market—can also drive up the cost of a medication. The generic manufacturing market is becoming more consolidated, and progressively some generics are being manufactured by a single company or are disappearing from the market. Limited competition—in almost any sector—limits the cost-containing power of competition. When there is no competition, patients have little choice. For example, if there is only one costly name brand drug for the patient, they really only have two options—either pay for the drug or forgo treatment and risk escalating their condition. Even the generic market is not immune to this happening, single-source generics are more expensive than other generics; some health plans place these drugs in the preferred drug tier in absence of a competitor, resulting in higher costs to the patient.

There have also been anti-competitive practices by a few manufacturers of brand name drugs to prevent or delay other companies from developing alternative lower-cost products. These few brand name manufacturers utilize the FDA's Risk Evaluation and Mitigation Strategies (REMS) process and its accompanying Elements to Assure Safe Use (ETASU) requirements in a manner that prevents development of lower-cost alternatives. In some instances, the REMS process and ETASU requirements have been used to deny availability of drug samples and participation in FDA safety protocols. Using the REMS process and ETASU requirements in this way by a few brand-name drug companies keeps lower-cost generics and biologicals off of the market, thereby decreasing patient access to lower-cost medications.

- **ACP supports the passage of S. 340—the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act**—This legislation was recently introduced in this Congress by Senators Leahy, Grassley, Lee, and Klobuchar. It attempts to stop brand name companies from misusing the REMS process and ETASU requirements by determining when the denial of adequate samples and impending participation in joint-safety protocol have occurred and creates a process a pathway for the lower-cost manufacturer to bring a cause of action in federal court for injunctive relief.

As we mentioned earlier, Dr. Nitin Damle testified in support of this legislation at a Senate Judiciary Committee hearing regarding this bill in 2016. This legislation was introduced in the 115th Congress and approved by the Senate Judiciary Committee and In May of 2017, ACP also submitted a letter in support of this legislation.

Develop a Process to Ensure Safe Reimportation of Drugs

As the Senate Finance Committee continues to examine the causes of rising drug costs, we urge you to consider policies to develop a process to ensure the safe reimportation of drugs. The ACP continues to support consideration of the reimportation of drugs, especially sole-source generic drugs, provided that their safety can be reasonably assured by regulators, as part of larger efforts to control the cost of prescription drugs. The ACP believes it should be a closed system, with participating pharmacies and suppliers required to meet FDA standards; have a tightly controlled and documented supply chain; not include controlled substances, biologics, or products that are infused or injected; and include adequate resources for inspections of facilities and enforcement of U.S. requirements, among others. The ACP acknowledges that drug importation is not a long-term solution to the high price of prescription medication, and there are various safety concerns about the reimportation of prescription drugs. Yet, we continue to support a careful evaluation of how existing

federal importation standards may be used to encourage the reimportation of drugs to the United States, and how existing technology and recent legislative initiatives may assist in safeguarding the supply chain against counterfeiting or contamination.

Increase Transparency in the Marketplace

For decades, pharmaceutical manufacturers have claimed that drug pricing is based on research and development cost and innovation and is well regulated by market forces. The spike in prices and increase in price for drugs already on the market have made many stakeholders wary, especially because many of these new therapies treat small populations and there are few data to support that overall health care costs are reduced. In 2018, a number of drug manufacturers announced they would not raise prices on drugs, noting the public concern about increasing drug prices. However, these decisions created a false sense of confidence that the issue was being addressed and in late 2018, most of companies reneged on these announcements and raised the prices of their products.

We appreciate the efforts of the Senators Grassley and Wyden to increase transparency in the marketplace by inviting Chief Executive Officers of Pharmaceutical Companies to testify at the Senate Finance Committee in the next several weeks to examine why drug companies are increasing prices, and what steps can be taken to reduce them. This effort to increase transparency in the prescription drug marketplace is necessary for Congress and the Administration to have the data that they need to enact legislative and regulatory policies to lower the cost of prescription drugs. ACP urges the Committee to exercise its oversight authority to urge pharmaceutical companies to disclose:

- **Actual material and production costs to regulators**—Pricing methodologies for biomedical products are notoriously covert, and it is difficult to pinpoint to what extent a price reflects research, development, marketing, or administration costs.
- **Research and development costs contributing to a drug's cost, including those drugs which were previously licensed by another company**—Pharmaceutical companies are often publicly held and disclose information on their research and development marketing portfolios which has allowed outside analysts to review how, and how effectively, companies use their research and development budgets. The average amount that a company spends on research and development per drug may vary, depending on the number of drugs each company is developing and how many gain regulatory approval.
- **Rigorous price transparency standards for drugs developed with taxpayer-funded research**—Companies that use basic research funded through the government as part of the development of a drug should be held to a high standard of pricing scrutiny. The National Institutes of Health (NIH) have historically made the largest government investments in basic research and play a key role in spurring innovations and breakthroughs. Between 1988 and 2005, federal research funding contributed to 45 percent of all drugs approved by the FDA and 65 percent of drugs that received priority review. Without this assistance, the cost of discovery, research, and development on the part of pharmaceutical companies may be prohibitive. At a minimum, pharmaceutical companies should disclose any grants, licensing agreements, or other investments by the federal government in the discovery, research, and development of the drug, in addition to material, production, and other research and development costs.

ACP supported several bills in the last Congress to improve the disclosure of information from pharmaceutical companies concerning their research and development costs and information regarding price increases of their products. These bills include:

- **The Drug Price Transparency in Communications Act**—This legislation, offered by Senator Durbin, would require drug companies to disclose the Wholesale Acquisition Cost of an Rx in Direct-to-Consumer Advertising. We are pleased that a similar measure offered by Senator Durbin to support mandatory price disclosures in OTC ads, passed the Senate in the last Congress. ACP also applauds an announcement by the Department of Health and Human Services (HHS) to issue a new regulation requiring pharmaceutical companies to list prices of their prescription drugs in DTC advertisements.
- **The Fair Accountability and Innovative Research (FAIR) Pricing Act**—This legislation, offered by Senator Baldwin, would require manufacturers to

disclose and provide more information about planned drug price increases, including research and development costs.

Reforming Medicare to Lower the Cost of Prescription Drugs

The Senate Finance Committee may have the greatest impact on lowering the cost of prescription drugs through its ability to conduct oversight over CMS and pass legislation to reform the Medicare Part Band D programs. ACP policies support a number of reforms to Medicare which will bring down the cost of prescription drugs for seniors.

Allow Medicare Part D to Negotiate Drug Prices

The ACP has a long-standing policy of advocating for the ability of Medicare Part D to negotiate drug prices and rebates directly with pharmaceutical manufacturers as a way to lower costs within the program. This idea has the bipartisan support of the American people and a 2018 poll conducted by the Kaiser Family Foundation showed that 92 percent of the American people favor allowing the federal government to negotiate with drug companies to get a lower price on medications for people on Medicare.

Although employer and self-insured plans are able to negotiate and use their bargaining power to lower the price of drugs, Medicare and Medicaid programs are directed by statutes that can impede their ability to obtain the best prices. Medicare Part D pays on average more than other federal health programs: 73 percent more than Medicaid and 80 percent more than the Veterans Health Administration. We believe that seniors can get a better deal on their drug costs if Medicare were allowed to negotiate prices and we urge the Finance Committee to support the following legislation that would allow Medicare to negotiate drug prices.

- **S. 62, The Empowering Medicare Seniors to Negotiate Drug Prices Act**—This legislation, offered by Senator Amy Klobuchar (D–MN) will empower the Secretary of Health and Human Services to negotiate with pharmaceutical manufacturers the prices (including discounts, rebates, and other price concessions) that may be charged for prescription drugs. ACP submitted a letter of support for this legislation in the last Congress and we also intend to support this bill in the 116th Congress.

Trump Administration Proposed Regulations to Reform Medicare to Lower Drug Costs

President Trump has also been an outspoken advocate for lowering the prices of prescription drugs and has issued a series of proposals designed to accomplish this goal. In May of 2018, the Department of Health and Human Services (HHS) issued a blueprint to lower drug prices that identified four key strategies for reform including: improved competition, better negotiation, incentives for lower list prices, lower out-of-pocket costs. ACP issued a comment letter that shared our views concerning key elements of the blueprint, expressed our key recommendations to lower drug costs, and urged the HHS to use the rulemaking process to continue to seek input from stakeholders prior to the implementation of any policy.

The President also seeks to issue a new regulation that would implement a new International Pricing Index payment model to lower drug costs for patients in the Medicare Part B program. The goal of this proposed rule would be to shift drug prices in the United States to more closely align them with prices in European countries that pay much less for the same drugs. Although ACP does not have direct policy on this pricing model, we did provide a comment letter to HHS that provides our views regarding a number of issues that should be considered before implementation of this rule.

CMS has also announced proposed changes to Medicare Part D designed to lower prescription drug prices for beneficiaries. The proposed rule would seek to allow plans to exclude certain protected class drugs if the manufacturer raises the price of the drug at a rate greater than inflation or if the drug maker brings to market a new formulation of the drug without any meaningful change to original formulation of the drug, regardless of whether or not the original formulation remains on the market or not. Additionally, the proposal introduces prior authorization and step therapy to the protected classes in an attempt to introduce more competition.

The administration also recently announced a new proposed rule that would attempt to lower out of pocket costs for patients using drugs with high prices and high rebates, particularly during the deductible or coinsurance phases of their benefits. This proposal aims to change perverse incentives in the system that allow drug companies to continue to increase the list prices of their drugs. The proposal would cre-

ate a new safe harbor protecting discounts offered to patients when they purchase their drugs at the pharmacy. It would also create new safe harbor for fixed fee services arrangements between manufacturers and pharmacy benefit managers. We are currently reviewing this proposal to evaluate how it relates to ACP policy and will most likely submit a comment letter to CMS to share our ideas regarding this new proposal.

Reforming Drug Formularies to Ensure Lower Costs for Patients

When health plans are faced with rising cost associated with high drug prices, they often look to increased cost-sharing, utilization management, or tiered formularies that place all drugs of a certain class into the highest tier, putting patients at risk for not being able to access or afford the medications they need or adhere to drug regimens properly.

Drug formularies divide prescription drugs into 4 or 5 tiers with varying levels of fixed prices (copayments) for all drugs in each tier, with the exception of the highest tier. The highest tier, typically the specialty tier, is subject to either the highest copayment or coinsurance in which the patient pays a percentage of the cost of the treatment. There has been a shift toward prescription drug plans with coinsurance in the top 2 tiers, typically the specialty tier and a non-preferred brand tier that has no restrictions on which drugs can be placed on the tier. This can lead to higher coinsurance rates than that of the specialty tier. Usually only the specialty tier has been subject to cost-sharing; all other tiers have copayments.

ACP believes that payers that use tiered or restrictive formularies must ensure that patient cost sharing for specialty drugs are not set at a level that imposes a substantial economic barrier to enrollees obtaining needed medications, especially for enrollees with lower incomes. Health plans should operate in a way consistent with ACP policy on formularies and pharmacy benefit management.

The ACP has a comprehensive policy on formulary benefit design including:

- ACP opposes any formulary that may operate to the detriment of patient care, such as those developed primarily to control costs.
- Decisions about which drugs are chosen for formulary inclusion should be based on the drug's effectiveness, safety, and ease of administration rather than solely based on cost.
- ACP recommends that pharmacy and therapeutic committees be representative of, and have the support of, the medical staffs that will utilize the formulary.

Improve Value Within the Prescription Drug Market

ACP supports research into novel approaches that would further value based decision making and encourages research into policies that would tie price innovations to clinical value. We urge the Finance Committee to consider the following options:

- **Value Frameworks**—With the great attention being paid to the price of drugs, determining how to assess the value of a drug, which patients may benefit the most from a certain drug, and the economic value of a drug has charged the conversation.
- **Bundled Payments**—The approach may encourage the use of older, lower-priced drugs before newer, more expensive treatments with similar benefit and in turn affect drug utilization. This shift to paying for value as opposed to the number of services provided mirrors other similar shifts toward an evidence- and value-based system of health care.
- **Indication Specific Pricing**—The variability of disease and how patients react to medications makes indication-specific pricing potentially beneficial for such diseases as cancer.
- **Evidence-Based Benefit Designs**—Innovative benefit designs can include incentives that vary by service, type of patient condition, or income. Evidence-based benefit design has also been advocated as a way to reduce health care costs and would be in line with the movement toward evidence-based medicine. Policies that encourage value-based benefit design can help consumers make educated choices about prescription drugs and keep costs low.

Improve the Use of Comparative Effectiveness Research

More and more, physicians, patients, and other stakeholders are questioning the value of drugs relative to their price. Many of the new specialty drugs coming to the market represent real breakthroughs and benefits for patients, and the market

should encourage future innovation. Those innovations do not mean that all other drugs should also be priced at the same level. Independent organizations, such as the Institute for Clinical and Economic Review and the Patient-Centered Outcomes Research Institute (PCORI), develop and evaluate clinical effectiveness data compared with other treatments. For example, PCORI has funded millions of dollars in head-to-head CER that can inform physicians and help patients understand all therapeutic options available as they relate to existing therapies and encourage informed decision-making and patient involvement. Establishing an evidence base of clinical effectiveness data is the crux of transitioning to a health care system that pays for and rewards value. Not only do comparative effectiveness data inform value judgments they can also help physicians and patients understand all available options as they relate to existing therapies, encouraging informed decision making and involvement by patients in their health care choices. ACP policy supports CER to measure the effectiveness of health care services and clinical management strategies and that all health care payers, including Medicare and other government programs, should use both comparative effectiveness and cost effectiveness in the evaluation of a clinical intervention. However, cost should not be used as the sole criterion for evaluating a clinical intervention,

However, by statute, PCORI is prohibited from using Quality Adjusted Life Years (QALYs), is a metric of cost-effectiveness research that takes into account the quantity and quality of life associated with a treatment and assigns an index number to that treatment, as "a threshold to establish what type of health care is cost effective or recommended." QALYs are commonly used in cost-utility studies to determine the cost of a treatment per QALY and compare medical interventions; however, they have been criticized for lacking sensitivity to patient preferences or goals. Incorporating QALYs into cost effectiveness studies will help patients, physicians, and policymakers compare the cost and health benefits of treatments and facilitate a better understanding of the value of different treatments. Part of a patient's overall determination of value may include the cost effectiveness of the treatment along with the benefits or risks of a drug.

Conclusion

ACP commends the Finance Committee for conducting this hearing, and additional hearings in the coming weeks, on drug pricing in America and we look forward to working with you, the Administration, and other stakeholders to develop and implement solutions to ensure that every patient has access to the medications that they need at a cost that they can afford. Should you have any further questions, please contact Brian Buckley at bbuckley@acponline.org.

AMERICAN SOCIETY OF CLINICAL ONCOLOGY
2318 Mill Road, Suite 800
Alexandria, VA 22314
T: 571–483–1300
F: 571–366–9530
www.asco.org

January 29, 2019

The Honorable Chuck Grassley
Chair
U.S. Senate
Committee on Finance
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
U.S. Senate
Committee on Finance
Washington, DC 20510

Dear Chairman Grassley and Ranking Member Wyden,

The American Society of Clinical Oncology (ASCO) shares your concern about the rising cost of prescription drugs. We appreciate the committee's efforts to examine prescription drug pricing and considering solutions to lower costs for American patients.

ASCO is the national organization representing more than 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and pre-

vention. We are committed to ensuring that evidence-based practices for the treatment of cancer are available to all Americans.

As you begin the series of hearings with today's hearing, "Drug Pricing in America: A Prescription for Change, Part I," ASCO offers for your review the *ASCO Position Statement on Addressing the Affordability of Cancer Drugs* and stands ready to work with you on real solutions that address the affordability of cancer drugs. Knowing that these conversations will be ongoing, we also welcome your consideration of the comments we have provided to the Centers for Medicare and Medicaid Services on a range of other issues including the potential relaunch of a Competitive Acquisition Program for Part B drugs, the 340B Drug Pricing Program, and further allowances of step therapy and other utilization management tactics in Parts C and D.

If you have questions on any issue involving the care of individuals with cancer or would like to be directed to ASCO's thoughts on a specific issue related to drug pricing, please contact Jennifer Brunelle at Jenniferbrunelle@asco.org.

Sincerely,

Monica M. Bertagnolli, M.D., FACS, FASCO
President, American Society of Clinical Oncology

American Society of Clinical Oncology Position Statement on Addressing the Affordability of Cancer Drugs

Introduction

The issue of drug price, particularly in the area of specialty pharmaceuticals, has emerged as a bipartisan concern with both Members of Congress and the Administration. Specialty medications typically include biological products that are often administered by injection or infusion, sometimes require special handling and administration, and are often substantially more expensive than the traditional small molecule drugs.[1] Specialty medications accounted for 37% of drug spending in 2015, and projections are that they will account for 50% of all drug spending by 2018.[2] Oncology drug pricing is expected to increase at a rate of more than 20% per year for the next several years.[3] Healthcare expenditures—including drug costs—have become a major cause of personal bankruptcy, and "financial toxicity" has become a common term used to describe the financial distress that now often accompanies cancer treatment for patients.

Many policymakers consider this a uniquely American problem, as the U.S. healthcare marketplace has few tools to control cost effectively. Projections are that the United States will continue to have the largest per capita drug spending increase of any developed country in the world, while countries like Spain and France will experience per capita spending decreases.[4]

At the same time, the last decade has seen tremendous progress in development of new classes of drugs that have greatly improved outcomes for patients with certain cancers. Immune checkpoint inhibitors, for example, have improved the prognosis for many patients with once rapidly fatal cancers. The speed with which new therapies enter the U.S. drug market and become available to patients tends to be faster than in other countries.[5] Nevertheless, one recent study revealed that only 19% of recently approved cancer drugs met ASCO's goals for producing clinically meaningful survival outcomes for patients, despite often entering the marketplace at extraordinarily high prices.[6] Balancing the need for continued innovation for our pa-

---

[1] Gleason PP, et al. "Health plan utilization and costs of specialty drugs within 4 chronic conditions." *J Manag Care Pharm.* 2013 September;19(7):542–8: *http://www.jmcp.org/doi/pdf/10.18553/jmcp.2013.19.7.542.*

[2] The Express Scripts Lab. *Express Scripts 2015 Drug Trend Report Executive Summary.* March 2016. *https://lab.express-scripts.com/lab/drug-trend-report.*

[3] *Ibid.*

[4] IMS Institute for Health Informatics. *Global Outlook for Medicines Through 2018. http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/qlobal-outlook-for-medicines-through-2018.*

[5] Kanavos, P, et al. "Higher U.S. Branded Drug Prices and Spending Compared to Other Countries May Stem Partly From Quick Uptake of New Drugs," *Health Affairs,* Vol. 32, pp. 753–761, 2013.

[6] Kumar H, Fojo T, Mailankody S. "An Appraisal of Clinically Meaningful Outcomes Guidelines for Oncology Clinical Trials." *JAMA Oncol.* 2016;2(9):1238–1240.

tients, equitable access to high quality care and unsustainable cost trends calls for bold but thoughtful action.

As the leading professional organization for physicians and oncology professionals caring for people with cancer, ASCO is deeply concerned about the effect rising drug prices have on individuals affected by cancer. We are a patient-centered professional society whose members deliver some of the most complex and expensive treatment regimens in health care during one of the most stressful healthcare episodes in most people's lives. Our members are expert in the technical benefits and risks of these drug regimens and treatment programs but we also witness the financial impact of cancer treatment on patients and families.

ASCO is committed to supporting and promoting practical policy solutions that ensure patients with cancer have access to—and can afford—drugs vital to the treatment of their disease. We propose a number of modest "experiments" to determine if any model can help rein in drug costs without jeopardizing innovation or access to care. We join our colleagues from the American College of Physicians,[7] the American Academy of Dermatology,[8] the Council of Medical Specialty Societies[9]—of which ASCO is a member—and the Society of Gynecologic Oncology,[10] who have all recently released positions on high drug prices and spending.

ASCO is firm in its position that any policy solutions to address the price of cancer drugs must promote access to care for patients, affordability of drugs vital to their treatment, and innovation in drug development. Regardless of the specific policy recommendations pursued, defining value must underpin the drug pricing debate. The principles below guided development of ASCO's position:

- Value-based solutions that are patient-centered and evidence-driven should inform drug prices in the United States.
- Oncology professionals should define optimal care and provide a framework to assess the comparative value of cancer treatment options from a clinical perspective.
- There should be a real and consistent relationship between the value of a given drug and its cost to patients.
- Physicians do not control the launch price of drugs. However, physicians do determine how drugs are used and are accountable for appropriate utilization.
- Cost-containment strategies should not limit the ability for patients to receive access to appropriate care, or for providers to prescribe such care.
- Cost-containment strategies should incentivize—not hamper—innovation that results in clinically meaningful improvements in patient outcomes.

Within this statement, we review a number of solutions that policymakers have proposed as a means of addressing the soaring prices of specialty drugs. We provide ASCO's perspective on whether these proposals should be tested, primarily from the standpoint of impact on patient care. We use both the term "drug pricing" and "drug spending" throughout this statement. We refer to "drug pricing" as the unit cost of the drug; "drug spending" represents the combination of price and utilization.

Defining Value in Cancer Therapeutics

ASCO has launched a number of programs designed to address the rising cost of cancer care in general, beginning with a 2009 ASCO Guidance Statement on the Cost of Cancer Care, continuing with efforts that include participation in the Choosing Wisely campaign and, most recently, the publication of ASCO's Value Framework.[11, 12] The Value Framework helps oncologists and patients assess treatment

---

[7] Daniel H, for the Health and Public Policy Committee of the American College of Physicians. "Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians." *Ann Intern Med.* 2016;165:50–52.

[8] *Position Statement on Patient Access to Affordable Treatments,* American Academy of Dermatology Association, 2015. *https://www.aad.org/Forms/Policies/Uploads/PS/PS%20-%20Patient%20Access%20to%20Affordable%20Treatments.pdf.*

[9] Council of Medical Specialty Societies. *CMSS Principles for Increasing Access to Needed Medications by Patients,* 2016. *https://cmss.org/cmss-principles-for-increasing-access-to-needed-medications-by-patients/.*

[10] Society for Gynecologic Oncology. *Addressing the High Cost of Drugs for Oncology Patients. https://www.sgo.org/public-policy/addressing-the-high-cost-of-drugs-for-oncology-patients/.*

[11] Meropol NJ, Schrag D, Smith TJ, et al. "American Society of Clinical Oncology Guidance Statement: The Cost of Cancer Care." *J Clin Oncol* 27(23): 3868–3874, 2009.

[12] Schnipper LE, Davidson NE, Wallins DS, et al. "Updating the American Society of Clinical Oncology Value Framework: Revisions and Reflections in Response to Comments Received." *J Clin Oncol* 34(24): 2925–2934, 2016.

options by providing a standard measure of net health benefit. ASCO also has worked to address the cost and quality of cancer care-apart from drug price-through initiatives such as its quality improvement program, the Quality Oncology Practice Initiative (QOPI®); encouraging use of high value clinical pathways; setting the bar for clinically meaningful outcomes in cancer clinical trials; and advancing payment reform through the Patient-Centered Oncology Payment Model (PCOP). These efforts have focused on cost reduction by encouraging appropriate resource utilization, with the goal of reducing excess spending associated with unnecessary or inappropriate care.

We are not alone in these efforts. The European Society for Medical Oncology (ESMO) has released a value framework very much compatible with the ASCO framework. Other serious efforts to describe value include the Memorial Sloan Kettering Drug Abacus, the Institute for Clinical and Economic Review (ICER) collaborative evaluation model, and the NCCN evidence block initiative. We are encouraged by these mature efforts, which demonstrate that a group of engaged stakeholders can provide the expertise to define and assess the value of cancer therapies. However, establishing a patient-centric, robust and broadly applicable value framework requires the assessment of a broader range of clinical trial endpoints during drug research and development. In particular, it requires collection of validated quality of life and patient-reported outcome measures for drug registration trials. It also requires rapid expansion of big data projects such as ASCO's CancerlinQ™ that collect real world outcomes that allow comparison of drug safety and effectiveness outside the setting of formal clinical trials.

For all stakeholders, the definition of value ultimately comes down to the relationship between price and meaningful improvements in health outcomes at the level of individual patients—and society more broadly. Optimizing the value of a new product begins with innovation to address an unmet medical need, followed by clinically meaningful improvements in health outcomes through well-designed and efficiently conducted clinical trials. Effectiveness research is essential to determine how well the new product performs compared to available alternatives—and its impact on more diverse populations than those typically included in the clinical trials used to establish efficacy. Patient goals, preferences, and choices shape the real world experience with a new product, and the direct and indirect costs of treatment to both patients and their families affect its widespread adoption. The medical community should be judicious in using new and costly products until there is clearly established value and clear understanding of how that value relates to treatment goals, available options, and the unique needs, preferences, and goals of individual patients. Doctors should also make sure their patients are aware of the cost, benefit, and personal financial impact of their treatment options and choices.

Research in many domains is necessary to improve assessment of the value of new cancer treatments. Advancing our understanding of value requires development of new clinical efficacy endpoints, both provider and patient-reported, that accurately describe how a patient functions and feels. These endpoints should reflect outcomes of value to patients other than survival, particularly in non-curative settings. Better predictive biomarkers can transform a drug of modest efficacy in an unselected population to one of high efficacy in a biomarker-defined subgroup, and thereby contribute to improving the value of a given treatment.

Policy initiatives that affect market approval, reimbursement, or price all deserve careful consideration to determine how well they balance cost while preserving both innovation and patient access to life improving therapies. In what follows, ASCO proposes consideration of strategies that could be pilot tested with a goal of improving the value of cancer care.

Ensuring High-Value Drug Development

In 2014, ASCO's Cancer Research Committee published a statement, "Raising the Bar for Clinical Trials by Defining Clinically Meaningful Outcomes."[13] The committee focused on several cancer scenarios in the metastatic setting, with a primary focus on median overall survival and hazard ratios. Secondary endpoints were improvement in 1-year survival rates and progression free survival. Using front line metastatic pancreatic cancer as an example, the statement suggested that any new therapy should demonstrate a median survival improvement of 4–5 months (HR 0.67–0.69) and a minimum 1-year survival improvement from 48% to 63% in order

[13] Ellis LM, Bernstein DS, Voest EE, et al. "American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes." *J Clin Oncol.* 2014 Apr 20;32 (12): 1277–80.

to meet the definition of "clinically meaningful." The goal of these recommendations was to encourage clinical trial developers to set higher goals for improving patient outcomes. As such, the recommendations also serve to provide an important context for the assessment of a new cancer treatment. To ensure the development of high-value drugs in cancer care, the Food and Drug Administration could limit its approval for indications/therapies to those that meet or exceed these recommended incremental benefits, rather than focusing on small benefits that achieve statistical significance in large trials.

Testing Different Value-Based Pricing Strategies

Value-based pathways are an approach that could be used to better align the pricing and utilization of drugs with the value they bring to patients. To test this approach, appropriate drug utilization would be used as a quality measure instead of a resource-use metric; drug therapies would be placed in hierarchical pathways based on their comparative value; and practice performance scores would be based on appropriate use of pathway recommendations. Practices that fall below a certain threshold would receive a negative adjustment in payment. This has the advantage of incentivizing both provider use of higher value treatments and development of therapies by the pharmaceutical industry that achieve high value through a combination of maximizing efficacy and minimizing toxicity and costs.

Another approach worthy of consideration is *indication-specific pricing.* Under such an approach, payment for the same drug would vary depending on its effectiveness in different approved indications. This approach requires the ability to compare relative value, again emphasizing the need for a widely accepted mechanism to determine value.

Outcomes-based pricing is another frequently discussed approach to controlling cost and improving value. In this scenario, reimbursement depends on how well the drug works in a particular patient. For example, if a patient survives beyond the median survival reported in the clinical trial population, reimbursement is higher than a stated benchmark. Conversely, if the drug therapy results in less than the expected median survival time, reimbursement would be lower. Payers could deploy this approach at the population level, *i.e.,* if a drug does not perform in the actual treatment population as indicated by the trial data, manufacturers would provide discounts/rebates to payers/patients. This approach requires agreement on average or baseline price and that would best be determined using a value model as above.

An approach that ASCO does not support is the use of *payment bundles* to control drug costs. Under such an approach, all costs for treating a patient, including drugs, are bundled into a single episode based payment. Payment bundles do not affect price directly. Further, bundled payment programs create circumstances that could force providers to make suboptimal or lower value choices. While appealing in the abstract to many in the health policy world, such bundles will likely never be sensitive enough in a world of increasing precision-based therapy and heterogeneous patient populations to account for appropriate variation in drug prescribing. ASCO is firm in its belief that no provider should experience financial penalty for providing the right drug to the right patient at the right time.

Encouraging Development and Use of Generics and Biosimilars

ASCO strongly endorses the position expressed by the American College of Physicians in opposition to "extending market or data exclusivity periods beyond the current exclusivities granted to small molecule, generic, orphan, and biologic drugs." We further agree that the provision in President Obama's 2016 budget to reduce data exclusivity on biologics from 12 to 7 years is worthy of consideration. We additionally agree with several other provider organizations that practices such as product hopping, evergreening, and pay for delay should not be allowed. According to the Federal Trade Commission (FTC), the tactic known as "product hopping" or "product switching" occurs when brand name pharmaceutical companies introduce reformulations of their branded product that offer little or no therapeutic advantage.[14] Similarly, "evergreening" occurs when brand name companies patent as new drugs slight modifications of old drugs.[15] This allows drug companies to maintain

[14] "FTC Files Amicus Brief Explaining That Pharmaceutical 'Product Hopping' Can Be the Basis for an Antitrust Lawsuit." November 2012. *https://www.ftc.gov/news-events/press-releases/2012/11/ftc-files-amicus-brief-explaining-pharmaceutical-product-hopping.*

[15] Krans B. "Pharmaceutical 'Evergreening' Raises Drug Costs, Study Says." *Healthline News* June 2013. *http://www.healthline.com/health-news/policy-drug-companies-use-evergreening-to-extend-market-share-060413.*

market share after drug patents expire. The company can withdraw its branded product, forcing patients to use its reformulated version, thereby obstructing generic competition and enabling the company to keep its market exclusivity. "Pay for delay" is a legal tactic in which branded drug manufacturers slow or obstruct generic competition by paying companies not to introduce lower cost alternatives to the marketplace. The FTC has estimated this practice costs consumers and taxpayers $3.5 billion in higher drug costs each year.[16] By definition, these strategies represent higher cost without meaningful improvements in care, a result that is not in the best interest of patients.

Limiting the Financial Burden That Payer Policies Place on Patients

While ASCO shares the overall goal of supporting value-based care, certain cost containment approaches used by a growing number of payers threaten to undermine patient access to medically necessary oncology care. In particular, ASCO strongly opposes the trend toward tiered formularies. This approach places specialty drugs in the highest tiers, which carry higher percentages of coinsurance. This places vulnerable patients in the cross hairs of a problem they did not create. If their disease requires the use of an effective and high value therapy, they should not be asked to bear the financial burden of the higher price tag associated with this necessary-and sometimes life-saving treatment. As with our objection to the bundling of drugs stated above, shifting this problem to patients who are receiving the right drug at the right time is not an acceptable solution.

Medicare Negotiation of Drug Payments

Current law prohibits the Medicare program from negotiating volume discounts with manufacturers. Significant savings may be possible through such an approach, exemplified by the fact that private Part D pharmacy benefit managers do, in fact, negotiate with manufacturers for rebates and achieved rebates totaling $6.5 billion in 2008.[17] While there is no question Medicare could use its market power to extract discounts and rebates as is done by Medicaid and the Veterans Administration system, there are several cautions to this approach. First, doing so effectively would ultimately require that Medicare have the ability to deny coverage of an FDA-approved drug if it deems the price to be above an assessed value. Whether the United States is willing to give Medicare such power requires considerable thought and debate. Second, at least a portion of the cost savings obtained by Medicare is likely to be shifted to private payers who have less negotiating power, which limits the societal impact of this approach. An alternative strategy would be for Medicare to require the use of value-based pathways as outlined above. In this way, the community at large-not the government establish value. We recommend that Medicare test a value-based pathway approach to reimbursement to determine its feasibility.

Transparency of Drug Costs

All provider organizations that have issued statements on drug pricing have endorsed greater transparency on drug pricing. Doing so requires that manufacturers disclose material and production costs, research and development costs (including those for drugs acquired from other companies), marketing costs, and any federal research dollars that contributed to the discovery, research and development of the drug. Such transparency would allow payers and patients to at least make some informed comparison of the relationship between development costs and price for drug products and exert public pressure on companies where the two appear to be widely divergent. Although ASCO supports the general premise of testing price transparency as a means for consumer and provider education, we note that a validated, agreed-upon methodology for value-based pricing could accomplish the same goal.

Re-importation of Drugs

This strategy assumes that all other developed countries in the world have some regulatory framework in place to control the quality and price of drugs. It also assumes that re-importation of these lower priced drugs would have a downward pressure on prices charged in the United States. Testing this approach would require consideration and resolution of a number of safety concerns. In addition, given the dynamic nature of world markets, widespread use of this practice would almost cer-

---

[16] Federal Trade Commission. "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions." An FTC Staff Study January 2010. *https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.*

[17] Daniel H for the Health and Public Policy Committee of the American College of Physicians. "Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians." *Ann Intern Med.* 2016.

tainly cause the price of drugs to rise in other countries, mitigating some, if not most, of the cost savings.

Conclusions and Recommendations

Rapidly rising drug prices and spending in the United States have engendered considerable passion and debate among all stakeholders in the system about how to constrain costs. Some proposals target market dynamics to control price, while others target provider and patient utilization to control spending. There is a growing call for more transparency by drug manufacturers, with particular emphasis on drugs that received federal funding or philanthropic support at any point during their development. There is also discussion about increasing Medicare's ability to leverage its market power in order to negotiate better drug prices for its beneficiaries (although there are few specifics on how this might work, or evaluation of potential unintended consequences).

Some of these strategies are worth exploring, but the ultimate solution to improving the affordability of drugs requires accelerated efforts to define value. The notion of value-based systems in health care has moved beyond a theoretical concept put forward by academics. Rather, it has been the subject of tangible, published efforts using real patient data in the United States and Europe. With appropriate authorization by Congress to identify a standardized, value-based evaluation of therapeutics, the community at large could deliver a model in short course. Moreover, with a standard framework for defining and assessing value, testing multiple value-based pricing models is possible. A valid and reliable framework, one that is evidence-based and patient-centered, could support value-based approval of new therapies.

Recommendations

Recognizing that many are actively engaged in this issue, ASCO makes the following recommendations as guidance to any ongoing and future efforts to address the affordability of cancer drugs in the United States either by the Administration, Congress, or other entities.

- *Solutions to address the affordability of cancer drugs—many of which are highlighted in this statement—should be identified, evaluated, prioritized and tested.* Any of the approaches examined earlier in this statement may lead to an array of unknown impacts. Efforts to address the affordability of cancer drugs must recognize the potential of unintended consequences and, therefore, should be carefully tested in pilot projects before a wide-scale, national launch.
- *The larger community—including providers, patient advocates, payers, hospitals, experts in health economics and health outcomes, representatives from the pharmaceutical and biotechnology industries, Members of Congress, and Administration policy makers-must actively participate in any effort to develop policy solutions to address the affordability of cancer drugs.*

  There is no simple solution to escalating drug prices, and many differing views on what constitutes value in cancer treatment. ASCO believes that active dialogue and engagement by all interested parties must be a centerpiece of efforts to address this issue—particularly with the involvement of patients, who will be directly impacted by proposed solutions, and physicians, who have the expertise to define clinically sound care.
- *Congress and/or the Administration can play an important role in bringing together a diverse group of experts to identify, evaluate, and prioritize a series of demonstrations designed to test some of the solutions highlighted in this statement—and, once tested, to recommend implementation for those that are successful. A high-priority effort of this group should be to propose a strategy for blending various value frameworks into a transparent and standardized approach to assessing value, and recommending drug pricing and reimbursement based on the value delivered.*

  As noted earlier, many private initiatives have developed tools to assess the value of cancer drugs. ASCO recommends that efforts be advanced to articulate a universally accepted definition of value in cancer care and to evaluate existing value frameworks for synergistic opportunities and possibly combine them into a single approach for use by physicians with their patients, policymakers, payers, manufacturers, and others.

Solutions to rising drug prices and spending should be considered with the following driving principles in mind:

- Patients should have access to life-prolonging and improving treatments and should not suffer financial harm when receiving the care they need.
- Providers should be confident they have support in delivering the right treatment at the right time to the right patients.
- Manufacturers and the investment community should continue to see value in high-risk, high-reward science.

We must balance these principles with recognition of the financial toll of drug costs on private and public budgets. ASCO contends that solutions centered on value stand the best chance of achieving this balance in the most equitable and effective way. Drawing on the collective knowledge of its more than 40,000 members, ASCO stands ready to work together with the larger community to define, test and agree upon solutions to ensure access, affordability and innovation-with the ultimate goal of ensuring the health and well-being of the patients our members serve.

AMERICA'S HEALTH INSURANCE PLANS (AHIP)

America's Health Insurance Plans (AHIP) is the national association whose members provide coverage for health care and related services to millions of Americans every day. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities, and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access, and well-being for consumers.

We thank the committee for holding a series of hearings on out-of-control prescription drug prices. Rising drug prices impose a heavy burden on all Americans—this is a direct result of high list prices determined solely by drug companies. We look forward to working with the committee to advance market-based solutions that hold drugmakers accountable for high list prices and provide relief to American families from soaring prices for prescription drugs.

In order to make life-saving drugs available and affordable for patients, health insurance providers (and our pharmacy benefit manager partners) negotiate with manufacturers. These discounts reduce drug prices and costs for patients, employers, and other payers. Still, additional steps are needed—at both the legislative and regulatory levels—to reduce list prices and achieve the goal of delivering more affordable medicines and lower costs for patients, consumers, employers, and taxpayers.

Our statement focuses on:

- The reality that the prescription drug pricing process is driven entirely by the original list price of a branded drug—which is determined solely by the drug company, not by the market or any other participant in the pharmaceutical supply chain; and
- Our support for market-based solutions that reduce drug prices by delivering real competition, creating more consumer choice, and ensuring that open and honest drug pricing is tied to the value delivered to patients and a high-level overview of key areas where we support efforts by Congress and the Administration to put downward pressure on prescription drug prices.

The Problem Is the Price

Out-of-control prescription drug prices have profound consequences for all Americans. Too many hardworking Americans have to choose between paying their bills and accessing life saving medicines. Outrageous drug prices harm patients who cannot afford life-saving medications, consumers who pay higher and higher premiums because of higher and higher drug prices, employers who have fewer resources to devote to employee wages, and hardworking taxpayers who fund public programs like Medicaid and Medicare.

Already this year, drug companies have raised the prices of hundreds of medicines—including top-selling drug Humira.[1] The price of Evzio, which is used to treat suspected opioid overdoses, increased 652 percent from 2014 to 2017. And the price of antidepressant Wellbutrin increased nearly six-fold in that same timeframe.[2]

---

[1] *https://www.axios.com/drug-price-increases-2019-fba56e62-8737-40c5-8cd7-57c9d5bbf5f6.html.*

[2] *https://www.ahip.org/then-vs-now/.*

As the committee addresses these concerns, we urge you to recognize that the entire pricing process is driven entirely by the original list price of a branded drug—which is determined solely by the drug company, not by the market or any other participant in the pharmaceutical supply chain. Congress needs to address this reality—**the problem is the price**—as part of any strategy for reducing pharmaceutical costs for the American people.

The problem with prescription drug pricing does not lie with health insurance providers, pharmacy benefit managers, wholesalers, pharmacies, providers, or patients. The cost crisis is a direct consequence of pharmaceutical companies taking advantage of a broken market for their own financial gain at the expense of patients. The lack of competition, transparency, and accountability in the prescription drug market has created extended, price-dictating monopolies with economic power that exist nowhere else in the U.S. economy. As a result, everyone pays more—patients, businesses, taxpayers, hospitals, doctors, and pharmacists.

Market-Based Solutions for Reducing Drug Prices

Bold steps are needed, at both the legislative and regulatory levels, to hold drug makers accountable for high list prices and ensure that the American people have access to affordable medications. With solutions that deliver real competition, create more consumer choice, and ensure open and honest drug prices, we can deliver more affordable pharmaceutical products—while at the same time protecting and supporting innovations to deliver new treatments and cures for patients.

Below we provide a high-level overview of key areas where we support efforts by Congress and the Administration to put downward pressure on prescription drug prices. As the committee continues to examine drug pricing in future hearings and through legislation, we look forward to working with you on these and other issues.

Promoting Generic Competition

Removing barriers to the availability of generic drugs is a critically important step toward lowering prescription drug costs for the American people. We appreciate that the Administration has prioritized the review and approval of applications for generic drugs, and we applaud Chairman Grassley and other committee members for your leadership in developing bipartisan legislative proposals that would promote generic competition.

We strongly support the "Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act." This bipartisan bill offers common sense reforms that would discourage brand name drug manufacturers from blocking the availability of generic drugs by abusing Risk Evaluation and Mitigation Strategies (REMS) —that are otherwise required by the Food and Drug Administration (FDA) to promote patient safety. If this legislation is enacted, branded manufacturers will no longer be able to hide behind REMS and limited distribution arrangements to restrict access to adequate samples of reference drugs and impede the development of lower cost generic competitors.

We also strongly support the "Preserve Access to Affordable Generics and Biosimilars Act." This bipartisan bill would give the Federal Trade Commission (FTC) enhanced authority to block "pay-for-delay" agreements under which prescription drug patent infringement claims are settled with a potential generic competitor agreeing (after receiving something "of value") not to research, develop, manufacture, market, or sell the product in question. Halting these anticompetitive settlements will remove a barrier to competition and expand the availability of lower-cost generic drugs and biosimilars.

Additionally, we believe it is important to preserve the Inter Partes Review (IPR) process at the U.S. Patent and Trademark Office. The IPR process plays an important role in invalidating patents that do not represent true innovation and should not have been issued in the first place. Weakening this process would effectively extend the original patent monopoly for pharmaceutical and biological products and result in significantly higher prices for consumers.

We support congressional action on revisions to the United States-Mexico-Canada Agreement (USMCA). In its current form, this proposed trade agreement includes problematic market exclusivity provisions that would benefit brand name drug manufacturers at the expense of lower cost generics.

Creating a Robust and Competitive Marketplace for Biosimilars

Biosimilars also offer great promise in generating cost savings and increasing patient access to needed treatments and therapies. To achieve this promise, it is important to promote a vibrant and competitive biosimilars market and ensure that

providers and patients have unbiased information about the benefits of biosimilars. Just as with generic medications, a truly competitive biosimilars market will mean greater use of these products which, in turn, will drive down costs and increase patient access.

AHIP supports key provisions of the FDA's Biosimilars Action Plan,[3] which takes important steps toward promoting competition and affordability in the market for biologics and biosimilar products. Our recommendations for the Action Plan include promoting regulatory clarity by finalizing FDA guidance related to interchangeability, improving efficiency in the biosimilars product development and approval process, and developing effective communication tools and resources to educate providers and patients on the safety and efficacy of biosimilars. We also support legislation to reduce the exclusivity period for brand name biologics and enhanced oversight of "pay-for-delay" arrangements that prevent generics and biosimilars from coming to market.

Increasing Transparency Around Pharmaceutical Prices

Requiring greater transparency on prescription drug prices is an important step toward ensuring that consumers have the information they need to make informed health care decisions. Currently, many patients do not have the pricing information they need to make informed choices about their treatment options. Increasing access to pricing information can help patients minimize their out-of-pocket costs, enabling them to compare different treatment options and help them identify lower cost, but equally effective options, such as generic drugs or biosimilars.

We believe pharmaceutical manufacturers should be required, as part of the FDA approval process, to disclose information regarding the intended launch price, the use of the drug, and direct and indirect research and development costs. After approval, manufacturers should provide appropriate transparency into list price increases.

In addition to empowering consumers, openly disclosing drug prices will bring additional public attention to drug price increases, which will discourage drug makers from raising their prices year after year—often multiple times a year—without justification. Government leaders, regulators, consumers, and insurance providers deserve to be part of a conversation about how prices are set and what causes them to go up. By understanding the market dynamics of why prices are going up, we can work together to mitigate those effects.

We support the Administration's proposal to require disclosure of drug list prices in direct-to-consumer (DTC) television ads. We also recommend that this proposed requirement be broadened to apply to all ads by drug companies, including those in newspapers, print publications and on the web. We further suggest that drug pricing transparency requirements—including disclosure of a drug's list price—be extended to include drug manufacturers' marketing or detailing materials distributed to physicians and other prescribers.

Additionally, we support the Administration's release of enhanced Drug Pricing Dashboards for Medicare Part B, Medicare Part D, and Medicaid. The Dashboards can provide patients, families, and caregivers with additional information to make informed decisions and predict their cost sharing.

Preserving Recent Improvements in Medicare Part D, Expanding Private Sector Negotiation Tools in Parts B and D, and Enhancing Benefit Flexibility

Since 2006, the Medicare Part D program has been a successful model of a public-private partnership, through which Part D plans have been able to negotiate lower drug costs so that tens of millions of seniors and individuals with disabilities have affordable and meaningful access to prescription drugs at consistently low and stable premiums year-over-year. This would not be possible without the Centers for Medicare and Medicaid Services' (CMS) symmetrical risk-based payment structure that incentivizes plans' cost-effective delivery of drug benefits, which reduces Part D bids and saves taxpayers money. Further, a Part D bid is approved by a plan actuary, and then by CMS, through a rigorous process to ensure payments are based on actuarially sound cost projections that rely on prior plan experience.

AHIP has strongly supported improvements to the Medicare Part D program, including increased drug manufacturer liability under the coverage gap discount program that Congress approved last year as part of the Bipartisan Budget Act of 2018.

---

[3] *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm613761.pdf.*

Efforts to reverse these improvements, if successful, would increase costs for seniors and taxpayers, and provide a massive bailout for the pharmaceutical industry. We urge the committee to reject any such efforts in the 2019 session.

In our many comments on CMS regulatory proposals, we consistently have advocated for greater leverage by plan sponsors to negotiate higher concessions from drug manufacturers and more flexibility to use private sector formulary tools to deliver safe, appropriate, and cost-effective care for Medicare beneficiaries.

Most recently, we expressed support for CMS proposals that would allow Part D plans to expand the use of clinically-appropriate, evidence-based medical management and formulary tools for certain high-cost "protected class" drugs and employ such tools for physician-administered medications covered by Medicare Advantage plans. These tools, which are widely used in the private sector outside of the Medicare program, would allow plan sponsors to ensure safe and appropriate care while negotiating lower drug costs on behalf of Medicare beneficiaries. We also highlighted how Part D's risk sharing structure, including rigorous review by CMS, has incentivized the cost-effective delivery of drug benefits, reduced bids and premiums, saved taxpayers money, and contributed to high levels of beneficiary satisfaction, since the program' s inception in 2006.

We also support recent CMS guidance that allows for indication-based formularies and for streamlining mid-year formulary changes relating to generic drugs in the Medicare Part D program. These added flexibilities allow plan sponsors to design innovative formularies and quickly respond to high prices and price increases imposed by manufacturers.

We also appreciate CMS' efforts to reduce prescription drug prices in Medicare Part B—including the proposal that would test changes to payments for certain Part B-covered drugs and biologics under an international pricing index (IPI) model. By seeking to lower prescription drug costs in Medicare Part B and addressing flawed incentives in the current payment system, this proposal holds promise in advancing the goals of improved access and affordability of medicines for millions of Medicare beneficiaries.

Medicaid Drug Rebate Program

Medicaid is an important safety-net health program that covers more than 73 million Americans, including low-income children and their parents, pregnant women, people with disabilities, and older adults. Due to the increasingly high drug prices set by manufacturers, we are concerned with the increasing impact of high-cost drugs on the Medicaid program, especially for states and their enrollees. The Medicaid Drug Rebate Program (MDRP) has been important in helping to offset some of these costs for state and federal government budgets, particularly with respect to high price drugs without competition that ordinarily do not generate rebates. However, we remain concerned that the MDRP cannot adequately protect against the impacts of high-cost drugs in Medicaid.

We also have concerns about the best price component of the rebate program, which requires that manufacturers charge Medicaid programs no more than the "best price" available to other customers (generally in the commercial market) if greater than the mandated discount. Studies show that best price inhibits the ability of plans to obtain larger discounts for other payers and consumers outside of Medicaid.

Accordingly, we recommend further evaluation of the impacts of the best price requirement on drug costs for consumers in other markets, including commercial markets. We also recommend changes to lower the overall cost of Medicaid drug spending by allowing states to use clinically appropriate, evidence-based mechanisms to encourage the use of lowest-cost, clinically effective drug products, rather than relying exclusively on the receipt of rebates.

Ultimately, AHIP believes that the path to lower drug costs and spending in Medicaid, as well as in any other program, depends on pointing out and neutralizing effects of the games that drug manufacturers play—their unfettered ability to set and raise drug prices, especially in the absence of meaningful competition, and an overall lack of transparency. As such, we support measures that would prevent drug manufacturers from gaming the Medicaid program, such as the "Right Rebate Act" which would prevent the misclassification of a drug to avoid significant Medicaid rebate payments.

Conclusion

Thank you for considering our support for market-based solutions to address the pharmaceutical cost crisis. As the committee holds additional hearings and con-

siders legislative options, we look forward to working with you to make prescription drugs more affordable. Everyone deserves access to the medications they need at a price they can afford. We should not have to choose between innovation and affordability. With the right solutions and genuine collaboration, we can have both.

ASSOCIATION FOR ACCESSIBLE MEDICINES
601 New Jersey Avenue, NW, Suite 850
Washington, DC 20001
Phone 202–249–7100
Fax 202–249–7105

Introduction

The Association for Accessible Medicines (AAM) applauds Chairman Grassley, Ranking Member Wyden, and the Senate Finance Committee for its leadership in holding today's hearing on the rising cost of prescription drugs.

Patients continue to struggle to afford the high cost of certain medications. High launch prices on new brand biologics and annual price increases on existing brand-name drugs, combined with an increasing trend of anti-competitive tactics designed to delay or prevent competition from more affordable biosimilars and generics, are pushing access to medicines out of reach for too many patients.

That's why lowering prescription drug prices continues to be the top health care priority for America's patients. In the latest *Politico*-Harvard poll, respondents ranked lowering the cost of prescription drugs as the number one priority—with 94 percent of Democrats and 89 percent of Republicans saying, "It is extremely important," for Congress to take action.[1]

As the Senate Finance Committee examines the affordability challenges of high-priced prescription drugs, it is essential to understand the differences between the brand-name and generic drug markets and how the different pharmaceutical supply chains operate. Not only is the Food and Drug Administration's (FDA) approval process different for generics and brand name drugs, but their respective markets and the path by which they reach patients diverge significantly, with important policy implications. These differences lead to different outcomes for patients, differences in the amount of spending funded by taxpayers, and differences in what consumers pay for health care coverage.

Independent research and data, however, demonstrates one undeniable conclusion. Brand-name drug prices continue to rise, while generic drug prices continue to fall. Brand-name drugs comprise only 10 percent of prescriptions filled annually by patients, but now constitute 77 percent of all spending on prescription drugs.[2] In contrast, the amount spent on generic medicines has declined for, the last 30 consecutive months.[3]

These trends present public policy challenges and necessitate meaningful action by Congress and the Administration to lower the cost of prescription drugs for patients.

The Generic Drug Market Is Fundamentally Different Than the Brand Drug Market

The pharmaceutical industry in the United States is predicated on a balance between innovation and access. Brand-name drug companies are rewarded for inventing and developing new treatments and cures. In return for the innovation, current law provides brand name drug companies with 12 years of guaranteed market exclusivity (*i.e.,* a monopoly) for biologics and 20 years for each patent. There is also extra monopoly time provided to incentivize pediatric drug development and orphan drugs. During the period of patent and marketing exclusivity, brand-name drugs are priced and sold free from competition and discounts or rebates are negotiated with others in the supply chain, such as pharmacy benefit managers (PBMs), wholesalers and pharmacies.

Once the exclusivity period expires and the brand-name drug is off-patent, generic manufacturers and the newly developing biosimilars market are provided with an opportunity to make the same medicine, with the same clinical benefit, for patients. The introduction of competition into the market significantly reduces the price of

---

[1] *Politico*-Harvard, "Americans' Health and Education Priorities for the New Congress in 2019," January 2019.
[2] AAM, "Generic Drug Access and Savings Report," July 2018.
[3] Morgan Stanley, Monthly YOY Generic Prescription Drug Sales, January 2019.

medicine, and patients benefit from greater, more affordable access to FDA-approved drugs. Experience shows prescription drug prices decline by more than half the first year generics enter the market.[4]

Generic drugs consequently play an integral role in health care. The expiration of patents and the introduction of multiple generic manufacturers competing against each other on price results in significant savings for the health care system. Over the last 10 years, generic manufacturers delivered savings of nearly $1.8 trillion—including $265 billion in 2017—to patients and the health care system.[5]

But the manner in which the generic drug market operates differs in meaningful ways from the one for brand-name drugs. These differences between brand-name drugs and generics drugs lead to different financial incentives for other stakeholders in the supply chain.

While brand-name drugs operate in a market where there is no direct price competition due to government-awarded exclusivities and patent protections, generic drugs compete within a multi-competitor model with drug prices decreasing as more competitors enter the market. In fact, today there are more than 200 manufacturers supplying generic drugs to the U.S. market.

While brand-name drug companies maximize revenue through price rather than volume and negotiate discounts or rebates with other stakeholders in the supply chain, generic drug manufacturers compete solely on the basis of price and the ability to supply. As a result, brand-name drug companies retain 76 percent of all revenue, while other stakeholders in the supply chain for generic drugs capture 64 percent of all revenue.[6]

In the brand-name drug market, brand-name drug companies use their leverage in the supply chain to negotiate formulary placement through rebate agreements with PBMs and health insurers. There is little room for wholesalers and pharmacies to capture large margins due to their relative lack of negotiating power. And pharmacy reimbursement for brand-name drugs is tied to the reported price and there is only one product available.

For generic drugs, wholesalers, through collaborative purchasing agreements with pharmacies across the country, and group purchasing organizations exert leverage through their purchasing power and the robust competition between multiple generic manufacturers who are making identical products. Generic drug manufacturers now compete for the business of three consolidated wholesaler pharmacy groups who now control more than 90 percent of all generic drug sales.[7] This competition results in significant savings for patients but leaves generic drugs vulnerable to drug shortages and easily impacted by increased operational costs.

Brand-Name Drugs Increase Costs, Generic Medicines Drive Savings

The differences between the brand-name drug and the generic drug markets lead to different results for patients. Patients thrive with access to generic medicines, both in terms of health outcomes and financial savings. Insured patients benefit from an average copay for generics of only $6.06, while paying more than $40 for brand-name drugs.[8] In fact over 90 percent of generic prescriptions are filled for $20 or less out-of-pocket.[9] That is in comparison to just 39 percent for brand-name drugs at that price.[10]

Experience also shows that patients are far less likely to fill a prescription for a high-priced brand-name drug. Brand-name drugs account for 40 percent of all abandoned claims for new patients, while constituting, only 20 percent of approved claims.[11] In contrast, new patient abandonment rates for generics are three times lower than those for brand-name drugs.[12] Prescription drug abandonment has a se-

---

[4] IMS Institute for Healthcare Informatics, *Price Declines After Branded Medicines Lose Exclusivity in the U.S.,* January 2016.
[5] *Ibid.,* AAM.
[6] USC Schaeffer, "The Flow of Money Through the Pharmaceutical Distribution System," June 2017.
[7] Fein, Adam, "The 2018–19 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors," October 2018.
[8] *Ibid.,* AAM.
[9] *Ibid.*
[10] *Ibid.*
[11] *Ibid.*
[12] *Ibid.*

rious effect on patient health—leading to hospitalizations, death, and extensive health care costs.

With brand-name drugs now accounting for 77 percent of total spending on prescription drugs in 2017, the high cost of many prescriptions is often out of reach for patients.[13] One of out every 10 prescriptions filled in the U.S. is for brand-name drugs.[14] In other words, 10 percent of prescriptions comprise 77 percent of the costs. And specialty medicines (including brand biologics) are rapidly approaching half of all spending although they are used by fewer than 3 percent of patients.[15]

Annual price increases of less than 10 percent on brand-name drugs and the cumulative impact of such price increases translates into hundreds, if not thousands, of dollars in higher prescription drug spending. AARP, for example, found 94 percent (133 of 142) of brand-name drugs more than doubled in price between 2005 and 2017.[16] And the Office of Inspector General at the Department of Health and Human Services (HHS) found that "reimbursement for brand-name drugs in Part D still increased 62 percent from 2011 to 2015" after accounting for rebates.[17]

Higher spending on prescription drugs impacts everyone—directly in the form of higher premiums and out-of-pocket costs and as taxpayers to cover the costs of Medicare, Medicaid, and other federal health care programs. Prescription drugs now account for $0.23 out of every premium dollar and the average co-pay for brand-name drugs was $40.30 in 2017.[18, 19] Moreover, in the latest National Health Expenditures report from the Centers for Medicare and Medicaid Services, Medicare spending on prescription drugs increased 36 percent, Medicaid spending increased 50 percent, and CHIP spending increased 35 percent over the last five years.[20]

In contrast, nine out of every 10 prescriptions filled in the U.S. are for generic drugs and spending on generic drugs accounted for only 23 percent of total prescription drug spending.[21] Continued growth in the use of generic drugs and declining generic drug prices led to savings of $265 billion in 2017—an average of $1,952 for every Medicare and $568 for every Medicaid enrollee.[22]

Savings, however, often go unrealized. HHS found "incompletely aligned incentives for generic substitution leave significant savings uncaptured."[23] Seniors and the Medicare Part D program would have saved $3 billion in 2016 if generics had been dispensed rather the brand-name drug.[24] Last year, the FDA reported that patients could have saved "more than $4.5 billion in 2017" if they had the ability to purchase FDA-approved biosimilars.[25]

In recent years, the Assistant Secretary for Planning and Evaluation (ASPE) at HHS and the Government Accountability Office (GAO) examined trends in the prices of generic drugs. Due to the relatively-low cost of generic medicines, minor price changes can result in significant percentage increases. GAO, for example, cited the price of hydrocortisone increasing from $0.16 per tablet in 2012 to $0.41 per tablet in 2013—an increase of 160 percent.[26] Correspondingly, the HHS ASPE report concluded, "Our review of the evidence strongly supports the conclusion that generic drug prices are not an important part of the drug cost problem facing the nation."[27]

Nowhere is the need for lower-priced alternatives, and the challenges facing them, more real than among high-price brand biologics: Biologics, many of which are specialty medicines, are the most rapidly growing segment of increasing brand-name prescription drug: costs in the U.S. Many brand biologics cost tens of thousands of dollars per year per patient—some more than $200,000.

---

[13] *Ibid.*
[14] *Ibid.*
[15] IQVIA, "Medicine Use and Spending in the U.S.," April 2018.
[16] AARP, "Trends in Retail Prices of Brand Name Prescription Drugs," September 2018.
[17] HHS OIG, "Increases in Reimbursement for Brand-Name Drugs in Part D," June 2018.
[18] America's Health Insurance Plans (AHIP), "Where Does Your Health Care Dollar Go?", May 2018.
[19] *Ibid.,* AAM.
[20] CMS, National Health Expenditure Data 2017, December 2018.
[21] *Ibid.,* AAM.
[22] *Ibid.*
[23] HHS, "Savings Available Under Full Generic Substitution of Multiple Source Brand Drugs in Medicare Part D," January 2018.
[24] *Ibid.*
[25] FDA, Remarks from FDA Commissioner Scott Gottlieb, M.D., "FDA's Biosimilars Action Plan," September 2018.
[26] GAO, "Generic Drugs Under Medicare," August 2016.
[27] HHS, "Understanding Recent Trends in Generic Drug Prices," January 2016.

Biosimilar medicines represent a key step forward in reducing high drug prices. Biosimilars are safe, effective and more affordable versions of costly brand biologics. By the year 2025, over 70 percent of drug approvals are expected to be biological products.[28] Experts estimate that FDA-approved biosimilars could save more than $54 billion over the next 10 years.[29] In doing so, biosimilars will mean greater access to lifesaving cures for an estimated 1.2 million Patients.[30] Research shows women, low-income families, and elderly patients would particularly benefit from access to biosimilar medicines.[31]

Unfortunately, the ability of biosimilars to fulfill their potential is threatened by market abuses by brand-name drug companies and misguided policies that block access to lower-cost medicines. Seventeen biosimilars are now approved in the U.S., yet only seven are on the market and available to patients.[32] In comparison, more than 50 biosimilars are available to patients in Europe.

It is sobering to consider what America's patients would face if there no FDA-approved generic or biosimilar medicines to provide reliable access to affordable treatments. Generics do not only deliver the most medicine at the lowest cost and the greatest savings; generic medicines cushion the significant impact dealt to patients and the health care system by high brand-name drug prices every day.

Put another way, the availability of low-cost generics offsets the impact of high brand-name drug prices.

Conclusion

Understanding the differences between brand-name drug, brand-name biologics, generic drugs, and biosimilars; how each market functions; and, the different incentives stakeholders have throughout the supply chain is essential when considering solutions to address the rising costs of prescription drugs and to ensuring that the policies that are adopted result in meaningful savings to patients at the pharmacy counter.

AAM is available to help explain how the prescription drug markets work, to help identify opportunities for improvement, and to discuss solutions that lower the cost of prescriptions for patients. We appreciate the Finance Committee's hearing today and look forward to working with the Chairman, Ranking Member, and members of the Committee to address this public health challenge.

ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS, INC.
1601 N. Tucson Blvd., Suite 9
Tucson, AZ 85716–3450
(800) 635–1196 or (520) 327–4885
FAX (520) 326–3529 or (520) 325–4230
https://www.aapsonline.org/

January 29, 2019

Thank you Chairman Grassley, Ranking Member Wyden and Members of the Senate Finance Committee, for your courage to hold these hearings despite intense pressure from middlemen—and others who benefit from high prices but add little value for patients—to preserve the status quo.

We appreciate this opportunity to share with the Committee some common sense solutions to the issue of rising prescription drug prices. While some inadvisedly suggest creating a government-run manufacturer, a common denominator to our suggestions is the need to unleash the competitive market forces that provide abundant options and push prices down in almost every other sector of the American economy.

We respectfully ask the Committee to consider the following actions.

End the Safe Harbor to Anti-Kickback Law Abused by Middlemen

One especially responsible culprit for soaring prices is the safe harbor to Medicare anti-kickback law enjoyed by Group Purchasing Organizations (GPOs) that has been further extended by administrative guidance to Pharmacy Benefit Managers (PBMs).

---

[28] *U.S. Pharmacist,* "Biosimilars: Current Approvals and Pipeline Agents," October 2016.
[29] RAND, "Biosimilars Cost Savings in the United States," October 2017.
[30] The Biosimilars Council, "Biosimilars in the United States: Providing More Patients Greater Access to Lifesaving Medicines," August 2017.
[31] *Ibid.*
[32] FDA, "FDA-Approved Biosimilar Products," January 2019.

The Federal statute granting this "safe harbor" is 42 U.S.C. 1320a–7b(b)(3)(C), the language of which was established by the "Omnibus Budget Reconciliation Act of 1986," strengthened by the "Medicare and Medicaid Patient and Program Protection Act of 1987," and subsequently ensconced in federal regulation at 42 CFR 1001.952 (j).

The provision ostensibly facilitates greater bargaining power for the purchasing of supplies and drugs. However, the safe harbor has in practice driven up costs and scarcity by perpetuating a system rife with hidden kickbacks, rebates, and single source contracts, that financially benefit GPOs, PBMs, and large manufacturers, but constrain competition and ultimately harm patients.

It is time to repeal 42 U.S.C. 1320a–7b(b)(3)(C) and direct HHS to revoke any related regulations and guidance that protect such improper kickbacks.

Physicians Against Drug Shortages calculates that such "corrupt practices have driven up the prices of drugs sold by PBMs to individual consumers by at least $100 billion annually." This is in addition to the $100 billion per year in inflated supply costs that result from kickbacks to GPOs. For additional details see *http://www.physiciansagainstdrugshortages.com/* and the enclosed article, "Group Purchasing Organizations: Gaming the System," by AAPS President Marilyn Singleton, M.D., JD published in the *Journal of American Physicians and Surgeons,* also available at *http://www.jpands.org/vol23no2/singleton.pdf.*

Diabetes patients are one group particularly hard hit by the collusion between PBMs and manufacturers. CBS News recently reported that "the cost of two common types of insulin increased 300 percent in the past decade" thanks in large part to kickbacks to PBMs. For example, lower cost generic insulin drugs are excluded from plan formularies, when brand name manufacturers agree to pay larger "rebates" to PBMs.

Research by Vanderbilt University Professor Stacie Dusetzina "found that only 17 percent of Medicare plans for seniors covered Basaglar [a biosimilar insulin drug] launched by Eli Lilly two years ago. Nearly all of them covered brand-name Lantus, sold by Sanofi, as of early last year."

What does this mean for patients? A diabetic patient "saved $800 last year after her insurance company started covering . . . Basaglar that was virtually identical to the brand she had used for years," reports *Kaiser Health News.* And the unnecessarily high costs are leading to patient harm. A 2018 study found, "nearly half (45 percent) of Americans with diabetes sometimes do without care because they can't afford it."

Sunshine on these practices is long overdue. Contracts between GPOs, PBMs, suppliers, and manufacturers "are guarded as fiercely as Fort Knox," warns Robin Feldman, a law professor at the University of California, Hastings College of the Law, despite the fact that taxpayers fund nearly two-thirds of every dollar spent on medical care *(https://khn.org/news/secretive-rebate-trap-keeps-generic-drugs-for-diabetes-and-other-ills-out-of-reach/).*

This Committee should request, subpoena if needed, and make public, contracts related to the sale of insulin to help shine sunlight on these secret backroom deals. In addition it should similarly obtain copies of contracts related to other medical products that have recently seen a dramatic rise in scarcity or price: *e.g.,* Baxter's contracts related to saline market allocation, the Hospira (now Pfizer) contracts for fentanyl, and Mylan's contracts for EpiPen.

Address Anti-Competitive Manufacturer Tactics That Delay Introduction of Generics

The FDA under the leadership of Scott Gottlieb, M.D. has made welcome progress in increasing the number of lower cost generic drugs available to American patients: 971 generics were approved by the agency in 2018, more than in any other year.

More is needed. We urge the Committee to support the reintroduction and passage of the "Creating and Restoring Equal Access to Equivalent Samples Act of 2018" (CREATES Act).

The legislation "would promote drug price competition by making it easier for medicines whose patents have expired to be sold as less expensive generic versions, by requiring manufacturers to provide drug samples at a fair market price within a reasonable time," explains Dean Clancy writing in *The Hill.*

Addressing "patent thickets that are purely designed to deter the entry," as Commissioner Gottlieb puts it, is another anti-competitive practice the Committee should investigate and address.

Support Efforts to End Anti-Competitive Price Fixing by Generic Manufacturers

Pharmacy Benefits Managers and brand name manufacturers are not alone in using improper practices to limit competition. Generic drug makers are also entering into anti-competitive agreements. "What started as an antitrust lawsuit brought by states over just two drugs in 2016 has exploded into an investigation of alleged price-fixing involving at least 16 [generic drug] companies and 300 drugs," reports *The Chicago Tribune (https://www.chicagotribune.com/business/ct-biz-generic-drug-alleged-price-fixing-20181210-story.html).*

We encourage the Committee to take a look into such abusive practices and consider how it can support ongoing efforts by state attorneys general to end them.

Cut the Red Tape Impeding Innovative Care Models

Meanwhile, independent physicians are providing tremendous savings to patients with in-office dispensing of prescriptions that cut out the cost increases caused by middlemen like PBMs. For example, a 72 year old female patient with multiple chronic conditions purchases all nine of her medications through a Direct Primary Care office for $14.63/month. Through her Medicare "coverage" her cost would be $294.25 per month.

The Senate Committee on Finance had jurisdiction, during the 115th Congress, over S. 1358, the Direct Primary Care Enhancement Act, which would increase patient access to this promising delivery model by simply clarifying that Health Savings Accounts can be used for these arrangements. We urge the Committee to expedite consideration and approval of similar legislation during this 116th Congress.

In conclusion, lowering costs for care is going to mean ending the improper flow of money to middlemen profiting without adding value to patient care. We encourage the Committee to take action to end failed policies that benefit the bottom lines of these special interests and simultaneously implement solutions that hand control back to patients.

Please do not hesitate to reach out to us for further discussion about our concerns.

Sincerely,

Jane M. Orient, M.D.
Executive Director
jane@aapsonline.org

From *Journal of American Physicians and Surgeons,* Volume 23, Number 2, Summer 2018

Group Purchasing Organizations: Gaming the System

Marilyn M. Singleton, M.D., JD

Introduction

Both government and private entities are looking for treatable causes of the high costs of medical care. Over the last 15 years, Group Purchasing Organizations (GPOs) have been on the radar as a contributing factor to rising hospital costs, medication shortages, and stifling introduction of innovative products from smaller companies.

Hospital supply costs are substantial. In 2013, U.S. hospitals on average spent $3.8 million each on supply expenses, with a median of $9.1 million. Supply expenses averaged 15 percent of total hospital expenses, and the average patient admission required $4,470 of supply expenses. Supply costs were as high as 30 or 40

percent in hospitals with, for example, complex cases or a large surgical service.[1] GPOs were intended to reduce these costs.

Background: A Good Idea Gone Bad

What is a GPO? GPOs are purchasing intermediaries that negotiate contracts between their customers—medical facilities such as hospitals, and vendors, distributors, and other suppliers of medical and pharmaceutical products and services. Such goods and services range from simple commodities like bandages to pharmaceuticals to high-tech devices like pacemakers. GPOs are supposed to facilitate better deals for their customers by means of volume purchasing. GPOs may also fund additional services outside of group purchasing for their customers, *e.g.,* product evaluation, and marketing and insurance services.

The Hospital Bureau of New York established the first GPO in 1910, and now approximately 97 percent of hospitals in the United States purchase through GPO contracts. The Healthcare Supply Chain Association, a trade association rep resenting 15 GPOs, estimates there are two to four GPOs per facility, and some 72 percent of hospital purchases are done using GPO contracts.[2, 3]

Until the 1970s, GPOs' main source of revenue was through membership dues. To lessen the burden on smaller or struggling hospitals that could not afford the dues, GPOs began collecting "contract administrative fees" (rebates, kickbacks) from the vendors (see Figure 1). Such fees are typically based on a percentage of the costs of the products that GPO customers purchase through GPO-negotiated contracts.[2]

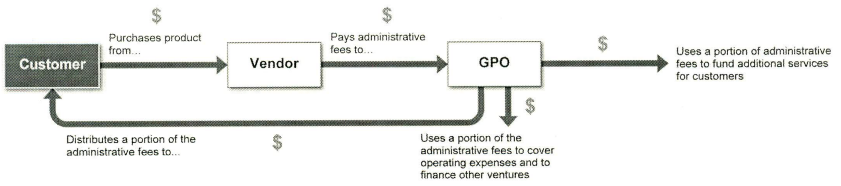


Figure 1. General Flow of Administrative Fees

Normally, this fee arrangement would violate the federal healthcare program Anti-Kickback Statute.[4] Federal anti-kickback provisions[5] were passed as part of the Social Security Act Amendments of 1972 to "protect patients and the federal health care programs from fraud and abuse by curtailing the corrupting influence of money on health care decisions."[6]

Initially, the statute made the receipt of kickbacks, bribes, or rebates in the Medicare and Medicaid programs a misdemeanor punishable by a fine, imprisonment, or both. In response to testimony that these penalties were not adequate deterrents and were inconsistent with other federal criminal codes sanctions that made similar actions felonies, Congress strengthened the statute. The Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977 broadened the language to also prohibit the offer or receipt of "any remuneration" to induce a referral, and elevated the mis-

---

[1] Abdulsalam Y, Schneller ES. "Hospital supply expenses: an important ingredient in health services research." *Med Care Res Rev,* July 24, 2017. Available at: *http://journals.sagepub.com/doi/10.1177/1077558717719928.* Accessed May 17, 2018.

[2] Government Accountability Office. "Group Purchasing Organizations: Federal Oversight and Self-Regulation," March 30, 2012. Available at: *https://www.gao.gov/assets/590/589778.pdf.* Accessed May 16, 2018.

[3] Definitive Healthcare. "Top 10 GPOs by Member Hospital Beds," August 16, 2016. Available at: *https://blog.definitivehc.com/top-10-gpos-by-member-hospital-beds.* Accessed May 17, 2018.

[4] Social Security Act Section 1128B(b), 42 U.S. Code § 1320a–7b—Criminal penalties for acts involving Federal health care programs. Available at: *https://www.law.cornell.edu/uscode/text/42/1320a-7b.* Accessed May 16, 2018.

[5] Section 242 of Social Security Amendments of 1972, Pub. L. 92–603, 86 Stat. 1329 (October 30, 1972), Penalties for fraudulent acts and false reporting under Medicare and Medicaid. Available at: *https://www.gpo.gov/fdsys/pkg/STATUTE-86/pdf/STATUTE-86-Pg1379-3.pdf.* Accessed May 18, 2018.

[6] Office of Inspector General, Department of Health and Human Services. "Federal anti-kickback law and regulatory safe harbors." Fact Sheet; November 1999. Available at: *https://oig.hhs.gov/fraud/docs/safeharborregulations/safefs.htm.* Accessed May 16, 2018.

demeanor classification to a felony.[7] However, this statute had an exception for discounts if the discount was (1) disclosed, and (2) reflected in the costs claimed for reimbursement from the government. The Senate Finance Committee included this provision to "ensure that the practice of discounting in the normal course of business transactions would not be deemed illegal. In fact, the [finance] committee would encourage providers to seek discounts as a good business practice which results in savings to Medicare and Medicaid program costs."[8]

In the early 1980s, the federal government's response to steeply rising Medicare costs may have triggered the interest in questionable business arrangements. The Medicare payment method was revised from a retrospective fee-for service system to a prospective payment system (PPS) in an effort to control costs. Under PPS, hospitals receive a fixed amount for treating patients diagnosed with a given illness, regardless of the length of stay or type of care received.[9]

Hospitals complained that PPS cut into their profit margin, so they expanded services and sought ways to enhance revenue, some of which may have violated the anti-kickback law.[10] Hospitals asserted that the 1977 amendments effectively prohibited long-standing industry practices necessary to day-to-day operations. Congress believed that GPOs could "help reduce health care costs for the government and the private sector alike by enabling a group of purchasers to obtain substantial volume discounts on the prices they are charged."[11] Consequently, as part of an Omnibus Budget Reconciliation Act of 1986 miscellaneous technical amendment to Medicare, Congress added an exception to the Anti-Kickback Statute to permit fees paid by vendors to a GPO if: (1) there was a written contract with fees at a fixed amount or a fixed percentage of the value of the purchases, and (2) entities that were service providers disclosed such fees to the customer.[12, 13]

The next year, Congress passed the Medicaid Patient and Program Protection Act of 1987, directing the Secretary of Health and Human Services (HHS) to create additional payment and business practice exceptions to the Anti-Kickback Statute ("safe harbors") because such practices would be unlikely to result in fraud or abuse.[14] (It also redesignated the GPO exception to a different section of the Social Security Act.)

On July 29, 1991, the HHS Office of Inspector General (HHS–OIG) issued the first in a series of regulations implementing the safe harbors. The GPO regulations fixed the contract administrative fee at 3 percent or less of the purchase price of the product or service, and required disclosure of fees received from all types of vendors to the respective customer.[15]

The Antitrust Safety Zone

In response to antitrust concerns, in 1996 the Federal Trade Commission (FTC) studied GPOs. The FTC determined that joint purchasing arrangements provided to hospitals or other health care providers do not raise antitrust concerns. The FTC reasoned that through such joint purchasing arrangements, the participants frequently obtain volume discounts, reduce transaction costs, and have access to con-

---

[7] Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977. Pub. L. 95–142, 91 Stat. 1175 (October 25, 1977). Available at: *https://www.gpo.gov/fdsys/pkgSTATUTE-91/pdf/STATUTE-91-Pg1175.pdf.* Accessed May 18, 2018.

[8] Report of the Committee on Finance on S. 143, Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977; September 22, 1977. Available at: *https://www.finance.senate.gov/imo/media/doc/srpt95-453.pdf.* Accessed May 18, 2018.

[9] Social Security Act Section 1886, 42 U.S.C. Section 1395ww—Payments to hospitals for inpatient hospital services. Available at: *https://www.law.cornell.edu/uscode/text/42/1395ww.* Accessed May 18, 2018.

[10] Rogers DB. Medicare and Medicaid Anti-Kickback Statute: safe harbors eradicate ambiguity. *J Law Health* 1993;8:223–244. Available at: *https://engagedscholarship.csuohio.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1294&context=jlh.* Accessed May 18, 2018.

[11] Office of Inspector General Advisory Opinion No. 16–06; May 2, 2016. Available at: *https://www.oig.hhs.gov/fraud/docs/advisoryopinions/2016/Adv0pn16-06.pdf.* Accessed May 16, 2018.

[12] Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99–509, § 9321(a), 100 Stat. 1874, 2016. Available at: *https://www.gpo.gov/fdsys/pkg/STATUTE-100/pdf/STATUTE-100-Pg1874.pdf.* Accessed May 16, 2018.

[13] House Conference Report 99–1012 to Accompany H.R. 5300, Providing Reconciliation Pursuant to Section 2 of the Concurrent Resolution on the Budget for Fiscal Year 1987; October 17, 1986. Available at: *https://www.finance.senate.gov/imo/media/doc/Confrpt99-1012.pdf.* Accessed May 16, 2018.

[14] Medicaid Patient and Program Protection Act of 1987. Available at: *https://www.gpo.gov/fdsys/pkg/STATUTE-101/pdf/STATUTE-101-Pg680.pdf.* Accessed May 16, 2018.

[15] 42 CFR § 1001.952(j)—Exceptions. Available at: *https://www.law.cornel.edu/cfr/text/42/1001.952.* Accessed May 16, 2018.

sulting advice that may not be available to each participant on its own. Thus, GPOs provided significantly more efficiency, benefited consumers, and did not raise antitrust concerns.

The resultant FTC enforcement guideline sets forth an "antitrust safety zone" for GPOs where the FTC and Department of Justice (DOJ) will not challenge, "absent extraordinary circumstances," any joint purchasing arrangement among health care providers where two conditions are met:

1. Purchases through a GPO must account for less than 35 percent of the total sales of the product or service in question (*e.g.,* stents) in the relevant market (which could be regional or national). This condition addresses whether the GPO accounts for such a large share of the purchases of the product or service that it can effectively exercise increased market power as a buyer. If the GPO's buying power drives the price of the product or service below competitive levels, consumers could be harmed if suppliers respond by reducing output, quality, or innovation.

2. The cost of purchases through a GPO by each member hospital that competes with other members must amount to less than 20 percent of each hospital's total revenues. This condition looks at whether the GPO purchases constitute such a large share of the revenues of competing member hospitals that they could result in standardizing the hospitals' costs enough to make it easier to fix or coordinate prices.[16]

GPO Fees: By the Numbers

While there are more than 600 GPOs in various industries, only a few GPOs dominate the medical market. A 2015 Government Accountability Office (GAO) study found that during fiscal year 2012, the five largest GPOs contracted for similar products reported a total purchasing volume of $130.7 billion, and received fees totaling about $2 .3 billion in 2012.[17] (While these GPOs were not named in that GAO report, later reports indicated they were MedAssets (purchased by Vizient), Premier, Novation (part of Vizient), HealthTrust, and Amerinet (now called Intalere). This was a 20 percent increase in the total fees collected from vendors in 2008 (adjusted for inflation). The GPOs attribute the growth in volume of fees to increases in purchasing volume by customers and additional products being added to contracts.

These five GPOs reported that the most frequent vendor fee they received in 2012 was 3 percent, and that such fees accounted for 92 percent of a GPO's revenue.[17] GPOs report that nearly 70 percent of these fees ($1 .6 billion) was passed on to GPO customers or owners ("share-backs;" a.k.a. rebates). The remainder of the revenue came from member fees, outside investments, vendor exhibit fees, and licensing fees-which are also based on a percentage of the purchase price of products-to market their products using the GPO's brand name.

Inherent Conflict of Interest

The current fee structure raises an obvious conflict of interest: when members (customers) paid the dues, the clear goal was to find lower prices for the member. Now, since vendors pay the fees as a percentage of the product cost, the higher the price, the higher the GPOs' fees. Since 2002, GPOs have come under scrutiny for their contribution to increased costs to federal health programs, drug shortages, and effect on the introduction of new products.

Additionally, it has been reported that at least two GPOs and/or their officials have accepted stock in supplier companies in lieu of or in addition to cash payments, or have significant investments in medical supply companies.[18]

Questions also have been raised about sole-source contracting, in which GPOs may contract with only one vendor for a given product when multiple vendors of comparable products are available. Here, the GPO contract may have minimum pur-

---

[16] Statement of Department of Justice and Federal Trade Commission Enforcement Policy on Joint Purchasing Arrangements Among Health Care Providers; August 1996. Available at: *https://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/statements_of_antitrust_enforcement_policy_in_health_care_august_1996.pdf.* Accessed May 16, 2018.

[17] Government Accountability Office. "Group Purchasing Organizations: Funding Structure Has Potential Implications for Medicare Costs;" October 24, 2014. Available at: *https://www.gao.gov/assets/670/666644.pdf.* Accessed May 16, 2018.

[18] Bogdanich W. "Medicine's middlemen; questions raised of conflicts at 2 hospital buying groups." *NY Times,* March 4, 2002. Available at: *https://www.nytimes.com/2002/03/04/business/medicine-s-middlemen-questions-raised-of-conflicts-at-2-hospital-buying-groups.html.* Accessed May 18, 2018.

chase requirements. Smaller hospitals may tend to purchase more than they need to reach the minimums. Overspending to get a purported discount is not a good trade-off. Other practices under scrutiny are product bundling, in which price discounts are linked to purchases of a specified group of products; long-term contracts of 5 years or more; and tiered or loyalty discounts where the discount (rebate) increases as the hospital buys a greater percentage of a specific product through that GPO. Additionally, the GAO had questioned whether GPOs were actually saving money.[19]

No Evidence of Consistent Cost Savings

The justification for allowing GPOs' rebates and fee structure to be exempt from the Anti-Kickback Statute was that it would save money. The GAO studied several representative hospitals and found that GPOs' contract prices were not always lower, and were often higher than prices paid by hospitals negotiating with vendors directly. One factor is that the price breaks varied by product model. For example, for some pacemaker models, the hospitals using GPO contracts got up to 26 percent lower prices than the hospitals not using a GPO contract. But for other models, hospitals using a GPO contract got prices that were up to 39 percent higher than hospitals not using a GPO contract. Additionally, the size of the hospital affected the price savings. Large hospitals (greater than 500 beds) got lower prices negotiating on their own. But while small and medium hospitals were more likely to benefit from a GPO contract, this was not a consistent finding. Price savings had little relationship to the size of the GPO. Hospitals contracting with large GPOs—those whose members purchase more than $6 billion per year with their contracts—did not necessarily obtain better prices than hospitals using smaller GPOs.[19]

Further, the GAO was unable to identify any published peer-reviewed studies that included an empirical analysis of pricing data that indicated whether GPO customers obtain lower prices from vendors.[20] Industry-supported studies claim savings, but a private 2012 study found hospitals achieved an average price reduction of 10–14 percent from 2001 through 2010 when the transaction was brokered by an agent not compensated by suppliers.[21]

Limited Government Oversight

The DOJ, the HHS–OIG, and the FTC are responsible for oversight of GPOs. After negative publicity in the early 2000s, GPOs formed a voluntary GPO membership association, the Healthcare Group Purchasing Industry Initiative (HGPII) in 2005 to "self-police" by promoting best practices and public accountability among member GPOs.[2]

In the antitrust arena, the DOJ and FTC receive and investigate about one complaint per year against GPOs. The GAO found one lawsuit filed by DOJ against a GPO in 2007. DOJ challenged actions by the GPO for temporary nursing services and its member hospitals, alleging that the GPO caused the wages paid to temporary nurses in Arizona to fall below competitive levels. The case was resolved with a settlement and consent decree. The DOJ received a complaint in 2010 from certain medical device manufacturers questioning the general structure of the industry and how the industry operates. Although DOJ spoke with the complainants, it did not open an investigation.[2] As of 2014, the FTC had not taken any enforcement action against a GPO since 2004.[22]

Safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the regulations.[11] Further, a lawful purpose will not legitimize a payment that also violates the statute. Neither the GPO safe harbor

---

[19] Scanlon WJ. Government Accountability Office. "Group Purchasing Organizations: pilot study suggests large buying groups do not always offer hospitals lower prices." Testimony before the Subcommittee on Antitrust, Competition, and Business and Consumer Rights, Committee on the Judiciary, U.S. Senate; April 30, 2002. Available at: *https://www.gao.gov/assets/90/81813.pdf.* Accessed May 16, 2018.

[20] Government Accountability Office. Group Purchasing Organizations: research on their pricing impact on health care providers. Letter to Senator Charles Grassley; January 29, 2010. Available at: *https://www.gao.gov/assets/100/96533.pdf.* Accessed May 17, 2018.

[21] Federal Trade Commission Workshop. Understanding Competition in the Prescription Drug Markets: Entry and Supply Chain Dynamics; November 2017: slide 174. Available at: *https://www.ftc.gov/system/files/documents/public_events/1255653/understanding_competition_in_prescription_drug_markets_workshop_slides_11-8-17.pdf.* Accessed May 25, 2018.

[22] Government Accountability Office. "Group Purchasing Organizations: services provided to customers and initiatives regarding their business practices." Report to the Ranking Member, Committee on Finance, U.S. Senate. GAO 10–738; August 2010. Available at: *https://www.gao.gov/assets/310/308830.pdf.* Accessed May 16, 2018.

statutory provision nor the regulation require HHS-OIG to routinely review or monitor the required GPO written agreements and disclosures.[15] Indeed, since 2004, HHS–OIG as a matter of course has not exercised its authority to request and review disclosures related to GPOs' contract administrative fees. However, it has collected information on GPOs' contract administrative fees while conducting audits of hospitals' cost reports. HHS–OIG did investigate with DOJ two cases involving allegations that certain GPOs did not comply with safe harbor requirements and violated the Anti-Kickback Statute.[2] Both lawsuits were brought by private citizens on behalf of the United States under the False Claims Act ("qui tam" action). DOJ may intervene and litigate the case along with the private party, but in each of these cases, DOJ declined to intervene.

Medicare provider reimbursement regulations generally require providers to offset purchase discounts, allowances, and refunds of expenses against expenses on their Medicare cost reports that reflect their costs of medical supplies.[23]

In 2005, HHS–OIG found that some GPO customers did not fully account for GPO revenue distributions on their Medicare cost reports. Despite the response by the Centers for Medicare and Medicaid Services (CMS), which issued guidance on proper reporting of GPO rebates, HHS has done no further reviews of cost reports for this information.[2]

The information in cost reports is one element that the Medicare Payment Advisory Commission (MedPAC) reviews in determining the reasonableness of Medicare payment levels for the Prospective Payment System. Additionally, Medicare contractors use parts of the cost reports to compute Medicare reimbursement.[17] If the rebates are not reported on the cost reports, Medicare could be overpaying hospitals.

In its review of GPO payment practices, the GAO's single recommendation was having HHS determine what her hospitals are appropriately reporting administrative fee revenues on their Medicare cost reports, and taking steps to address any under-reporting that may be found.[17]

Consolidation of the GPO Market

As one medical device supplier noted in 2016, "When I started in this space 27 years ago, there were about two dozen GPOs that we recognized as national GPOs. Today there are five."[24] Four GPOs (Vizient, Premier, HealthTrust, and lntalere) have about 90 percent of the market.

Vizient was founded in 2015 as the integration of VHA Inc., a national network of not-for-profit hospitals; University Health System Consortium, an alliance of the nation's leading academic medical centers; and Novation, the health care contracting company they jointly owned. In 2016, Vizient acquired MedAssets' Spend and Clinical Resource Management segment. Vizient has $100 billion annual spend volume, and its membership consists of a little more than50 percent of the nation's acute care providers.[25] Vizient also serves more than 20 percent of the nation's ambulatory market.

Premier has more than $50 billion annual spend volume. Premier members include 3,750 hospitals, which includes 76 percent of U.S. community hospitals, and more than 130,000 other provider organizations. Premier also provides data analytics and information technology (IT) services, among other services. Health Trust has $30 billion annual spend volume. Its members include 1,600 hospitals and more than 26,000 non-acute care sites in the U.S. and UK. Intalere has $9 billion annual spend volume and its members include 3,734 hospitals and more than 85,000 non-acute healthcare providers.[25]

The competition and choice promised in the early years of GPOs is clearly lacking.

Medication Shortages

Medication shortages have resulted in tremendous patient harm. Shortages increased by almost 200 percent from 2005 to 2010, and they increased 13 percent

---

[23] 42 CFR § 413.98—Purchase discounts and allowances, and refunds of expenses. Available at: *https://www.law.cornell.edu/cfr/text/42/413.98.* Accessed May 18, 2018.

[24] Cline A. "The new GPO landscape and its impacts on healthcare." *Modern Healthcare,* April 2016. Available at: *http://www.modernhealthcare.com/article/20160331/SPONSORED/303319993.* Accessed May 18, 2018.

[25] Gooch K. "4 of the Largest GPOs." *Becker's Hospital CFO Report,* February 6, 2017. Available at: *https://www.beckershospitalreview.com/finance/4-of-the-largest-gpos-2017.html.* Accessed May 16, 2018.

between 2009 and 2010 al one.[26] A 2011 U.S. Food and Drug Administration (FDA) study concluded that the cause of shortages was multi factorial, including economic, legal, regulatory, policy, and clinical factors. However, FDA notes that despite high demand for generics and oncology medications, the supply system is "vulnerable to drug shortages because a large supply disruption is difficult to make up with alternative suppliers."[26] A 2014 GAO report found studies that indicated GPOs' administrative fees contributed to generic drug shortages by reducing the profit margins, thereby discouraging increased production, adding to supply-chain fragility.[27, 28] A 2011 HHS study focusing on sterile injectables attributed manufacturers' inability to meet the demand s to inadequate manufacturing capacity as a consequence of the expansion in scope and volume of products.[29]

The presence of a variety of vendors is key to maintaining a stable supply chain, which can protect against medication shortages. GPOs' exclusive, high-volume, sole-source contracts are awarded to those who can pony up the highest fees. Contracts that bundle products favor vendors offering a broad range of products. Consequently, smaller or single product companies are shut out of the market. The end users (patients) suffer by being deprived of lower-cost or innovative products-and in some cases can obtain no product at any price.

Conclusion

Since the federal healthcare Anti-Kickback Statute GPO exception was created 30 years ago, the landscape has changed. The current GPO funding structure's incentive is to "negotiate" higher prices for its customers. The vendors with the most money can afford to pay the high fees and buy themselves into the game. The term "payola"—pay to play—comes to mind. The situation is exacerbated because insurers absorb the higher prices and thus hospitals may have less incentive to monitor pricing.

GPOs assert that there is sufficient competition between them to mitigate any potential conflicts of interest with regard to negotiating the lowest prices. But when the FTC issued its "antitrust safety zone" 22 years ago, it noted, "The existence of a large number and variety of purchasing groups in the health care field suggests that entry barriers to forming new groups currently are not great:"[16] Only four companies now comprise 90 percent of the GPO market. This industry consolidation should re-ignite antitrust concerns: limited choices, difficulty in changing GPOs, higher prices, and barriers to entry into the market by smaller companies. Worse yet is that patients suffer because of higher prices and insurance premiums.

Vendors could take "dirty" money if doing so helped patient s by increasing medical care access and/or choice, or saved the government money. But the arrangements must precisely meet all of the conditions set forth in the regulations. Assuming the inducement was "knowing and willful," based on the three questions the government is supposed to ask current discounting or GPO arrangements look like impermissible kickbacks. Does the arrangement have a potential to interfere with, or skew clinical decision-making? Yes. The vendor who can afford the fees or provide other financial perks gets the contract.

Does it have a potential to undermine the clinical integrity of a formulary process? Yes. Smaller pharmaceutical companies with a less expensive or better product are frozen out of the contracting process.

---

[26] U.S. Food and Drug Administration, "A Review of FDA's Approach to Medical Product Shortages;" October 31, 2011. Available at: *https://www.ipqpubscom/wp-content/uploads/2012/02/FDA_drug_shortages_report.pdf.* Accessed May 18, 2018.

[27] Government Accountability Office, "Drug shortages: public health threat continues, despite efforts to help ensure product availability." Report to Congressional Addressees; February 2014. Available at: *https://www.gao.gov/assets/670/660785.pdf.* Accessed May 25, 2018.

[28] Government Accountability Office, "Drug shortages: certain factors are strongly associated with this persistent public health challenge." Report to Congressional Committees; July 2016. Available at: *https://www.gao.gov/assets/680/678281.pdf.* Accessed May 18, 2018.

[29] Office of the Assistant Secretary for Planning and Evaluation, Office of Science and Data Policy, U.S. Department of Health and Human Services, "Economic analysis of the causes of drug shortages." ASPE Issue Brief; October 2011. Available at: *https://aspe.hhs.gov/pdf-report/economic-analysis-causes-drug-shortages.* Accessed May 18, 2018.

Does the arrangement have the potential to increase costs to federal health care programs, beneficiaries, or enrollees? Yes. There is no evidence that supply costs are lower.[30]

In short, GPOs do not always choose the products that are best for their customers, patients, or the taxpayers. An honest look at the current state of GPOs should label the conduct illegal, yet Congress has not acted to repeal or sharply limit the safe harbor. Just as with GPO contracts, money talks. Premier has 19 lobbyists and spent $1,790,000 on lobbying in 2017. It contributes to Democrat and Republican congressional committees, and to individuals on both sides of the aisle, including former vice-presidential candidate Tim Kaine, and two prominent physician senators, John Barrasso and Bill Cassidy.[31]

On the positive side, if the government will not enforce the law, the private sector may again take action. According to a large business consulting firm's annual study conducted with hospital administrators, health systems are increasingly receptive to bypassing GPOs for their medical technology contracts.[28] Additionally, there are a growing number of health systems that are "owning and controlling their own supply chain destinies."[32] And, not to be outdone, Amazon's B2B program has entered the healthcare market and promises a marketplace to comparison-shop for the best prices and selection.

The time has come to do what is best for patients and to restore integrity, competition, choice, and cost savings to the purchasing process.

Marilyn M. Singleton, M.D., JD, is an anesthesiologist in Redondo Beach, CA, and serves as president-elect of AAPS. Contact: marilynmsingleton@gmail.com.

CAMPAIGN FOR SUSTAINABLE RX PRICING (CSRXP)
1341 G Street, NW, Suite 1100
Washington, DC 20005

Statement of Lauren Aronson, Executive Director

Chairman Grassley, Ranking Member Wyden, and members of the Senate Committee on Finance, the Campaign for Sustainable Rx Pricing (CSRxP) thanks you for the opportunity to submit testimony for the record on drug company pricing practices that have resulted in out-of-control and unsustainable growth in prescription drug prices. We very much appreciate your leadership in addressing this critically important issue that American consumers face every day.

CSRxP is a nonpartisan coalition of organizations committed to fostering an informed discussion on sustainable drug pricing and to developing bipartisan, market-based solutions that promote competition, transparency, and value to improve affordability while maintaining patient access to innovative prescription drugs that can improve health outcomes and save lives. Our members represent organizations including consumers, hospitals, physicians, nurses, pharmacists, employers, pharmacy benefit managers and insurance providers.

Prescription drug prices are needlessly high and continue to grow at unsustainable rates. Twenty-three cents of every health care dollar goes toward prescription drugs.[1] One in four Americans cannot afford their medications. Excessively high prices unfairly threaten the financial security, health and well-being of U.S. patients and their families every day, as well as strain Federal and state health budgets and the taxpayers who fund them. Too often patients are faced with the unfortunate and unfair choice of purchasing the medications they need to get well and stay healthy and paying their bills. Patients should never be presented with such a choice.

CSRxP thus strongly believes it is imperative to rein in out-of-control drug prices and welcomes the leadership of this Committee in seeking to address this vexing problem that impacts Americans every day. In particular, we firmly believe that sig-

---

[30] Office of Inspector General. "Compliance Program Guidance for Pharmaceutical Manufacturers;" April 2003. Available at: *https://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf.* Accessed May 25, 2018.

[31] Center for Responsive Politics. "Premier, Inc." Available at: *https://www.opensecrets.org/lobby/clientsum.php?id=D000028434&year=2017.* Accessed May 18, 2018.

[32] Graves K, Grabenstatter K. "Time for medtechs to rethink GPOs?" *LEK Executive Insights.* 2018;20(13). Available at: *https://www.lek.com/sites/default/files/insights/pdf-attachments/2013-Medtech-GPOs.pdf.* Accessed May 30, 2018.

[1] AHIP. "Where Does Your Healthcare Dollar Go?" May 22, 2018.

nificant actions must be taken to address the root cause of the core problem: drug manufacturers—and drug manufacturers alone—set list prices too high and continue to raise them at unsustainably high rates.

Below we describe how the current marketplace enables the brand pharmaceutical industry to set excessively high drug prices and increase them by rates that often far exceed general inflation. We then present bipartisan, market-based solutions that improve prescription drug affordability while at the same time foster innovation and preserve access to novel therapies. CSRxP firmly believes that without major actions by this Committee and others, the pharmaceutical industry will continue to excessively profit from the anti-competitive and unsustainable pricing practices that make prescription drugs unaffordable and jeopardize access for the patients who need them. We look forward to working with the Committee to curbing unfair drug company pricing practices and implementing these bipartisan, market-based solutions that blunt the unsustainable growth in out-of-control prescription drug prices.

I. Growth in U.S. spending on prescription drugs is unsustainable and exceeds spending in other parts of the U.S. healthcare sector.

U.S. spending on prescription drugs is growing at an unsustainable rate—one that exceeds the rate of growth in other categories of U.S. healthcare spending. Although 2018 showed a slightly smaller growth rate in drug prices due in large part to heightened public attention over the unfair pricing practices employed by the pharmaceutical industry, historical data generally shows that spending on prescription drugs has grown at rates higher than other rates of medical spending and Medicare expenditures on Part Band Part D drugs have followed this overall historical trend.[2] To this point, the U.S. Department of Health and Human Services (HHS) Assistant Secretary for Planning and Evaluation (ASPE) found that Medicare Part B spending on prescription drugs increased at a rapid average annual rate of 7.7 percent from 2005 to 2014; during that period, specialty biologic medicines grew at a particularly fast rate, increasing from 39 percent to 62 percent of total spending, with a significant share of the growth due to price increases rather than number of patients using the medications.[3] Likewise, the HHS Office of the Inspector General (OIG) recently found that Medicare Part D spending for brand drugs grew by 77 percent from 2011 to 2015 (or 62 percent when netting out manufacturer rebates)—even though the actual number of prescriptions fell by 17 percent over the period, suggesting price increases contributed substantially to the growth in overall Part D spending.[4]

II. The brand pharmaceutical industry is driving excessive drug cost growth by setting needlessly high list prices for its products and increasing those prices by amounts that substantially exceed inflation after they enter the market.

Despite efforts from the brand drug industry to suggest otherwise, the drug industry—and the drug industry alone—is the primary driver of the needlessly high and unsustainable prescription drug prices and costs that American consumers and taxpayers face today. Brand manufacturers set high launch prices for their products and typically increase those prices at rates that far exceed inflation. As healthcare expert Avik Roy recently said: "[I]n the absence of competition, manufacturers frequently charge the highest prices they believe they can justify in the court of public opinion."[5]

To this point, one recent analysis concluded that the increasing costs of prescription drugs were due largely to price increases imposed by manufacturers of drugs already on the market. From 2008 to 2016, the analysis found costs of oral and injectable drugs increased by 9.2 percent and 15.1 percent, respectively, on an an-

---

[2] In 2014, for example, while overall growth in U.S. healthcare spending increased by 5.5 percent, prescription drugs grew by 12.6 percent, according to Keehan et al. Similarly, in 2015, while overall growth in U.S. healthcare spending increased by 5.8 percent, growth in spending on prescription drugs increased by 9 percent and outpaced spending on all other medical services, according to Martin et al.

[3] HHS Assistant Secretary for Planning and Evaluation. "Medicare Part B Drugs: Pricing and Incentives," page 6. March 8, 2016.

[4] HHS OIG. "Increases in Reimbursement for Brand-Name Drugs in Part D." June 2018.

[5] Roy, Avik. "Drug Companies, 'Not Middlemen,' Are Responsible for High Drug Prices." *The Apothecary.* October 22, 2018.

nual basis with existing drugs contributing to much of the growth.[6, 7] Costs increased for specialty oral and injectable drugs by 20.6 percent and 12.5 percent, respectively, with 71.1 percent and 52.4 percent of these increases attributable to new drugs.[8] A separate recent study from AARP found that retail prices for 87 percent of the most widely used brand name drugs by older Americans increased from 2016 to 2017, with 30 percent having price increases of 10 percent or higher.[9] Overall, prices for prescription drugs in the AARP study increased by an average of 8.4 percent from 2016 to 2017—or four times the 2.1 percent rate of general inflation for the period.[10] These 2017 price increases followed average double-digit annual price increases every year from 2012 to 2016.[11]

High-cost specialty medications in particular are driving much of this unsustainable growth in prescription drug prices and spending. Pharmacy benefit manager Express Scripts reported, for example, that even with strategies in place to lower costs for consumers on specialty medications, growth in commercial spending on high-cost specialty products far outpaced growth in overall prescription drug spending in 2017: 11.3 percent versus 1.5 percent.[12] Similarly, a separate AARP analysis found that retail prices for 101 widely used specialty drugs increased by 9.6 percent in 2015, continuing the increasing trend of specialty product price increases seen since 2006.[13] In 2015, the average annual cost of for a single specialty medication used on a chronic basis exceeded $52,000, with the annual cost of these therapies growing by almost $35,000 from 2006 to 2015.[14]

III. Drug manufacturers suggest that research and development (R&D) justifies high drug prices—but data show that the excessive amounts charged to *U.S.* patients in aggregate exceed the industry's *global* R&D budget.

Researchers have found that the drug prices paid by U.S. consumers create significantly more revenue for the brand pharmaceutical industry than the amount the industry expends globally on research and development. Specifically, the research concluded that the 15 drug companies manufacturing the 20 best-selling drugs worldwide in 2015 made $116 billion in excess revenue from U.S. drug prices.[15, 16]

Meanwhile, brand drug makers only spent $76 billion—or $40 billion less—on global research and development that same year.[17] As one author of the analysis, Dr. Peter Bach, Director of Memorial Sloan Kettering Cancer Center's Center for Health Policy and Outcomes, clearly said: "the math doesn't work out."[18] Indeed, when discussing the relationship between drug prices and industry research and development costs, John Hopkins University professor of health policy and management Gerard Anderson recently said: "Research and development is only about 17 percent of total spending in most large drug companies. Once a drug has been approved by the FDA, there is minimal additional research and development costs so drug companies cannot justify price increases by claiming research and development costs."[19]

Moreover, brand drugs with the highest prices sometimes are the ones that are the least costly to develop, indicating that a drug maker's R&D budget does not necessarily justify the setting of high drug launch prices or imposing price increases

---

[6] Hernandez et al. "The Contribution of New Product Entry Versus Existing Product Inflation in the Rising Cost of Drugs." *Health Affairs.* Vol. 38, No. 1. January 2019.

[7] Kodjak, Alison. "Prescription Drug Costs Driven by Manufacturer Price Hikes, Not Innovation." *National Public Radio.* January 7, 2019.

[8] Hernandez et al. "The Contribution of New Product Entry Versus Existing Product Inflation in the Rising Cost of Drugs." *Health Affairs.* Vol. 38, No. 1. January 2019.

[9] AARP Public Policy Institute. "Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans: 2017 Year-End Update," page 8. September 2018.

[10] *Ibid.,* page 5.

[11] *Ibid.,* page 6.

[12] Express Scripts. "2017 Drug Trend Report," page 4.

[13] AARP. "Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans, 2006 to 2015," page 1. September 2017.

[14] *Ibid.*

[15] Note that this study looked at net prices—not list prices—that U.S. consumers paid for prescription drugs. Net prices reflect discounts and rebates that pharmacy benefit managers, wholesalers, pharmacies, and other members of the supply chain negotiate with drug manufacturers to lower the list price initially set.

[16] Yu, Nancy et al. "R&D Costs for Pharmaceutical Companies Do Not Explain Elevated U.S. Drug Prices." *Health Affairs Blog.* March 7, 2017.

[17] *Ibid.*

[18] Sagonowsky, Eric. "High U.S. Drug Prices Cover Pharma's Global R&D—And a Whole Lot More, Study Finds." *Fierce Pharma.* March 10, 2017.

[19] Kodjak, Alison. "Prescription Drug Costs Driven by Manufacturer Price Hikes, Not Innovation." National Public Radio. January 7, 2019.

that vastly exceed inflation. In other words, high prices do not necessarily correlate with the innovative R&D that the pharmaceutical industry maintains it is supporting in part through high drug prices, as a separate analysis concluded.[20] This analysis found that the "costliest drugs to develop are those which require large phase III clinical trials involving tens of thousands of patients, such as drugs for diabetes, high blood pressure, and heart disease. . . . But, in fact, new drugs in these areas have little pricing power, because doctors have the ability to prescribe effective and inexpensive generics for these conditions."[21] By contrast, the "cheapest drugs to develop are those which require small clinical trials involving dozens of patients, such as drugs for ultra-rare, or 'ultra-orphan' conditions. . . . Phase III trials for these conditions, which only affect several thousand people in the United States, run in the tens of millions. But manufacturers have generated billions in revenues from them."[22]

IV. Out-of-control drug prices paid by U.S. consumers enable the drug industry to pay for needless advertising and marketing—and contribute to drug makers' profitability and bottom lines.

If the drug industry does not spend all of the money it receives from U.S. consumers on its products on R&D as shown above, the question arises as to where the industry actually spends those excessive revenues. It turns out that brand manufacturers are using a significant portion those funds for marketing and advertising—and to increase their bottom lines.

First, the drug industry spends a significant amount of money on direct-to-consumer (DTC) advertising—over $5.5 billion in 2017, including nearly $4.2 billion on television advertising.[23] In 2016, drug advertising represented the sixth largest category of TV advertising, accounting for 8 percent of total TV advertising revenue and increasing six places from 12th place in the category in 2012.[24] Of significant concern is the fact that many brand drug manufacturers spend more on advertising and marketing than R&O. One analysis found that 9 of the 10 largest drug companies spent more on sales and marketing, including marketing directly to prescribers, than they did on research in 2013.[25]

Importantly, while brand drug manufacturers suggest marketing and advertising help inform patients and their providers of treatment options, these industry tactics can result in unnecessary utilization of often expensive prescription drugs, causing needless out-of-pocket spending by patients on drugs that they may or may not need based on their individual medical conditions or that may not be the most cost-effective choice according to their individual insurance plans. Indeed, research has shown that DTC advertisements can induce demand and increase unnecessary utilization.[26, 27, 28] One recent survey found, for example, that one in eight adults (12 percent) reported a doctor prescribed them a specific drug after asking about it as a result of seeing or hearing a DTC advertisement.[29] Notably, unnecessary utilization increases costs not just for the patients who use them, but also for all consumers through higher aggregate healthcare spending—which must be paid for in part by higher consumer premiums.[30]

Second, and very importantly, brand drug manufacturers depend on these unsustainable high drug prices to help support their bottom line growth; price increases now are replacing a decline in prescription volume that the industry is facing for at least certain types of medications. To this point, a recent analysis concluded that between 2011 and 2014, sales from the top 10 drugs increased 44 per-

---

[20] Roy, Avik. "The Competition Prescription: A Market-Based Plan for Making Innovative Medicines Affordable," page 7.
[21] *Ibid.,* page 7.
[22] *Ibid.,* page 8.
[23] 83 FR 52792.
[24] Appleby, Anne and Horovitz, Bruce. "Prescription Drug Costs Are Up; So Are TV Ads Promoting Them." *USA Today.* March 16, 2017.
[25] Swanson, Ana. "Big Pharmaceutical Companies Are Spending Far More on Marketing Than Research." *The Washington Post.* February 11, 2015.
[26] Dhaval, Dave and Saffer, Henry. "Impact of Direct-to-Consumer Advertising on Pharmaceutical Prices and Demand," 79 *Southern Economic Journal* 97–126 (2012).
[27] Balaji, Datti and Carter, Mary W. "The Effect of Direct-to-Consumer Advertising on Prescription Drug Use by Older Adults," 23 *Drugs Aging* 71–81 (2006).
[28] Mintzes, Barbara et al. "Influence of direct to consumer pharmaceutical advertising and patients' requests on prescribing decisions: Two site cross sectional survey," 324 *The BMJ* 278–29 (2002).
[29] Kaiser Health Tracking Poll. October 2015.
[30] 83 FR 52793.

cent even though *prescriptions* for the medications decreased by 22 percent.[31] Likewise, yet another analysis determined that drug price increases contributed $8.7 billion to net income for 28 companies analyzed, representing 100 percent of earnings growth for those companies in 2016.[32] Hence, it seems very unlikely that brand drug makers have little to any incentive to curb the unsustainable and excessive growth in prescription drug prices absent bipartisan action to change these unfair pricing practices and tactics employed by drug companies that hurt American patients and their families every day.

V. Bipartisan, market-based solutions can help rein in unfair drug company pricing practices that have caused out-of-control drug prices to increase at unsustainable rates.

CSRxP supports adoption of bipartisan, market-based solutions to help curb the excessive and unsustainable growth in prescription drug prices for U.S. consumers and taxpayers. To that end, CSRxP strongly urges the Committee to consider enactment of legislation that would implement the following policies to promote transparency, foster competition, and incentivize value in the marketplace, making prescriptions drugs more affordable and accessible for the patients who need them while at the same time preserving incentives for innovation and new drug development.

Promote Transparency

CSRxP ardently believes that improving transparency in prescription drug pricing is a critical component to making prescription drugs more affordable for consumers and taxpayers. Among other benefits, increased transparency will better enable transformation of the U.S. healthcare system toward one based on value; will better inform patients, prescribers, and dispensers of actual drug costs as they determine the most appropriate treatments to meet individual patient needs; and encourage drug makers to actually justify the high prices they set for their products. Hence, CSRxP urges the Committee to consider policies that promote pricing transparency, including:

- **Require drug manufacturers to include list prices in all forms of direct-to-consumer (DTC) advertising:** DTC advertising has come under scrutiny as prescription drug spending takes up a bigger portion of health care dollars each year both for consumers and taxpayers and has the potential to lead to over-utilization of—and unnecessary spending on—high-cost medicines. Requiring the inclusion of list prices—as well as price increases—in all forms of DTC advertising will make patients much more aware of prescription drug costs when they talk with their providers about treatment options for their individual healthcare needs.
- **Mandate that drug makers release details of a drug's unit price, cost of treatment, and projection on federal spending before FDA approval:** Given the significant impact pharmaceuticals have on overall health care spending, manufacturers should be required to disclose information on the estimated unit price for the product, the cost of a course of treatment, and a projection of federal spending on the product so that patients, providers, taxpayers and policymakers have a better understanding of actual treatment costs.
- **Require drug companies to annually report increases in their drugs' list prices:** Similar to requirements already in place for other entities like health plan issuers, hospitals and nursing facilities, pharmaceutical companies should have to report increases in drug' s list price on an annual basis, as well as how many times during the year the price has increased. To this end, CSRxP urges the Committee to consider the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act, which would require manufacturers to report to HHS expensive drugs with significant price increases.
- **Compel drug manufacturers to disclose R&D costs:** Drug makers should be required to disclose how much research was funded by public entities like the National Institutes of Health (NIH) or other academic entities or by other private companies, so that regulators and taxpayers can properly weigh return on investment.
- **Produce annual HHS reports on overall prescription drug spending trends and price increases for individual prescription drugs:** HHS

[31] Humer, Caroline. "Analysis: Drugmakers Take Big Price Increases on Popular Meds in U.S." *Scientific American.*

[32] Tirrell, Meg. "The Drug Industry Is Addicted to Price Increases, Report Shows." *CNBC.* April 20, 2017.

should produce and publicly release annual reports covering (1) overall prescription drug pricing trends similar to the one produced by the HHS ASPE in March 2016; and (2) the top 50 price increases per year by branded or generic drugs; the top 50 drugs by annual spending and how much the government pays in total for these drugs; and historical price increases for common drugs, including those in Medicare Part 8.[33] These important pieces of information will better inform patients, prescribers, dispensers, policymakers, and taxpayers about the high drug prices and substantial costs of prescription drugs that U.S. consumers face today.

- **Update routinely and expand the amount of information available on the Medicare and Medicaid Drug Dashboards:** The Medicare and Medicaid Dashboards have provided valuable data and information to consumers and providers on prescription drug costs in a transparent manner. HHS should continue routinely updating information included on both dash boards, including list prices, price increases, and year-over-year pricing data, among other data points, so that consumers have a more transparent understanding of the prescription drug cost increases they face each year.

Foster Competition

CSRxP strongly believes that bringing more competition to the prescription drug market will give consumers more choices and more control—resulting in lower prices and improved access. As such, we urge the Committee to consider policies that foster competition, including:

- **Curb misuse of FDA's Risk Evaluation Mitigation and Strategy (REMS) program:** FDA uses the REMS program to allow products with potential safety issues to enter the market. Drug manufacturers often abuse REMS to block generic drugs from obtaining samples of brand drugs under the guise of addressing patient safety concerns, effectively preventing them from pursuing the research needed to bring generic drugs to market. There is concern that this practice could extend into the burgeoning biosimilars market as well. To thwart this anti competitive practice by manufacturers, CSRxP urges quick enactment of bipartisan legislation—the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act and the Fair Access to Safe and Timely (FAST} Generics Act—that would curb misuse of REMS.
- **Give FDA additional resources to speed approval of generic drug applications—especially for lifesaving drugs and for drugs with no or limited generic competition:** The FDA faces a backlog of nearly 4,000 generic drug applications, yet approval times can be three or more years. The FDA should receive the resources necessary to clear this backlog and prioritize generic drug approval applications, especially for lifesaving drugs and drugs with no or limited generic competition.
- **Promote a robust market for more cost-effective biosimilars and interchangeable biologic products:** Biosimilars and interchangeable biologic products have the potential to expand treatment options and substantially lower prescription drug costs for consumers and taxpayers. For example, one study found that 11 biosimilars already approved for sale in Europe and elsewhere could generate approximately $250 billion in savings over 10 years if they were available in the U.S.[34] Multiple policies could bolster the burgeoning U.S. market for biosimilar and interchangeable biologics, including:
    - **Shorten market exclusivity for brand biologics from 12 years to 7 years:** Currently, reference biologics enjoy a 12 year market exclusivity period. Analyses suggest this amount of time may be unnecessary and prevents lower-cost alternatives from entering the market.
    - **Speed the availability of interchangeable biologics:** FDA should release final guidance documents on interchangeable biologic development so that developers of these products have more regulatory certainty.
    - **Educate patients, providers, and payers about the value, safety, and effectiveness of biosimilars:** FDA and the Centers for Medicare and Medicaid Services (CMS) should engage in a robust education campaign to increase physician and patient confidence about these products and encourage their use.

[33] HHS ASPE. "Observation on Trends in Prescription Drug Spending." March 8, 2016.
[34] Express Scripts. "The $250 Billion Potential of Biosimilars." April 23, 2013.

- **Improve information in FDA's Purple Book:** FDA should increase the amount of information available and make the Purple Book more user-friendly so that developers of biosimilars and interchangeable biologics better understand the regulatory landscape they face when developing these products.

- **Target exclusivity protections to the most innovative products:** Drug manufacturers can extend patent and market exclusivity protections by seeking approval for a "new" product that is essentially the same as the original product, such as extended release formulations or combination therapies that simply combine two existing drugs into one pill. These anti-competitive tactics—often referred to as "evergreening" or "product hopping"—inhibit entry of generic drugs into the market. For example, a recent analysis suggested that anti-competitive drug reformulations potentially can result in up to $2 billion in losses per anti-competitive reformulation for consumers each year.[35] Appropriate federal agencies should closely monitor these schemes and prosecute if they find any violation of anti-trust laws.
- **Target Orphan Drug incentives to those products that treat orphan diseases:** The Orphan Drug Act introduced a range of incentives to encourage the development of medications to treat rare diseases that treat a patient population of 200,000 or less individuals. A recent investigation found that about a third of orphan approvals by the FDA since the program began have been either for repurposed mass market drugs or for drugs that have received multiple orphan approvals; of the approximately 450 drugs that have garnered an orphan designation since the program's inception in 1983, more than 70 were first approved for mass market use.[36] Given the potential for abuse, steps should be taken assess such trends and ensure that the Orphan Drug Act's incentives are utilized to develop medicines to treat truly rare diseases.
- **Reduce drug monopolies by incentivizing competition for additional market entrants:** Several FDA programs are intended to expedite review of new drugs that address unmet medical needs for serious or life-threatening conditions. Incentives should drive competition for expensive treatments where no competitors exist and encourage a second or third market entrant.
- **Strengthen post-market clinical trials and surveillance:** Currently, expedited drug approvals often involve small clinical trials with a narrow patient population and trials are not regularly reported publicly. Once a drug enters the market, research into the long-term efficacy and side effects should continue within specific timeframes and reporting requirements. Even if a product is not approved, manufacturers should be required to report data for all trials that summarizes non-identifiable demographics and participant characteristics, primary and secondary outcomes results, and adverse event information.
- **Thwart abuse of the patent system:** Drug companies increasingly have used "patent thickets" and "patent estates" to game the regulatory system and inappropriately extend market exclusivity for their products. A recent study of the roughly 100 best-selling drugs between 2005 and 2015 found, for example, that on average 78 percent of the drugs associated with new patents in the FDA's records were not for new drugs coming on the market, but rather for existing drugs.[37] These anti-competitive abuses of the patent system to extend brand drug market monopolies should be stopped by having appropriate Federal agencies apply increased scrutiny to biopharmaceutical patents. In addition, Congress should enact the Preserving Access to Cost-Effective Drugs (PACED) Act to prevent drug manufacturers from transferring their patents to Native American tribes with sovereign immunity.
- **Curb anti-competitive "pay-for-delay" settlements:** Brand and generic drug makers enter into patent dispute settlements—often referred to as "pay-for-delay" settlements—that result in a generic company agreeing to refrain from marketing its products for a specific period of time in return for compensation (often undisclosed) from the branded company. The Federal Trade Commission (FTC) has cited these arrangements as anti-competitive and estimates that

---

[35] Shadowen, Steve et al. "Anticompetitive Product Changes in the Pharmaceutical Industry." *Rutgers Law Journal,* Vol. 41, No. 1–2, Fall/Winter 2009. Page 78.

[36] Tribble and Lupkin. "Drugmakers Manipulate Orphan Drug Rules to Create Prized Monopolies." *Kaiser Health News.* January 17, 2017.

[37] Feldman, Robin et al. "May Your Drug Price Ever Be Green." UC Hastings Research Paper No. 256. October 31, 2017, page 48.

they cost consumers and taxpayers $3.5 billion in higher drug costs every year.[38] More recently, these settlements unfortunately have extended to biologics, delaying the entry of less costly biosimilars into the market. For example, the top-selling product in the world, Humira, with global sales exceeding $18 billion in 2017 and a more than doubling of its price over the past five years, will not face biosimilar competition until 2023 due to a settlement agreed to by the brand and biosimilar manufacturer of the product.[39, 40, 41] Federal agencies should apply increased scrutiny to these "pay-for-delay" agreements so that consumers can access more affordable generic drugs and biosimilars.

- **Improved flexibility to better manage high-cost medications in Medicare Part D:** High-cost drugs are significant drivers in the unsustainable growth in prescription drug costs. With increased flexibility and additional tools employed in the commercial sector, health plans can employ their substantial private sector experience to Medicare Part D and lower costs particularly for high-cost medications while maintaining appropriate beneficiary access to treatments needed to get well and stay healthy.

Incentivize Value

CSRxP believes that patients deserve reliable information regarding whether a drug's "therapeutic outcome"—or its health benefit—is in line with its price. This information is critical to moving America's prescription drug market toward a system that empowers doctors and patients to choose medications based on the value they provide—not the "value" set by drug manufacturers. Therefore, CSRxP urges the Committee to consider policies that would incentivize greater incorporation of value into the use and purchase of prescription drugs, including:

- **Increase funding for private and public research efforts like the nonprofit Institute for Clinical and Economic Review (ICER) to test the value of medical tests and treatments.** Investment in objective information is critical for physicians, patients and payers as more and more high-price drugs enter the healthcare system.
- **Require drug makers to conduct comparative effectiveness research (CER) studies of new versus existing drug products.** Through CER studies, manufacturers should have to demonstrate that their product is better than others, so that physicians and patients can make smart decisions about the value of different treatments, particularly those with very high costs. Many other countries currently require drug manufacturers to provide CER studies; they should be expanded in the U.S. to reduce spending on unnecessary or ineffective treatments.
- **Expand value-based pricing in public health programs like Medicare and Medicaid.** Currently Medicare and Medicaid purchase prescription drugs for their beneficiaries, but not generally in a manner to accommodate value-based payment models. Steps should be taken to ensure these program can best take advantage of recent developments in value-based purchasing to ensure all parts of the U.S. healthcare system benefit from market-based negotiating efforts to lower drug prices.

VI. Conclusion

In conclusion, CSRxP again thanks the Committee for the opportunity to submit testimony for the record to address the unsustainable and excessive growth in prescription drug prices in the U.S. We very much appreciate the leadership from the Committee in addressing this critically important issue that affects American patients and their families every day. Policies must be implemented to address the root of the problem: brand drug makers set list prices too high and increase them at excessively high rates. Prescription drug prices will continue to grow at unacceptably unsustainable rates unless serious actions are taken to thwart the anti-competitive pricing practices of the brand industry. CSRxP looks forward to working with the Committee to implementing bipartisan, market-based policies that promote transparency, foster competition, and incentivize value to make prescription drugs more

---

[38] FTC. "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions." January 2010.

[39] AbbVie. "AbbVie Reports Full-Year and Fourth-Quarter 2017 Financial Results." January 26, 2018.

[40] Reuters. "AbbVie, Amgen settlement sets Humira U.S. biosimilar launch for 2023." September 28, 2017.

[41] The Center for Biosimilars. "Latest Humira Price Increase Could Add $1 Billion to U.S. Healthcare System in 2018." January 5, 2018.

affordable for all consumers while at the same time maintaining access to the treatments that can improve health outcomes and save lives.

CENTER FOR FISCAL EQUITY
14448 Parkvale Road, Suite 6
Rockville, Maryland 20853
fiscalequitycenter@yahoo.com

Statement of Michael G. Bindner

Chairman Grassley and Ranking Member Wyden, thank you for the opportunity to submit these comments for the record to the Committee on Finance.

As you may recall from last year's hearing and before, we have advocated for a combination of catastrophic insurance, health savings accounts (Archer) and medical lines of credit, which is a bit more liquid version of a flexible spending account, with all accessed by one card with costs allocated based on account balances and income levels. Poor people would have minimum or even no copays, but would always have credit access. As income rises, so would copays and available balances, as well as catastrophic deductibles. Suchplan, however, has no chance of passage and if adequate to maintain access, would not save money either. We no longer endorse this approach

Our proposed Net Business Receipts Tax/Subtraction Value-Added Tax would replace corporate income taxes and proprietary and pass through taxes and treat all business income the same. It would provide for the health insurance exclusion or fund single payer insurance.

Single payer health care, aka, Medicare for All (with Medicaid level copays and premiums) could allow consumer advertising to be waste if the government plays hardball with drug makers, although for now it cannot even play hardball on Medicare Part D purchases. In single payer, there would likely be VAT funding, and advertising costs would come with a VAT paid to the advertiser and passed along to the consumer.

Companies who hire their own doctors and pharmacists and buy their own drugs would get a tax exclusion from single payer (third party insurance would be discouraged), and would negotiate with drug makers for lower prices, although this would leave small firms at a distinct disadvantage and would discourage such practices as franchising and 1099 employment. Still, on the whole, it would decrease cost while not discouraging innovation. Expanding the Uniformed Public Health Service into the Medicare and Medicaid markets (edging out HMOs) would also lead to cost cutting on drugs.

Limiting advertising has been proposed by Senator Shaheen and her cosponsors. This dances on limiting the freedom of speech, although this is not absolute for commercial speech. The FDA could limit these ads, as could the Federal Trade Commission.

While some favor restricting patent rights, I would argue in favor of having every drug approval disclose all government supported research used to develop the product, giving the sponsoring agency the right to both share in the profits and have a say in the pricing. This both keeps the research dollars flowing and limits cost.

A main problem with high cost drugs, especially orphan drugs, is the high development costs and the cost of small batch manufacturing. This could drive the need to raise drug prices for mature drugs in order to subsidize the orphans, although some hikes are undertaken because no one can stop them. The solution for this is for NIH and the FDA to own the rights to orphan drugs and to contract out research and development costs as it does basic research, as well as testing and production.

Pharma would still make reasonable profit, but the government would eat the risk and sometimes reap the rewards. HIH/FDA might even break even in the long term, especially if large volume drugs which were developed with government grants must pay back a share of basic research costs and the attached profits, as well as regulatory cost.

Thank you for the opportunity to address the committee. We are, of course, available for direct testimony or to answer questions by members and staff.

COALITION FOR AFFORDABLE PRESCRIPTION DRUGS

U.S. Senate
Committee on Finance
Dirksen Senate Office Bldg.
Washington, DC 20510-6200

Tuesday, January 29, 2019

The Coalition for Affordable Prescription Drugs (CAPD) appreciates the opportunity to submit the following statement for the record.

The Senate Finance Committee will discuss a critical concern of Americans across the country: how to alleviate the burden of high and ever-rising prescription drug prices on seniors, patients, and their families. In fact, a recent *Politico*/Harvard Chan School of Public Health poll showed that 80 percent of Americans see high prescription drug prices as a top priority for the new Congress and the Administration.

CAPD and our members—a diverse group of employers, unions, public sector employees and retirees who partner with pharmacy benefit managers (PBMs) to provide more affordable prescription drug coverage for millions of Americans—encourage policymakers to address this critical issue and believe that any workable solutions must recognize the root cause of this problem: drug companies setting the high price of their medicines, and often raising those prices multiple times a year for the exact same product.

Drug Company Price Hikes Driving High Drug Prices

Despite the public outcry, drug manufacturers show no signs of reversing this trend. Since January 1st, we have witnessed price hikes on over 250 medications.

These increases include Humira, which remains the world's top-selling prescription drug. This year's increase in Humira's price came on top of another 9.7 percent price increase at the start of 2018. In another example, Allergan raised prices on 50 of its drugs, half of which were increases of at least 9.5 percent. Over the last five years, prices increased on the top 20 most prescribed brand-name drugs for seniors by an average of 12 percent each year.

The truth is simple: Drug companies hike their prices because they can. When they do so, millions of patients pay more at the counter. And they continue to do so year after year. One way to prevent ever-increasing price hikes is to stop the gamesmanship of the patent and regulatory systems that drug companies use to maintain their monopoly pricing power and keep lower-cost generic alternatives from entering the market.

Brand drug manufacturers exploit the FDA Risk Evaluation and Mitigation Strategies (REMS) program to prevent generic drug makers from accessing needed samples, costing the U.S. health care system $5.4B each year. The CREATES Act, which passed out of the Senate Judiciary Committee last year, is a targeted, market-based, bipartisan solution to the longstanding problem of brand name pharmaceutical companies denying generic manufacturers access to the samples they require to conduct necessary equivalence testing to bring their product to market. We encourage Congress to pass this bipartisan legislation and explore other proposals that target patent and regulatory abuses by drug companies in order to lower drug prices for patients.

Another way brand drug manufacturers game the patent and regulatory system is through "pay-for-delay" deals, in which drug makers engage in anticompetitive patent settlements with potential generic competitors, resulting in $3.5B in higher drug costs each year. In the most high-profile example of these abuses, drug maker AbbVie last year reached agreements with Amgen, Samsung Bioepis and Mylan to delay entry of a lower-cost biosimilar version of the drug to 2023 in the United States.

PBM Value

In the face of rising drug prices, pharmacy benefit managers (PBMs) partner with employers, unions, public sector retirees and other organizations who purchase health care to help manage prescription drug coverage for millions of Americans. By negotiating with drug companies and providing patient-centered tools to improve care and help lower out-of-pocket costs, PBMs save over $900 per person each year.

In addition, PBMs are expanding visibility into drug prices by enabling doctors and patients to see the price of various medicines at the point of prescribing, based on

the individual's specific drug benefits, so they can make more informed decisions. Nearly 20 percent of the time, physicians switch to a more affordable medicine when clinically equivalent alternatives are offered through UnitedHealth Group's RTBT, PreCheck MyScript, and 30 percent of prior authorizations are avoided or initiated electronically. CVS Health's Real Time Benefits tool has saved patients an average of $120 to $130 per fill.

PBMs are most effective in delivering savings for patients and the employers, unions and public sector retirees they partner with when there is competition in the marketplace. When competition is undermined though regulatory schemes or abuses of the patent system, drug companies maintain their monopoly pricing power and continue to raise prices at will.

Policymakers are considering proposals to address these patent and regulatory abuses and we believe the time to act is now. CAPD is committed to working with Congress and other stakeholders on this and other solutions to meaningfully lower prescription drug prices for all Americans. We look forward to supporting this critical effort.

Debra Barrett
Executive Director, Coalition for Affordable Prescription Drugs

Contact: Meghan Scott
Spokesperson, Coalition for Affordable Prescription Drugs
mscott@affordableprescriptiondrugs.org
(202) 341–2060

LETTER SUBMITTED BY BRUCE CUTLER

February 1, 2019

U.S. Senate
Committee on Finance
Dirksen Senate Office Bldg.
Washington, DC 20510–6200

cc: Jerry Moran, U.S. Senate, SD 521; Pat Roberts, U.S. Senate, SH 109; Steven Watkins, 1205 Longworth House Office Building

I wish to comment on the cost of insulin for treatment of Type 1 diabetes. I was diagnosed nearly 55 years ago with Type 1 diabetes. Until about 20 years ago prices of insulin were reasonable, however since that time the cost of insulin has multiplied extravagantly. I take a low-moderate amount of insulin daily, unlike some younger diabetics who may need larger amounts. The monthly cost of my insulin before Medicare and Part D coverage is ~$760/month. I am fortunate that I have the insurance coverage that I do, and am able to afford it, as well as the out-of-pocket costs. However, for those less fortunate, it means going without their recommended daily dosage, and the resulting damage such as, blindness and kidney disease requiring dialysis puts a significant burden, not only on the individual but on society as a whole. There is no cheaper, alternative substitute for insulin. As such the pharmaceutical industry has a captive market and they are milking it for all it is worth. Further, there have been no huge breakthroughs in insulin manufacture and formulation in the past 15 years that could justify supposed R&D investment to the tune of 10 or more times the cost of what it was at the turn of the century. Even suppliers of illicit drugs work to keep the cost of their product down, we have seen no such restraint in the suppliers of insulin.

Respectfully,

Bruce Cutler

LETTER SUBMITTED BY DAVID J. DUBOURDIEU

U.S. Senate
Committee on Finance
Dirksen Senate Office Bldg.
Washington, DC 20510–6200

Dear Sirs:

Thank you for finally turning your attention to the fact that market forces are not involved in setting "prices" in the health-care product industry.

There is clearly no relationship whatsoever between the costs of producing these products and the prices which are charged for them.

There is also clearly no "market" at work here: no informed group buyers selecting product from a range of suppliers and using "price" and "features" as the information to make a purchase decision.

Instead, there is a collection of businesses who have succeeded in taking control of all aspects of (a) government, (b) the medical community, and (c) the insurance industry to manipulate a result highly beneficial to themselves.

Let me relate several personal cases.

Last night, I purchased a 60 gram bottle (7 inches high) of a skin treatment for psoriasis named Enstilar from Leo Laboratories, Dublin, Ireland. This bottle cost me $745. The pharmacist was very helpful and spend a great deal of time today on the web and on the phone with the manufacturer. It turns out the list price is $1,200, and because I have good private insurance and because they gave me a $300 discount, it was only $745. Perhaps they think I should be grateful to them. Their website, however, has the temerity to provide a "copay" card which should make the product available for "as little as $20."

My deceased wife Paula was hospitalized several times in her final year. Fortunately, I had good private insurance. The bills came, and there was the charge: $140,000 for her 10 day stay. However, the insurance company said "no, actually that bill is only going be $15,000 and your copay is $6,000." Again, they think I should be grateful. Obviously, 90% of that hospital price was not considered valid by anyone involved, just like the fact that 99% of the price of this Enstilar is not valid.

The same ridiculous situation was repeated at the Emergency Room at the Lake Forest Hospital, where the sham of posting a "price list" was invoked for several years. That price list meant nothing, and everybody knew it. They finally took it down after a while because it was clearly an embarrassing charade.

The definition of "Economics" is that it is the study of the allocation of scarce resources.

What we have here in America is an industry which does not use markets or pricing in any meaningful way. Some of us are old enough to still remember how we would mock the Soviet Union for its non-priced/non-market-based approach to the basic process of economics. We should realize that now we are doing the same with our healthcare products, and the injustice to our country and our people of this Soviet economic model calls out for our government to change this situation. We would not be a Soviet Communist nation, but we adopted their insane approach to our healthcare industry.

Sincerely,

David J. DuBourdieu

HEALTHCARE LEADERSHIP COUNCIL
750 9th Street, NW, Suite 500
Washington, DC 20001
(202) 452–8700 • (202) 296–9561
https://www.hlc.org/

January 29, 2019

The Honorable Charles E. Grassley
Chairman
U.S. Senate
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
U.S. Senate
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Grassley and Ranking Member Wyden:

The Healthcare Leadership Council (HLC) appreciates the opportunity to submit this letter for the U.S. Senate Committee on Finance hearing, "Drug Pricing in America: A Prescription for Change, Part I" on January 29, 2019.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC—hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, home care providers, and information technology companies—advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

Competition and Innovation

The U.S. healthcare system has seen an increase in the cost of prescription drugs which has adversely affected patients, providers, payers, and other healthcare stakeholders. Increases in drug prices are often due to the lack of competition in the prescription drug marketplace. As a diverse coalition of healthcare stakeholders across the U.S. healthcare system, we believe innovation is essential to increasing market competition to deliver affordable, cutting-edge drug therapies to the public. HLC believes policies that encourage competitive markets and support innovation will lower drug costs and improve access to treatment. Additionally, competition from generic drugs is critical to lowering drug prices. Addressing barriers to and encouraging the entry of new generic drugs into the market will create more competition and help to lower drug prices.

Promoting Value-Based Care

HLC supports a shift towards a value-based system that pays based on value versus volume. In a value-based system, payment for medications is tied to patient outcomes and achieving clinical targets. A value-based payment system creates a disincentive for inappropriate prescribing practices and overutilization, protecting both patient and federal healthcare dollars. However, the adoption of value-based systems, including for prescription drugs, has been stifled by laws designed to discourage inappropriate behavior in a fee-for-service payment model. The most notable barriers in our current healthcare system, the physician self-referral law ("Stark Law"), and the Anti-Kickback Statute require modernization as our healthcare system shifts from volume-based care to increasing the value of care. Modernization of federal fraud and abuse laws will enable pro-patient, value-focused collaboration among payers, providers, and manufacturers.

A significant regulatory barrier is the Medicaid Best Price rule requiring drug manufacturers to offer the Medicaid program the lowest price negotiated with any other buyer. This requirement can deter companies from entering into value-based contracts. To utilize value-based contracting, manufacturers must be able to work with providers and health plans to assess the efficacy of a certain drug in a clinical setting and then set prices based on the results. Under current regulations, if a manufacturer sets a substantially discounted price for a drug while waiting for an evaluation of patient outcomes that artificially lowered price would have to be offered to the Medicaid program. This creates a disincentive for pharmaceutical companies to accept increased risk in value-based contracting and thus, decreases patient access to innovative drug therapies.

Innovation, competition, and a collaborative environment for payers, providers, manufacturers, and patients are conduits for lowering prescription drug costs for all Americans. Thank you for examining this important issue and please feel free to reach out to Tina Grande, Senior Vice President for Policy, at (202) 449–3433 or tgrande@hlc.org with any questions.

Sincerely,

Mary R. Grealy
President

LETTER SUBMITTED BY HANNAH J. MIKESELL

To the Senate Committee on Finance:

I wanted to write a letter concerning my personal experiences with the outrageous prices of healthcare and prescriptions in the United States.

I am a Type 1 Diabetic, I was diagnosed 3 years ago and have already spent hundreds of thousands of dollars on hospital stays, medications and doctors visits. When I was first diagnosed I went through denial, I said this isn't happening to me, I

don't have to do any of this. I'm a cross country and track athlete; before I was diagnosed my running was suffering severely, and when I began using insulin my times greatly improved and I was feeling better all around. When I stopped taking insulin as part of my denial and rebellious teenager stage of my life I began to get sick again and my times became slower and slower.

This life changing experience of watching myself get sicker and sicker while holding in my hand the needle and drug that would reverse this and keep me alive convinced me to turn myself around. And so here I am. A collegiate runner at the most prestigious college in the state thriving as a pre-med chemistry and French major, but I've run into a new hurdle: I can't afford the drugs that keep me alive. Allow me to repeat that, I don't have the money for the one thing that keeps me alive.

Can you imagine making the decision between your own life and dinner or groceries? The answer is no for the majority of you, you've never been faced with this decision. I only make about $200 a month with a part time job, and that is not nearly enough for groceries and prescriptions. So I do the only thing I can do, I cut back on my insulin. In order to do that while remaining mostly healthy I have to greatly decrease my carbohydrate intake.

Type 1 diabetes means I don't have the hormone insulin to properly metabolize carbohydrates, and as a distance runner this is an extremely fine line to walk between eating well and maintaining blood glucose levels that don't dip too low or high. With a diet of reduced carbs I'm losing weight and training is becoming increasingly difficult, however if I eat a proper diet my sugars are too high and I run the risk of diabetic ketoacidosis and high A1C levels.

In French there is a saying that goes "entre le marteau et l'enclume" which (roughly) translates to "trapped between the devil and the deep blue sea" or in English we like to use "between a rock and a hard place." How am I supposed to make this impossible choice?

This is why I implore you to reduce the price of prescription drugs, so that young people like me can have a chance to succeed in life. I came very close to dying before being diagnosed my sophomore year of high school. Thanks to a fantastic staff of doctors and nurses I lived to see my junior and senior prom, my high school graduation and now I'm going to the college of my dreams, but at what cost? I plan on going to medical school, so along with fears of the crushing student loans and hitting the ceiling of federal aid I have to worry about the drugs that allow me to wake up each morning and do the things I love.

I don't want to have to rely on my (amazing) friends to give me their expired insulin, or loan me a couple hundred bucks they know won't be repaid anytime soon. I want to fall asleep each night knowing I'll wake up in the morning, and be able to live each day knowing I will have a tomorrow.

Please make a change that will benefit the nation you are representing, and help the people that voted you into office.

Thank you for your time,

Hannah J. Mikesell

NATIONAL RETIREE LEGISLATIVE NETWORK
601 Pennsylvania Avenue, NW, Suite 900, South Building
Washington, DC 20004–2601
Email: contact@nrln.org Toll Free: 866–360–7197

Congress and President Must Act to Reduce Price of Prescription Drugs

Talk Is Cheap—Drugs Are Not!

In spite of a lot of talk by members of Congress and the President on the importance of making prescription drug prices more affordable, 30 drug companies announced at the beginning of 2019 price increases in the United States on more than 250 drugs. The price increases—the first of more to come in 2019—ranged from 5% to 9.5%, well above the nation's rate of inflation.

Americans, Especially Seniors, Caught in Pharma's Perfect Storm

Americans, especially the 58 million Americans age 65 and older and people with disabilities on Medicare, are caught in the terrible perfect storm of prescription drug price gouging. They are taking more expensive medications while living on fixed in-

comes. Even with their Medicare Part D prescription drug plan they are paying substantial out-of-pocket costs. This means that they especially feel the pain of pharmaceutical companies' relentless price increases while bills that would provide lower prices have not been passed by Congress.

The 62 million seniors and people with disabilities who receive Social Security have been especially harmed. Since 1992, the growth in out-of-pocket healthcare costs, including prescription drugs, has outstripped Social Security's cost-of-living adjustments by more than a third.

Total U.S. prescription sales in the 2017 calendar year were $455.9 billion, according to a May 7, 2018 report by the American Journal of Health-System Pharmacy. On a per capita basis, inflation-adjusted retail prescription drug spending in the U.S. increased from $90 in 1960 to $1,025 in 2017, according to a February 14, 2018 report in *Health News.* In the same report, prescription drugs are expected to see the fastest annual growth over the next decade, rising an average of 6.3% per year, due to higher drug prices and more use of specialty drugs such as those for genetic disorders and cancer.

Per capita prescription drug spending in the United States exceeds that in all other countries—even 40% more than Canada for essentially the same medications—largely driven by brand-name drug prices that have been increasing in recent years at rates far beyond the Consumer Price Index (CPI). Just because there are more drugs on the American market, that doesn't mean all patients can access them. "To think that patients have full access to a wide range of products isn't right," Aaron Kesselheim, an associate professor of medicine at Harvard Medical School, said in a May 10, 2018 article on *Vox.Com.* "If the drugs are so expensive that you can't afford them, that's functionally the same thing as not even having them on the market."

Price Increases for Brand-Name Drugs

Brand-name prescription drug prices have doubled between 2008 and 2016 and retail prices for some of the most popular prescription drugs older Americans take to treat everything from diabetes to high blood pressure to asthma increased by an average of 8.4% in 2017, far exceeding the 2.1% inflation rate for other consumer goods and services, according to a September 26, 2018 report from the AARP Public Policy Institute.

A September 26, 2018 *Forbes* article reported that the Associated Press (AP) analyzed 26,176 changes in list prices for branded drugs from 2015 through mid-September 2018 and concluded drug companies raised prices more frequently than they cut them. In fact, price increases outpaced decreases by 16.5-to-1 in June and July 2018.

In July 2018, *Bloomberg* introduced a tool to track what has happened to prices for some of the most widely used drugs. The prices for 40 commonly used drugs in six categories—diabetes, cancer, HIV, multiple sclerosis, asthma and chronic obstructive pulmonary disease, and autoimmune diseases such as rheumatoid arthritis and psoriasis—were compared over a three-year period. Starting from June 2015, the indexes tracked the average percent increase in drug prices through late June 2018.

For all six categories of drugs, list prices rose far faster than inflation. Prices for 10 commonly used diabetes drugs rose 25.6%, on average, while average prices for rheumatoid arthritis and other autoimmune treatments rose 40.1%. The latter category includes AbbVie Inc.'s Humira, the biggest-selling drug in the world. Prices for the injection soared 52% on five separate price increases.

Americans Want Action to Reduce Drug Prices

Americans are outraged that they are losing access to lifesaving and life-enhancing treatments because they have become less and less affordable.

Three-quarters of Americans consider the cost of prescription drugs in the United States to be "unreasonable," despite promises from Congress and the President to rein in prices, according to poll results released on September 13, 2018 by the West Health Institute, a nonpartisan, nonprofit healthcare research organization, and conducted by NORG at the University of Chicago.

In that poll, only 16% approve of how of how Republicans in Congress are addressing high prescription drug prices and only 20% approve of what Democrats in Congress are doing to reduce drug prices. Only 23% of the public approves of how President Trump is dealing with the high cost of prescription drugs.

Also, the survey found that 82% of Americans favor allowing Medicare to negotiate directly with drug companies to get lower prices; 82% support allowing more generics to compete with name brand drugs; 80% want more transparency on pricing from drug companies; 65% want Americans to be allowed to purchase drugs from Canada, and 52% want prescription drug advertising eliminated.

"The rising cost of prescription drugs is a growing economic and public health crisis that hurts the U.S. economy and threatens individual health and financial security, and Americans want solutions. Unfortunately, they don't feel like they're getting them from Washington," said Shelley Lyford, president and CEO of the West Health Institute. "Our representatives in Washington D.C. need to make lower drug prices a reality instead of simply an empty campaign promise."

A poll conducted by Goldman Sachs (GS) Strategy Group and reported in an article in *The Hill* newspaper on February 5, 2018 showed 85.5% of registered voters surveyed think lowering the cost of prescription drugs should be a "top priority" or an "important priority" for Congress. The poll also showed three-fourths of registered voters think Congress and President Trump need to do more to lower the cost of drugs.

The Kaiser Family Foundation (KFF), a nonprofit, nonpartisan organization focused on health care, periodically conducts its Health Tracking Poll. Poll results released on March 23, 2018 found that approximately 80% of Americans think that the cost of prescription drugs is unreasonable, and 73% believe that pharmaceutical companies are making too much profit on their products.

Most respondents (72%) said that pharmaceutical companies have too much influence in Washington, 77% said that pharma's profits are a major factor contributing to the high cost of drugs, and just over half had an unfavorable view of pharmaceutical companies.

Respondents said that the government should negotiate lower prices for the Medicare program (92%); encourage generic market entry (87%); require manufacturers to disclose pricing information (86%), and allow for importation of cheaper drugs from Canada (72%). With respect to drug importation, more respondents (76%) felt confident that buying imported Canadian drugs would make medicine affordable without sacrificing quality versus buying drugs from Canadian online pharmacies (68%).

More than half of respondents (52%) said that passing legislation to bring down the price of drugs should be a top priority for Congress and President Trump.

The poll results were not unique to 2018. KFF reported poll results in March 2017 that more than half of Americans say that lowering the cost of prescription drugs is a top priority. The KFF poll in October 2016 found that 74% of responders said Congress and the President should make sure that high-cost drugs for chronic conditions are affordable to those who need them and 63% said the government should take action to lower prescription drug prices. A KFF poll of 1,800 Americans in July 2015 showed that allowing Medicare to negotiate lower drug prices is supported by 87% of Americans.

Despite the calls by Americans for actions by the 114th Congress (2015 and 2016), the 115th Congress (2017 and 2018) and two Presidential administrations, nothing tangible has been done to curtail prescription drugs prices.

NRLN Advocates Legislation to Reduce Drug Prices

Since 2009 the National Retiree Legislative Network (NRLN) has aggressively advocated federal legislation to curtail rising health care cost through more competition in America's pharmaceutical market through competitive bidding by Medicare for prescription drugs and the importation of safe lower cost prescription drugs from Canada and other nations that meet Federal Drug Administration (FDA) safety standards.

The NRLN supports passage of legislation for Medicare to be directed to take competitive bids for prescription drugs and allowing importation of safe and less expensive drugs from Canada.

NRLN's Position on Prescription Drug Competitive Bidding

Members of Congress have quoted CBO studies to wrongly justify a claim that the CBO and others have said that there would be very little savings if Health and Human Services (HHS) required competitive bidding for Medicare's drug business. These are old irrelevant claims. Other than two letters written in the 2006–2007 period by two incumbent CBO Directors to Oregon Senator Ron Wyden and others,

there are no published relevant studies made available to support this claim. It has been said that the Health and Human Services (HHS) Secretary would have to be authorized to set (not competitively bid) prices. In some cases, such as in chronic and fatal disease treatment drugs, this may be even more problematic today.

Total retail prescription drugs filled at pharmacies in 2017 reached 4.063 billion. Since 2007, generic drug availability has mushroomed from less than 20% of drugs dispensed in the U.S. to where today they represent around 90% of the pills, capsule and injected drug units sold. A growing number of these drugs treat the same ailments! And, a growing number will treat even more as drug patents expire. This data is not speculation or political rhetoric.

Current law bars Medicare from negotiating drug prices. This is known as the "noninterference" clause in the Medicare Modernization Act of 2003 which stipulates that the HHS Secretary "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors, and may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs." In effect, this provision means that the government can have no role in negotiating or setting drug prices in Medicare Part D.

Medicare is required to cover nearly all drugs that the Food and Drug Administration approves. This means that Medicare must cover drugs that aren't an improvement over what currently exists, so long as the FDA finds they're safe for human consumption. Drugmakers know that as long as their products are safe, Medicare must buy them.

CNN Business reported on May 15, 2018 that the Centers for Medicare and Medicaid Services (CMS) spent $174 billion on prescription medications in 2016, or 23% of its total budget. CMS has not updated its Drug Spending Dashboard for 2017 or 2018. The Congressional Budget Office (CBO) estimates that spending on Medicare Part D benefits will total $99 billion in 2019. A 2018 report by the U.S. Senate Homeland Security and Governmental Affairs Committee revealed that the Medicare program pays 61% higher prices for the 20 most commonly prescribed drugs than the Veterans Administration which negotiates for drug prices.

There is only one solution to this problem:

Congress should remove the prohibition on Medicare competitive bidding and replace it with a competitive bidding mandate to be applied wherever two or more FDA approved generic drugs, or two or more brand drugs, or a generic and brand drugs (upon patent expiration) treat the same medical condition.

The following prescription drug bills have been introduced in the 116th and one should be passed:

S. 62, Empowering Medicare Seniors to Negotiate Drug Prices Act would allow the Secretary of Health and Human Services to directly negotiate with drug companies for price discounts of their drugs, which is banned under current law. **Or . . .**

S. 99, Medicare Drug Price Negotiation Act, would direct the Secretary of Health and Human Services (HHS) to negotiate lower prices for prescription drugs under Medicare Part D. **Or . . .**

H.R. 275, To amend Medicare Part D to require the Secretary of Health and Human Services to negotiate covered Part D drug prices on behalf of Medicare beneficiaries.

NRLN's Position on Prescription Drug Importation

Countries that practice socialized medicine exact low prices for people served in their countries by demanding below market pricing from American pharmaceutical manufacturers.

As the prescription drug price gouging has taken place, tens of millions of generally law-abiding Americans have committed a technically illegal act in response by purchasing prescriptions, online or otherwise, outside the U.S., imported pills that are subject to confiscation.

Making it legal to import medication at a lower cost, will break the stranglehold of the drug companies on the throats of American patients.

There are two counter-measures to U.S. manufacturers being forced to take losses:

A. Pharma companies should exit these markets, thus protecting Americans and our economy from subsidizing socialized medicine.

B. To the extent pharma and Congress don't eliminate this unethical practice of absorption and passing of losses on to Americans and the U.S. economy, Congress must pass laws allowing importation of safe, and lower priced prescription drugs from Canada and elsewhere so that Americans and our economy benefit. Start with Canada NOW.

Congress Has Failed to Pass Drug Importation Bills

The following prescription drug bills have been introduced in the 116th and one should be passed:

S. 61, Safe and Affordable Drugs From Canada Act of 2019, would allow for the personal importation of safe and affordable drugs from approved pharmacies in Canada. **Or . . .**

S. 97, Affordable and Safe Prescription Drug Importation Act, which would allow patients, pharmacists and wholesalers to import safe, affordable medicine from Canada and other major countries. **Or . . .**

H.R. 447, To amend the Federal Food, Drug, and Cosmetic Act to allow for the importation of affordable and safe drugs by wholesale distributors, pharmacies, and individuals. **Or . . .**

H.R. 478, To amend the Federal Food, Drug, and Cosmetic Act to allow for the personal importation of safe and affordable drugs from approved pharmacies in Canada.

Pay-for-Delay on Generics Must Be Stopped

In a May 4, 2017 article in *ModernHealth.Com,* Dr. Scott Knoer, chief pharmacy officer of the Cleveland Clinic, said pharmaceutical companies have paid manufactures not to develop generics.

The NRLN urges Congress to pass legislation that bans pay-for-delay. The Supreme Court ruled on a single case that this practice restrained trade but that each case must be dragged through the courts for years while Americans—especially retirees—are denied access to cheaper generic drugs.

Congress should pass this bill:

S. 64, Preserve Access to Affordable Generics and Biosimilars Act, would prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market and to prohibit biological product manufacturers from compensating biosimilar and interchangeable companies to delay the entry of biosimilar biological products and interchangeable biological products.

President Trump's Plan for International Price Indexing

President Trump announced on October 25, 2018 that his administration is moving to stop "global freeloading" by foreign nations when it comes to the price that Americans pay for prescription drugs. Saying that drug companies have "rigged the system" against American consumers by charging higher prices in the U.S. than they do abroad, President Trump proposed creating an "international pricing index" as a benchmark to decide how much the government should pay for prescription drugs covered by Medicare's Part B outpatient program.

HHS estimates the new pricing index—which the agency says would apply to 50% of the country—would save Medicare $17.2 billion over five years. Medicare now pays the average sales price of a medicine in the United States, plus a fee based on a percentage of that price. Under the new model, Medicare would pay fees to doctors that are more closely aligned with what other countries pay.

Although President Trump called the proposal "a revolutionary change," *it wouldn't affect prescription drugs bought from pharmacies.* It would only apply to infused and injected drugs administered by physicians at doctor's offices and in hospitals (some of the most expensive drugs older patients get), and only in half the country which has not been identified. It would take effect in late 2019 or 2020.

The NRLN prefers passage of the following bill that would provide prescription drug savings for all Americans.

S. 102, The Prescription Drug Price Relief Act, would peg the price of prescription drugs in the United States to the median price in five major countries: Canada, the United Kingdom, France, Germany and Japan.

Prices of Many Generic Drugs Climb Higher

Generic drugs represent about 90% of all prescription filled and have been one of the few bargains for Americans. However, the cost savings on generics are slowing. Pharmaceutical experts have begun to notice something even more disturbing. The prices of many generic drugs that have been around for years have suddenly spiked. AARP's Public Policy Institute found that 27% of the most widely used generics have gone up in price, in some cases into the stratosphere.

On June 13, 2017 as members of the Senate Committee on Health, Education, Labor and Pensions gathered to discuss the rising cost of prescription drugs, the prices of 14 common medications were increased by some 20% to 85%. The affected drugs would appear to be unlikely candidates for price hikes. All were generic drugs, which lack patent protection and therefore tend to be much less expensive.

NRLN Supports Funding FDA to Speed Approval of Generics

The NRLN supports providing adequate funding to clear the FDA product approval backlog of over 4,000 generics. This would make more affordable alternatives more readily available to patients.

It was reported in a July 25, 2017 *Los Angeles Times* article that Dr. Scott Gottlieb, head of the Food and Drug Administration, told a conference that since the FDA has no power to dictate price to drug companies the agency will focus on speeding up the approval process for generic drugs so consumers have cheaper alternatives to branded drugs. He also wants to encourage greater competition among drug companies to lower prices.

Consumers pay 94% of the branded drug price on average when one generic firm enters the market, but that drops to 52% with two competitors and to 44% with three, according to an FDA analysis. The savings ripple across the health-care system, and in 2016 generics saved $253 billion, according to a June 2017 report from the Association for Accessible Medicines.

A Grim Scenario

It's a grim scenario some doctors say they are all too familiar with. "As physicians, all too often we are seeing the situation where we prescribe a medication and a patient says 'doc, I just can't afford it.' We hear that all the time," says Wayne Riley, M.D., past president of the American College of Physicians.

Pharmacists are worried too, seeing the everyday effects of not being able to afford medications. Says Beverly Schaefer, RPh, co-owner of Katterman's Sand Point Pharmacy in Seattle, "More and more I'm seeing that consumers are becoming acutely aware of rising drug prices. They are stretching doses, seeking alternatives, asking more questions of their doctor and pharmacist, and sometimes refusing prescriptions or asking for a less expensive treatment option."

It's Time to Pass Bills to Reduce Prescription Drug Prices

Too many Americans are having to choose between paying for food, housing and other necessities, or try to stretch out their drug supply by cutting the prescribed dose or worse, simply going without their medicines.

Retirees, prospective retirees, and most Americans are suffering with prescription drug price gouging. This is at the expense of deferring or passing up altogether the purchase of goods and services that prop up the U.S. economy and thus federal tax revenue that sustains our country. Members of Congress cite internal opinions and old studies that defy logic and reality, and Pharma has far too much influence over public policy on this matter. It is time to change policy, to pass prescription drug importation and Medicare competitive bidding bills and to outlaw pay-for-delay and other obstructing tactics once and for all!

Retirees know that interim steps already suggested by several in Congress would not go anywhere near the realm of government price setting. Retirees also know that the high prices they are paying for prescription drugs only serves to support market entry of those same drugs into countries around the world. It is time for Congress to pass and the President to sign common-sense legislation and stand up for Americans' health and stop the prescription drug price gouging. Talk is cheap, drugs are not. There is no time to waste!

PHARMACYCHECKER.COM, LLC
333 Mamaroneck Avenue
White Plains, NY 10605
Phone: (718) 554–3067
Fax: (718) 715–1033

February 5, 2019

U.S. Senate
Committee on Finance
Dirksen Senate Office Bldg.
Washington, DC 20510–6200

To Editorial and Document Section:

We are submitting the two enclosed documents for the congressional record associated with the Senate Committee on Finance hearing held on January 29, 2019, called "Drug Pricing in America: A Prescription for Change, Part I." We believe these documents supplement the hearing's discussion points related to drug prices in other countries and drug importation:

Levitt, Gabriel, Executive Summary from "Online Pharmacies, Personal Drug Importation and Public Health: Ill-Considered Enforcement Prevents Access to Safe and Affordable Medication," February 2015; submitted to the Senate Committee on Health, Education, Labor, and Pensions and the House Committee on Energy and Commerce.

Bate, Roger, "Bing's Disservice to Online Drug Safety," American Enterprise Institute, January 2019.

Chairman Grassley has expressed serious concerns about FDA's personal importation policies and enforcement actions that may interfere with Americans obtaining needed medicines. These submissions give voice to American patients who are suffering from high drug prices and rely on personal importation.

Sincerely,

Gabriel Levitt
President
PharmacyChecker

Online Pharmacies, Personal Drug Importation and Public Health

Ill-Considered Enforcement Prevents Access to Safe and Affordable Medication

GAO Report on Internet Pharmacies Can Mislead Lawmakers and the Public About International Online Pharmacies

For the Senate Committee on Health, Education, Labor, and Pensions, and the House Committee on Energy and Commerce

Gabriel Levitt, Vice President, *PharmacyChecker.com*

February 12, 2015

A GAO report entitled "Internet Pharmacies: Federal Agencies and States Face Challenges Combatting Rogue Sites, Particularly Those Abroad," contains critical inaccuracies and omits important peer reviewed research that could lead lawmakers and their staffs to draw erroneous conclusions about international online pharmacies, potentially resulting in unnecessary enforcement actions that disadvantage consumers and threaten the public health. According to the U.S. Centers for Disease Control and Prevention (CDC) about five million Americans buy prescription drugs from foreign sources each year for reasons of cost. The evidence provided herein, including consumer testimonials and empirical data, shows that safe international online pharmacies are lifelines of affordable medication for many Americans. While rogue pharmacy sites can be very dangerous, overly broad and ill-considered Federal enforcement against safe international online pharmacies will lead to fewer Americans taking prescribed medication.

EXECUTIVE SUMMARY

The U.S. government relies on the Government Accountability Office (GAO) for objective and independent research and analysis of government programs and policies that affect public health. GAO's report entitled *Internet Pharmacies: Federal Agencies and States Face Challenges Combatting Rogue Sites, Particularly Those Abroad* (the "GAO report")[1] contains critical inaccuracies and omits important peer-reviewed research to the extent that lawmakers and their staffs will likely draw erroneous conclusions about international online pharmacies that could lead to overreaching and unnecessary enforcement actions that disadvantage consumers and threaten public health. The GAO report was written pursuant to Section 1127 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), a law dedicated to protecting public health.[2]

In contrast to the GAO report, the following holistic, consumer-focused, evidence-based analysis discusses online pharmacies within the important context of a health crisis caused by high drug prices in America, and can more appropriately guide lawmakers on how to protect the public from counterfeit or substandard medication. Legitimate public health concerns about rogue online pharmacies are being used to encourage legislative, regulatory, and private sector actions that curtail online access to safe and affordable medication.[3] The consequence of overreach could be millions more Americans facing economic hardship or having to forgo prescribed medication, which studies show can lead to more sickness and death.[4]

Fifty million Americans did not fill a prescription due to cost in 2012, according to the Commonwealth Fund.[5] According to the Harvard School of Public Health, over half of Americans who do not take prescription medication due to cost report becoming sicker.[6] That means potentially 25 million Americans become sicker each year because they can't afford prescribed medication.[7] According to the U.S. Centers for Disease Control and Prevention (CDC), about 5 million Americans buy prescription drugs from foreign sources each year for reasons of cost.[8] Additional estimates show that between 4 and 5 million Americans get their imported prescription drugs through international online pharmacies due to their lower prices.[9]

As a government performance audit, the GAO report must abide by generally accepted government auditing standards (GAGAS). Those standards include a responsibility to meet stringent professional and ethical standards, including ". . . exercising reasonable care and professional skepticism. Reasonable care includes acting

---

[1] *Internet Pharmacies: Federal Agencies and States Face Challenges Combatting Rogue Sites, Particularly Abroad,* GAO–13–560 (Washington, DC July 2013). See *https://www.gao.gov/assets/660/655751.pdf* [last accessed 10/7/2014].

[2] Pub. L. No. 112–144, § 1127, 126 Stat. 993, 1117–18 (2012).

[3] Graczyk, Lee, "Americans Can't Afford U.S. Medication, Need a Safe Alternative," November 12, 2014, *The Hill Congress Blog,* see *https://thehill.com/blogs/congress-blog/healthcare/223650-americans-cant-afford-us-medication-need-a-safe-alternative* [last accessed 11/12/14]. See Gabriel Levitt, "Inconvenient Truths About Foreign Online Pharmacies," October 8, 2014, *The Hill Congress Blog,* see *https://thehill.com/blogs/congress-blog/healthcare/220034-inconvenient-truths-about-foreign-onlinepharmacies* [last accessed 10/30/2014]. See Roger Bate, "Google's Ad Freedom Wrongly Curtailed," September 28, 2011, *RealClearMarkets.com,* see *https://www.realclearmarkets.com/articles/2011/09/28/googles_advertizing_freedom_is_curtailed_99281.html* [last accessed 10/19/2014].

[4] Brown, Marie T., and Jennifer K. Bussell, "Medication Adherence: WHO Cares?" *Mayo Clinic Proceedings* 86.4 (2011): 304–314 [last accessed 1/19/2015] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3068890/*.

[5] S.R. Collins, R. Robertson, T. Garber, and M.M. Doty, "Insuring the Future: Current Trends in Health Coverage and the Effects of Implementing the Affordable Care Act," *The Commonwealth Fund,* April 2013, *https://www.commonwealthfund.org/~/media/files/publications/fundreport/2011/mar/1486_collins_help_on_the_horizon_2010_biennial_survey_report_final_v2.pdf,* [last accessed 9/17/2014].

[6] Harvard School of Public Health/*USA Today*/Kaiser Family Foundation, *Health Care Costs Survey* (conducted April 25–June 9, 2005). The survey finds that 20% of respondents, adult Americans, report not filling a prescription due to cost; 54% of those respondents said their condition got worse as a result. Extrapolated to the 2012 population of adults 18 and older, which is 234,564,071, the number is approximately 25 million people. See *https://kff.org/health-costs/poll-finding/health-care-costssurvey-summary-and-chartpack/* [last accessed 7/5/2014].

[7] *Ibid.*

[8] Cohen R.A., Kirzinger W.K., Gindi R.M., "Strategies used by adults to reduce their prescription drug costs," *National Center for Health Statistics data brief,* no 119, U.S. Centers for Disease Control and Prevention, April 2013, Hyattsville, MD; see *https://www.cdc.gov/nchs/data/databriefs/db119.pdf,* [last accessed 7/22/2013].

[9] Consumer Reports National Research Center, "Best Buy Prescription Drug Tracking Poll 3," August 10, 2011. See *https://www.consumerreports.org/health/resources/pdf/best-buy-drugs/2011-BBD-Rx-poll-public-release.pdf* [last accessed 9/17/2014].

diligently in accordance with applicable professional standards and ethical principles. Professional skepticism is an attitude that includes a questioning mind and a critical assessment of evidence."[10]

The GAO report does not meet the appropriate performance audit standards because its conclusions are mostly based on consultations with stakeholders that have significant financial interests in the audit's outcome or the organizations they fund: the GAO seems to rely on their data and positions without a "questioning mind and a critical assessment of evidence." The GAO also misreports critical data it was provided by industry and government sources. GAO did not consult a wider range of available data, expert analyses, and stakeholders known to its authors that would have resulted in a more balanced analysis.[11] Central to the above, the GAO seems to neglect the public interest by completely omitting a discussion about Americans who rely on safe and effective prescription drug imports ordered from foreign Internet pharmacies, ones the GAO report mistakenly refers to as "rogue."

The GAO correctly presents the regulatory challenges to shutting down *rogue* online pharmacies, but *incorrectly* conflates such dangerous pharmacy websites with safe online pharmacies that sell medication from licensed pharmacies in Canada and other countries, which offer Americans a source of affordable medication ("safe international online pharmacies"). This conflation unnecessarily curtails access to safe medication because federal regulatory and private enforcement actions against rogue online pharmacies engulf safe international online pharmacies that Americans rely on.

In part, the problem stems from different classification systems to define "rogue online pharmacy." The National Association of Boards of Pharmacy (NABP) and the GAO report wrongly refer to safe international online pharmacies as "rogue." LegitScript, a stakeholder that is repeatedly cited in the GAO report, classifies these safe online pharmacies as "unapproved," but not "rogue," a critical fact overlooked in the GAO report. A more useful and honest definition of "rogue online pharmacy" is *a drug-selling website that intentionally sells fake, adulterated, or unlicensed medication; genuine and regulated medication that is not dispensed by a licensed pharmacist and /or pursuant to a valid prescription; or engages in fraud.* This definition provides a clear framework to enable lawmakers and regulators to target dangerous foreign and domestic pharmacy websites without overreaching enforcement action against safe ones.

The GAO report asserts that most rogue online pharmacies operate from abroad. However, according to the data of industry stakeholders consulted by the GAO, it is actually not clear whether there are more rogue online pharmacies based in the United States or abroad. In its focus on pharmacies "abroad," the GAO report obfuscates technical violations of drug importation laws by Americans who import safe and effective medication for personal use with the use of dangerous web pharmacies, foreign and domestic.

The GAO report largely relies on data and analysis it obtained from pharmaceutical companies, U.S. pharmacies and organizations they fund, and federal agencies, particularly the U.S. Food and Drug Administration (FDA). The aforementioned entities do not recognize the public health benefits of online access to safe and more affordable pharmacies outside the U.S. Their positions are untenable because the public health benefits of safe, personally imported medication purchased online are indisputable—as explained below.

The National Consumers League (NCL) identifies 125,000 annual deaths due to prescription medication non-adherence, but that number only applies to non-adherence related to heart conditions and is based on data from a 1998 article.[12] It's unknown how many deaths are currently due to prohibitive drug costs, but given the prominence of cost as a barrier to access, the numbers are clearly unacceptable. A 2012

---

[10] *Government Auditing Standards,* GAO–12–331G (Washington, DC, December 2011), see *https://gao.gov/assets/590/587281.pdf* [last accessed 9/17/2014].

[11] Such as peer reviewed studies by Roger Bate and Aparna Mathur at the American Enterprise Institute; recommendations from studies funded by the California HealthCare Foundation; and earlier studies by GAO on Internet pharmacies, all of which are discussed in this report. Supporters of buying medications from international online pharmacies include Mature Voices Minnesota, Coalition of Wisconsin Aging Groups, the Congress of California Seniors, Third Power Age, and New York Statewide Senior Action Council; and non-governmental organizations such as *RxRights.org* and Demand Progress; and companies such as *PharmacyChecker.com,* founded in 2002 to evaluate online pharmacies, U.S. and foreign, and compare their drug prices.

[12] McCarthy R. "The Price You Pay for the Drug Not Taken," *Business Health* 1998.

CVS survey found that 61% of U.S. pharmacists cite drug costs as the main reason Americans don't take their medications.[13]

For the past 15 years Americans have ordered medication from Canada and many other countries over the Internet from licensed pharmacies that require a valid prescription,[14] employ trained and licensed pharmacists, and protect their patients' privacy.[15] There are no reported incidents of an American dying or experiencing a severe adverse reaction from taking a medication ordered online from a pharmacy outside the U.S. that requires a prescription from a licensed healthcare provider who has physically examined the patient.[16] There are also no reported deaths or serious illnesses due to dispensing errors committed by safe international online pharmacies, while dispensing problems in U.S. pharmacies are routine and have killed and sickened many Americans over the past decade.[17]

Thousands of Americans have publicly affirmed that they greatly benefit from lower cost medication available from international online pharmacies and that such access saves their lives, and prevents financial hardship.[18, 19] Here are a few examples of what Americans are saying:

Morton Ross, Palm Harbor, FL 2014–04–03, "The meds I take daily, are the difference between 'life and death.' I cannot afford the higher prices at local pharmacies."

Darilyn Schlie, Fort Worth, TX 2014–04–03, "Without the ability to go outside the U.S. I will not be able to afford the medication I need."

James Marshall, Nashville, TN 2014–04–03, "I have emphysema and could not afford my medications if not for being able to order some of them from outside the USA."

---

[13] "CVS/Caremark Survey Says Cost is Biggest Barrier to Prescription Adherence," *CVS/Caremark Insights,* September 27, 2012, see *https://info.cvscaremark.com/cvs-insights/cvs-caremark-survey-says-cost-biggest-barrier-prescription-adherence* [last accessed 9/17/2014]; or see *https://www.prnewswire.com/news-releases/cvs-caremark-survey-pharmacists-say-cost-is-biggest-barrier-to-medication-adherence-171516471.html* [last accessed 9/17/2014].

[14] This report concurs with the definition of "valid prescription" identified in the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy. A valid prescription is one written pursuant to a "valid patient-practitioner relationship" consultation between a licensed healthcare practitioner and a patient. "Valid Patient-Practitioner Relationship" means the following have been established: (1) a patient has a medical complaint; (2) a medical history has been taken; (3) a face-to-face physical examination adequate to establish the medical complaint has been performed by the prescribing practitioner or in the instances of telemedicine through telemedicine practice approved by the appropriate Practitioner Board; and (4) some logical connection exists between the medical complaint, the medical history, and the physical examination and the drug prescribed.

[15] For example, such pharmacists have provided testimony before Congress. The Canadian International Pharmacy Association was founded in 2002. That association's vice president at the time, Dr. Andy Troszok, testified before the House Committee on Government Reform, Subcommittee on Human Rights and Wellness. He said: "I am a Canadian licensed pharmacist, and when I graduated I pledged an oath to take the health, safety, and well-being of my patients as a priority. I have the privilege of working in community pharmacy for 8 years, and also in academia, and I have had the ability to work with patients, and every time I did I took that to the strongest possible level. I think patient safety and overall patient health should be the priority of any pharmacist working in any kind of realm, be it hospital, retail, or innovative delivery of service such as distance-based delivery or mail order." U.S. House, Committee on Government Reform, Subcommittee on Human Rights and Wellness, *International Prescription Drug Parity: Are Americans Being Protected or Gouged?,* source, hearing, April 3, 2003, Serial No. 108–12. Washington: Government Printing Office 2003. See *http://webcache.googleusercontent.com/search?q=cache:ua5hIPDo8yYJ:https://bulk.resource.org/gpo.gov/hearings/108h/87228.txt+&cd=4&hl=en&ct=clnk&gl=us* [last accessed 9/17/2014].

[16] Neither the FDA nor any other federal or state agency, or group, whether for or non-profit, has reported a single death or serious adverse effect from personal drug importation in a situation where the importing consumer had a valid prescription. This is after about 15 years during which Americans have purchased medication online from foreign pharmacies.

[17] Cohen, Elizabeth, "Don't Be a Victim of Pharmacy Errors," *CNN Health,* October 30, 2007. See *https://www.cnn.com/2007/HEALTH/10/25/pharmacy.errors/* [last accessed 9/7/2014]. See Henry I. Miller, "Medication Mistakes Are a Tough Pill to Swallow," *Forbes,* February 16, 2011; *https://www.forbes.com/sites/henrymiller/2011/02/16/medication-mistakes-are-a-tough-pill-to-swallow* [last accessed 9/17/2014].

[18] *Change.org* petition 2014—over 2,000 people, who identify their names and where they live in the U.S., comment about buying their medications internationally; *https://www.pharmacychecker.com/pdf/comments-by-americans-concerned-section708-fdasia.pdf.* The comments were made on a petition of over 8,000 signatures hosted on *Change.org; https://www.change.org/p/kathleen-sebelius-please-don-t-stop-americans-from-getting-medicine-at-lower-cost-outside-the-u-s* [last accessed 9/19/2014].

[19] Also see *RxRights.org* consumer testimonials; *http://www.rxrights.org/testimonials/.*

By failing to note that personal drug importation from safe international online pharmacies is a public health benefit, as exemplified by the above testimonials, the GAO report does not properly or fully inform Congress about foreign Internet pharmacies.

The GAO report does not take into account pertinent data about international online pharmacy safety, which was published in two peer-reviewed studies. Those studies demonstrate that medication ordered from *credentialed* online pharmacies, foreign and domestic, were safe and effective, and that those credentialed online pharmacies all required valid prescriptions. The credentialing agencies were the National Association of Boards of Pharmacy (NABP), LegitScript, a private investigation and verification company contracted by the FDA,[20] *PharmacyChecker.com,* a private pharmacy credentialing company and drug price comparison website, and the Canadian International Pharmacy Association (CIPA), a Canadian trade association of pharmacies and pharmacists that sell medication globally.[21] The medication purchased domestically in that study was about 50% more expensive than the same medication purchased from other countries.[22] That level of savings is substantial but much lower than Americans often save. *PharmacyChecker.com* price comparison data demonstrate that savings are often as high as 90% from credentialed international online pharmacies when consumers have access to online price comparisons and can find the lowest prices.[23] The FDA has relied on and cited *PharmacyChecker.com's* data for its own drug price analyses.[24]

The GAO report omits a central finding about the safety of Canadian Internet pharmacies found in an earlier GAO report.[25] Through test purchases of prescription drugs online, GAO's earlier report found that *all Canadian Internet pharmacies required prescriptions and sent genuine medication,* whereas some U.S. online pharmacies did not require valid prescriptions.[26] The earlier GAO report was written, at least in part, by the author of the new GAO report, Marcia Crosse.[27]

In addition to its previous, and more evidence-based report, the GAO might have considered independent analysis published by the Center for Studying Health System Change, funded by the California HealthCare foundation and the Robert Wood Johnson Foundation, which recommends that U.S. states provide their residents with, "A user's guide and price comparison tool for Canada-based or other foreign-based online pharmacies, which would be particularly helpful to consumers who need brand-name drugs."[28]

The GAO could argue that the language of Section 1127 neither expressly requests an independent analysis on the issue of online pharmacy safety and usage, nor asks the question whether safe non-U.S. online pharmacies are accessed by and help Americans. Indeed, Section 1127 contained nuanced biases to maintain a narrow line of inquiry favorable to the commercial interests of pharmaceutical and U.S. pharmacy companies. As evidence of that bias the record shows that a government

---

[20] U.S. Food and Drug Administration, Department of Health and Human Services, FDA Contract Solicitation Number: FDA–SOL–10–1068201–02; *Internet Monitoring and Support Services;* contract award date, September 17, 2010, contract award dollar amount: $2,571,765.00; see *https://www.fbo.gov/index?s=opportunity&mode=form&tab=core&id=6e179a4b6e9d90bb5696dbfbc2edd065* [last accessed 10/7/14].

[21] Bate, Roger, Ginger Zhe Jin, and Aparna Mather, "In Whom We Trust: The Role of Certification Agencies in Online Drug Markets," *The B.E. Journal of Economic Analysis and Policy,* December 2013, Volume 14, Issue 1, pages 111–150, ISSN (online) 1935–1682, ISSN (print) 2194–6108, DOI. See 10.1515/bejeap–2013–0085 [last accessed 9/19/2014].

[22] *Ibid.*

[23] *PharmacyChecker.com* (September 30, 2013), *Online Pharmacies May Help Many Afford Prescription Medication Under Obamacare* [press release]. See *https://www.pharmacychecker.com/news/online_pharmacy_prescription_savings_obamacare_2013.asp* [last accessed9/20/14].

[24] "FDA: U.S. Generics Can Be a Better Bargain than Canadian Drugs," Associated Press in *St. Petersburg Times Online,* see *http://www.sptimes.com/2004/01/18/news_pf/Worldandnation/FDA_US_generics_can_.shtml* [last accessed 9/23/2014].

[25] *Internet Pharmacies: Some Pose Safety Risks for Consumers,* GAO–04–820 (Washington, DC: June 17, 2004). See *http://www.gao.gov/new.items/d04820.pdf* [last accessed 9/17/2014].

[26] *Ibid.*

[27] Marcia Crosse is an exceedingly talented and dedicated public servant. Her research and policy analysis have served Congress and the American public well for over 30 years. That Ms. Crosse is responsible for this report was surprising and disappointing. The flawed analysis of the GAO report is mostly a reflection of the legislative and regulatory capture by pharmaceutical commercial interests in this issue area—not Ms. Crosse's dedication and ability, which I admire.

[28] Tu, Ha T. and Catherine Corey, "State Prescription Drug Price Websites: How Useful to Consumers," *Health System Change Research Brief #1,* February 2008, Center for Studying Health System Change; see *http://www.hschange.com/CONTENT/966/* [last accessed 9/20/14].

relations advisor and lobbyist working with drug companies and a U.S. pharmacy trade association drafted Section 1127.[29] While this may explain the language of Section 1127 it does not excuse GAO from failing to: (1) consult sources that are not known to be hostile to American consumers buying medication from Canada and other countries, online or otherwise; and (2) engaging in an independent inquiry and analysis.

Even within the biased parameters of inquiry found in Section 1127, the GAO report is not sufficiently responsive. For instance, Section 1127 requests an analysis of "the harmful health effects that patients experience when they consume prescription drugs purchased through such pharmacy Internet Web sites"—referring to websites that "sell prescription medication in violation of federal and state laws."[30] The industry stakeholders consulted by the GAO have compiled data on this core issue of safety and found not a single example of patient harm resulting from purchasing medication outside the U.S. from international online pharmacies that require a valid prescription.[31] The GAO did not mention those findings, which are specifically responsive to the core issue of safety and lend further evidence that international online pharmacies requiring a prescription are safe.

The GAO report calls into question the appropriateness of the U.S. Drug Enforcement Agency's efforts to combat dangerous web pharmacies. The DEA views the Internet as an insignificant source of illegally obtained controlled drugs, and online pharmacies are not a DEA priority.[32] As explained in greater detailbelow, the problem may be somewhat larger than DEA asserts but GAO appears to defend the position of one of its stakeholders, LegitScript, instead of analyzing the hard data. Specifically, the GAO report does not mention the source of the most extensive survey data relating to the nation's prescription abuse problem, which shows 0.2% of prescription narcotic abuse is attributed to the Internet.[33]

Despite the absence of any discussion about safe international online pharmacies in the GAO report, the lead author clearly recognizes that international online pharmacies can be safe, as evidenced by an online video in which Ms. Crosse discusses her report.[34] The key safety issue, according to Ms. Crosse, isthat the dispensing pharmacy is "real" and that the patient has a prescription from a licensed health provider. She affirms the safety of personal drug importation when Americans buy online from licensed Canadian pharmacies pursuant to valid prescriptions.[35] In speaking to a consumer who orders from a Canadian online pharmacy, she states that if the patient has "done some kind of verification that it's a Canadian pharmacy, and she knows that the drug she has been receiving is the drug that has been prescribed, that's fine."[36]

Current federal and state laws that curtail access to safe and affordable medication from pharmacies outside the U.S. hurt American consumers. New regulations, executive branch initiatives, and private sector actions are now threatening that access completely. Section 708 of FDASIA gives the FDA new authority to destroy genuine and safe imported medication valued at $2,500 or less, but only after creating regulations that allow people an appropriate due process to provide testimony to defend

---

[29] Ms. Libby Baney is identified as a lobbyist for the Alliance for Safe Online Pharmacies in this lobbying disclosure report: *https://soprweb.senate.gov/index.cfm?event=getFilingDetails&filingID=6B1B406C-D5C0-48C6-9484-B9FF3B372B1F&filingTypeID=51* [last accessed 10/21/2014]. Ms. Baney, now executive director of the Alliance for Safe Online Pharmacies, is also now principal at FWD Strategies International. In marking her consulting firm Ms. Baney takes credit for drafting Sec. 1127, see *http://fwdstrategies.com/services/* [last accessed 9/20/14].

[30] Pub. L. No. 112–144, § 1127, 126 Stat. 993, 1117–18 (2012).

[31] The Alliance for Safe Online Pharmacies' Response to the U.S. Intellectual Property Enforcement Coordinator's Request for Public Comment on the Development of the Joint Strategic Plan on Intellectual Property Enforcement, August 2012, see *https://safeonlinerx.com/wp-content/uploads/2012/08/ASOP-Response-to-IPEC.pdf* [last accessed 12/19/2013].

[32] DEA Agent Robert Hill presentation at the Partnership for Safe Medicines Interchange Conference in October 2010. See *http://www.tubechop.com/watch/1046694* [last accessed 9/20/14].

[33] Substance Abuse and Mental Health Services Administration, *Results From the 2012 National Survey on Drug Use and Health: Summary of National Findings,* NSDUH Series H–46, HHS Publication No. (SMA) 13–4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013. See *https://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.pdf* [last accessed 9/19/2014].

[34] For the relevant clip of an interview with Marcia Crosse, see *Ask GAO Live: Chat on Internet Pharmacies,* August 12, 2013 at *http://www.tubechop.com/watch/1407272;* for the whole discussion, see *https://www.youtube.com/watch?v=qzvVK6GhF5Q* [last accessed 9/19/14].

[35] *Ibid.*

[36] *Ibid.*

their prescription drug imports.[37] The GAO report mentions section 708 once in a footnote, but does not explore the unintended consequences of seizing and destroying medications imported for personal use.

In a floor statement in 2012 during debate on FDASIA, former Representative Jo Ann Emerson (R–MO) warned her colleagues about similar language to Section 708 that was in an earlier version of the bill: "This language threatens a critical, cost-effective supply of medications and pharmaceuticals. These drugs are exactly the same as their counterparts sold in America. I urge further discussion of this critical issue in conference and a full examination of the consequences of passing this provision into law."[38]

More recently, Senators Charles Grassley (R–IA), Dean Heller (R–NV), Angus King (I–ME), David Vitter (R–LA) expressed serious concerns about the "potential health threat to hundreds of thousands of Americans" from Section 708.[39] Congressman Keith Ellison wrote the FDA about many of his constituents expressing serious concerns with how Section 708 will impede their access to safe and affordable medication.[40]

Through its Office of the Intellectual Property Coordinator (IPEC), the Obama administration created and encouraged policies and actions affecting access to online pharmacies.[41] One of its focuses is on encouraging the private sector to take "voluntary" actions against rogue online pharmacies.[42] IPEC encouraged the formation of a business consortium, one now established as a non-profit called the Center for Safe Internet Pharmacies (CSIP). While CSIP helps curb access to rogue pharmacies, it also acts to discourage Americans from accessing safe, affordable pharmacies outside the U.S. The CSIP website is largely a clearing house for information from pharmaceutical industry-funded groups such as The Partnership for Safe Medicines, which is funded by the Pharmaceutical Researchers and Manufacturers of America (PhRMA) and led by one of Pharma's vice presidents, and the National Association of Boards of Pharmacy, which runs Internet pharmacy programs that rely on funding from the pharmaceutical industry: an industry that engages in scare campaigns by labeling any pharmacy outside the U.S. that sells to Americans as rogue, thus conflating licensed pharmacies with dangerous pharmacy websites.[43]

Using funds provided by Eli Lilly, Merck, and Pfizer, the NABP applied to the Internet Corporation for Assigned Names and Numbers (ICANN) to operate a generic top-level domain (gTLD) called .pharmacy. The NABP will use the .pharmacy designation to identify any international online pharmacy as a rogue if it sells to people in the U.S. Pharmacies such as Walgreens, CVS, and Rite Aid can expect to obtain permission to register a .pharmacy web address, whereas the safest international online pharmacy will be prohibited from doing so.[44] NABP will launch public education campaigns urging consumers to avoid any drug-selling website that does not have .pharmacy at the end of it, which could scare more Americans away from safe and affordable medication. At the time of this writing, the .pharmacy string has

---

[37] Pub. L. No. 112–144, § 708 (2012).

[38] Representative JoAnn Emerson (MO), "Food and Drug Administration Reform Act," May 30, 2012. See *https://votesmart.org/public-statement/702416/food-and-drug-administration-reform-act-of-2012#.UxVJN-co4s9* [last accessed 9/22/14].

[39] U.S. Senator David Vitter, "Vitter Fights to Keep Prescription Drug Prices Affordable Through Reimportation," July 9, 2014 [press release]; see *http://www.vitter.senate.gov/newsroom/press/vitter-fights-to-keep-prescription-drug-prices-affordablethrough-reimportation* [last accessed 9/20/14].

[40] Letter to the U.S. Food and Drug Administration by Congressman Keith Ellison dated July 1, 2014. See *https://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0504-0022* [last accessed 9/20/14].

[41] "Obama Seeks Action on Online Pharmacies," *Securing Industry,* September 3, 2010, see *https://www.securingindustry.com/pharmaceuticals/obama-seeks-action-on-online-pharmacies-domainnames/s40/a567/#.VB3d-OfD_mI* [last accessed 9/20/14].

[42] *Ibid.*

[43] Levitt, Gabriel, Statement to the House Judiciary Committee Subcommittee on the Courts, Intellectual Property, and the Internet, September 18, 2013, see *http://docs.house.gov/meetings/JU/JU03/20130918/101316/HHRG-113-JU03-WstateLevittG-20130918-U1.pdf* [last accessed 10/21/2014]. Also by Gabriel Levitt, "Why Is Google Supporting Big Pharma?", January 6, 2014, in *http://infojustice.org/archives/31846.*

[44] According to the NABP's new registration program for .pharmacy gTLD, eligible applicants must have a pharmacy license "in the jurisdictions where they are based and where they serve patients." Since Canadian pharmacies that serve U.S. patients are licensed in Canada but not in a U.S. state, they will all be banned from the program. See *http://www.dotpharmacy.net/*.

been delegated to NABP, but ICANN is facing pressures from consumer groups and the ICANN community to delay its full implementation.[45]

The "voluntary" protocols encouraged by the Obama administration have now led online and physical "gatekeepers" such as credit card companies, mail carriers and domain registration to deny service to safe international online pharmacies. For example, VISA, a member of CSIP, recently adopted policies in coordination with LegitScript that restrict the use of Visa credit cards for prescription sales to U.S.-based consumers to U.S. pharmacies only.[46]

Coordination with gatekeepers is one way to protect consumers from rogue pharmacy websites but it need not and should not affect a consumer's ability to access a safe international online pharmacy. The way to shut down rogue online pharmacies is demonstrated in a series of coordinated federal and global actions called Operation Pangea, which bring together efforts by law enforcement and private industry.[47] According to Interpol's website, Pangea's "activities target the three principal components used by illegal websites to conduct their trade—the Internet Service Provider (ISP), payment systems and the delivery service."[48] Additionally, through Operation Pangea, counterfeiters (people who make counterfeit drugs) and those threatening public health through online drug sales have been arrested and imprisoned.[49]

The question for lawmakers is this: which online pharmacies should be targeted by FDA and private sector enforcement operations? A definition of "rogue online pharmacy" that focuses strictly on public health considerations, rather than technical restrictions on personal drug importation and intellectual property law, provides the answer. Those online pharmacies in the business of selling genuine medications, dispensed by a licensed pharmacy and pharmacist that require a patient's prescription should not be considered "rogue." In stark contrast, criminals in the business of intentionally selling fake, spurious, or adulterated medications online, or real prescription drugs without requiring a valid prescription are "rogue." Millions of Americans are buying genuine medications internationally, despite technical legal prohibitions, because they are much lower cost. Stopping them from doing so would be unethical and likely lead to more people becoming sick and dying.[50] Furthermore, actions that are necessary to protect one's health should not be sanctioned as criminal to begin with. Lawmakers should pass legislation to remove criminal penalties (even if they are never enforced) that can be applied to individuals who import small quantities of medication for their own use. Such laws are inimical to our basic rights of life and liberty.

FROM THE AMERICAN ENTERPRISE INSTITUTE (AEI)

Bing's Disservice to Online Drug Safety

By Roger Bate

January 2019

Key Points

- To warn consumers of the dangers of importing medicine, the search engine Bing has placed pop-up warnings against foreign websites selling medicines.

---

[45] "Your 24,349 Signature Petition Had an Impact," October 22, 2014, *RxRights.org,* see *http://www.rxrights.org/24349-signature-petition-impact/* [last accessed 11/6/2014].

[46] "VISA Policies Curtail Consumer Access to Safe Medicines Online: Reminiscent of China or North Korea!!", *PharmacyCheckerBlog,* December 4, 2014, by Gabriel Levitt, Vice President, *PharmacyChecker.com* see *https://pharmacycheckerblog.com/visa-policies-curtail-consumer-access-to-safe-medicines-online-reminiscent-of-china-ornorth-korea* [last accessed 1/19/2015]. Also see from the Canadian International Pharmacy Association, "Checks Are Best When Ordering From CIPA Member Pharmacies," see *https://www.cipa.com/news/checks-are-best-when-ordering-from-cipamember-pharmacies/* [last accessed 11/10/2014].

[47] Interpol on Operation Pangea; see *https://www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations/OperationPangea* [last accessed 9/22/14].

[48] *Ibid.*

[49] *Ibid.*

[50] Levitt, Gabriel, "Scare Tactics Over Foreign Drugs," March 24, 2014, *New York Times;* see *https://www.nytimes.com/2014/03/25/opinion/scare-tactics-over-foreign-drugs.html* [last accessed 10/21/2014]. Since cost is noted as the factor most likely to cause an American to skip filling a prescription, it follows that many consumers who rely on safe international online pharmacies will go without needed medications if that option is removed.

Unfortunately, the sites targeted are credentialed foreign pharmacies, while potentially rogue sites are in effect given a clean bill of health by having no pop-up warnings.

- Original research confirms this folly. Using the search terms "Viagra" and "Canada," I identified websites and ordered the prescription drug Viagra from nine credentialed sites with warnings; all sold legitimate Viagra. I also ordered Viagra from 14 uncredentialed sites with no warnings; two of these sites sold fake Viagra. To add insult to possible injury, the uncredentialed sites were on average 25 percent more expensive.
- Bing must change its policy, since the current one is driving traffic to unsafe sites and away from legitimate international pharmacies.

It is well-known that Americans pay more for medication than the citizens of other nations. To avoid high prices, some enterprising Americans, perhaps as many as four million, buy from foreign web pharmacies, often at under half the price they would pay in the U.S.[1]

Until web sales took off, many Americans, particularly seniors in states bordering Canada, would travel over the border to buy their medication. A string of pharmacies in Western Canada sprung up to service this demand. Early in this century, demand switched from physically visiting Canada to online purchases from Canadian websites.

There are obvious risks to purchasing medication online due to the anonymity of the web, where rogue actors have established sites to sell bogus medicine and steal identities. Therefore, groups such as the Canadian International Pharmacy Association (CIPA) and *PharmacyChecker.com* were established to credential websites linked with real pharmacies selling proper medicine and assist patients looking for cheaper good-quality medication.

U.S. pharmacies and all major pharmaceutical companies always disliked Americans purchasing foreign pharmaceuticals since the former directly lost business and the latter wanted to maintain consistently higher prices on medicines in the U.S. The argument advanced by the pharmaceutical companies is that higher pricing leads to more research and development. While there is truth to this stance, higher prices harm millions of poor or underinsured Americans, who may forgo or not take their medication as often as prescribed to save money.

With a nod to this reality, historically the Food and Drug Administration (FDA) has allowed individuals to import a 90-day supply of most prescription medicines, even though the law forbids such importation. While importation is prevented primarily to inhibit price arbitrage, it is often argued that importation aids safety.[2]

Recently, due to the alarming increase in fatal opioid overdoses fueled predominantly from foreign sources, legislative efforts and policy have increased the powers of various agencies, including the FDA, to intercept and destroy medicine imports. Clearly the target is illegally trafficked narcotics, especially opioids. Yet other medicines, such as personal imports of life-saving medicines, may be prevented in the

---

[1] Robin A. Cohen and Maria A. Villarroel, "Strategies Used by Adults to Reduce Their Prescription Drug Costs: United States, 2013," U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, January 2015, *https://www.cdc.gov/nchs/data/databriefs/db184.pdf;* and Gabriel Levitt, "Fewer Americans Importing Medications in 2016: Good or Bad? Oh, and Happy New Year!", *PharmacyCheckerBlog,* December 31, 2015, *https://www.pharmacycheckerblog.com/fewer-americans-importing-medications-in-2016-good-or-bad-oh-and-happy-new-year.*

[2] Congress has passed laws, implemented by the FDA, that makes the personal importation of medicine illegal. But Congress applies exceptions. The Prescription Drug Import Fairness Act of 2000 was passed into law as Section 746 of an appropriations bill for the FDA and other agencies in 2000 (H.R. 4461). In this law, Congress articulates these findings: "Patients and their families sometimes have reason to import into the United States drugs that have been approved by the Food and Drug Administration ("FDA")." Prescription Drug Import Fairness Act of 2000, Pub. L. No. 106–387. Furthermore, the FDA's "Coverage of Personal Importation" says that "FDA personnel may allow entry of shipments when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user." U.S. Department of Health and Human Services, Food and Drug Administration, *Regulatory Procedures Manual,* December 12, 2017, chap. 9, 23, *https://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm*; and U.S. Department of Health and Human Services, Food and Drug Administration, "Is it Legal for Me to Personally Import Drugs?", August 22, 2018, *https://www.fda.gov/aboutfda/transparency/basics/ucm194904.htm.*

process, as companies seek to limit any potential liability and packages are stopped without much reason.[3]

Fortunately this new opioid law—known as the SUPPORT for Patients and Communities Act—includes a measure protecting those importing drugs for "personal or household use," putting into law, albeit not exhaustively, the sentiment that limited personal importation will be tolerated.[4] However, reports persist of the FDA interdicting drugs intended for personal use.[5] It is too early to tell how these recent policy measures are affecting drug imports systematically, but search engines and payment companies are clearly being pressured to limit people's ability to import medicine.

Specifically related to Bing, informed sources tell me that Microsoft has been pressured by the FDA and legislators to prevent the sale of opioids over the Internet. The message is clear that the government's priority is preventing the sale of opioids rather than allowing access to medicines.

What Did Bing Do?

On November 12th, Bing, Microsoft's Internet search engine, announced a change in its policy on access to medicines via the web.[6] The search engine will now generate a pop-up warning whenever a user attempts to access a site that has been flagged by the National Association of Boards of Pharmacy (NABP) as appearing "to be out of compliance with state or federal laws or NABP patient safety and pharmacy practice standards."[7] Simply dispensing foreign medicines is sufficient to make the list.

Bing is trying to alert those seeking drugs from overseas of the potential dangers of such practices. There are numerous risks of buying pharmaceuticals online, ranging from bogus medicines to identity theft. However, as I have attested in the peer-review literature, buying from credentialed overseas sites can be done safely, at least in the general understanding of that word.[8] Purchasing pharmaceuticals can never be 100 percent safe, including those bought from brick-and-mortar pharmacies in the U.S. Nevertheless, the dangers of buying online remain, and U.S. pharma and pharmacy interests have used those risks to scare people from buying online and alarm policymakers who have not legislated to explicitly allow such purchasing.

Convincing Bing to highlight the CIPA- and *PharmacyChecker.com*-credentialed sites with pop-up warnings represents a major conquest for pharma interests. One can argue that since these sites encourage folks to break the law (a law that is not enforced, but still a law), it is legitimate. Bing has bought into the NABP's dangerous self-interested argument that any overseas site, even if linked to a legitimate foreign pharmacy, is illegitimate for simply taking business from a U.S. pharmacy.

---

[3] See Chapter 3 of the SUPPORT for Patients and Communities Act, expanding the authority of Health and Human Services (through the FDA) to debar individuals importing controlled substances on the basis that they have engaged in "a pattern of importing or offering for import . . . adulterated or misbranded" drugs. (Misbranded drugs include simply imported drugs.) SUPPORT for Patients and Communities Act, Pub. L. No. 115–271, *https://www.congress.gov/115/bills/hr6/BILLS-115hr6enr.pdf.*

[4] Curiously, while the initial House version of the bill included the protection for personal importation, the language was dropped in the Senate version of the bill. See SUPPORT for Patients and Communities Act, Pub. L. No. 115–271, § 3022, *https://www.congress.gov/115/bills/hr6/BILLS-115hr6enr.pdf;* and SUPPORT for Patients and Communities Act, S. 6193, 115th Cong., 27, *https://www.congress.gov/115/bills/hr6/BILLS-115hr6eas.pdf.* A Kaiser Family Foundation article noted that congressional staffers speaking on background stated the change was because senators "believed it was unnecessary." Adding further: "The FDA already has discretion to look the other way on personal imports and told lawmakers it has no intention of changing the policy." Michael McAuliff, "Buried in Congress' Opioid Bill Is Protection for Personal Drug Imports," *Kaiser Health News,* September 27, 2018, *https://khn.org/news/buried-in-congress-opioid-bill-is-protection-for-personal-drug-imports/*. While on the surface the comment may be true, the subtle change nevertheless stresses the political stakes involved.

[5] Michael McAuliff, "Trump Administration Seizing Cheaper Medications From Canada and Other Countries," *Tarbell,* June 14, 2018, *https//www.tarbell.org/2018/06/trump-administration-seizing-cheaper-medications-from-canada-and-other-countries/Pref=featured.*

[6] Bing Blogs, "Bing to Warn Customers About the Threats of Fake Online Pharmacies," November 12, 2018, *https://blogs.bing.com/search/2015/08/06/bing-to-warn-customers-about-the-threats-of-fake-online-pharmacies/*.

[7] National Association of Boards of Pharmacy, "Not Recommended Sites," January 2, 2019, *https://safe.pharmacy/not-recommended-sites/*.

[8] Roger Bate and Kimberly Hess, "Assessing Website Pharmacy Drug Quality: Safer Than You Think?", *PloS One5,* no. 8 (August 13, 2010), *https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0012199;* and Roger Bate, Ginger Zhe Jin, and Aparna Mathur, "In Whom We Trust: The Role of Certification Agencies in Online Drug Markets," *B.E. Journal of Economic Analysis and Policy* 14, no.1 (2013):111–50.

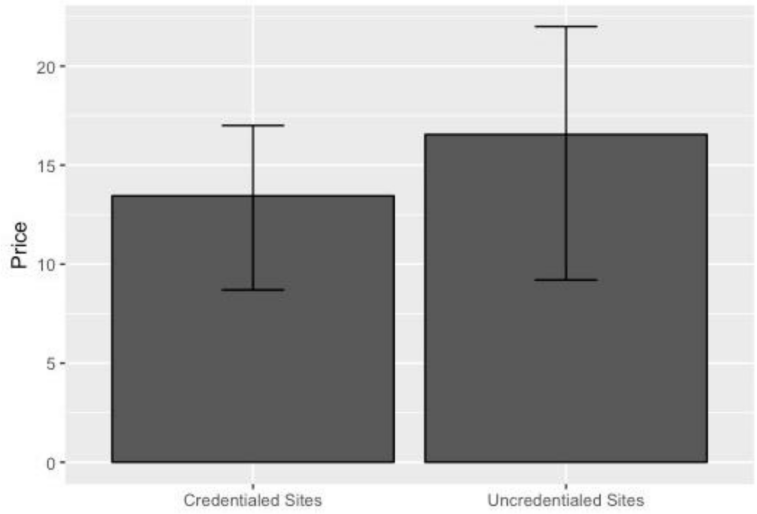
Using the NABP list of sites it deems unacceptable has led to a ludicrous and dangerous outcome, as a myriad of non-credentialed sites have no such pop-up warnings.

This report investigates the quality of a key medicine dispensed by sites with warnings and without warnings. In doing so, this report will evaluate the quality of Bing's warning system and offer commentary on the use of online notifications to ensure patient safety in purchasing pharmaceuticals.

Online Buying

I undertook a simple Bing search using the terms "Viagra" and "Canada," and a string of adverts and websites popped up. The foreign sites credentialed by *PharmacyChecker.com* or the CIPA (such as Canadian Pharmacy King) have a pop-up warning against them. But sites such as *Canadian-pharmacyon.com,* which explicitly state that one can get prescription drugs without prescriptions and are not credentialed by any entity, have no pop-up warnings.

Figure 1. Average Price of Viagra Obtained from Credentialed and Uncredentialed Sites



Source: Author.

Using the same methodology as with previously published peer-review studies,[9] I sampled Viagra from credentialed sites with Bing pop-up warnings and from uncredentialed sites not displaying pop-up warnings. I bought the smallest samples possible from nine credentialed sites and 14 uncredentialed sites, primarily based on how someone might shop using a Bing search: The earlier an item appears in a search of "Viagra" and "Canada," the more likely it is to be purchased.

Using a handheld Raman spectrometer, I tested for authenticity as per previous research. Raman spectrometers are frequently used as a quick, reliable, and cost-effective way to differentiate between genuine and counterfeit drugs.[10] The device compares an unknown sample—in this case a pill—to a reference standard by comparing the frequencies of certain kinds of light that are scattered after the two substances have been illuminated with a monochromatic laser.[11] The device compares the resulting "spectra" from the scans, which generates a p-value denoting the probability that the difference between the reference standard and the sample is due to measurement uncertainty rather than the difference in molecular structure. There-

[9] See Bate and Hess, "Assessing Website Pharmacy Drug Quality."
[10] Bate and Hess, "Assessing Website Pharmacy Drug Quality."
[11] Mark R. Witkowski, "The Use of Raman Spectroscopy in the Detection of Counterfeit and Adulterated Pharmaceutical Products," *American Pharmaceutical Review* (January/February 2005), *http://www.horiba.com/fileadmin/uploads/Scientific/Documents/Raman/aprraman.pdf.*

fore, a p-value of greater than or equal to 0.05 would represent a pass result (*i.e.,* any difference is due to measurement uncertainty), while a p-value of less than 0.05 would represent a failed result.[12]

Results

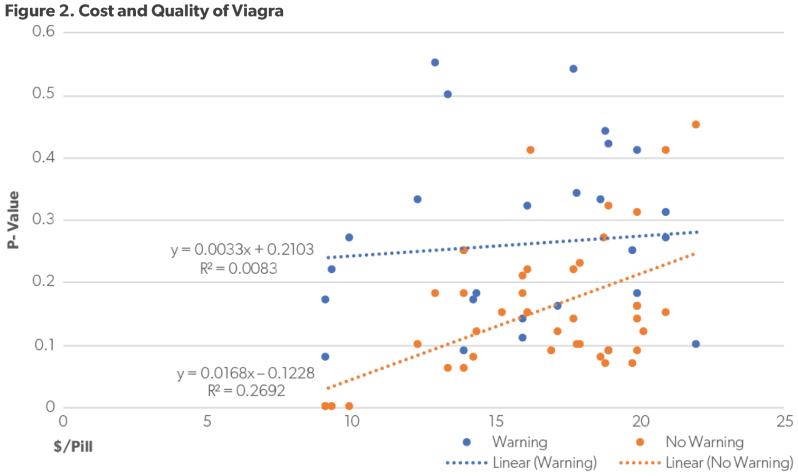
After testing several pills from each site, the nine credentialed sites yielded 28 results, and the 14 uncredentialed sites yielded 39 results. None of the samples from the credentialed sites failed, whereas four of the 39 samples from two of the uncredentialed sites were not authentic and appeared to be fake, displaying no correct spectra for Sildenafil (the active ingredient in Viagra).

In addition to the uncredentialed sites including fake medicines, on average they were about 25 percent more expensive. The average cost was $16.55 per pill (ranging from $9.20 to $22.00 per pill), whereas it was $13.45 (ranging $8.70 to $17.00 per pill) from the credentialed sites (Figure 1). The fake pills were at the cheaper end at $9.50 per pill. But as the saying goes, nothing is as expensive as a fake medicine. It does not work, and it might kill you.

These prices were then compared with U.S. brick-and-mortar pharmacies, which from a quick online search averaged around $41.00 per pill. With pills bought from credentialed sites being a third of the price of those bought at U.S. pharmacies, one can see why people buy online. The discount price from foreign sites is actually understated because I did not buy the cheapest per-pill deals but just the smallest sample size possible. People who buy in larger quantities could get pills at the lowest end of the range, well under $9.00 each.

Figure 2 shows the quality measurements (p-values) plotted against the price. Of the sites with a warning, the trendline is almost flat, implying that price has no relationship with quality. Within this sample, that makes sense. All the samples are from licensed pharmacies selling products, presumably identical Pfizer or Pfizer-licensed products.

Figure 2. Cost and Quality of Viagra



Source: Author.

However, the sites without a warning show a rising trendline and an R-squared with some explanatory power. The implication is that more expensive products are better quality, probably actual Pfizer products. Extrapolating from the trend line, anything cheaper than $10.28 a pill is likely to fail authentication, and anything below $7.30 is likely to have zero p-value and be a fake.

---

[12] Thermo Scientific, "Analytical Methods for Field-Based Material Identification and Verification: Probabilistic Evaluation vs. HQI Similarity Assessment," 2014, *https://assets.thermofisher.com/TFS-Assets/CAD/Application-Notes/TS-Pharma-pvalue-HQI.pdf;* and Gurvinder Singh Bumbrah and Rakesh Mohan Sharma, "Raman Spectroscopy—Basic Principle, Instrumentation and Selected Applications for the Characterization of Drugs of Abuse," *Egyptian Journal of Forensic Sciences* 6, no. 3 (September 2016): 209–15, *https://www.sciencedirect.com/science/article/pii/S2090536X15000477.*

It is interesting that the failing products are cheaper. Web sellers (of drugs and probably most products) fall into two main camps: those that want repeat business and hence do the best job they can satisfying the customer (cheap, quality products reliably delivered) and those that want to make what they can from a customer now, not expecting their business again. These sellers may sell shoddy products or not even deliver the product after the money is taken. They obviously want to sell at high prices, but with competition from good sellers, they will probably price low to attract customers. So those selling fake products are likely to sell cheaply to attract buyers. This finding is particularly disconcerting with drugs because those looking online on overseas sites are by definition looking to save money and hence may go to the cheapest sources.

I noted in extensive prior research that fake drugs are usually priced similarly to the legitimate product they are copying, sitting literally alongside real drugs on shelves.[13] This was in order *not* to differentiate themselves from the market primarily because the vast majority of pharmacists are not complicit in their sale but are being duped too. But the unique characteristics of buying on the web—where sellers can be anonymous and where repeat business may be less likely—can make the pricing different.

In earlier work on web purchasing, I saw some cheaper pricing of fake Viagra, but it was more pronounced in this latest sample.[14] Viagra is an unusual product in that it is in high demand but not often covered by insurance, and some men will not want to ask for a prescription. As a result, individuals maybe more likely to buy from risky sources than they would for other pharmaceuticals. To confirm a pricing and quality bias, one would need to sample different types of drugs over time.

But from this small sample, one can conclude that someone going to Bing to find Viagra is being directed to less safe sites, some of which are selling fake products. That is not to say that those sites know they are selling bogus products. Often, sellers go to an intermediary, or an intermediary seeks them out, offering to sell cheaper versions of the product. Commercial buyers of these products should, on their customers' behalf, test the products, but often they will not go to the expense of doing so. This also gives them plausible deniability if the products end up being bogus. Such action is negligent, but sellers may genuinely not know whether they are selling a good deal or a dangerous fake.

Conclusion

One repeatedly hears of the dangers of buying online. When a respected search engine such as Bing warns one against a site, only a fool would buy from it. Yet Bing's policy is driving people away from sites selling authentic and cheaper Viagra and onto ones that sell potentially fake, more expensive products. The results may differ if one picked other medicines to sample. But Viagra is one of the most popular medicines to buy online, and it must at least represent a scenario of the dangers involved in Bing's policy.

Bing's policy to alert searchers of the possible dangers of buying medicine from foreign websites has backfired. Rather than encouraging safer purchasing of pharmaceuticals, the measure is driving consumers to uncredentialed sites that may be dangerous and did send me fake Viagra while advising consumers not to buy from credentialed sites with good track records. Bing has made a mistake and should rectify its policy immediately.

About the Author

Roger Bate is an economist who researches international health policy, with a particular focus on tropical disease and substandard and counterfeit medicines. He is a visiting scholar at the American Enterprise Institute.

[13] Roger Bate, *Phake: The Deadly World of Falsified and Substandard Medicines* (Washington, DC: AEI Press, 2014).

[14] Bate and Hess, "Assessing Website Pharmacy Drug Quality"; and Bate, Jin, and Mathur, "In Whom We Trust."

PREMIER, INC.
444 North Capitol Street, NW, Suite 625
Washington, DC 20001
T 202–393–0860
F 202–393–6499
https://www.premierinc.com/

The Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the Senate Finance hearing titled "Drug Pricing in America: A Prescription for Change, Part I" scheduled for January 29, 2019. We applaud the leadership of Chairman Grassley, Ranking Member Wyden and members of the Committee for holding this first in a series of hearings scrutinizing prescription drug pricing and considering policy and oversight solutions to lower costs for American patients.

Premier is a leading healthcare improvement company, uniting an alliance of more than 4,000 U.S. hospitals and health systems and approximately 165,000 other providers and organizations to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. A 2006 Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. A key component of our alliance is our Integrated Pharmacy Program, which combines essential clinical data with purchasing power to deliver reduced costs, improved quality and safety, and increased knowledge-sharing with other healthcare professionals.

Premier is a solution to the rising cost of drugs. We need, however, policy changes for us to continue to succeed in our work to reduce healthcare spending. We have developed policy solutions that are attainable, practical, and sustainable.[1] As the Committee begins to examine the rising cost of drugs and develop policy and oversight solutions to help lower costs for Americans, Premier urges the Committee to focus on the following as overarching principles:

- ***Solutions that use competitive forces to lower drug prices and increase the availability of generic medications and biosimilars in the marketplace***—A wealth of research and Premier analytics show that competition in the pharmaceutical marketplace brings down prices. Competition from generic drugs has saved the U.S. healthcare system $1.46 trillion from 2005 to 2015.[2] According to the FDA, drug prices drop to roughly 52 percent of brand-name drug prices with two manufacturers producing a generic product, 44 percent with three manufacturers and 13 percent with 15 manufacturers.[3] This dynamic is reflected in the fact that 88 percent of dispensed prescriptions are for generic drugs, yet they account for only 28 percent of total drug spending.[4] But in order to increase the competitive forces, more players are needed.

  By aggregating the buying power of U.S. hospitals, Premier's drug portfolio prices have grown less than half the rate of the industry average inflation rate. Premier is saving our members millions of dollars by driving economies of scale, creating transparency around pricing and quality and applying competitive pressure to the marketplace.

  Therefore, solutions to address drug prices should focus on promoting the use of competitive forces to bring additional generic and biosimilar competition to the market.

- ***Sustainable solutions to address drug shortages that decrease barriers to entry, namely the time and cost to enter the marketplace, while maintaining the quality and safety of the product***—Drug shortages continue to plague the healthcare system and have grown in both number and intensity in

[1] Premier previously provided detailed comments in response to the "HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" request for information. Available at: *https://www.premierinc.com/wpdm-package/premiers-response-trump-administrations-rfi-drug-pricing/*.

[2] "Generic Drug Access and Savings in the U.S. 2017." Available at: *https://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf*.

[3] IMS Health, "Price Declines After Branded Medicines Lose Exclusivity in the U.S." January 2016. Available at: *https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/price-declines-after-branded-medicines-lose-exclusivity-in-the-us.pdf*.

[4] *Id.*

the past two years.[5] Over the past 15 years Premier has implemented innovative strategies enabling us to reliably supply our members with 91 National Drug Codes (NDCs) that are on the drug shortage list. We have also embarked on an expanded partnership strategy with suppliers we expect will extend this progress. This work, therefore, is not done, and we will not stop until we have eliminated drug shortages. A recent study found that prices for drugs under shortage between 2015 and 2016 increased more than twice as quickly as they were expected to in the absence of a shortage.[6] Another recent study found that the price of fluphenazine tablets in 2016 increased by over 2000% during a shortage.[7] Therefore, solutions to address drug prices should focus on eliminating drug shortages to prevent the subsequent price increases that occur during a shortage.

In closing, the Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the Senate Finance Committee's hearing on drug pricing. As an established leader in using competitive forces to lower drug prices and working towards eliminating drug shortages, Premier is available as a resource and looks forward to working with Congress as it considers policy options to address this very important issue.

If you have any questions regarding our comments or need more information, please contact Soumi Saha, Senior Director of Advocacy, at soumi_saha@premierinc.comor 202–879–8005.

PUBLIC CITIZEN
1600 20th Street, NW
Washington, DC 20009
202–588–7769

Public Citizen, a national public interest organization with more than 500,000 members and supporters, urges senators to advance legislation to address the top congressional priority of people across the country: taking action to lower prescription drug prices.[1]

Currently, one in five Americans reports not taking their medication as prescribed because of cost,[2] while many others face financial hardship and are forced to reduce spending on other necessities, like groceries, because of high drug prices.[3]

Public Citizen is encouraged by the Senate Committee on Finance demonstrating that it takes the problem of high prescription drug prices seriously by dedicating its first hearing of the 116th Congress to the subject, but this hearing must be followed by passing bold, meaningful policies that will deliver the relief that is needed and demanded by people around the United States.

Numerous pieces of legislation were introduced in the 115th Congress and some already in the 116th Congress that would increase access to medicines and collectively provide tens of billions of dollars in savings annually. Specifically,

- The Medicare Negotiation and Competitive Licensing Act (H.R. 6505, 115th Congress) would lower prices for prescription drugs for Medicare Part D beneficiaries and taxpayers by requiring the U.S. government to negotiate directly with pharmaceutical manufacturers. Through competitive licensing, the Act safeguards patients' access to medicines, even when negotiations fail to reach a reasonable price.

---

[5] FDA public hearing, "Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions." Available at: *https://healthpolicy.duke.edu/events/drug-shortage-task-force.*

[6] Hernandez I, Sampathkumar S, Good CB, Kesselheim AS, Shrank WH. "Changes in Drug Pricing After Drug Shortages in the United States." *Ann Intern Med;* 170:74–76. doi: 10.7326/M18–1137.

[7] Fox E.R., Tyler L.S. (2017). "Potential association between drug shortages and high-cost medications." *Pharmacotherapy* 37, 36–42. 10.1002/phar.1861.

[1] *Politico* and Harvard T.H. Chan School of Public Health, "Americans' Top Priorities for the New Congress in 2019" (December 2018), *https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2019/01/Politico-Harvard-Poll-Jan-2019-Health-and-Education-Priorities-for-New-Congress-in-2019.pdf.*

[2] The Commonwealth Fund, "How the Affordable Care Act Has Improved Americans' Ability to Buy Health Insurance on Their Own" (2016), *https://www.commonwealthfund.org/publications/issue-briefs/2017/feb/how-affordable-care-act-has-improved-americans-ability-buy?redirect_source=/publications/issue-briefs/2017/feb/how-the-aca-has-improved-ability-to-buy-insurance.*

[3] Lisa Gill, *Consumer Reports,* "How to Pay Less for Your Meds," *https://www.consumerreports.org/drug-prices/how-to-pay-less-for-your-meds/.*

- The Stop Price Gouging Act (S. 1369, 115th Congress), would put an end to steep, unfair prescription drug price spikes by imposing penalties on corporations that price gouge proportionate to the severity of the abuse. Researchers estimated that this bill would have saved $26 billion in taxpayer dollars through Medicare Part D alone in 2015.[4]
- The Prescription Drug Price Relief Act (S. 102) would help put an end to patients rationing treatment and suffering financial hardship because of exorbitant drug prices. It would ensure that U.S. drug prices are not higher than those paid in other large, wealthy economies and enable the government to license competition when pharmaceutical corporations set excessive prices on the medicines that people need.
- The Affordable Drug Manufacturing Act (S. 3775, 115th Congress) would establish an Office of Drug Manufacturing within the Department of Health and Human Services to ensure drug corporations with *de facto* monopolies are not able to spike prices with impunity and to provide stability in the supply of important generic medicines.
- The CREATES Act (S. 974, 115th Congress) would help put an end to brand-name pharmaceutical companies engaging in anticompetitive tactics to deny manufacturers of generics and biosimilars access to product samples they need to obtain FDA approval and market entry. This practice delays the introduction of price-lowering generic and biosimilar competition, and the brand-name manufacturers inappropriately extend their monopolies.
- The Preserve Access to Affordable Generics and Biosimilars Act (S. 64) and the Competitive DRUGS Act (H.R. 4117, 115th Congress) would help end pay-for-delay deals, wherein brand-name companies pay generic firms not to bring low-price generic or biosimilar versions of their brand-name prescription drug product on the market for a certain period of time, by making such deals presumptively anticompetitive, helping to bring price-lowering competition to market sooner.

High prescription drug prices will continue to be an issue of national significance and a priority for all Americans. It is crucial for legislators to advance meaningful policies that will be felt by people across the country who are rationing treatment and facing financial hardship because of exorbitant prescription drug prices.

LETTER SUBMITTED BY DEBRA L. RAFFLE

February 26, 2019

Chairman Grassley and the Committee:

I hope I am not too late and will be read at least. I only received this notification a few days ago from the American Diabetes Association.

I have type 1 diabetes. I was diagnosed around 9–11, sadly that it makes it easy to remember. The cost of insulin that I need to stay alive 24 hour a day has escalated from $70 per 1,000 ml vial to nearly $300 a bottle. The same bottle of Novolog sells for $47.99 in Canada. I just had to pay $2,300 out of pocket for 3 months of insulin (and that was with a supposed discount!) The insurance I have through my employer has an extremely high deductible and high co-pays and some items are not covered at all. If my insulin pump supplies are not covered, I simply cannot afford them. If I can't afford to manage my diabetes the way my doctor and I have been successfully through pump therapy all these years, I will likely get sick, get a complication or two and then ultimately die. This is insane to me! I should be able to afford my insulin and pump supplies, as in the past, but due to escalating prices of medications, insulin and insurance costs (so they can all make their profits) it is becoming unsustainable. I can't afford it and I am very healthy and have a good paying job.

I would like to fight insurance companies who seem to think we can do without these drugs—insulin is not even a drug, it's something my body quit making that most of you all take for granted, but without it, I will, in fact, die within a few days/possibly lingering a few weeks in a coma. I didn't ask for this; however, if I am able

[4] Thomas Hwang and Aaron Kesselheim, "Taxing Drug Price Spikes: Assessing the Potential Impact," *Health Affairs Blog,* May 12, 2017, *https://www.healthaffairs.org/do/10.1377/hblog20170512.060041/full/*.

to get what I need, what my doctor prescribes for me and have that covered by my insurance, I remain healthy. I also take a medication called Symlin that allows me to utilize my insulin more efficiently. It decreases my insulin intake about 30%. This helps me maintain a healthy weight. More insulin means more weight and more weight means taking more insulin. It's a vicious circle. I am a type 1 so I have never been over weight and I struggle to maintain my weight for the reasons I have listed above. If I can maintain my weight, not only will I be healthier, but I can take slightly less insulin to help combat the astronomical cost of something that I MUST HAVE EVERY SINGLE DAY OF MY LIFE. By reducing my intake by 10 units a day, I may get another day or two out each vial and that's a lot! It certainly will NOT help my overall health to put on extra pounds! Anyhow, my new insurance will not cover Symlin at all and they tell me it will cost $5,800 for a 3 month's supply that I used to pay $70 co-pay when I had Premera. I have been on this drug about 10 years. This is ridiculous and clearly, I cannot afford this, so I get to go off its cold turkey, increase my insulin intake and pay more than I ever have for the same insulin!

I don't think they understand how this all works nor do insurance companies and administrators care, but if you give us the tools (medications and supplies) to manage our diseases with, we will not have as many costly complications. So, it is cost effective to give us what we need now to avoid higher costs of complications later! To date, since I was diagnosed as a type I in 2001 and having been on an insulin pump for 17 years, I have never had any complications due to my diabetes and would like to keep it that way.

I am so disgusted with insurance companies and I want to know what we can do to get things changed. Can I go up to Canada and purchase my insulin? What can I do to lower my medication and durable medical equipment costs? The insurance company cannot even tell me what things cost until I purchase them, which is ridiculous since I don't want to pay for things I clearly cannot afford. I'm lost and feeling desperate. I look to you to make this manageable disease. It is manageable if we can afford what we need to survive and there's NO reason for the price to quadruple in the last 10 years, NONE except for greed and profits.

I spent over $6.5K last year on out pocket medical costs, mostly insulin and pump supplies. I had no surgeries, I had no illnesses, I had no procedures. This is becoming very difficult to afford.

I don't think I should have to struggle to afford groceries and lose my home or just make simple choices because I can't afford my insulin and supplies. Please do something about the escalating cost of health care, specifically common insulin, Novolog in my case and do what you have promised for many years. This is unsustainable!

Thank you for listening,

Debra L. Raffle

STATEMENT OF MARY J. RUWART, PH.D.

How to Lower Drug Prices Virtually Overnight Without Compromising Safety, Effectiveness, or Innovation

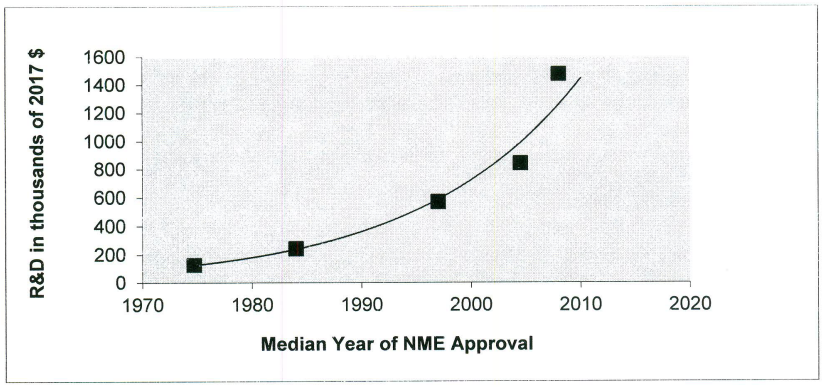
Chairman Grassley, Ranking Member Wyden, and distinguished members of the Committee, my name is Mary J. Ruwart, Ph.D. For 19 years, I was an award-winning Research Scientist at the Upjohn Company in Kalamazoo, Michigan. My job was to discover and develop new drugs.

After leaving pharmaceutical research, I presented some of the following information at the American Association for Pharmaceutical Sciences. Others still in the industry told me that they wholeheartedly agreed with my data and its conclusions, but would never speak out publicly because of their fear that the FDA might retaliate against the companies that employed them. Consequently, drug company executives who testify to your committee may be hesitant to confirm the material I share with you today.

Figure 1 shows how the industry's R&D costs are rising exponentially each year for new drugs (referred to in the industry as a "new molecular entity" or NME). For the past 4 decades, the collaborators cited in footnote 1 have used consistent methodology, including the cost of failures, to estimate R&D. Therefore, while one might

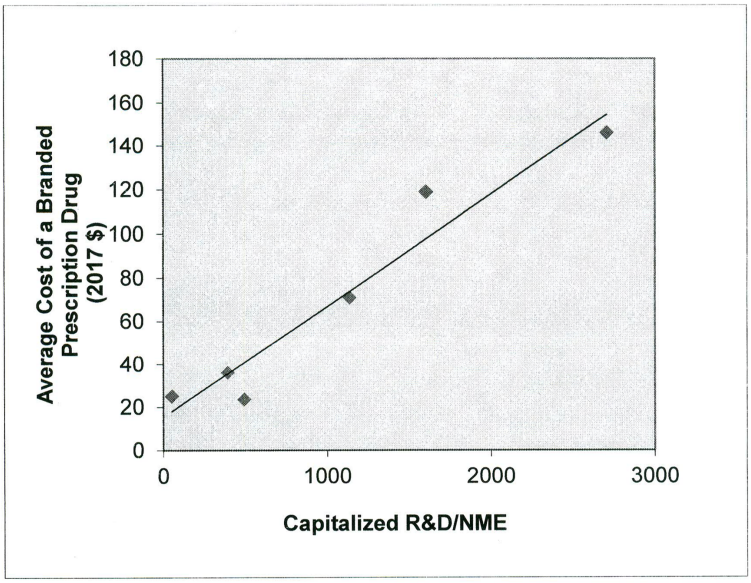
dispute their reported out-of-pocket R&D costs, there should be no disagreement about the trend, which is greatly increasing each decade. Capitalizing these costs would approximately double these estimates.

Figure 1. Average Out-of-Pocket R&D Costs per NME Plotted against Median Year of NME Approval[1]



Economics 101 tells us that to stay solvent, businesses must pass the cost of producing their products on to consumers. The largest single cost of a new drug is its R&D, not its manufacturing costs. Indeed, as you can see from Figure 2, the price of new (brand-name) drugs rises along with R&D (r^2 = 0.93 for the technically inclined).

Figure 2. Inflation-Adjusted Average Branded Prescription Drug Prices[2] as a Function of Capitalized New Drug R&D[3]



[1] Data taken from Hansen (1979); DiMasi, Hansen, Grabowski, et al. (1991); DiMasi, Hansen, Grabowski (2003); DiMasi and Grabowski (2007); and DiMasi, Grabowski, and Hansen (2016) and converted to 2017 $ by the author.

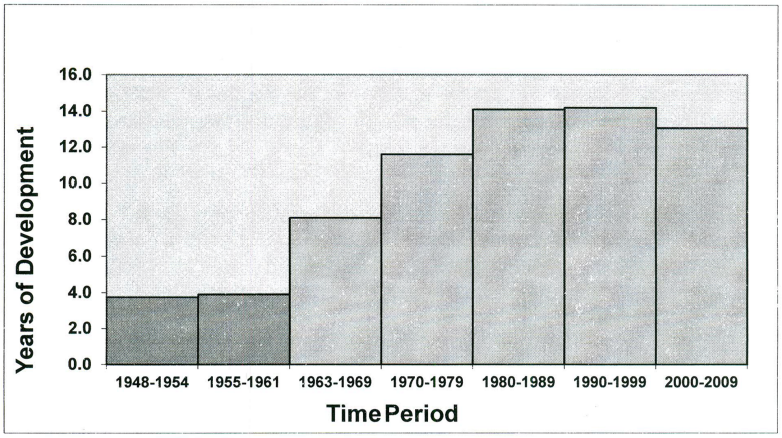
Clearly, new drug R&D drives what we pay at the pharmacy. However, even after approval, only about 3 out of 10 new post-Amendment drugs recover their R&D costs.[4] The entire industry relies on blockbuster drugs for its survival. Drugs launched between 2005 and 2009 are not even expected to recover their R&D, let alone produce an after-tax profit.[5]

Why are R&D costs soaring and driving drug prices up? As a scientist involved in R&D, *I saw first-hand that increased regulatory demands were largely responsible for rising development costs.* Even as research became more efficient with computers, automation, and the rapid data sharing made possible by the Internet, regulatory demands grew. Instead of bringing in more researchers for drug discovery, the industry hired more scientists to run FDA-mandated studies.

The soaring drug prices of the past several decades give the impression that they've always been on the rise. In fact, real (inflation-adjusted) drug prices *fell 32%* from 1949 to 1961.[6] Only since the passage of the 1962 Kefauver-Harris Amendments has the cost of getting FDA approval risen so steeply.

How did the Amendments shift us from declining drug prices to soaring ones? Figure 3 illustrates how the Amendments more than tripled the time needed to take a drug from the lab bench to the marketplace, with a slight decrease after the Prescription Drug User Fee Act was passed in 1992.

Figure 3: Average Development Time of NMEs before (black bars)[7] and after (gray bars)[8] the Passage of the 1962 Kefauver-Harris Amendments to the Food & Drug Act



[2] The average price for a branded prescription drug was taken from Eli Lilly Company (1972, 24) and U.S. Census Bureau (2012, 113, Table 159) and converted to 2015 dollars by author.

[3] Capitalized R&D/NME was calculated by author from data taken from Schnee (1970); Baily (1972); Hansen (1979); DiMasi, Hansen, Grabowski, et al. (1991); DiMasi, Hansen, Grabowski (2003); DiMasi and Grabowski (2007); and DiMasi, Grabowski, and Hansen (2016) and converted to 2017 $ by the author.

[4] Grabowski, Vernon, and DiMasi (2002); Grabowski and Vernon (1994).

[5] Berndt, Nass, Kleinrock, and Murray Aitken (2015).

[6] Telser (1975).

[7] Pre-Amendment development times for self-originated and acquired new drugs were taken from Schnee (1970). Development times were adjusted by the author to reflect a mixture of 78% self-originated new drugs and 22% acquired new drugs to correspond to the post-Amendment data. Acquired drugs generally take longer to get to market because the time to negotiate a licensing agreement can greatly extend development time. The transition year 1962 is not included in the graph.

[8] The 1963–99 post-Amendment development times were taken directly from DiMasi (2001), which reported a mixture of 78% self-originated new drugs and 22% acquired new drugs. The estimate of the 2000–09 development times was made as follows: The 1990s development time for self-originated new drugs was 11.8 years as per DiMasi, Hansen, and Grabowski (2003). The 2000s development time for self-originated drugs was 10.7 years as per DiMasi, Grabowski, and Hansen (2016). The difference between the two time periods was 1.1 years (11.8 years–10.7 years). If we assume that acquired new drugs in the 2000s enjoyed the same decrease in development time from the 1990s as self-originated ones, the estimated development times for the 2000s would be 13.1 years (14.2 years–1.1 years).

Figure 3 suggests that the FDA requirements have stabilized, but this is not the case. The Amendments are open-ended; the FDA can, and does, increase regulatory requirements. Regulatory-driven clinical trial requirements are the costliest; the Tufts group credit human trial complexity as responsible for the largest cost increases.

The development timeline has been kept steady in recent years as drug companies have become more efficient at development, in spite of the increasing regulatory demands. However, part of that "efficiency" is gained through increasing the cost of development, such as doing animal dose-response studies concurrently instead of sequentially. Such a strategy requires the addition of extra groups and doses that would otherwise not be needed, for example.

If increased regulatory demands gave us safer and more effective drugs, we might find the skyrocketing drug prices a small price to pay. However, there is little or no evidence for these presumed benefits. For example, prior to the Amendments, the rate at which drugs approved by the FDA were withdrawn from the market because of safety concerns was 2.5%.[9] Since Amendment passage, the withdrawal rate has actually been somewhat higher, averaging 3.4%.[10] Clearly, the Amendments have not prevented more unsafe drugs from reaching the market.

Why wouldn't the extra studies required by the Amendments result in more safety? The reason is simple: animal studies and the relatively small clinical studies that precede FDA approval simply cannot predict every side effect that we'll see when large numbers of people take new drugs.

In addition, because of the difficulty in recovering R&D costs, drug companies favor development of drugs meant to be taken for years, if not decades. While our bodies can detoxify drugs taken for a short period of time, lengthy treatments deplete the cofactors, such as vitamins, that the body uses to transform drugs into less harmful metabolites. In addition, people take more drugs than ever before, creating drug-drug interactions that can be harmful. As a consequence, about 106,000 people die each year from properly prescribed drugs.[11]

If anything, the Amendments have brought us less safety, not more. Indeed, Vioxx was arguably the deadliest drug ever marketed in the United States and it was approved under the Amendments.

Proponents of the Amendments believe that without them that thalidomide-like drugs would reach the American market. However, pre-Amendment regulations had sufficient power to stop thalidomide approval in the United States and did so. The Amendments were overkill.

The primary thrust of the Amendments was to ensure that all marketed drugs were effective, so that people wouldn't waste their money on drugs that didn't work. Studies suggest that about 7–10% of pre-Amendment drugs were totally ineffective,[12] presumably because the marketplace discouraged companies from marketing drugs that didn't work. Manufacturers feared that doctors would be hesitant to prescribe their products in the future if today's drugs were ineffective. The Amendments might have done a slightly better job of regulating effectiveness, but the cost was soaring drug prices, clearly a poor trade-off.

The biggest cost of the Amendments, however, is not in skyrocketing drug prices, but in the premature death of millions of Americans who died waiting because of the long development time line or the loss of innovation as pharmaceutical companies shifted their funds from research to development. I estimate that each of us may have lost as many as 5–10 years[13] of our lives to the Amendments.

The good news is that if these costly regulations are harming us instead of helping us, we could dispense with them, thereby slashing development costs, encouraging innovation, and making drugs much more affordable. Safety won't be compromised, because the Amendments have, if anything, decreased it.

---

[9] Gieringer (1985); Wikipedia; Bakke, Wardell, and Lasagna (1984).

[10] Bakke, Manocchia, de Abajo, et al. (1995); U.S. FDA (2005); Wikipedia; Throckmorton (2014).

[11] Lazarou, Pomeranz, and Corey (1998).

[12] Peltzman (1974). The National Academy rated about 7% of prescription drugs approved before 1962 as "lacking substantial evidence of effectiveness" for any of the indications for which they were sold (NRC 1969, 12). Jondrow (1972) re-evaluated their data and concluded that evidence of effectiveness was lacking for as many as 9% of pre Amendment prescription drugs.

[13] Data too voluminous for this testimony, but can be submitted upon request.

Based on past experience, effectiveness might be expected to decline, but I find that unlikely. Because of the Internet, patients can widely share their own opinions of whether or not drugs help them. Producers of ineffective drugs are likely to be punished by bad reviews, which may deter physicians from readily prescribing them.

On the other hand, today's patients are acutely aware that the regulations keep them from getting access to new drugs. Right to Try (RTI) legislation was passed to alleviate this problem, but manufacturers often don't have enough drug supplies prior to approval to supply RTI patients. Companies often hesitate to engage in direct negotiations with patients for fear, warranted or not, of FDA retaliation.

Doing away with the Amendments will likely be considered too drastic to be politically expedient. However, plans have been proposed which could allow for an intermediate solution. Heartland's *Free to Choose Medicine* (FTCM) initiative,[14] for example, would permit drugs that have had FDA-regulated human safety trials to enter a totally separate market-regulated development track. FTCM requires more rigorous disclosure by the pharmaceutical companies, so that a comparison could be made between drugs marketed under the current FDA-regulated pathway and the FTCM track. FTCM drugs will have regulatory oversight only in the early stages of development; the decision as when to market would be made by the developing company.

In conclusion, this abbreviated testimony illustrates how soaring drug prices are driven by ever increasing regulatory costs, identifies the 1962 Kefauver-Harris Amendments as driving this regulatory expansion, and provides evidence that this legislation didn't give us safer drugs or greatly improve drug efficacy. Indeed, we all have probably lost 5–10 years of our lives due to the Amendments.

Until the 1962 Amendments are rolled back or modified, drug prices will continue to soar. Other proposed tweaks will be, at best, temporary fixes if the underlying problem behind rising drug prices is not addressed.

References

Baily, MN. 1972. Research and Development Costs and Returns: The U.S. Pharmaceutical Industry. *Journal of Political Economy,* Jan.–Feb.;80(1): 70–85.

Bakke, OM, MA Manocchia, F de Abajo, et al. 1995. Drug Safety Discontinuations in the United Kingdom, the United States, and Spain from 1974 through 1993: A Regulatory Perspective. *Clinical Pharmacology and Therapeutics,* Aug.;58(1): 108–17.

Bakke, OM, WM Wardell, and L Lasagna. 1984. Drug Discontinuations in the United Kingdom and the United States, 1964–1983. *Issues of Safety, Clinical Pharmacology, and Therapeutics,* May;35(5): 559–67.

Berndt, ER, DN Nass, M Kleinrock, and M Aitken. 2015. Decline in Economic Returns from New Drugs Raises Questions About Sustaining Innovations. *Health Affairs* Feb;34 (2): 245–252.

DiMasi, JA. 2001. New Drug Development in the United States From 1963 to 1999. *Clinical Pharmacology and Therapeutics,* May;69(5): 286–96, Figure 5.

DiMasi, JA, and HG Grabowski. 2007. The Cost of Biopharmaceutical R&D: Is Biotech Different? *Managerial and Decision Economics,* June;28: 469–79.

DiMasi, JA, HG Grabowski, and RW Hansen. 2016. Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs. *Journal of Health Economics,* May;47: 20–33.

DiMasi, JA, RW Hansen, and HG Grabowski. 2003. The Price of Innovation: New Estimates of Drug Development Costs. *Journal of Health Economics,* Mar.;22(2): 151–85.

DiMasi, JA, RW Hansen, HG Grabowski, et al. 1991. Cost of Innovation in the Pharmaceutical Industry. *Journal of Health Economics;* 10: 107–42.

Eli Lilly Company. 1972. The Lilly Digest. (Indianapolis, IN: Eli Lilly Company), 24.

Gieringer, DH. 1985. The Safety and Efficacy of New Drug Approval. *Cato Journal,* Spring/Summer;5(1): 177–201.

Grabowski, HG and J Vernon. 1994. Returns to R&D on New Drug Introductions in the 1980s. *Journal of Health Economics* 13: 383–406.

[14] *https://www.heartland.org/Center-Health-Care/free-to-choose-medicine/index.html.*

Grabowski, HG, J Vernon, and JA DiMasi. 2002. Returns on Research and Development for 1990s New Drug Introductions. *Pharmacoeconomica;* 20 Suppl. 3:11–29.

Hansen, RW. 1979. The Pharmaceutical Development Process: Estimates of Current Development Times and Effects of Regulatory Changes. In *Issues in Pharmaceutical Economics,* ed. RI Chien (Lexington, MA: Lexington Books).

Jondrow, JA. 1972. Measure of the Monetary Benefits and Costs to Consumers of the Regulation of Prescription Drug Effectiveness [dissertation]. (Madison: University of Wisconsin).

Lazarou, J, BH Pomeranz, and PN Corey. 1998. Incidence of Adverse Drug Reactions in Hospitalized Patients. *Journal of the American Medical Association,* Apr. 15;279(15): 1200–05.

Peltzman, S. 1974. Regulation of Pharmaceutical Innovation: The 1962 Amendments (Washington, DC: American Enterprise Institute for Public Policy Research).

Schnee, JE. 1970. Research and Technological Change in the Ethical Pharmaceutical Industry [dissertation]. (Philadelphia: University of Pennsylvania).

U.S. Census Bureau. 2012. Table No. 159. Statistical Abstract of the United States. (Washington, DC: U.S. Government Printing Office).

Telser, LG. 1975. The Supply Response to Shifting Demand in the Ethical Pharmaceutical Industry. In *Drug Development and Marketing,* ed. RB Helms. (Washington, DC: American Enterprise Institute for Health Policy Research).

Throckmorton, DC. 2014. Non-Clinical Cardiovascular Safety Testing: Moving Forward. Oct. 22, 6. *http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm420834.pdf,* acc. May 15, 2016.

U.S. FDA. 2005. CDER 2005 Report to the Nation: Improving Public Health Through Human Drugs. (Rockville, MD: U.S. Food and Drug Administration).

Wikipedia. List of Withdrawn Drugs. *https://en.wikipedia.org/wiki/List_of_withdrawn_drugs,* acc. Oct. 25, 2013.

LETTER SUBMITTED BY JERRY I. SCHAEFER, ATTORNEY AT LAW

2201 Vista Grande Drive
Vista, California 92084–2734
(760) 724–5681 Tel
(760) 726–8427 Fax
Email: jerry@jerryschaefer.com

March 12, 2019

U.S. Senate
Committee on Finance
Dirksen Senate Office Bldg.
Washington, DC 20510–6200

Re: Import prescription drugs from Canada

Dear Sen. Chuck Grassley of Iowa:

The costs of prescriptions in America are inflated; I can speak from experience because I need to take two separate medications. The cost in the States at Walgreens for one medication is $380.00 per month, the other is $337.00 per month, and totaling $717.00 month; with the discounts offered the cost is $638.63 for 1 month. One of the medications is manufactured in Germany by Boehringer Ingelheim and sold by Pharmaceuticals, Inc. in Ridgefield, CT. The other medication is manufactured in Loughborough, England, and sold by Merck in Whitehouse Station, NJ. Both drug companies also sell the same medications in Canada and Germany. Yes, not counterfeit, but the same companies, and I purchase them through a legit pharmacy in Canada, and for a 3-month supply the total cost is $663.18. If I purchased the drugs at Walgreens, the 3-month supply would total $1,915.89. Yes the drugs are manufactured by the same firms, and are not generic.

I can provide the committee with invoices to verify what I paid for the medications if you require, including the labels of where and who manufactures them.

In addition, the U.S. Government has threatened both Visa and MasterCard from taking payments for the medications, and American Express is the only credit card company that stills allow the payments.

We know where the former congresspeople are now employed who voted for Plan D and blocked Medicare from negotiating for lower costs of medicine.

Sincerely,

Jerry I. Schaefer

○