S. HRG. 115–869

THE COST OF PRESCRIPTION DRUGS: AN EXAMINATION OF THE NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE REPORT "MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE"

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED FIFTEENTH CONGRESS

FIRST SESSION

ON

EXAMINING THE COST OF PRESCRIPTION DRUGS, FOCUSING ON AN EXAMINATION OF THE NATIONAL ACADEMIES OF SCIENCES, ENGINEERING AND MEDICINE REPORT "MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE"

DECEMBER 12, 2017

Printed for the use of the Committee on Health, Education, Labor, and Pensions

Available via the World Wide Web: *http://www.govinfo.gov*

U.S. GOVERNMENT PUBLISHING OFFICE

48–379 PDF WASHINGTON : 2022

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

LAMAR ALEXANDER, Tennessee, *Chairman*

MICHAEL B. ENZI, Wyoming
RICHARD BURR, North Carolina
JOHNNY ISAKSON, Georgia
RAND PAUL, Kentucky
SUSAN M. COLLINS, Maine
BILL CASSIDY, M.D., Louisiana
TODD YOUNG, Indiana
ORRIN G. HATCH, Utah
PAT ROBERTS, Kansas
LISA MURKOWSKI, Alaska
TIM SCOTT, South Carolina

PATTY MURRAY, Washington
BERNARD SANDERS (I), Vermont
ROBERT P. CASEY, JR., Pennsylvania
AL FRANKEN, Minnesota
MICHAEL F. BENNET, Colorado
SHELDON WHITEHOUSE, Rhode Island
TAMMY BALDWIN, Wisconsin
CHRISTOPHER S. MURPHY, Connecticut
ELIZABETH WARREN, Massachusetts
TIM KAINE, Virginia
MAGGIE WOOD HASSAN, New Hampshire

DAVID P. CLEARY, *Republican Staff Director*
LINDSEY WARD SEIDMAN, *Republican Deputy Staff Director*
EVAN SCHATZ, *Democratic Staff Director*
JOHN RIGHTER, *Democratic Deputy Staff Director*

(II)

C O N T E N T S

STATEMENTS

TUESDAY, DECEMBER 12, 2017

THE COST OF PRESCRIPTION DRUGS: AN EXAMINATION OF THE NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE REPORT "MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE"

Tuesday, December 12, 2017

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The Committee met, pursuant to notice, at 10:02 a.m. in room SD–430, Dirksen Senate Office Building, Hon. Lamar Alexander, Chairman of the Committee, presiding.

Present: Senators Alexander [presiding], Isakson, Paul, Collins, Cassidy, Young, Murray, Casey, Franken, Bennet, Whitehouse, Baldwin, Murphy, Warren, Kaine, and Hassan.

OPENING STATEMENT OF SENATOR ALEXANDER

The CHAIRMAN. The Committee on Health, Education, Labor, and Pensions will please come to order.

Today, we are holding our third hearing on drug pricing to look at the new National Academies Report, "Making Medicines Affordable: A National Imperative."

Senator Murray and I will each have an opening statement. Then we will introduce the witnesses, and after their testimony, Senators will have 5 minutes for questions.

Recently, I received a letter from Joseph in Cordova, Tennessee. We say it Cordova in Tennessee.

[Laughter.]

The CHAIRMAN. He wrote, "Senator Alexander, I just got back from a trip to my local pharmacy. Unfortunately, I was unable to purchase some of the medicine my family needs because one of the medications was $150. I want to know how you plan to get this problem under control. In the meantime, I guess my family will just have to suffer since we cannot afford the medications that they need."

I know that every Member of this Committee has heard similar stories from their constituents.

Our three hearings on the cost of prescription drugs have been based on a bipartisan request, led by Senators Cassidy and Franken, along with Senators Collins, Baldwin, Murkowski, White-

house, Capito, Sanders, Enzi, and Warren; almost all the Members of our Committee.

This is our fourth hearing on drug prices, if you consider how many questions on drug prices Alex Azar, the nominee for Health and Human Services Secretary, had to answer at his confirmation hearing 2 weeks ago.

At our first two hearings, we heard from prescription drug manufacturers, pharmacists, doctors, health policy experts, and others to try to understand what goes into the price patients pay when picking up their prescriptions.

The cost Americans pay for their prescription drugs is an important topic. More than 4.5 billion prescriptions are written for drugs each year for Americans, who then pick up those prescriptions at 60,000 pharmacies, or receive them from doctors or hospitals, and from online pharmacies.

While we are living in a time of remarkable biomedical research that is leading to new drugs, that can stop a stroke and cure hepatitis C, it is critical that patients can afford to pay for these miracle drugs.

According to the Centers for Medicare and Medicaid Services, national health expenditures in the United States were nearly 18 percent of our Gross Domestic Product in 2016, or $3.3 trillion, and are projected to rise to 20 percent in 2025.

Our reason for concern is how this compares to other industrialized countries. In 2014, the World Bank showed the United Kingdom was spending 9.8 percent of its Gross Domestic Product on health care, Germany 11.1 percent, and Finland 9.6 percent.

To give what we are talking about today some context, the Center for Medicare and Medicaid Services says that hospital stays and doctor visits account for about half of national health expenditures. The other half includes home healthcare, nursing care, medical equipment such as wheelchairs and eyeglasses, and our subject for today, prescription drugs.

According to the National Academies Report, about 10 percent of healthcare expenditures is on prescription drugs; 17 percent if you include prescription drugs received in hospitals and at the doctor's office.

Like most elements in our healthcare system, spending on prescription drugs increases every year, sometimes by as little as 1.3 percent as in 2016, and in other years by as much as 12.4 percent as in 2014. Big increases in spending may be driven by the introduction of a new and lifesaving drug, such as the hepatitis C treatment introduced in 2014.

But there can be differences between what the overall increase on spending on prescription drugs is in any given year and what a patient actually spends on his or her prescription when he or she goes to fill it.

The system is extremely complex. There are many factors that could have caused Joseph, who wrote the constituent letter I mentioned, to be charged $150 for his prescription.

For example, what type of insurance plan did his family have? Is it a prescription drug where there is only one manufacturer? Is it a new drug with no generic substitute available? What is the list price of the drug established by the manufacturer and what is the

actual net price of that drug after all of the negotiations and rebates?

What we learned at our first two hearings is that all of these factors affect what patients pay when they pick up a prescription from the pharmacy or receive it at the hospital.

I think we all recognize it is a complex system to get a prescription drug from the manufacturer to the patient, and that the complexity affects what and how much of his or her own money a patient pays for their prescription drugs.

That is why it is important we have Norm Augustine testifying here today, to hear about the National Academies' work on prescription drug prices, and to discuss the thoughtful recommendations published in their new report, "Making Medicines Affordable: A National Imperative."

The Academies noted in their report, "There is not enough accessible information to determine with certainty which segments of the biopharmaceutical sector are principally accountable for the rising cost of many pharmaceuticals."

I think many of us here today would agree that more information is needed to find reasonable solutions for people like Joseph.

I believe most ideas in Washington fail for the lack of the idea, so it is important for us to hear concrete recommendations from independent and knowledgeable experts.

These are thoughtful recommendations from the Academies. They deserve careful analysis. I am sure there will be a vigorous debate before Congress comes to any conclusion.

My understanding is the research for this report was concluded in May, so it does not take into account policy changes since then. Since May, Congress has taken some significant steps to address some of the concerns in the report.

In August, Congress passed, and the President signed, updated user fee agreements, which pay for a quarter of the Food and Drug Administration's work that, we hope, will take steps to help FDA approve more new drugs more quickly.

For example, the new law includes a provision from Senators Collins, McCaskill, Cotton, and Franken to encourage the development of new generic drugs to increase competition and bring down prices.

In addition, through a provision in the new law offered by Senators Hatch and Menendez, and action taken by Dr. Gottlieb at the FDA, two loopholes have been closed to prevent drug manufacturers from taking inappropriate advantage of incentives for the development of prescription drugs for rare diseases.

Mr. Augustine, we are looking forward to hearing more about these recommendations from you today.

We will also hear from David Mitchell, a cancer patient, who has become an advocate for policies to make drugs more affordable.

We were sorry that our former colleague, Dr. Tom Coburn, could not make it today. We wish him a speedy recovery.

We welcome, instead, Doug Holtz-Eakin, and thank him for accommodating our request to join the panel today. He is a well-respected economist and a former head of the Congressional Budget Office.

Senator Murray.

OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. Well, thank you very much, Chairman Alexander.

I really do appreciate your continued commitment to hold these bipartisan hearings on prescription drug costs.

This truly is an urgent discussion. It is an issue that touches so much of this Committee's other work. In fact, there are few concerns I hear more about in my travels across Washington State, and the country, than the high cost of prescription drugs.

Today's high prices are an unsustainable burden on our healthcare system as a whole, for doctors and hospitals, insurers and employers, and most importantly for the patients and families we all represent.

I have heard from far too many people who are forced to choose between a high priced medication and paying the bills or putting food on the table. Not only is that no choice at all, but it is plain wrong and unacceptable.

It is well past time for this conversation and for more progress on this issue.

Now, as I have noted before in these hearings, we have taken some key actions to address this issue. Together, this Committee worked to increase transparency and foster more competition in the generic drug market in the FDA Reauthorization Act of 2017 which, as you heard, passed in August.

In that bill, we accelerated the review of generics that can alleviate anticompetitive markets. We improved the process for bringing a generic to market by increasing communication and transparency between FDA and drug manufacturers.

We encouraged the development of new generics to compete with sole source products vulnerable to price hikes and shortages.

We made sure orphan drug exclusivities are only granted to new or superior products and eliminated mechanisms being exploited by some companies to delay the entry of generic competitors.

Those are all important steps, but there is more we can, and should, be doing to adequately tackle this issue, which means making more progress to get at the root of the problem, which are the high prices set by drug manufacturers.

On this, we have seen far too much finger pointing from industry and a lot of missed opportunities.

Generic competition alone will not address the high prices paid by so many patients in out-of-pocket costs and high premiums, because as long as manufacturers can actively avoid competition, we are going to continue to see little impact and little change on drug prices.

We have to do more to rein in drug companies' market monopolies, and their abuses, and gaming of our patent regulatory system.

Now, I am proud that Democrats have put forward a number of ideas to tackle these, and other, significant challenges. We have legislation that would demand more transparency from pharmaceutical companies, allow Medicare to negotiate fair drug prices for prescription drugs, prevent manufacturers from engaging in price gouging, and crack down on the various anticompetitive practices that keep prices high.

Now, that will not solve all of our challenges. It will take more and all of us working together. Just as we need the industry to play a more active role on this issue in order to make progress, what is also required is that this Administration has to be a partner, not a hindrance, to our efforts.

As I talked about during our last hearing on drug costs, I see this as a persistent, and very serious, problem from when I challenged President Trump to nominate a new Secretary for Health and Human Services who would actually put patients and families first when it comes to prescription drug prices and other issues.

Unfortunately, President Trump's nominee to lead HHS, Alex Azar, has not convinced me he would be willing to stand up to the Administration's extreme agenda.

I remain very concerned with many of his responses during our nomination hearing on his previous background working in the pharmaceutical industry where, as a senior executive, he supported raising drug costs and about what new steps he would take at HHS to help lower drug prices.

Another issue I raised at our last hearing was the 340B program, which supports hospitals and clinics in serving the very communities who cannot afford the care they need to stay healthy.

On this, the Trump administration has also taken us backward under the guise of reducing drug prices. CMS is cutting the reimbursement for drugs purchased by most 340B eligible hospitals by nearly 30 percent staring in January.

Not only will this do absolutely nothing to combat high drug prices, it will result in less funding for safety net providers to provide critical services to low income and vulnerable patients.

That action is disappointing, and it represents a continued failure, in my belief, by this President to seriously address this issue.

Now, I am glad today we will hear about the report from the National Academies of Sciences, Engineering, and Medicine on improving patient access to drug treatments. I am very much looking forward to our testimony today because the National Academies Report does include several recommendations that, I believe, would make a real difference in bringing down drug prices including many issues I just raised like the Federal negotiation of drug prices, refining methods for determining the value of drugs to improve payment, and greater transparency from drug manufacturers to preventing perpetual market monopolies.

I really want to thank all of our colleagues who are here today, and our witnesses, for joining us.

We have shown here on this Committee that we can make bipartisan progress on this issue, and we really need to build on that foundation to do more, and make sure prescription medications, and lifesaving treatments, are not just available, but accessible and affordable for our patients.

Thank you.

The CHAIRMAN. Thank you, Senator Murray.

I would ask each of the witnesses to summarize your testimony in 5 minutes, please, and that will leave more time for back and forth with questions.

I introduced our witnesses briefly before, and so I will be brief again.

Mr. Augustine, welcome. You have been Chair of the Committee on Ensuring Patient Access to Affordable Drug Therapies at the National Academies of Sciences, Engineering, and Medicine. Over the last 2 years, you have chaired a project at the Academies entitled Ensuring Patient Access to Affordable Drug Therapies. This is your report that is the focus of today's hearing.

David Mitchell is the President and Founder of Patients for Affordable Drugs. A cancer patient with an incurable blood cancer, his experience accessing drugs to treat his cancer led him to found that organization to help change policy.

Doug Holtz-Eakin is the President of the American Action Forum. He is an economist who is a former Director of the Congressional Budget Office, and he also served as Chief Economist of the President's Council of Economic Advisors.

Welcome, again, to all three of you. Thank you for your time.

Let us begin with Mr. Augustine. Welcome.

STATEMENT OF NORMAN R. AUGUSTINE, CHAIR, COMMITTEE ON ENSURING PATIENT ACCESS TO AFFORDABLE DRUG THERAPIES, NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, WASHINGTON, DC

Mr. AUGUSTINE. Thank you, Chairman Alexander, and Ranking Member Murray, and Members of the Committee for this opportunity to share with you the results of the National Academies study of the affordability and availability of prescription drugs.

Our report contains 27 findings, recommendations and 32 specific implementing actions for those recommendations. Our committee sought to find common ground where we could agree upon a package of recommendations that might be helpful to you and others concerned about the issue.

Our report, the recommendations in it and the implementing actions, has the support of a substantial majority of the members of the group. In the case of each of those recommendations, some of the cases, we have unanimous support of the recommendations and the implementing actions.

This is in spite of the fact that we intentionally created the 17 member committee of people with very diverse backgrounds, backgrounds that range from service in Federal and state government, pharmaceutical manufacturing, the practice of medicine, health policy, consumer engagement, R&D, economics, law, public health, and business management.

We are living in what has been described as a Golden Age of the science of healthcare. Yet, in spite of that, as you have pointed out in your opening remarks, that healthcare is not available to many people today for affordability issues, and that certainly includes the ability to buy biopharmaceuticals.

Healthcare represents, as the Chairman pointed out, 18 percent of the GDP today. The closest nation to us in that level of spending, spends 11 percent. To add a sense of context here, with the 7 percent difference between what we spend and the next highest nation, we could pay for our entire primary and secondary education system. We could pay for two defense budgets. We could pay for three transportation and highway systems with just the difference.

Biopharmaceuticals do represent 17 percent of the cost of healthcare. It is over half a trillion dollars a year and increasing rapidly.

A recent study of adult Americans asked the question, "What is the most important thing that the Congress could work on to solve by the end of the year?" The leading answer in that survey was to reduce the cost of pharmaceuticals. That ranked above raising the minimum wage, lowering the deficit, rebuilding the infrastructure, or reducing taxes. This is clearly an important issue.

Effective biopharmaceutical enterprise in this country is vital to our well-being. Very likely there are people in this room who would not be alive today were it not for the accomplishments of the biopharmaceutical industry in years past. But drugs that are not affordable are of no value and drugs that are not available, or have not been developed, are of no value at all.

A few of the package of recommendations that we have offered, I will summarize very quickly. There are many more that are in the book.

The first that I would mention, not in priority order, is to prevent manufacturers from paying other producers to remain out of the market with regard to generics and biosimilars.

Another is to identify specific means to reduce evergreening of drug exclusivity that takes place via the use of peripheral patents or extensions to existing patents.

Allow Federal negotiation of drug prices.

Refine methods for determining the value of drugs and apply that to formulary design and to pricing policy.

Expand the flexibility of formulary design to allow selected exclusion of drugs, such as when other, less costly drugs are available that produce similar clinical outcomes.

Require biopharmaceutical companies, and insurance plans, to disclose net prices received and paid, including discounts and rebates.

Terminate the tax deductibility of direct to consumer advertising.

Remove the cost sharing requirement for patients who exceed the current catastrophic limit under Medicare Part D.

Calculate patient deductibles and co-payments based on net prices, not on list prices.

Increase the oversight of the 340B program to be sure that its use is consistent with the original intent, which was to assist financially vulnerable patients.

Ensure that drugs with orphan designation receive program benefits under the Act only for the target family of diseases intended by the original legislation.

There are many additional recommendations, findings, and specific implementing actions in our report, and we look forward to the opportunity to discuss with the Committee today.

Thank you very much.

[The prepared statement of Mr. Augustine follows:]

PREPARED STATEMENT OF NORMAN R. AUGUSTINE

Chairman Alexander, Ranking Member Murray and Members of the Committee, thank you for this opportunity to share with you the results of the National Academies of Science, Engineering and Medicine study on the affordability and availability of prescription biopharmaceuticals. The National Academies of Sciences, En-

gineering, and Medicine provide independent, objective analysis and advice to the Nation and conduct other activities to solve complex problems and inform public policy decisions.

I appear today in my capacity as Chair of the Committee that performed the study and I will therefore be presenting materials contained in our report. The report is an evidence-based consensus document in which all of the eight recommendations and twenty-seven implementing actions contained therein enjoy the support of a substantial majority of the Committee Members, while some enjoy unanimous support. Two of our colleagues, while agreeing with some of the recommendations, have prepared a minority dissenting view which expresses the concern that the recommendations taken in totality would prove excessive and thus damaging to the Nation's health care and biopharmaceutical system in particular. Seven other colleagues have expressed full support of all of the recommendations and findings but believe further actions are warranted, particularly in the areas of pricing, transparency and value assessment. The recommendations and implementing actions contained in the report thus represent the views of a strong consensus of the Committee's Members.

Our Committee was composed of individuals with highly diverse professional backgrounds in such fields as Federal and state government, pharmaceutical manufacturing, the practice of medicine, health policy, consumer engagement, research and development, economics, law, public health and business management. During our year-long deliberations, the Committee received presentations from 39 individuals either representing themselves or specific organizations, received inputs from members of the public, reviewed several thousand pages of documents, and benefited from written submittals provided by various individuals and organizations. The Committee's draft report was subjected to in-depth review by 16 anonymous reviewers and two overseers chosen by the National Academies and the Committee provided specific responses as to the disposition of each of the reviewers' comments.

Notwithstanding the broad range of perspectives of our members, we sought to find common ground on which to base recommendations that would serve today's patients by reducing the cost of biopharmaceuticals while enabling a vigorous program to develop new drugs to serve future patients. The result of this effort is contained in our report "Making Medicine Affordable—A National Imperative," a report we collectively hope can assist the Nation in resolving what is currently an unacceptable circumstance.

As our presence here today attests, making medicines affordable has emerged as a national priority. The cost of biopharmaceuticals now represents 17 percent of the total cost of healthcare in America. Further, the rate of growth in the cost of biopharmaceuticals significantly exceeds the rate of inflation in the economy, the rate of growth of family income and the cost of healthcare as a whole. A recent survey of adult Americans' priorities for the U.S. Congress through the end of this year placed reducing prescription drug prices as highest ranked; above raising the minimum wage, lowering the deficit, rebuilding the Nation's infrastructure, and reducing taxes.

The amount of money Americans spend on health care as a whole now equals 18 percent of the Nation's gross domestic product. This number has increased steadily for the past 60 years, leading to what today is the highest per capita expenditure on health care in the world. Further, the trend of increasing spending, including on biopharmaceuticals, is projected to continue for the foreseeable future as the Baby Boomer generation ages.

The nation with health care spending that most closely approaches that of the United States allocates about 7 percentage points less of its gross domestic product to this purpose. For perspective, that difference, 7 percent of the United States gross domestic product, would fund America's primary and secondary education system or two of its defense budgets or three of its public transportation and highway budgets.

While it is clearly in the public interest to devote significant resources to health care, such spending is not without its opportunity costs.

Annual expenditures on biopharmaceuticals in the United States now exceed a half trillion dollars. As the cost of drugs has escalated in recent years, insurance plans have implemented benefit designs that attempted to preserve access to care yet keep health insurance premiums affordable by adjusting formularies and increasing co-payments and deductibles—each of which impacts patient cost. Deductibles themselves have, on average, increased by a factor of 2.5 in the past decade.

Yet, while few argue that the current situation is acceptable, virtually each newly proposed potential corrective measure has confronted strong opposition from one or more quarters.

This is in part because an overarching moral issue remains unresolved in the United States: is access to health care—including prescription drugs—a fundamental human right? If it is not, who is to decide, and based on what criteria, which individuals are to be denied access to the drugs and the care that they need? But if health care is a right, who is to pay its costs? Is this cost affordable not only to the individual but also to society as a whole, and does it represent the most appropriate allocation of the Nation's resources?

The burden of high-priced drugs often falls disproportionately on vulnerable elements of the population in spite of government, industry and charitable efforts to alleviate its impact. For example, the Kaiser Family Foundation reports that in 2015, about 20 percent of Americans did not fill at least one prescription due to affordability considerations, while others rationed the drugs that they did acquire. Two-thirds of personal bankruptcies in the United States have been attributed in part or entirely to the overall cost of medical care, including drugs.

Public concern regarding the cost of biopharmaceuticals has been accentuated in recent years by sudden unexplained increases in the price of various existing drugs. For example, media reports cited the unanticipated increase in the price of a two-pack of EpiPens (used to administer epinephrine, a treatment for potentially fatal allergic reactions) from $160 to more than $600. Perhaps the most egregious case involved rights to the existing, non-patent-protected drug Daraprim (used in the treatment of severe infections) with a relatively small market that makes it unattractive to potential competitors. The rights to Daraprim were purchased from its developer by Turing Pharmaceuticals, which raised the drug's price from $13.50 to $750 per tablet.

An effective biopharmaceutical enterprise, the source of a long history of life-enhancing and life-saving accomplishments, is critically important to the Nation's well-being. Without past contributions of this sector, supported by research funded by various agencies of the Federal Government, universities, private philanthropy, venture capital, and biopharmaceutical firms themselves, there would have been no vaccines for many deadly diseases, no statins, and no cure for conditions such as hepatitis C. Almost certainly, some of us in this room would not be here today were it not for the past accomplishments of America's biopharmaceutical enterprise.

Yet, rising prices today threaten to make the products of that enterprise unaffordable to patients, and potentially even to society as a whole.

In the case of most business sectors in the United States, the pressure of competition is the dominant force controlling prices and, to the extent that competition is present, the biopharmaceutical industry is no exception. Nonetheless, if firms that have invested heavily to introduce new products were to be immediately confronted with competitors not having made such investments, there would be little motivation or justification for conducting research and innovating.

In recognition of the importance of encouraging innovation, the U.S. Constitution provided Congress with the authority "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." That is, in exchange for undertaking research and development to introduce new products, the government can, and does, grant patents to firms and individuals, thereby conferring on them for a specified period of time what are in effect sole-source positions in the market.

When the period of patent exclusivity for a drug expires, companies other than the developer are free to introduce "copies"—known as generics or biosimilars—into the market. These latter products represent 89 percent of all prescriptions written and 24 percent of the total cost of all prescription drugs. When generics enter the market, experience shows that the price of the original patented product frequently drops precipitously as the developer seeks to compete with the new, lower-cost entrants or else forfeits some or all of the market. As but one example, the price of Lipitor, the widely used anti-cholesterol drug, dropped from $3.29 per unit to 11 cents per unit when its patent protection expired.

Market forces that promote innovation, while also providing price controlling pressures, have worked quite effectively in most United States industrial settings, raising the question why they appear to be far less effective in the prescription biopharmaceutical arena. The answer resides in the fact that this particular market has important features that distinguish it from most other markets.

Perhaps most significant among these features is that the products of the biopharmaceutical industry can be indispensable, even to life itself—thereby leaving the most important element of the biopharmaceutical chain, the patient, with little or no negotiating strength. Further, the biopharmaceutical sector of the United States has a market structure that is more complex than any other sector in health care—and perhaps more complex than any other sector in the entire economy. It is fraught with discordant viewpoints, divergent priorities and potential conflicts of in-

terest that impede the provision of affordable biopharmaceuticals, especially to socioeconomically disadvantaged populations. The party often possessing the least power in this complex, rather opaque structure is, ironically, its *raison d'être*: the patient.

The Committee concludes that the current approach to the provision of biopharmaceuticals in the United States is not sustainable. If that is indeed the case, only two broad options remain: repair the current system or replace it with a new system. Having dismissed the option of doing nothing, the report offers recommendations based on the preponderance of the available evidence and seeks to substantially improve the existing system. Should such steps, or others like those proposed, prove insufficient, the remaining choice is a system involving substantially increased government sponsorship and control, a single payer (i.e., government insurance), accompanied by governmentally imposed explicit or de facto price regulation.

Some of the package of actions proposed by the Committee are as follows:

The Federal Government should consolidate and apply its purchasing power to directly negotiate prices with the producers and suppliers of medicines and strengthen formulary design. The government should also improve methods for assessing the value that drugs provide and ensure that incentives to develop drugs for rare diseases are not extended to widely sold drugs. In addition, increased disclosure of the financial flows and profitability among the participants in the biopharmaceutical sector should be required.

Action should be taken to continually foster greater access to off-patent generic drugs, which are usually much less expensive than branded products. One way this can be accomplished is to prevent practices that delay entry of generics into the market and thereby extend market exclusivity of branded products. Another critical step is to accelerate the review processes that are required of manufacturers before they can produce generic drugs.

Actions should be taken to eliminate existing incentives that encourage patients and clinicians to seek or prescribe more expensive drugs rather than less expensive alternatives of comparable efficacy. One such action would be to discourage direct-to-consumer advertisements for prescription drugs and to provide substantially more balanced information to patients about the potential benefits and costs of alternative treatments, thereby reducing unjustified demand for higher priced drugs.

Insurance plans should be modified to reduce the financial burden that patients and their families currently experience when they need costly prescription drugs, and individual cost-sharing arrangements that are based on drug prices should be calculated as a fraction of the net purchase price of drugs rather than the list price set by manufacturers. The government should also tighten qualifications for discount programs that have drifted from their original intent which was to help vulnerable populations. Finally, cost-sharing by patients enrolled in Medicare Part D should be terminated when the annual catastrophic coverage threshold has been reached.

Other implementing actions are discussed in detail in the report.

In the end, drugs that are not affordable are of little value; and drugs that do not exist, are of no value.

Thank you for this opportunity to appear before you on behalf of my colleagues on the National Academies Committee and myself.

[SUMMARY STATEMENT OF NORMAN R. AUGUSTINE]

Synopsis from Making Medicines Affordable

Over the past several decades the biopharmaceutical sector in the United States has been very successful in developing and delivering effective drugs for improving health and fighting disease. Indeed, many medical conditions that were long deemed untreatable can now be cured or managed effectively.

This success has come at a cost, however. Spending on prescription drugs has been rising dramatically, to the point that many individuals have difficulty paying for the drugs that they or their family members need. Drug costs are a significant part of the Nation's total spending on health care.

This report, Making Medicines Affordable: A National Imperative, from the National Academies of Sciences, Engineering, and Medicine recommends several strategies to tackle the rising costs of prescription drugs without discouraging the development of new and more effective drugs for the future.

This is a difficult challenge. There may be tradeoffs between current drug affordability and new drug availability. Controlling drug costs too rigidly, for instance,

could potentially reduce the expected profits of drug companies, and this could alter their decisions regarding major investments to develop new drugs.

Furthermore, the complex nature of the Nation's medical system-which includes patients, clinicians, hospitals, insurance companies, drug companies, pharmacists, pharmacy benefit managers, various government agencies, advocacy organizations, and many others-makes it very difficult to predict the precise effects of any specific policy changes. This is exacerbated by the fact that there is very little publicly available information on the costs and profitability for the drug companies and various other participants in the system.

Nonetheless, there are a number of measures that can and should be taken to improve the affordability of prescription drugs for patients in the United States.

The Federal Government should consolidate and apply its purchasing power to directly negotiate prices with the producers and suppliers of medicines, and strengthen formulary design and management. The government should also improve methods for assessing the value that drugs provide and also ensure that incentives to develop drugs for rare diseases are not extended to widely sold drugs. In addition, increased disclosure about the financial flows and profitability among the participants in the biopharmaceutical sector should be required.

Actions to continually foster greater access to off-patent generic drugs, which are usually much less expensive than branded products, should be taken. One way this could be accomplished would be to prevent the common industry practices that delay entry of generics into the market and extend market exclusivity of branded products. Another critical step is to speed up the review processes that are required of manufacturers to produce generic drugs, to ensure healthy competition and lower costs.

Also, various actions should be taken to eliminate incentives in the system that encourage clinicians and patients to prescribe or use more expensive drugs rather than less expensive alternatives that provide comparable results. One action would be to discourage direct-to-consumer advertisements for prescription drugs and to provide more useful information to patients about the potential benefits and costs of treatments, thereby reducing inappropriate demand for higher priced drugs.

Finally, insurance plans should be modified to reduce the financial burden that patients and their families currently experience when they need costly prescription drugs, and individual cost-sharing arrangements that are based on drug prices should be calculated as a fraction of the net purchase prices of drugs rather than the list prices from manufacturers. The government should also tighten qualifications for discount programs that have drifted from their original intent to help vulnerable populations.

Ongoing monitoring will be needed, but taking these steps should bring down the cost of prescription drugs while still enabling the continuing development of new drugs.

The CHAIRMAN. Thank you, Mr. Augustine.

Mr. Mitchell, welcome.

STATEMENT OF DAVID MITCHELL, PRESIDENT AND FOUNDER, PATIENTS FOR AFFORDABLE DRUGS, BETHESDA, MD

Mr. MITCHELL. Thank you, Senator.

Chairman Alexander, Ranking Member Murray, Members of the Committee.

I am very honored to be here today, especially alongside such distinguished panelists.

I am David Mitchell. I am Founder of Patients for Affordable Drugs. We are bipartisan. We focus on policies to lower drug prices. We do not accept funding from any organizations that profit from the development, or distribution, of prescription drugs.

More importantly for today, I have an incurable blood cancer, and I am one of those people alive today because of the work of the biopharmaceutical industry. Prescription drugs are keeping me alive.

Right now, my treatment is 5 hours of infusions that carry a price tag of $450,000 a year. I am very grateful to the science and research community for these drugs.

Because my disease is incurable, it mutates and finds its way around drugs. I need new ones if I am going to live as long as I hope. This is not theoretical for me. This is literally life and death.

But my experience has taught me one irrefutable fact, and that is: drugs do not work if people cannot afford them.

Since our launch in February, we have built a community of almost 20,000 Americans from every state. They tell us devastating stories of skipping doses, cutting pills in half, going without food, even declaring bankruptcy because of the price of their drugs. They are scared, they are angry, and they need help.

The National Academies of Sciences Report includes many excellent recommendations that will help them, and we are here today to encourage Congress to act on it. Here is a patient perspective on a few of those recommendations.

We agree with the National Academies that Congress has to end patent abuses that circumvent Hatch-Waxman. Drug corporations get up to 12 years of exclusivity to recoup their investment and earn handsome profits. But too many drug companies game the system to block generic competition that would lower prices. Here is a personal example.

I took a drug called Revlimid for 5 years. Over the course of my treatment, Celgene, the company that makes the drug, refused to provide samples to generic companies so that a cheaper alternative could come to market.

At the same time, the price of Revlimid increased by 34 percent, and my co-payments went up by 600 percent. In fact, Revlimid became the most expensive out of pocket drug on Medicare Part D with a median out of pocket cost for beneficiaries of $11,500 a year. That is one impact of patent abuse.

Patients are foregoing their medications. They are spending their retirement funds, emptying their kids' college savings to afford drugs when a generic competitor is sitting around the corner, if we could get to it. The bipartisan CREATES Act would fix this specific problem.

Two, we should limit out of pocket costs for Medicare Part D. We believe beneficiaries should not be charged based on retail prices when everyone else in the system pays based on rebated prices. The Trump Administration is moving to address this and we encourage Congress to support that.

Three, Medicare should be able to negotiate directly to lower prices, to balance Government granted monopoly pricing power given to the drug companies so that we can get the benefit as purchasers. Every other developed country in the world negotiates. We should too.

Four, Congress should end tax breaks for drug company advertising. Willie Gray is a farmer from North Carolina. He told us, "I cannot afford my diabetes medication and the only way I stayed afloat was to use our savings account. Then I had to start cashing in my annuities and retirement at the Farm Bureau."

Drug companies spend significantly more on advertising and marketing than they do on research and development. We do not believe that Willie and his wife should subsidize their TV ads.

Five, we really need to increase transparency all along the supply chain. Three pharmacy benefit managers control almost 80 percent of the market, and they operate in secret. The National Academies recommendations would pull back the curtain and require disclosure of discounts and rebates.

In conclusion, we believe our healthcare system should maximize affordability and accessibility of drugs while ensuring a robust R&D pipeline and fair profits for companies. We believe that balance has been lost and patients are paying the price.

I will close with a story from Oregon. Anne Nielsen's doctor prescribed Restasis to treat her chronic dry eye. The drug will cost her $1,400 this year and there is no cheaper generic for a drug whose active ingredient went off patent in 2014. She does not use the recommended dose because it is so expensive.

On behalf of Anne, and all the patients across the country, I am extremely encouraged that Members on both sides of the aisle are focused on helping patients in lowering drug prices. In my experience, the most enduring legislative successes in our country have come with bipartisan action.

Thank you.

[The prepared statement of Mr. Mitchell follows:]

PREPARED STATEMENT OF DAVID MITCHELL

Chairman Alexander, Ranking Member Murray, Members of the Committee: I am honored to be here today.

Section I. Background and Introduction

My name is David Mitchell. I am the Founder of Patients For Affordable Drugs. We are a bipartisan, national patient organization focused on policies to lower drug prices. We don't accept funding from any organizations that profit from the development or distribution of prescription drugs.

More importantly to today's hearing, I have an incurable blood cancer, and prescription drugs are keeping me alive. Several days ago, I received 5 hours of drug infusions that carry a price tag of more than $20,000 every time I get them. I've had them 22 times over the course of the year. $450,000 worth of drugs are keeping me upright.

I am very grateful to the science and research communities in our country for these drugs. Because my disease is incurable, I need innovation and new drugs if I am going to live as long as I hope to. This is not theoretical for me—it is life and death.

But my experience as a cancer patient has taught me one irrefutable fact: **Drugs don't work if people can't afford them.**

Since our launch in February, we have built a community of almost 20,000 Americans across every state.

Piper Peltz of Clinton, Tennessee wrote, "I have a pacemaker and suffer from other conditions as well. I have to resort to taking my expensive heart medicines every other day."

Angel Porche of Montegut, Louisiana was diagnosed with Rheumatoid Arthritis at age 39. Her doctor prescribed Humira to put it in remission, but the drug cost more than she could afford. "So, needless to say, I went without this prescription," she writes. "I was in so much pain because I could literally feel my feet crippling."

There are thousands more stories like Piper and Angel.

People are scared and angry, and they need help.

A September Harvard poll showed that 4 in 10 Americans want lowering prescription drug prices to be Congress' top priority.

Sixty four percent of Americans, including a majority of Democrats, Independents, and Republicans, listed lowering drug prices as their top health care priority, according to a Kaiser Health poll.

The message we hear from patients is simple. They understand that drug corporations have monopoly pricing power. Patients and taxpayers know the prescription drug pricing system in the U.S. is rigged against them. They want leaders in Washington to fight to lower the price of drugs, and to get something done.

This is a central health care issue that impacts millions of people every day. We agree with President Trump: "Drug companies frankly are getting away with murder." Drug companies are not the only ones who take advantage of patients' pocketbooks.

When prices rise, drug manufacturers, PBMs, doctors, and hospitals all make more money. The people our system hurts are patients, consumers, taxpayers, and employers who foot the bill.

Section II. Reflections on the 2017 National Academies of Sciences Report

Last week's National Academies of Sciences, Engineering and Medicine (NASEM) report included a number of excellent recommendations which we support. Here is a patient perspective on some of the most promising recommendations and one potential pitfall.

Recommendations Patients For Affordable Drugs Supports:

- **Limit out-of-pocket costs for Medicare Part D.** We believe beneficiaries should not be charged out-of-pocket costs based on retail prices of drugs when everyone else in the system—employers, insurers, the government—pay based on rebated prices. The Trump Administration requested feedback on implementing this reform, and we encourage Congress to support such a change. We should also cap patient exposure at the catastrophic level of Part D. When drugs cost $20,000 a month, the current system can be crushing for patients.
- End patent abuses that circumvent the bipartisan Hatch-Waxman framework. Examples of patent abuse include: pay for delay, exploitation of restricted distribution systems, product hopping, evergreening, and rental of sovereign immunity from an independent entity.

FDA Commissioner Scott Gottlieb recently told drug manufacturers, "Stop the shenanigans." We agree with him. The Hatch-Waxman Act provides five, seven, or 12 years of exclusivity to ensure drug corporations recoup their investments and earn handsome returns. But too many drug companies game the system to block free-market competition far beyond the stated legal time frames.

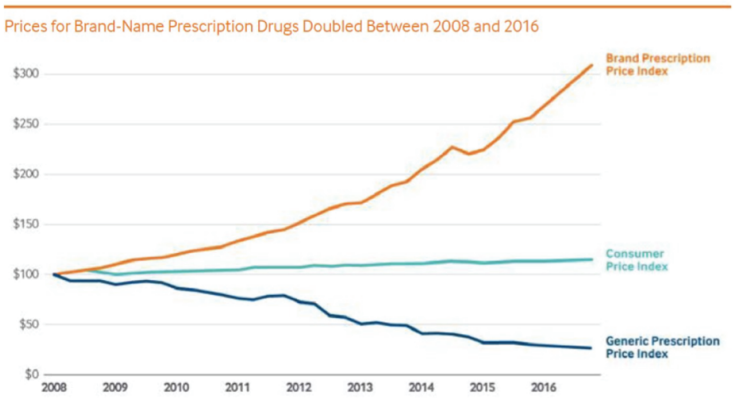
Here's one example. I took a drug called Revlimid for 5 years to keep my cancer at bay. Over the course of my treatment, Revlimid's manufacturer, Celgene, refused to provide samples to generic manufacturers looking to create a competitor. At the same time, the price of Revlimid increased by 34 percent and my co-payments rose by 600 percent. In fact, Revlimid became the most expensive drug for Medicare Part D beneficiaries with a median annual out-of-pocket cost of $11,500.

Pam Holt of Granger, Indiana is a widowed, retired schoolteacher with multiple myeloma. She wants to spend her remaining years spoiling her grandchildren. But she can't. Her Revlimid co-pay is $577 per month.

Patients like Pam also forgo their medications altogether or spend their retirement funds and empty their kids' college savings to afford drugs. This occurs while a generic competitor sits just out of reach.

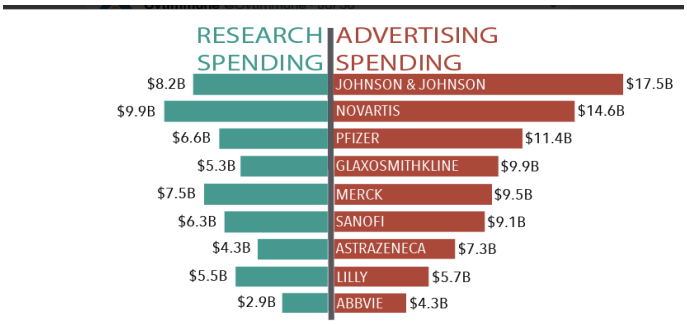
Bipartisan legislation has been reintroduced in both the House and Senate to fix this particular abuse of our system while maintaining safety for patients. The bipartisan CREATES Act (S. 974, H.R. 2212) will help speed generics to market, increase competition, and provide patients access to more affordable drugs. It is supported by experts across the ideological spectrum—from scholars at the Heritage Foundation to academic experts at Harvard University.

- **Allow Medicare to negotiate lower costs for patients.** The government grants drug manufacturers a pricing monopoly during a period of exclusivity. Medicare negotiations would help balance that monopoly pricing power. Below is a chart that demonstrates why we need negotiations—especially for brand drugs—the fastest growing sector of health spending.



Source: Kaiser Family Foundation analysis of data from Express Scripts 2015 Prescription Price Index.

- **End tax breaks for drug companies that spend millions of dollars advertising.** As NASEM noted, drug companies spend significantly more on advertising and marketing than on research and development. It is generally recognized that the drug industry spends 20–40 percent of its overall budget on advertisements and related activities. Only one other country in the world permits direct to consumer advertising for drugs. We don't need to step on a drug company's First Amendment right to advertise, but we don't believe taxpayers should subsidize their TV ads.



The Washington Post, Big Pharmaceutical Companies are Spending Far More on Marketing than Research; February 11, 2015

- **Increase transparency throughout the drug supply chain.** Three pharmacy benefit managers control about 75 percent of the drug market. PBMs negotiate deals in secret, leaving consumers and policymakers in the dark. Americans can't tell if these corporations provide value in the form of rebates for patients or if they keep rebates to increase profits. We do know the combined operating profit of the three largest PBMs was $10.1 billion in 2015, up 30 percent from 2013. The NASEM recommendations aim to pull back the curtains so consumers and policymakers can better understand drug prices by requiring disclosure on all discounts and rebates. The recommendation avoids specific disclosures that PBMs claim would inhibit their negotiating success by recommending disclosures be made quarterly at the national drug code level.
- **We urge caution against so-called outcomes-based pricing arrangements.** First, it is important to distinguish between value-pricing and outcomes-pricing. Value-pricing is conducted by organizations like the Institute for Clinical and Economic Review, the American Society of Clinical Oncology, and the National Comprehensive Cancer Network. They examine the value of a new drug to patients and can serve as one input for negotiations by—for example—the Veterans Administration. Value-pricing can be a useful tool.

On the other hand, outcomes-based pricing is different. It ties reimbursement of a drug to its effectiveness. While this sounds attractive, it's a disaster for patients. Outcomes-pricing in general stipulates that if a drug fails, the drug company will provide a refund. But that system contains a major flaw. It does not lower drug prices; it allows drug companies to keep prices high. Drug companies have the clinical data that tell them exactly how many patients react positively to a drug and how many will fail. Rather than lower prices, drug companies will simply raise the price of a drug to compensate for failures. Furthermore, it is not clear any refunds will make their way to patients. It is also not clear how to use such a process for drugs like insulin where patients react differently as individuals and drug companies may want to claim user error if the patient doesn't do everything right to manage their disease.

Section III: Not Paying Twice For Taxpayer Investment

On August 30, 2017, America crossed into new territory. The drug company, Novartis, chose to price a breakthrough cancer drug called CAR-T at $475,000 per treatment. As NIH Director Francis Collins wrote at the time, the drug is "grounded in initial basic research supported by NIH."

To be specific, taxpayers invested more than $200 million in CAR-T's discovery. We believe drug corporations should disclose how they set prices if a drug is invented using taxpayer funding.

In October, taxpayers unknowingly entered into a partnership with drug corporations to speed new immunotherapies to market. Under this scheme, taxpayers will fund 75 percent of the research—a total of $160 million—and 11 drug corporations will contribute the remaining 25 percent or $55 million.

As a cancer patient, the potential of new drugs is exciting. But in an era of drugs priced at over half a million dollars per treatment, it is no longer appropriate for NIH to conduct basic research and turn that science over to commercializers with no strings attached. Frankly, NIH is helping invent drugs that will bankrupt families and cause our system to buckle under the weight.

We urge Congress to consider ways to require or incentivize price transparency and reasonable pricing when a drug is invented through NIH research. If a drug is built on science and innovation financed by American taxpayers, we have a right know how a drug company chose to price the drug.

Section IV. Immediate bipartisan steps to lower drug prices.

We recognize that many of the suggestions contained in this testimony may be out of reach in the near future. So, we conclude by highlighting five bipartisan ideas we believe could be implemented immediately and would meaningfully lower drug prices for patients.

- **Pass the CREATES Act.** This bipartisan legislation would save taxpayers $3.3 billion, according to CBO, and it would address a loophole that delays generic drug competition.
- **Follow the Trump Administration's lead** to allow Part D Medicare beneficiaries to pay out-of-pocket costs based on rebated—not retail—drug prices.
- **Support FDA in its efforts to eliminate the generic backlog**—especially for off-patent drugs where there is no generic competitor. This could mean additional resources or an increased focus on the problem.
- **Investigate the insulin market.** Three insulin manufacturers command 80 percent of the market for this lifesaving drug. Together, the companies raised prices more than 300 percent in the past 10 years—for a drug invented in 1923 and for which the patents were sold for $3. The prices move in lockstep and people with diabetes suffer at the hands of what can only be called an insulin cartel. Democratic and Republican Members in the House are already looking into the insulin market. We encourage Congress to conduct an investigation into anti-competitive behavior and possible price-fixing by Eli Lilly, Novo Nordisk, and Sanofi.
- **Outlaw rental of sovereign immunity.** Recently, the Irish drug company, Allergan, transferred patent rights to its blockbuster drug Restasis to the St. Regis Mohawk Tribe. The drug company explicitly acknowledged the move was intended to prevent vulnerability from inter partes review under the America Invents Act. A Federal judge correctly characterized this as a rental of sovereign immunity designed to dodge our patent laws. Such rental from any sovereign entity should be outlawed.

In conclusion, we believe our health care system should maximize affordability and accessibility of drugs while ensuring a robust R&D pipeline and fair profits for

companies. We believe that balance has been lost. The current system encourages companies to take advantage of patent loopholes, thwart competition, and put profits over patients. The system encourages high prices that only benefit big players. We hope to work with Congress to lower drug prices and let Americans focus on living healthy and productive lives rather than struggling with the rising cost of medicines they depend on.

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

[SUMMARY STATEMENT OF DAVID MITCHELL]

David Mitchell is the founder of Patients For Affordable Drugs. He has an incurable blood cancer, and innovative drugs are keeping him alive. The price tag of those drugs is over $450,000 a year.

Mitchell is grateful to the science and research communities in our country as he's reliant on new drugs to keep him alive. But he notes in his testimony, "Drugs don't work if people can't afford them."

David and Patients For Affordable Drugs support the National Academies of Sciences (NAS) proposals to:

- **Limit out-of-pocket costs for Medicare Part D.** Beneficiaries should not be charged out-of-pocket costs based on retail prices of drugs when everyone else in the system—employers, insurers, the government—pay based on rebated prices.
- **End patent abuses that circumvent the Hatch-Waxman framework.** Examples of patent abuse include pay for delay, exploitation of REMS and restricted distribution system, product hopping or evergreening, and rental of sovereign immunity.
- **End tax breaks for direct-to-consumer advertising.** As NAS noted, drug companies spend significantly more on advertising and marketing than on research and development.
- **Increase transparency in the drug supply chain.** Three pharmacy benefit managers control about 75 percent of the drug market. Americans can't tell if these corporations provide value in the form of rebates for patients or if they keep rebates to increase profits.
- **Allow Medicare to negotiate lower costs for patients.** The government grants drug manufacturers a pricing monopoly during a period of exclusivity. Medicare negotiations would help balance that monopoly pricing power.

The testimony recognizes that some of the suggestions contained in NAS report may be out of reach in the current environment, so it highlights five bipartisan ideas that would help patients now:

- **Pass the CREATES Act.** This bipartisan legislation would save taxpayers $3.3 billion, according to CBO, and it would address a loophole that delays generic drug competition.
- **Support the Trump Administration's proposal** to allow Part D Medicare beneficiaries to pay out-of-pocket costs based on rebated—not retail—drug prices.
- **Support FDA in its efforts to eliminate the generic backlog**—especially for off-patent drugs where there is no generic competitor.
- **Investigate the insulin market.** Three insulin manufacturers command 80 percent of the market. Together, the companies raised prices more than 300 percent in the past 10 years.
- **Outlaw rental of sovereign immunity.** Do not allow drug companies to transfer patents to sovereign entities to avoid patent challenges under the America Invents Act.

Patients For Affordable Drugs is encouraged that Members on both sides of the aisle are focused on drug prices. We believe the most enduring legislative successes in our country come with bipartisan action.

The CHAIRMAN. Thank you, Mr. Mitchell.

Dr. Holtz-Eakin, welcome.

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

Dr. HOLTZ-EAKIN. Thank you, Chairman Alexander, Ranking Member Murray, and Members of the Committee.

It is a privilege to be here today. I want to congratulate the National Academies on the outstanding report that they have produced, but which I have not read.

Let me outline how I think about this problem and then I would be happy to talk about some of the specifics.

First, I think it is important to recognize that we do not have a single, broad-based problem in the pricing of drugs.

We have some very specific markets that are not working very well, notably sole source generics and some specialty drugs, particularly oncology drugs, which are subject to problems, but by and large, the markets are working well. It is important not to overreach in thinking about solving those problems.

In thinking about high drug prices, there are two separate and distinct things that one ought to keep in mind.

The first is lowering the overall cost of bringing drugs to market and the purchase price of those drugs. In that area, the single most important thing is to encourage entry and competition, eliminate monopoly power, and have markets work effectively to lower prices.

The second is shifting the cost of the drug from one payer to another, from an individual, which is the sole purpose of insurance, to shift those costs elsewhere. Cost shifting lowers a target person's cost, but does not lower the cost of those drugs simultaneously for everyone.

If you really want to solve problems, you need better competition and more entry. Shifting costs will not solve that problem in general.

There are lots of examples of cost shifting in the system. Medicaid "best price," for example, undercuts the competitive pressures in the private market and effectively shifts costs from Medicaid onto private payers.

There is a lot of interest in focusing on net prices, direct and indirect remuneration policies, those which shift costs from the beneficiaries from the ultimate consumer. The question is who is going to pick up that tab? Where will the cost get shifted? Do we want those particular outcomes?

I encourage the Committee to think carefully about that.

In this regard, let me say a little bit about Government negotiation. I was the CBO Director during the passage of the Medicare Modernization Act, which created the Part D program. In that capacity, I wrote numerous letters to Congress about the undesirability of having the Secretary of HHS negotiate on behalf of the Medicare program. I have not changed my views since that time.

In doing that negotiation, the Secretary of HHS does not have anything that a private, prescription drug program has. I mean, they bring large market shares and the capacity to deliver profits to manufacturers. That is what you need.

They also have one more thing that the Secretary does not have. They have a formulary. They have the ability to say to a manufacturer, "I can give you preferential treatment of your product at the expense of a competitor." That is the essence of the negotiation.

In the Academies recommendations, the most important thing is not aggregating the power of Medicare or Medicaid, V.A., or whatever it might be. The most important thing is saying, "We are going to have the Government pick among manufacturers and say yes to one and no to another having a formulary."

That is the essence of the negotiating power and that has nothing to do with it being the Government. It has to do with having a formulary and discriminating among private producers.

If you were to go down that road, one possibility is that the Government would negotiate very effective, good prices for its programs for Medicare, for Medicaid. But in the process, it would force manufacturers to charge higher prices to private payers in order to continue to produce the drugs that we value so much. That would amount to a large cost shift from the private sector onto the Government and not a real success in lowering drug prices.

In all of these cases, there is the potential for big, unintended consequences. This is an important problem. I am thrilled that the Committee is looking at it, but I urge them to focus their solutions in the way that they did in August.

I commend the Committee, and the Congress, for the work it did in trying to speed the drugs to market through the FDA.

In, I think, one of the most important recommendations in the report is the notion that if you have a program, like the orphan drug program or 340B—which has grown in a way that is no longer well targeted on the original problem—reforms are appropriate. The steps have been taken, I think, you should be commended for, and further work can probably be done.

I thank you for the chance to be here today and I look forward to answering your questions.

[The prepared statement of Dr. Holtz-Eakin follows:]

PREPARED STATEMENT OF DOUGLAS HOLTZ-EAKIN

1. Thank the National Academy of Sciences for their contribution to this important policy debate. Let me make a few general remarks and then I will be happy to respond to questions about the specifics.

2. To begin, there is not single drug market and there is not a general problem. There are some specific markets that are generating the attention at the moment—sole-source generics and specialty drugs (especially oncology). The rest are working fine.

3. In thinking about drug prices, it is important to be very clear about two distinct issues:

- Lowering the cost of bringing drugs to market, and the prices generated by market competition
- Shifting the overall cost among stakeholders so as to make drugs more "affordable" to a target group—but not everybody simultaneously

4. Addressing the overall cost issue is inevitably a matter of fostering competition and getting more than on drug on the market. The NAS report as a number of suggestions in this area; for example I like some of the ideas in: "Accelerate market entry and use of safe and effective generics as well as biosimilars; foster competition to ensure the continued affordability and availability of these products."

5. Cost-shifting is pervasive in pharmaceuticals; indeed, it is important to keep in mind that insurance is basically a financial product for cost-shifting. The issue is whether the cost-shifting is deliberate or unanticipated, and furthers a policy goal.

- For example, Medicaid best price undercuts vigorous competition in the private market; effectively shifting costs from Medicaid to private payers
- Proposals to focus on net prices (e.g., "DIR") would shift costs away from beneficiaries. Who would pick up the tab?

- In this regard, let me say a few words about "government negotiations"
  - I have been quite vocal about the non-interference clause in Part D and the absence of any real savings from allowing the Secretary to negotiate. This would not change if Part D were aggregated with Medicaid, or the VA or other programs.
  - What does matter is allowing the programs to institute a formulary and deny manufacturers access to the beneficiary population. It is precisely this ability to impose tiered pricing that has made private competition in Part D so successful. It has nothing to do with the government *per se*.
  - Doing this on a large scale runs the risk of permitting the government to negotiate "good prices", while private sector payer get stuck with higher prices to make up the shortfall. This would be a large cost-shift and not a genuine improvement in drug pricing.

6. Finally, if one has a public policy problem, first stop making it worse. Well-intentioned programs that have grown to be poorly targeted and inefficient—340B and the Orphan Drug program come to mind—should be reformed.

The CHAIRMAN. Thanks to all three of you.

We will now begin a round of 5 minute questions.

Mr. Augustine, the report says that prescription drug prices are about 17 percent of the total national health expenditures.

What should it be? What percent?

Mr. AUGUSTINE. That is probably the most difficult question I faced on this topic.

I think the simplest answer is not to try to quote a percent, but to say that it should be a price that is affordable to each individual. Clearly, that would be a number well below 17 percent.

The CHAIRMAN. But to press the point a little bit.

If you confiscated all the profits of the drug companies—which, I do not know what they are, they might be 6, 8, 10, 12 percent; you are a former businessperson—that would reduce the national expenditure on health by 1 percent.

If you took away all the advertising, that would be another few percent.

I guess, to keep all this in context, the overall prices of drugs, as a part of our national health expenditure, it looks to me like it would only be a modest reduction in cost as a percentage, if we were able to be successful with, say, your recommendations that you have made.

Mr. AUGUSTINE. It is our belief that we could see a substantial reduction.

Many of the abuses that we see in the system, for example, in the 340B program, half the cancer treatments that are provided in hospitals today come under 340B, which was intended for a very narrow, select part of the population.

I think also that as you look at the profitability, the profit margins are much higher than you cite in our view.

Chairman ALEXANDER. I do not know what they are.

Do you know what they are?

Mr. AUGUSTINE. It is very hard to determine for the reason of lack of transparency.

But I think we have been through a lot of the numbers, and a lot of the studies, and I think it seems pretty clear that on-brand manufacturers, it is probably in the 25 to 30 percent range, generics are probably in the 20 to 25 percent range, and you go on down from that. Wholesalers, the PBM's are well below that.

The branded manufacturers, obviously, bear a great risk and great capital requirements, so one would expect them to have high margins.

The CHAIRMAN. Well, let me move since I only have 5 minutes, let me move.

It seems to me, though, that the real thing that we need to try to understand is that my constituent—Joseph, who showed up and tried to buy a pharmaceutical that would help him or Mr. Mitchell trying to buy one that will help him—sees a price increase or a price for that product that is much higher than the overall increase in prescription drugs.

For example, if it went up 10 percent 2 years ago, and 12 percent 1 year ago, and 1.3 percent last year, the overall cost of prescription drugs. Those are, in two of those 3 years, those are pretty large increases, but they are not massive increases.

But is it not true that the person who pays for a prescription at the drugstore, at the pharmacy may be seeing a much bigger increase in prices than the overall cost of producing drugs? If that is the case, how do we deal with that? For example, do we need rebates at all? It seems to me that——

We had a panel in our last hearing, and I asked each one of the witnesses, do you favor having rebates at all from the manufacturers to other people in this process?

Would it not be easier if we just eliminated them?

Would that not make it more likely that Joseph, or the person who buys his prescription drug at the pharmacy, would see and understand what the real cost of producing that specific prescription is?

Did you address the question of rebates and whether we need them at all or not?

Mr. AUGUSTINE. We did spend a good deal of time on the subject of rebates and we did not make a recommendation to eliminate them.

But I think that a recommendation that we made that would best answer your question is that if the Federal Government, and HHS in particular, could negotiate with the manufacturers, they could do that on a package basis.

The problem here is not the cost of the average drug so much, it is the cost of the specialty drugs that are about 30 percent of the total cost of drugs, prescription drugs.

If HHS could negotiate with the manufacturers on Drug A and get a better price on Drug B—because they paid a little bit more on Drug A—they could equalize this burden on a given individual.

I think the idea that the Government could——

The CHAIRMAN. But is that not what the Pharmacy Benefit Managers do?

Mr. AUGUSTINE. They do, but as was pointed out, the largest PBM has a great deal of power in the market, but nothing like the Federal Government would or like HHS would. Of course, the PBM's are there to make a profit too.

It would be our view that giving HHS the power would neutralize, or equalize, this imbalance that exists today.

The CHAIRMAN. My time is up and I try to set a reasonable example for other Senators.

Senator Murray.

Senator MURRAY. Thank you.

Mr. Mitchell, thank you for your testimony. You obviously know firsthand that the impact that prescription drugs have on prices, have on patients and families.

We focus a lot on people who are uninsured or have high deductibles. But high prices actually impact everyone's ability to afford their care and insurance, whether they are covered on Federal programs, or get coverage through their jobs, or buy coverage on their own.

Can you share how high prices impact each of those types of patients?

Mr. MITCHELL. Yes. We hear from people who are on Medicare, on private insurance, on Medicaid, or who are without insurance. The people without insurance, obviously, are bearing the heaviest burden.

When I was on my employer coverage for very expensive drugs like I am taking now, my out of pocket was $6,000 a year.

Medicare beneficiaries, especially under Part D, have an enormous burden because they are paying high prices for some of these drugs, like the one I referenced in my testimony. But the out of pocket ranges for Medicare Part D beneficiaries for the highest priced drugs annually from $4,400 a year to over about $12,000 a year. These are for people whose median income is about $26,000 a year.

Across all forms of insurance, patients are bearing a bigger burden, and the headwaters of this problem are when the price is set by the manufacturer. The pain is worse for patients because they pay their out of pockets based on that retail price set by the manufacturer, not based on the rebate that everyone else is getting.

Senator MURRAY. Right.

Mr. MITCHELL. So that the pain extends across all forms of coverage or lack of it.

Senator MURRAY. The 340B program helps community health centers and safety net hospitals care for those who can least afford it by providing lower cost drugs.

For instance, my home State of Washington, St. Joseph Medical Center in Tacoma saves $5 million on drugs, and that helps them cover the cost of uncompensated care, and supports programs like the diabetes assistance program that provides underinsured diabetic patients with insulin, something we all know has been subject to massive price hikes over the last few years.

As I talked about in my opening statement, the drug industry has spent more time finger pointing on who is responsible for high prices instead of taking action.

Their latest claim is that the 340B program is driving up drug prices for everyone else. But according to HRSA estimates, the discounts manufacturers provided in 2015 only totaled a little over 1 percent of the total drug market that year, and 340B is one of the few mechanisms our system has to keep the prices of drugs down.

I wanted to ask you, Mr. Mitchell, is there any evidence that restrictions on the 340B program would actually result in lower drug prices?

Mr. MITCHELL. Based on my experience from a patient perspective, I do not understand the focus on 340B precisely because of what you just referenced. It is 1.3 percent. The rebates are not the 1.3 percent of our total drug spend.

If there are issues in the 340B program, and it needs to be tightened up in terms of its execution so it can still deliver the result that Congress intended when it enacted it, that seems to be, to me, to be the right step forward that protects those hospitals that provide for our neediest.

But it does not try and use 340B as a way to repair our drug pricing problems because there is not enough money there to do that.

Senator MURRAY. Yes.

There was a recent report that found that 74 percent of the drugs associated with new patents listed with the FDA are actually drugs already on the market. That means that companies are systematically continuing to layer new patents on old ones, on old drugs in order to keep competitors off the market.

The National Academies recommended that in order to foster competition for generics and biosimilars, and allow market forces to drive those prices down, drug companies have to stop gaming the patent and regulatory system to extend these market monopolies.

I really agree with that, and I wanted to ask you, Mr. Mitchell, what are some of the policy proposals we should be considering to help address that?

Mr. MITCHELL. Well, I would urge Congress to enact the CREATES Act right away, this session. It will solve a specific problem of REMS abuse where companies hide behind safety programs to avoid giving samples of drugs so that generics can be developed.

It is bipartisan. It will save the Government about $3.3 billion. We can do that right now.

There are bipartisan bills on paper delay. Paper delay is egregious. It is just a way for them to keep the generic from coming to market. Paper delay should be addressed and then, there are bills to do that right now.

Then product hopping, evergreening, all of those issues need to be dealt with. The most egregious recently is the transfer of a patent to a sovereign entity to defeat patent review under the America Invents Act, and that is just plain offensive.

It is not a game. Patients are really being hurt by this. We hear from them now saying, "I cannot afford the drug and I do not understand why there is not a generic."

Senator MURRAY. Thank you very much. Appreciate that.

The CHAIRMAN. Thank you, Senator Murray.

Senator Paul.

Senator PAUL. Well, I think the Chairman asked a very important question about rebates, and I think it goes exactly to the point of the problem.

We have rising healthcare prices in medical costs. We also have rising drug costs. What the common theme between the two is that the prices are not transparent.

The consumer is disconnected from the price and from the product. You have an intermediary: insurance, your employer, all these other things. Someone else is making the decision.

Almost no one in our country goes to the doctor and bases their decision on price because from Medicare, we all have the same price.

There really is no capitalism or competition in healthcare primarily. Ninety-seven percent of healthcare has somebody in between you and the price.

Occasionally, someone has an HSA and pays, and that is the only true marketplace that you have is 3 percent of healthcare. The same problem exists with drugs.

When we talk about getting rid of rebates so we could make the price transparent to make competition work, we have to go back even further and say, "Why did we get to the rebate system?"

There was, apparently, a court case in 1996 that disallowed discounts. Discounts for big purchasers are a part of competition and capitalism. If Walmart buys a drug and they buy a gazillion of it, they get it at a cheaper price than I do if I buy one lot of it.

The court case apparently made that illegal. Then the drug companies came back over time and reinstituted discounting through rebating, but it is so complicated, nobody understands it. The drug companies are the only people who have the data.

Then you have three Pharmacy Benefit Managers connected to the people selling you the drugs, now wanting to be connected to one of the biggest healthcare providers.

It is a terrible system and it is never going to work. But the only way you would ever make it work is people have to know the price so we could mandate transparency or mandate getting rid of rebates, which is one way of doing it. Or maybe we ought to go back to the very beginning and look at these court cases.

Is there a way we can go back to transparent discounting? Because we should allow discounting, but the system is a terrible system and nobody makes their decision based on cost.

Then as Senator Collins pointed out, you are not even allowed to tell somebody. They have a gag order on people.

Mr. Augustine, when we look at all your recommendations, is there one that you think, or your members thought, had more economic impact if we were to do one thing, one thing that was the most important of the recommendations?

Mr. AUGUSTINE. The recommendations that we made were really a package that were intended to balance the treatment of various problems and the issue.

But to try to answer your question, I think it would be fair to say that the issue you raised, namely, let us get competition back in to this market. We have seen the case where generics enter the marketplace that typically, within a year, the price will drop about in half, and sometimes, of course, much more.

We have also seen that within about 10 years, the price will drop by a factor of 5 from what it was when it was a branded product.

Introducing competition to the marketplace would be probably the most useful thing we could do.

Senator PAUL. One of the things you mentioned was buying out the competition, preventing generics from coming forward.

If we had a purely free market and capitalism, buying out your competition should be legal. However, many of these companies make half of their profits off of Government.

Even I, who believes in an open and free marketplace, if you are contracting with Medicare and Medicaid, maybe we could have a rule that says, "If you want to make money off of Medicare and Medicaid, you have to agree not to have a gag rule. You have to agree not to buyout the generics," and we could make rules. And, "If you do not participate in Medicare or Medicaid, you can still buyout your competition."

But all these people want the Government money and the taxpayer money. Maybe we could have some rules on these things.

I think the evergreening is a big thing, and I think we ought to be able to come to a bipartisan agreement where we just say, "Patents end. You tweak your drug." Then, if you want your monopoly, maybe you should have to provide samples because you are getting a Government monopoly for a certain period of time. Maybe you should have to provide samples.

Then maybe when we look at the evergreening problems, we simply say, "Your patent lasts X long. If you want to tweak your thing, you can have a new patent, but your old drug becomes generic."

That is the mistake is we keep the old drug in the patent system and we do not allow it to become generic. The EpiPen is a great example of this.

But I think there is a possibility we could get to a bipartisan agreement on some of this stuff. Particularly when they are using Government money, I think there could be some more rules on the people that are consuming a lot of Government money.

But we have to somehow get to a price transparency and you can try mandating it or we could try figuring out maybe legalizing the ability to have HSA's and things like that would expand the market where people actually make a decision on their money.

Thank you.

The CHAIRMAN. Thank you, Senator Paul.

Senator Casey.

Senator CASEY. Thanks, Mr. Chairman.

I want to thank the Chairman and the Ranking Member for these bipartisan hearings on this issue. I guess this is our third bipartisan hearing. We are grateful for that.

We have seen some new drugs come to the market with terribly high, even astronomical prices. We have also seen some other, older drugs experience massive price increases. So it is important to understand how each actor in the chain contributes to the high cost.

We all believe, I think, that Congress can act to solve this problem and to contribute to getting costs down for the consumer.

Mr. Augustine, I wanted to start with you, and I guess most of us are at this stage of the hearing.

You said on page 2 of your testimony that, quote, "The burden of high priced drugs often falls disproportionately on vulnerable elements of the population in spite of Government, industry, and charitable efforts to alleviate its impact."

Then you give examples of that. Twenty percent of Americans are not filling a prescription due to affordability and others are rationing drugs that they have used.

I wanted to start with the use of value based payment models. As innovative new drugs are coming to the market, often with significant price tags, many drug companies and payers are exploring this model as a way to manage costs.

They could also improve an individual's health outcomes and the quality of life so significantly that individuals could incur significantly lower costs for healthcare and social services over time.

Mr. Augustine, the fist question I have is one of the recommended actions in the report is to identify approaches to support value based payments.

Can you talk more about that?

Mr. AUGUSTINE. Well, I would be happy to.

From a logic standpoint, I think it is easy to argue that value based pricing makes a great deal of sense. That is what is used in virtually every commodity or article that people buy.

The question is, then, why is it so difficult to use in the case of biopharmaceuticals?

The answer seems to lie in the fact that there is no real agreement on how to measure value. That is really a huge roadblock and that is the reason we did not make that a recommendation, other than to say we ought to try to figure out how to make it work.

The issue one usually runs into is: what is the economic value of a year of human life? Certainly, no one knows how to answer that question, I believe.

Our view is that it offers great promise. It is probably the right long term answer, but we do not know how to do it today.

Senator CASEY. What can you tell us about other countries and their approaches to this?

Mr. AUGUSTINE. Other countries do use something akin to value based pricing.

Generally, those are countries where the government, more or less unilaterally, sets the value of cost effectiveness, if you will, of a drug and they take inputs from all quarters.

But they set the value and it becomes an effective form of not price setting, but they say, "This is the most we will pay." And it becomes a de facto price setting.

Senator CASEY. We recently, the Senate Finance Committee leaders of both Chairman Hatch and Ranking Member Wyden, came together on the CHRONIC Care Act of 2017.

We know that an increasing number of adults will age into the Medicare program over the next two decades, but those same individuals, who are currently not eligible for Medicare, will live with multiple, chronic conditions. More than two-thirds of beneficiaries in the program today have multiple chronic conditions. Chronically ill patients account for, obviously, a large percentage of Medicare spending.

I want to ask you about delivery system reform. What have you found? What can you tell us about the prospects for that and what would you hope we would do on delivery system reform?

I will start with you and others if you have an opinion on it.

Mr. AUGUSTINE. Well, I will just be very brief.

Within the delivery system, there are many conflicts of interest built in due to the structure of the industry, if you will.

If one thinks some of the problems are introduced by direct to consumer advertising, and just to cite that as one example, that represents around $5 billion a year. That does not include digital advertising. It sort of equalizes all companies in the business.

If one were able to control expenditures on direct to consumer advertising, I will be brief here, just by saying it would clearly save a great deal of money.

Senator CASEY. I know we are out of time.

The CHAIRMAN. I am afraid we need to go on.

Senator CASEY. We can get some other answers in writing.

The CHAIRMAN. Sure.

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

The CHAIRMAN. Thank you, Senator Casey.

Senator Isakson.

Senator ISAKSON. Thank you, Mr. Chairman.

I have enjoyed working with Senator Casey on any number of children's-related and drug-related issues. One of them popped into mind a minute ago to ask a question.

Priority review vouchers, I think it came up when I was walking. I heard it mentioned by some. But that is a good way to incentivize the drug industry to develop drugs that might not otherwise be that high on their list because of the anticipated profitability.

Do you all agree that priority review vouchers, and that mechanism to incentivize development, is a good idea?

Mr. AUGUSTINE. Is that addressed to me?

Senator ISAKSON. To you, yes, sir.

Mr. AUGUSTINE. All right. Thank you, Senator.

We did not specifically address that approach, if you will. But anything that would accelerate the process of providing pharmaceuticals would, to us, make a great deal of sense, affordable pharmaceuticals.

Senator ISAKSON. It is an idea that has worked already on some rare childhood cancer drugs, and we think it will work on a lot of other things as well.

It incentivizes the drug company to go to the marketplace, go to the development of a drug in anticipation of getting something that works, to get it to the market as fast as possible, and to help them with the cost of getting it to market.

One way that Novartis has dealt with that issue, I understand, Mr. Chairman, Novartis has negotiated. My staff was telling me this as I sat down, so I am not going to talk as intelligently as I should, but it intrigued me that they are doing results-based pricing. Is that right?

They negotiated the price with CMS for a drug based on the outcome of the drug and its use which, I think, is a terrific idea because a lot of times, you do not know how well these things are going to work or are going to work, except for in field trials which, to a limited basis, limits the information.

I do not know what you think about that idea, but does having a pricing based on results make sense to you?

Mr. AUGUSTINE. The proposal Novartis has made is a very interesting one. It will be a very useful experiment.

The notion of payments being proportional to the result is something we do in every other part of the world, the business world.

If we can figure out a way to actually make it work, it would seem to be a very good step forward.

Senator ISAKSON. I happen to think so, too.

Let me add one other comment, if I may, on pricing.

The average constituent in my state, you ask them, "What is your problem with the drug industry?" All of them talk about advertising. Everybody in my state thinks that advertising is the basic cost in all pharmaceuticals.

You mentioned Restasis a minute ago, and I do not want to pick on anybody, but when I heard that name pop up, after about a month of watching their ads, I figured dry eye was the biggest disease in the United States of America.

[Laughter.]

Senator ISAKSON. It was on every ad on every news show every morning I was watching TV But that is to develop a market for the drug that has been developed, I would assume.

Is that not correct?

Mr. AUGUSTINE. Well, clearly, that is true. It has a number of negative effects.

First of all, the price of the advertising has to go into the price of the product eventually.

Advertising is also used to encourage patients to buy products on a higher tier very many times.

Advertising puts doctors in somewhat of a controversial position of having to defend their judgment against the advertising.

There are just many negative aspects.

The problem we ran into with advertising is that there is a First Amendment issue here, obviously. While it is somewhat ambiguous, the court ruling seemed to suggest it is a real issue.

That is why we did not try to ban advertising, but we said at least do not allow a tax deduction for it.

Senator ISAKSON. Well, I understand the First Amendment question as far as banning the advertising, but it seems to me like some responsibility in the amount of advertising used, there is some way to measure that ought to be judged against the pharmaceutical companies that do it because this stuff we talked about on the dry eye and Restasis and that type thing.

That cost is a tremendous component. The cost of those drugs that the consumer is paying, they could spare it because they think they have the problem because the advertising told them, "You might need it."

We might think of some way we can, like the outcomes-based results for Novartis, same type thing, outcome-based results in terms of the cost of advertising.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Isakson.

Senator Franken.

Senator FRANKEN. First of all, thank you, Mr. Chairman, and the Ranking Member, for holding this series of hearings on prescription drug prices.

Earlier this year, Senator Cassidy and I led a bipartisan group of Senators in asking for these hearings. I am especially proud that many of the recommendations from the Academies track closely the changes that my colleagues and I proposed in the Improving Access

to Affordable Prescription Drugs Act, a comprehensive bill I introduced earlier this spring.

For example the report, like my bill, calls on Congress and the Administration to combat practices that hinder generic competition, to negotiate lower prices for drugs under Medicare and other Federal programs, to discourage direct to consumer advertising. I think, Mr. Mitchell, in your testimony, only one other country gives a deduction, and that is New Zealand.

Right?

Mr. MITCHELL. Only one other country permits it.

Senator FRANKEN. Permits it. Okay.

Mr. AUGUSTINE. New Zealand.

Senator FRANKEN. New Zealand, yes.

Shine a light on financial flows, and profit margins within this extremely complex market structure in the drug industry.

My colleagues will have to carry forward this work after I am gone and I urge them to do so in an expedient and bipartisan manner. Patients, especially those in Minnesota, need relief.

Mr. Augustine, you just recommended that Congress should do what it can to increase competition.

What additional authorities do FDA, FTC, and other agencies need to meaningfully collaborate to tackle drug industry gaming and evergreening?

Mr. AUGUSTINE. Yes, there is a long list of things that would be helpful.

Number 1 would be to permit negotiation between producers and those who represent the patient.

Other things that could be done would be to make it much more difficult to have renewed patents for very similar products.

Another would be to make it difficult to have renewed patents on just related products.

Other regulations that come to mind would relate to the Section 340B and to the Orphan Drug Act, which you have dealt with in your proposed legislation.

There is a long list of things in both the regulatory area and the legislative area that would be very helpful.

Senator FRANKEN. Thank you. I want to move onto Medicare negotiation.

President Trump's nominee to HHS, Mr. Azar, recently appeared before this Committee. During that hearing, I asked Mr. Azar whether he supported policy reforms that would allow Medicare to negotiate lower drug prices just as President Trump has recommended.

Mr. Azar responded by explaining that Medicare Part D, working with Pharmacy Benefit Managers, already secures the best net pricing available, implying that further authority was unwarranted.

Mr. Augustine, it seems that a very large majority of the Members of your Committee disagree with Mr. Azar's assessment and instead have recommended that the Federal Government, working with Congress, consolidate its purchasing power to directly negotiate with producers and suppliers of medicines.

Why do you think this is a better approach?

Mr. AUGUSTINE. Well, the report itself does say that it would be useful for HHS to be able to negotiate on behalf of the patient, if you will. The basis for that is that today, there is an imbalance in strength between the provider and the buyer.

This negotiating process works in most every other element of the U.S. economy. Why does it not work in the biopharmaceutical area?

The reason is that the representative of the patient does not have the choice to walk away from the table or to say, "I will only buy half that many drugs." All the strength is really on the seller's side.

The buyer, unlike most other industries, finds himself or herself in a position where they have something that is absolutely essential and they cannot walk away.

Senator FRANKEN. I would just point out that other countries do this and I do not think that the cost of drugs is like a balloon, as Dr. Holtz-Eakin seems to be saying, that if you lower them here, they are going to increase there.

For some reason in other countries, they are able to do this. They are able to contain this. The difference that we spend on healthcare versus what they spend on healthcare, including on pharmaceuticals, as you pointed out in your testimony, Mr. Augustine, it would pay for primary and secondary education. This is an enormous issue going forward.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Franken.

Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman.

An issue that I brought up at previous hearings, as my colleague Senator Paul has mentioned, is the imposition of gag clauses on pharmacists to prevent them from informing patients that they may be better off paying out-of-pocket than using their health insurance.

For example, NBC did a piece that showed that a consumer who had a co-pay of $43 for a cholesterol drug would have only paid $19 if that consumer had paid out of pocket.

"The New York Times" also wrote about this issue and found that consumers who do not use their insurance, and pay cash in order to save money, find that they are in the situation where insurers will not allow them to apply that purchase to their deductible or their out-of-pocket spending maximum.

Mr. Augustine, what would you think of having the Federal Government ban this practice of gag clauses as a condition of participation in the Medicare or Medicaid programs?

Mr. AUGUSTINE. Senator Collins, our Committee addressed the broad issues that you raise and it is our belief that the way to resolve that is dealing with the larger issue of the lack of transparency.

The fact that people do not know what all is in the agreements that are made between, for example, the drug companies and those in the supply chain, so most people will never even know that a gag clause is there today.

One thing one certainly could do would be to outlaw such clauses or other clauses that come to mind. But there is a broader issue

that we need to address and that is this whole issue of lack of transparency.

Just a quick personal example, not long ago I got a telephone call from the company that provides my drugs. They said they were not allowed to make a choice for me and I needed to make a decision. They had two drugs. Which one did I want?

One was $86 and the other was $5. I said, "Well, what is the difference?" They said, "They are identical." I said, "Well, I think I will go with the $5 drug."

Well, why could they not make that decision for me? They are not allowed to.

Senator COLLINS. Thank you.

Dr. Holtz-Eakin, I know that you firmly believe that what we need is more competition in the marketplace. A bill that has been signed into law that Senator Claire McCaskill and I authored is intended to move more competitors into the market.

But an obstacle is what is called the "patent thicket strategy" that too many drug companies pursue. For example, Humira, which is the best selling drug in the world with $16 billion in annual sales, does not have a generic equivalent because its manufacturer has obtained more than 100 patents with various changes in the bill to block generic companies from coming to the market.

How can we counter the strategy of a manufacturer making minor changes in a drug in order to extend the patent, in this case, to almost twice what it should have been, and thus, block competitors from coming into the marketplace?

Dr. HOLTZ-EAKIN. I think in the end, the key is to get better value-based pricing because you will not increase the value with a "me too" patent and you are not going to be able to charge more money for it.

One of the things to do is to get the better competition, the better pricing in the retail market, then it is clear that, in many circumstances, we are seeing abuse of monopoly power.

It is okay in America to have a monopoly. It is not okay to abuse your monopoly power. There are circumstances, that I have seen recently, that appear to be just sheer abuse of monopoly power.

That should be referred to the antitrust authorities and should be prosecuted.

Senator COLLINS. I completely agree with you that this monopoly is being used to protect profits rather than patients and R&D development of new drugs. I think it is something we need to take a look at.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Collins.

Senator Bennet.

Senator BENNET. Great panel, Mr. Chairman. Thank you for organizing it.

As much as I would love to spend my time talking about tax cuts with Dr. Holtz-Eakin, I will relent for the moment.

Dr. HOLTZ-EAKIN. God bless you.

Senator BENNET. But he is an honest man in Washington, DC, maybe one of the last ones.

I wondered whether you would say, just briefly, why we are spending 18 percent of our GDP on healthcare when the rest of the industrialized world is spending half that or less than half that.

Dr. HOLTZ-EAKIN. There are multiple reasons, but I think the important thing is to focus less on the number than getting our money's worth.

I think the biggest indictment of the overall performance of the U.S. health sector is that we are spending an enormous amount of money and we are not getting high quality results.

We need a high value system from stem to stern, quite frankly, and pharmaceuticals are part of that. That is why I am a big fan of all the innovations in outcome based pricing, value based contracting, whatever it might be.

But more generally, to have a delivery system where people are rewarded for high quality outcomes, not merely pay for service. There have been important steps taken to move away from that.

If we do that, we might spend 18, 19, 20 percent of GDP, but we will feel like we are getting our money's worth.

I think the problem is, right now, we do not feel we are.

Senator BENNET. The reason that number is important is because of the pressure it is putting on our fiscal situation. But I also agree that we are spending twice as much and getting worse results in a lot of other places.

Mr. Augustine, it is wonderful to see you. You are one of the great graduates of East High School in Denver, Colorado. I am glad we taught you enough to know that you get the $5 and not the $86 product.

[Laughter.]

Senator BENNET. I wonder if, in your work, whether you saw some instances where Medicare Part D is actually working well in terms of drug reimbursement or where you think we should focus our attention.

You mentioned, for example, specialty drugs and you talked about how it is not necessarily the cost of the average drug.

Could you talk a little bit more about that as we seek to avoid unintended consequences?

Mr. AUGUSTINE. Yes, Senator.

Unintended consequences are the big issue here because almost anything you recommend, the system is so complex that it could pop up somewhere else.

I think one of the places the system is working well is with generics. Now, unfortunately, they are difficult to enter into the market. They are often delayed. But when we do get generics in the market, we get prices that are market based and things are much more affordable.

Our principle problems are with that 30 percent of the cost of drugs that goes to specialty drugs, and these are drugs that are not widely used, and they are very expensive to make.

I think one of the things I would like to say, if I might, that I think is a very important point that is somewhat tangential—and I apologize—to your question.

But somehow we have the notion in this country that if you reduced the revenues of a pharmaceutical company by $1 that takes a dollar out of research and development. There is nothing that

could be further from true. It might take a dollar out, if that is the way they chose to take it out.

But if a company loses a dollar in revenues, they have many choices. In the case of the pharmaceutical industry, they could do less research and development, but they might also reduce lobbying. They might also reduce the mergers and acquisitions. They could reduce dividends. They could reduce executive compensation. They could reduce stock buybacks. They could reduce overhead costs.

Picking up on your point, I think you lead to something very important and that is, there is this disconnect.

Senator BENNET. They could stop running that ad with the two people in the bathtub that I do not understand.

[Laughter.]

Senator BENNET. That could be a choice.

Mr. AUGUSTINE. I have never figured that out.

Senator BENNET. Did you have any recommendations in my last minute, Mr. Augustine, for how the Government could reimburse for drugs under Medicare Part B?

Mr. AUGUSTINE. Part B.

Senator BENNET. Part B, so the hospitals and doctors.

Mr. AUGUSTINE. Well, of course, under Medicare, with the exception of drugs, prices are basically fixed for hospitals for a given procedure.

In the case of drugs, are you alluding to the 340B program in particular?

Senator BENNET. I am thinking of chemotherapy drugs; drugs that are administered.

Mr. AUGUSTINE. Well, one of the things that is at issue here is that the payment to the hospital is often proportional to the cost of the drug, and so, the higher the cost of the drug, the higher the payment. You have this instability in the pricing mechanism.

It would be much better to pay a flat fee that was representative of the true cost of administering the drug and a reasonable profit, rather than to have it be based on cost plus percent of cost.

Senator BENNET. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Bennet.

Senator Cassidy.

Senator CASSIDY. Mr. Augustine, I read your report and so, I am going to disagree now, not because I disagree with you, but I find it more profitable to probe, as opposed to merely agree.

Obviously, a challenge facing our society is finding a cure-treatment-something for Alzheimer's. If such is developed, the Federal Government will be probably the sole purchaser thereof. There will be a few in private insurance. But let us just assume 95 percent.

Now the issue, of course, is whether monopsony purchasing power on behalf of the Government would give a return less than sufficient to incentivize development. We have some examples of that.

In the Medicaid program, just about every Medicaid program in the Nation, except maybe Wyoming and Alaska, pays their providers below cost because they can. It is a way to give a benefit without necessarily the expense of actually paying for.

If there was a future Government that said, "Listen. We have to take care of all these Alzheimer's patients, but we do not want to pay the," you pick the number, $100,000 a year that the drug company wants. "We are going to pay you $10,000 and if you do not like it, lump it, because we are the only person that purchases."

That would have a chilling effect on the drug company, but would it have a chilling effect on the venture capital required at the outset in order to develop the new therapy?

Now I pose this, kind of long winded, I apologize, just to get your thoughts on that, and then I will go to you, Dr. Holtz-Eakin.

Mr. AUGUSTINE. With regard to Alzheimer's, you point to a critical issue. As the population ages, the Baby Boomers become eligible for Medicare and the like, the average person over 65 spends three times what a person under 65 does. So it is a critical issue.

The question you raise about the impact on development, if a Government, or any supplier, comes in and says, "This is all we will pay." If that charge is not rationally set, it will indeed cause firms to not invest in research, and it will cause venture capitalists to not support the funding that the firms need.

That is one reason why it is, I think, so much better to let market forces operate here to the extent they can rather than to have the Government step in and just set prices.

Senator CASSIDY. But if we allowed all the Federal agencies to combine to purchase—and if Federal agencies would end up paying for it, maybe Medicaid as a portion—95 percent of that drug, that truly would give monopsony power. They would really be able to dictate a price.

Mr. AUGUSTINE. Well, if I am not mistaken, private insurers provide like half of the insurance in the country, so there is a private insurance market that will be stabilizing.

Senator CASSIDY. Now, the reason I say that, though, for Alzheimer's disproportionately affects those 65 and above.

Mr. AUGUSTINE. It would affect retirees that were in the private insurance plans, but without question, the costs have to be set at a reasonable level.

I come from the industrial world where our biggest customer was the Government. It was basically a monopsony.

There is still a stabilizing fact, and that is that the Government wants to be able to get treatments for these diseases, just as the firm selling the treatments wants to be able to sell them.

I would not be that concerned about the particular issue you raised.

Senator CASSIDY. Douglas.

Dr. HOLTZ-EAKIN. Imagine that it is essentially coming through the Part D program.

What we would like to see happen is the drug gets developed. It gets put on the market. It gets provided to Alzheimer's patients. It is initially a monopoly, and it costs too much, and people scream and yell, and there is not much the prescription drug plan can do about that.

Competitors recognize that there is a lot of money to be made here and they enter with a competitor drug.

Senator CASSIDY. Under status quo.

Dr. HOLTZ-EAKIN. Under status quo.

If, in fact, we start doing value based purchasing, they want to make that drug better. It might keep people in remission longer, and might improve the quality of their lives better, and that would be a much better product. Now you have a beneficial competition, and that first drug would not be able to exploit everybody.

If you have monopsony buying—setting a fixed price based on no information about the actual efficacy or market conditions—you run the risk of not only not getting the first drug, you do not get the second one or any subsequent drugs. That is the danger.

Senator CASSIDY. I yield back. Thank you.

The CHAIRMAN. Thank you, Senator Cassidy.

Senator Warren.

Senator WARREN. Thank you, Mr. Chairman.

We have to find ways to bring down the cost of prescription drugs and the National Academies recommends that the Federal Government negotiate prices directly with drug companies. I agree.

But today, I want to focus on another part of your report.

You explain that drug companies use so-called patient assistance programs to rake-in extra profits from branded drugs, even when there are cheaper generics available. One of these strategies is to offer coupons.

The data shows that for top selling brand name drugs, the use of these coupons has more than tripled in recent years, and patients are now using coupons for nearly one out of every three brand name drug purchases.

Mr. Augustine, it would seem on its face like offering these coupons would cost the drug companies money, but your report finds exactly the opposite.

Could you just say a word about how coupons drive up drug prices?

Mr. AUGUSTINE. I will be happy to do that.

Coupons are a bit of an enigma. They appear to be helping the patient who cannot afford a drug.

One of the effects they have, though, is that from the patient's standpoint, it causes them to prefer a higher priced drug because they are not having to pay the full amount. They may choose the drug at a higher tier than otherwise would have been necessary. It would have had the same clinical effect.

The insurance company, then, has paid the full amount, and so the insurance rates go up. In effect, the patient saves money at the transaction. They lose part of the money when their insurance rate goes up and society as a whole pays a higher insurance rate overall.

Coupons, in the balance, in our view, have a negative effect.

Senator WARREN. Right.

I noticed the National Academies Report recommends banning these coupons unless there is no other competitor drug available.

In fact, these coupons are already illegal in the Medicare program because the Federal Government prohibits drug companies from offering kickbacks to steer patients to pricier drugs, and then sticking taxpayers with the remainder of the cost.

Drug companies have found another strategy for Medicare beneficiaries funneling billions of dollars to organizations called patient assisted charities. Here is how this one works.

The drug company jacks up its price for a drug, donates the money to an independent charity, writes off the donation on its taxes, and then the charity turns around and gives patients help covering the out of pocket costs of the more expensive drug. Once again, Medicare has been stuck picking up the remainder of the cost of the high priced drug. So let me start.

Mr. Augustine, is this legal as long as drug companies do not have any sway over the nonprofit charity that it parcels out to patients?

Mr. AUGUSTINE. Senator, with the condition you applied, to the best of my knowledge, it would be legal.

Senator WARREN. Okay. It is legal, but if drug companies have influence over which drugs these charities help patients buy, then under current law, it would be illegal.

The drug company has violated the anti-kickback laws in that case and the charity would have violated the IRS rules by acting like an arm of the drug company instead of like a tax exempt nonprofit.

Mr. Augustine, did the National Academies Report find that the rules governing these charities make them disclose enough to the IRS on their Form 990 to know when charities and drug companies are breaking the law?

Mr. AUGUSTINE. Senator, it was not at all clear that there is enough information that they provided and one of our recommendations pertains to the IRS Form 990 that you are familiar with.

One of the purposes of Form 990, of course, is to guarantee that a charity is operating independently of the sponsors or the funders of the charity. The concern here is that is not happening.

We have made recommendations that additional information be disclosed on the 990 Form so that you can really control how that money was being used, and that it was being used independently of the source.

Senator WARREN. Well, I support strengthening those disclosure rules. I have written legislative language to do it.

I have also called for new requirements to force drug companies to disclose all types of patient assistance including coupons so that we can get the whole picture of what is going on.

It seems to me that patients and taxpayers deserve policies that will actually lower drug costs rather than this shell game that funnels more profits to drug companies.

I think these are good recommendations and I hope that we will be able to see them soon here in the Committee, write them into law, and get them passed through Congress.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Warren.

Senator Kaine.

Senator KAINE. Thank you, Mr. Chair, and thanks to the witnesses. This is very important.

Mr. Augustine, you started off in a provocative way when you said in many ways, we are living through the Golden Age of research, and I think a lot of our constituents wonder whether we are living through a Golden Age or a Gilded Age in terms of the prices that they are seeing for pharmaceuticals.

There is no single issue on which I hear more about than pharmaceutical costs within the healthcare space. A common answer is, "It is oh-so complicated." It is like what we hear when we talk about gun violence because there is no one answer. We should not do anything and we often are told, "There is no one answer to pharmaceutical prices being high, so we should not do anything."

The thing that is very helpful about these recommendations—many of which Senator Franken discussed are already part of legislation before the Committee—is that you give us some really practical things we can do.

I used to be a Member of Senator Collins' Committee, the Aging Committee, and she has done a superb job with her Ranking in spotlighting one of the worst abuses I see in society right now, and that is the idea of patients as hostages.

When we have hearings in that committee about some of the particular abuses that you describe in your testimony that all of you have referenced in your testimony today, this notion that there are certain patients who really need something, and we can take a pill, and a venture capital company can buy a company, and then jack up the prices dramatically.

It is more than just about profit. It is about just outright abuse of people when they are vulnerable. We are really called to try to come up with ways to battle that.

I think your report has many good recommendations and I actually do not want to ask about the recommendations. They speak for themselves, and I hope we will tackle them, as Senator Warren said.

I want to ask each of you a question about what is in the news.

There has been a recent news story, obviously, that got a lot of attention about CVS deciding to buy Aetna. Many of the news stories about CVS's proposed purchase of Aetna said that they were doing that because of a worry that Amazon is going to be jumping into the pharmaceutical market.

We are here to talk about prescription drug pricing.

What should we be looking at either with respect to the CVS-Aetna deal or Amazon getting into the prescription drug business? How are those developments likely to affect the cost that our constituents will be paying?

I would love each of you to tackle that one question.

Mr. AUGUSTINE. Well, I will start, if that is acceptable.

What we are seeing is consolidation of the industry, further consolidation. It is already a highly consolidated industry with the exception of the insurers.

We are seeing PBM's, pharmacies, insurers going together in various combinations that will give each more power.

Our committee did not look at any specific M&A issues, such as you describe, but we did provide a recommendation that said that the FTC and the Department of Justice should be very deliberative in permitting or should, frankly, not permit consolidations within the industry where there is not clear competition, ample competition after the merger or the acquisition.

I would have to say, acquisitions perform a useful role when there is lots of competition. They eliminate duplicative costs. They reduce overhead.

When you are lacking competition, as we are in this industry, I think our committee would say, as our recommendation did, that one should be very cautious.

Senator KAINE. Mr. Mitchell.

Mr. MITCHELL. Thank you, Senator.

I heard from a patient just over this last weekend who wrote to me and said, "The price for my subcutaneous cancer injection increased by $1,400 the last time I went to get it. I cannot find out why. I cannot figure out if it is the insurer, or the doctor, or the drug company, or the Pharmacy Benefit Manager. I am asking, but I cannot figure out why."

If Amazon were to come into the system and introduce some of its customer friendly approaches in terms of transparency, being able to compare prices, being able to shop, getting information about what things cost and why, I think it would be a useful addition.

Further concentration in the market, I just want to associate myself with Mr. Augustine's remarks. It scares me.

Senator KAINE. Dr. Holtz-Eakin.

Dr. HOLTZ-EAKIN. I think this is fascinating and very complicated.

Amazon is a pure entry. It is not consolidation and it is entering in what is, essentially, a commodity space, pharmaceuticals, the easiest place to enter and compete.

CVS and Aetna do not compete. It is part of this trend toward creating entities that do not carry financial risk, the traditional insurance function, and managed delivery systems. They have chosen a weird delivery system, a pharmaceutical chain, but we need that.

Senator KAINE. Where they are already offering allied health.

Dr. HOLTZ-EAKIN. May be able to do a lot more especially at a low cost, and so, there are some potential benefits there that I have always argued for.

My thinking on these is always to be humble about what we know in advance of the way these entities will operate. Businesses can organize themselves in a lot of ways, and how they choose to do so is their business.

How they conduct themselves is the issue of public policy. I would urge to okay the merger, but monitor conduct and market performance very carefully. If there is misconduct, apply a remedy.

Senator KAINE. Thank you, Mr. Chair.

The CHAIRMAN. Thank you, Senator Kaine.

Senator Young.

Senator YOUNG. Well, thank you, Chairman.

I thank our panelists for being here today.

Mr. Augustine, this report recommends allowing the Government to exclude drugs from its formulary based on cost.

How does the Academies support its claim that it is not discouraging patients in the development of innovative products, when the report proposes adoption of this exclusionary practice?

Mr. AUGUSTINE. Senator Young, thank you for that question, because the condition we applied to that recommendation is extremely important.

We said that there should be the possibility of excluding drugs under circumstances where alternative drugs of comparable clinical

benefit are available. It is that last piece that is extremely important.

Senator YOUNG. It is an issue of value, not strictly cost.

Is that your point?

Mr. AUGUSTINE. Well, that would have the same medical benefit. So it would have greater value, the alternative would.

Senator YOUNG. Okay. Well, we want to make sure, I would hope you would agree and go on record, we want to make sure we are not restricting access to new medicines for the country's most vulnerable patients, right, where they can receive the same sort of value.

Mr. AUGUSTINE. As I say, thank you for making that clear.

Senator YOUNG. Yes.

Mr. AUGUSTINE. Because it is very important we do agree.

Senator YOUNG. Okay.

Perhaps you could speak to the dissenting views. I will give you an opportunity to respond to those in the report.

Dr. Rosenblatt and Dr. Termeer, who were two members of the committee, they indicated that some of the potential consequences in the recommended actions were things that they just could not contemplate.

Could you give a quick overview of their dissenting views in the report?

Mr. AUGUSTINE. I would be happy to do that.

The committee, as I had mentioned, was set up to have people from all viewpoints on this issue. We did not try to have just a neutral party.

Dr. Termeer and Dr. Rosenblatt stated that they thought many of the recommendations were of value. They included those that pertained to competition and to transparency.

What they did say that they thought, taken as a body, that many recommendations and implementing actions that we offered would be too stressful to the process of producing pharmaceuticals in this country, particularly to the industry. And that it would impact the industry such that it would have difficulty providing new drugs for further patients. That they did take exception to the overall combined impact. That was 2 of our 17 members.

Senator YOUNG. That seems it is a very serious concern.

Could you elaborate on how they arrived at that conclusion?

Mr. AUGUSTINE. Well, I think it is a judgment call. Fifteen of our 17 members did not take that position, and we tried very hard to find common ground, and where did, we included that in the recommendations; when we could not, we did not.

I also need to say that seven other members did not write a dissent, but they asked to provide an expansion on their views. And their views were that they agreed with all the recommendations and all implementing actions, but felt that the recommendations did not go far enough. And that if we are to solve a problem of this magnitude, we needed to do additional things in the areas, particularly of competitiveness, negotiation, and transparency.

Senator YOUNG. The dissenters indicate on page 161 of your report that the U.S. bears a disproportionate burden for the cost of drugs and support of medical innovation, something I have lamented time and again that we are subsidizing wealthy countries.

They are allies. They are partners. They are friends, but frankly, we ought not be subsidizing to the extent we are this innovation, to my mind. This was highlight by the dissenters on page 161.

How do foreign countries' pricing and reimbursement systems affect our prescription drug costs?

Mr. AUGUSTINE. It is a complicated issue.

Senator YOUNG. In 30 seconds or less.

Mr. AUGUSTINE. Okay. Thank you.

Foreign countries, by and large, either set prices or do so in a de facto manner by saying, "That is all we will pay." In this country, of course, we have not chosen to do that.

Foreign countries clearly are not investing in R&D to the extent we are and they benefit from the R&D we do which, from a morality standpoint, is probably a good thing. But it would seem that we are bearing more than a fair share of the burden and the U.S. patient is paying for it.

What could you do about that?

The answer is not a great deal.

Senator YOUNG. Trade agreements are one possibility, are they not?

Mr. AUGUSTINE. That is it exactly, and that is probably the only thing you can do.

There are agreements that both parties have to agree to, and there seems to be very little that we can do unilaterally to assure that others pay a greater share of the burden. Certainly, nothing we would want to do from a morality standpoint.

But it requires sitting down with other governments and trying to get a fairer relationship, but it is a negotiation.

Senator YOUNG. Thank you.

The CHAIRMAN. Thank you, Senator Young.

Senator Hassan.

Senator HASSAN. Thank you very much, Mr. Chair.

Thank you to our panelists so much for your testimony today and for your work in this area.

Before I get to my questions, I just wanted to start by echoing something Senator Young just said which, when he talked about our most vulnerable populations, because I think one of the things that makes this topic so challenging is that we are dealing with a market that is not like every other market because we have people whose lives depend on it. They do not have bargaining power when there is only one lifesaving drug for them.

I happen to have two family members who fit into that category, who suffer from seizure disorders. Even when there is something called a comparable drug with a comparable clinical value available to them as a generic, it does not do for them what it does for the majority of patients, and the brand name does.

One of my concerns, as we talked about, to Mr. Augustine's point, the economic value of a year of human life is for us to always focus on the issue of healthcare, understanding it is a unique market and has a unique value in our democracy.

With that in mind, I do have a couple of questions. I do not necessarily mean to pick on Allergan and Restasis either, but both Senator Isakson's question and mine deal with issues that have come up with that drug.

To Mr. Mitchell, one of the recommendations in the National Academies Report is related to accelerating the entry of generic drugs, and we have talked a lot about that.

Then we have the topic of, or the example of Allergan essentially, which makes Restasis, with behavior that runs counter to what we heard from the National Academies recommendations because in September, it announced it had paid a Native American tribe to take ownership of its patents for Restasis. Then, Allergan licensed the patents back from the tribe continuing to sell the drug as usual.

It is exploiting the doctrine of tribal sovereign immunity to protect its profits, and it is essentially renting the tribe's sovereign immunity to prevent generic products from entering the market, and denying consumers more affordable alternatives. It has been called a ploy recently by a court.

Can you talk to us a little bit about this deal? Mr. Mitchell, describe what it may mean for patients.

Mr. MITCHELL. One of the most offensive things about this, as another strategy to create the patent thicket, avoid allowing generics to come to market is that the company involved called it, "novel, brilliant," when they announced that they were going to do it.

The fact is, it hurts people like Joe Landy from Boca Raton, Florida. He is a retired police officer. He is going to spend at least $1,000 this year for Restasis and he has had to stop taking other drugs in order to afford this one.

The company is treating it like it is a game and, "How can we figure out a way around the laws of the United States? How can we defeat the Hatch-Waxman framework?" that tries to compensate companies who take the risk to make a good return, but then lets competition come into play and gets the lower prices through the introduction of generics.

Allergan's behavior is offensive and it hurts people. It is not a game.

Senator HASSAN. Well, thank you.

Following up with the example that Senator Isakson gave to Mr. Augustine about advertising because we see ads for Restasis and there are patients like the one Mr. Mitchell just mentioned who definitely need the drug Restasis. I will say with firsthand knowledge, dry eye can be extremely painful and debilitating when it gets bad enough. It also can be treated without Restasis. I would urge people to talk to their doctors before they take it.

But let us talk about advertising and the fact that we still allow, Mr. Augustine, companies to get tax breaks for advertising. The Academies recommend that we try to address that.

Can you talk to us about why it might be appropriate to end tax breaks for direct to consumer advertising by pharmaceutical companies?

Mr. AUGUSTINE. Yes. In the committee's view, there are several negative aspects of this form of advertising.

One is that the patient goes to their doctor and tells the doctor, "I saw this on TV and this is what I need," and it may be a very expensive drug. In fact, most of the drugs that are advertised tend to be the more expensive in their class.

The doctor is then under the pressure of telling a patient that you could get another drug that is equally good and costs less. It causes a conflict that is not easily dealt with.

The other aspect, of course, is that advertising costs a lot of money and it shows up in the end price of the product of the advertiser.

Also, much of this advertising just neutralizes itself and I would think the drug companies, it probably would be an antitrust violation, but if they all would say, "We will quit advertising and stand on the merits of our products," they would probably all be better off. But that is not going to happen.

Our first reaction was to say, "Let us ban advertising in this arena." That, we think, runs into a First Amendment issue.

Our second reaction was, "Well, let us at least not let people take that as an exemption, as a cost of doing business."

The CHAIRMAN. We are running out of time.

Mr. AUGUSTINE. That is our recommendation.

Senator HASSAN. Thank you, very much.

Thank you, Mr. Chair, for your indulgence.

The CHAIRMAN. Thank you, Senator Hassan.

Senator Baldwin.

Senator BALDWIN. Thank you. Appreciate the Chairman and the Ranking Member for this series of hearings on high drug prices.

Mr. Mitchell, I wanted to thank you for sharing your personal story and the organizing you have done to elevate the voices of others who have similar experiences.

Throughout this hearing series, I have been sharing stories of Wisconsinites who have shared their experiences with me, including Diane, who was diagnosed with multiple sclerosis at 28 years of age, and has been on a medication for 23 years. But she and her husband sadly decided this past January that she would stop taking it when it reached $90,000 a year.

Greg, who has two young adult sons with Type 1 diabetes, and has seen the insulin and test strips required go up, and up, and up, and now it is about $1,000 a month in his family.

This seems to be absolutely rampant and you were just mentioning an individual who tried to get an explanation for why there was a sudden increase in the price of a medication he relied on.

Patients and taxpayers and, frankly, policymakers get far too little information.

You have shared a number of the stories that you have collected with us. I want to have you share with us why it is critical to require transparency, particularly for drug list prices, retail prices, especially surrounding the company's, say, R&D costs, advertising costs, expenditures on stock buybacks, or executive pay.

Why is this vital? What information do you think needs to be out there that currently is not?

Mr. MITCHELL. Thank you, Senator, for the question.

I would start by saying we are not dealing with flat screen televisions here. I have nothing against flat screen televisions, but these are lifesaving drugs, and when we are consuming 20 percent of our Medicare budget on drugs and we are spending 18 percent of our GDP on healthcare.

I do no know how individuals, employers, or you all who make the laws to take care of these matters can make intelligent decisions without transparency at any level. In markets, markets function with transparency. In the absence of transparency, bad things happen.

It is one of the reasons we feel it is so important to get transparency inside PBM's. We do not know what is going on there. We do not know how much of the rebates they are putting in their pocket or how much is going to the insurer, if any of it is making its way to patients.

We believe that transparency up and down, starting with the setting of the retail price and the justification for it, is so important. Especially if the drug is invented using taxpayer money and 50 percent of all major new breakthrough drugs are invented with money from the NIH or paid by the Federal Government to academic medical centers.

Senator BALDWIN. Thank you.

Mr. Augustine, I was sharing with the committee in the last hearing we had of, I think, our first in this series where we had people in different parts of the system, and it seemed like there was just a ton of finger pointing. "Oh, it is their fault that the price is going up." "No, it is theirs."

When asked directly about the starting point, the drug list price, we could not even get straight answers. It was still pointing to the other players in a very complex system. You have already answered questions by saying, "Well, it is complex." Or, "It is hard to figure out without the data."

Your report also states, and I quote, "List price matters because it is the starting point for all negotiations in the supply chain." I could not agree more.

Can you elaborate on how the lack of transparency perpetuates the blame game, the finger pointing, and why your report specifically recommends that Congress require pharmaceutical companies to publicly disclose list prices, price increases, and other details like profits?

The CHAIRMAN. If you could do that succinctly, that would be helpful because she is out of time.

Mr. AUGUSTINE. Okay, Mr. Chairman.

Clearly the issue of blaming each other, which takes place a good deal in this arena, is made possible by the lack of transparency. If we are to fix the problems, we have to understand what the problems are.

There is some insight to be gained by outsiders making assumptions, but the fact is that we do not know with great confidence where the money is going. There are reasons why some parts of the enterprise should make more money than others, but frankly, we just do not know adequately.

We have made our recommendations on the best data we can find.

The CHAIRMAN. Thank you, Senator Baldwin.

Senator Whitehouse.

Senator WHITEHOUSE. Thank you, Chairman.

Thank you to the panel for being here and thank you for the work that you have done to help us address this challenging problem.

Thank you, particularly, for making recommendations about these direct to consumer ads and what a poor effect they have on our system of healthcare delivery, and on the gaming of the patent system by evergreening. I think those are very important recommendations that we should pay attention to.

I am not a technical expert, but it strikes me that with these pharmaceuticals, they tend to fall into three general categories when they are sold.

One is that they are not a monopoly. There are a bunch of alternatives. There is competition and you can let market pricing work itself out.

The second is it is an approved monopoly. You have invented something. You have patented it. To reward yourself for your investment, you get an approved monopoly for a period of time.

It seems to me, though, that there is a third category as well, which is monopolies that are not approved that are just monopolies. Very often, we see very strong signals of monopolistic pricing behavior happening in that space.

One signal of it seems to me is when people—who are not even in the pharmaceutical business, but are simply in the maximizing return on their investment business—come in, buy a company that makes a particular drug, add no value, jack its price up 10, 15, or 20 times. Then take advantage of a pure monopoly over that product to extract maximum rents despite what, I think, every economist thinks is appropriate with monopolies. Or a little bit more complicatedly, kind of game the system and dare anybody else to come in and invest in a facility that could compete with them, and if they try to, boom. They drop the price and make the case for their competitor noneconomic so they can go back to charging monopoly rents.

I do not see any economic justification for that kind of a monopoly, and I am concerned that your recommendations, do not use the word "monopoly". And seem to pay no attention to this problem of when a predatory actor moves into this space, often from outside the pharmaceutical industry, and just grabs a monopoly in order to extract improper rents from the public.

How do you address that? First, have I correctly articulated a real problem that is actually happening in the real world? And if I have, what is your recommendation for that problem?

Mr. AUGUSTINE. I assume you are addressing that to me.

Senator WHITEHOUSE. I will go right down the line and you each have about 30 seconds because the Chairman is wielding his gavel with great force today.

Mr. AUGUSTINE. Okay.

We chose not to use the word "monopoly," but we use the word "exclusive rights," which are basically the same thing.

Senator WHITEHOUSE. Well, although the implication from the use of the term "exclusive rights," is that it is an approved monopoly under a patent.

Mr. AUGUSTINE. But it is.

Senator WHITEHOUSE. I am not talking about that. I am talking about something that is off patent where somebody has just moved in to take advantage of the fact that they are the only manufacturer of something.

Mr. AUGUSTINE. In those cases, we have tried to point out that I think the pharmaceutical industry does a disservice to itself when these things take place.

This industry is unusual in many ways.

One is that the managements not only have to compete for capital and talent with every other company in America, and the fact that they are in the pharmaceutical industry does not give them a break on Wall Street.

But they also have this other, very deep responsibility that they are dealing with human lives that most other industries are not, certainly not to that extent. It places them in a very difficult position.

When you find people making judgments, such as we found with the EpiPen, Daraprim, the Mohawk Tribe. It damages the industry as a whole. Those things cannot be allowed just as monopolies are not allowed in the marketplace as a whole. Even in the free enterprise system, we do not allow monopolies.

We have got to do the same thing in this industry.

Senator WHITEHOUSE. Except we do here and it strikes me that the problem of unapproved monopolies in this space is something that you all signal we need to address when we talk about your recommendations. That there are some areas in which there simply is not a Government agency that has the authority to address the problem. The public is just left naked out there.

Mr. AUGUSTINE. Well, I will be——

Senator WHITEHOUSE. My time has expired. I am going to turn this into a question for the record, so that I can get your answers in writing.

Mr. AUGUSTINE. We will be happy to do that.

Senator WHITEHOUSE. I do think that this space, Mr. Chairman, of non-approved monopolies that are being taken advantage of by, frankly, non-pharmaceutical interests is an area where we have long, long known how to deal with it.

We did it with railroad rates, grain silo rates, electric utility rates, telephone rates when there was Ma Bell. This is not necessarily that complicated and so I will follow-up with a question for the record.

The CHAIRMAN. Thank you, Senator Whitehouse.

I think we would all be interested in your responses to Senator Whitehouse's questions about non-approved monopolies.

[The following information can be found in Additional Materials.]

The CHAIRMAN. Both Senator Murray and I have to leave for other appointments, and so, I have asked Senator Murphy if he will ask his round of questions and then conclude the hearing.

Before that, I want to thank each of you for coming and thank you, Dr. Holtz-Eakin for being fast on your feet and coming when Senator Coburn could not.

Mr. Mitchell, thank you.

Mr. Augustine, thank you for the work of your commission. We will look forward to considering the recommendations and discussing with you the follow-up.

Senator Murphy.

Senator Murphy [presiding]. Thank you, very much, Mr. Chairman.

Thank you all.

Mr. Augustine, I was hoping you might say a word about pharmaceutical detailing. The pharmaceutical companies spend billions of dollars annually in a practice that is referred to as pharmaceutical detailing.

What it is, essentially, is direct visits with clinicians, providing presentations, booths at professional medical meetings, trying to get them to prescribe their particular drug.

There is a study in the "Journal of the American Medical Association," that suggests that academic medical centers that restricted pharmaceutical detailing saw a modest, but significant reductions in the prescribing of detail drugs across six of eight major drug classes.

Can you talk about whether you have or whether the group has recommendations on any restrictions that should be placed on pharmaceutical detailing?

Mr. AUGUSTINE. Yes, we did make some recommendations in that regard.

As your question suggests, detailing is a more costly part of marketing as a whole than is direct to the consumer advertising on which we have spent so much time.

Detailing performs some useful purposes of conveying information to prescribers. At the same time, detailing adds to cost and, in many cases, distorts the marketplace.

The AMA, as you point out, has made a number of statements on the subject. Much of it comes down to ethical issues of conflicts of interest.

Our recommendation has to do mostly with the latter that one should put limitations on cases of what bluntly might be called quid pro quo, not intentionally so, but turn out to be that way.

Senator MURPHY. Then the second question is to, I will direct it to Mr. Mitchell. Dr. Holtz-Eakin, glad to have you join in.

I was not here for the discussion on value based pricing, but I would love for you both to chime in on that subject.

We made great strides in moving toward value based purchasing when it comes to services that we are procuring from doctors and hospitals. Obviously, we have not made as much progress, but it is there for the taking.

There is this example where Harvard Pilgrim and Amgen did a deal by which if patients on a particular cholesterol medication had a heart attack, the drug company would reimburse the insurance company a portion of the cost. It seems like a pretty commonsense way to hold drug companies accountable for the claims that they are making in all of these detailing.

Just asking the question through the prism of Medicare, Medicare obviously is the driving force behind payment reform. It is hard to ask a private insurance company to do it when they only hold a small percentage of lives that walk into a particular hospital

or a small percentage of sales to a particular pharmaceutical company.

What more can Medicare be doing specifically to try to promote more of this value based pricing?

Mr. MITCHELL. Thank you, Senator.

I would start by saying that there are two different versions of value based pricing.

One is the kind that is practiced by the Institute for Clinical and Economic Review that looks at the value of a drug to patients, and it is an input that can be used in setting an appropriate price for the system. It can be an input for negotiations by Medicare.

It is, in fact, being used as an input for negotiations right now by the V.A. We think value pricing has potential to inform rational negotiations about the price of a drug. It is also being used in the private sector.

As a patient, I am very concerned about the other kind of value pricing that is really outcomes pricing. The FDA decides what is safe and effective and I only want drugs that are safe and effective.

If, under the Repatha Agreement that you talked about at Harvard Pilgrim, I land in a hospital with a heart attack, I am not so keen on the idea of my insurer getting a refund. I just do not want to be given the drug anymore.

The other big flaw with outcomes based pricing, which is being pushed by the drug companies, is it does not lower drug prices. The drug company keeps control of the price, but then gives a refund to an insurer and I do not know if any of that money would ever make it to someone like me.

We think value based pricing has real potential to contribute to rational pricing by the Government and private sector purchasers, and outcomes based pricing is a trap.

Senator MURPHY. Here is the way I would sort of frame the response to you, Dr. Holtz-Eakin.

We have instances where drugs are being prescribed that are not adding value to patients.

Dr. HOLTZ-EAKIN. Yes.

Senator MURPHY. The question is how do you change that behavior?

I understand the danger that you suggest, Mr. Mitchell, but without holding the prescriber accountable from a reimbursement standpoint, I worry that there are not other effective ways to stop drugs from being prescribed that are not adding value or are, in fact, hurting patients.

Dr. HOLTZ-EAKIN. The trouble is we are paying for the drug.

If we are paying the provider for the outcome and that sort of care, they would have zero interest——

Senator MURPHY. Right.

Dr. HOLTZ-EAKIN ——in having an expensive, poor value drug as part of a regimen.

A lot of the problems that were alluded to today—the direct to consumer advertising, all of those things—would just disappear if we were paying physicians for the right thing, and that is high quality outcomes.

Senator MURPHY. Yes, I think it is all tied together, and that the detailing often makes providers believe that a drug can maybe be of greater help than it is.

I think there is a combined responsibility in these situations, but I understand the limitations.

I will not abuse my privilege here and go beyond my time. I will hold myself to the same standard that Senator Alexander held others and thank you all for being here.

The hearing record will remain open for 10 days. Members may submit additional information for the record within that time, if they would like.

Senator MURPHY. The HELP Committee will meet again, December 13 at 10 a.m., for a hearing on the "Implementation of the 21st Century Cures Act," and its response to mental health needs.

Thank you for being here today.

This Committee now stands adjourned.

RESPONSE BY NORMAN R. AUGUSTINE TO QUESTIONS FROM SENATOR ALEXANDER, SENATOR CASEY, AND SENATOR WHITEHOUSE

CHAIRMAN ALEXANDER

Question 1. Dr. Collins reaffirmed some of his breathtaking predictions in front of this Committee last week when testifying about the potential of 21st Century Cures. Those predictions include that: Scientists will find ways to identify Alzheimer's before symptoms appear as well as how to slow or even prevent the disease. Alzheimer's causes untold family grief and costs $259 billion a year. Doctors could rebuild a patient's heart using his or her own cells. This personalized heart would make transplant waiting lists and anti-rejection drugs obsolete. Drug companies will research, develop, get approved by FDA, and sell a Zika vaccine, a universal flu vaccine and an HIV/AIDS vaccine within the decade. Also, that companies will research, develop, get approved by FDA, and sell non-addictive pain medicines to help patients as we continue to battle the opioid crisis that kills 91 Americans every day. The National Academies report concludes that "There is little value in new drugs that patients cannot afford—and there is no value in drugs that do not exist." If the amount Americans spent on drugs last year went up 1.3 percent, I'd like to ask all of the witnesses how we can reduce that further and still get the biomedical miracles Dr. Collins has predicted?

Answer 1. Dr. Collins' projections are indeed encouraging and he is well-qualified to make such projections. But if drug costs continue to rise as they have in the past, drugs will in many instances be unaffordable. The 1.3 percent increase in the past year should probably be viewed in the context of the large increases the two prior years.

The amount of money the United States spends on biopharmaceuticals now exceeds half-a-trillion dollars per year and the costs will continue to rise if nothing is done. The fundamental conclusion of the National Academies' report is that the biopharmaceutical sector of the United States is on an unsustainable trajectory and failing to adequately serve the health care needs of patients. Actions proposed to help reduce the cost of drugs include:

- Accelerating market entry and use of safe and effective generics as well as biosimilars, and fostering competition to ensure the continued affordability and availability of these products.
- Consolidating and applying governmental purchasing power; strengthening formulary design; and improving drug valuation methods.
- Assuring greater transparency of financial flows and profit margins in the biopharmaceutical supply chain.
- Promoting the adoption of industry codes of conduct, and discouraging direct-to-consumer advertising of prescription drugs as well as direct financial incentives for patients
- Modifying insurance benefits designs to mitigate prescription drug cost burdens for patients.
- Eliminating misapplication of funds and inefficiencies in Federal discount programs that are intended to aid vulnerable populations.

- Ensuring that financial incentives for the prevention and treatment of rare diseases are not extended to widely sold drugs.
- Increasing available information and implementing reimbursement incentives to more closely align prescribing practices of clinicians with treatment value.

Question 2. What policies have already been enacted that you think need to be allowed to work, improved upon or revisited to address the broader policy questions or the discreet issues you think should be our focus?

Answer 2. The prohibition on governmental agencies negotiating prices directly with manufacturers should be removed. In addition, the current effort of the FDA to streamline administrative aspects of the drug approval process should be supported and extended.

The Federal Government should tighten qualifications for discount programs that have drifted from their original intent to help vulnerable populations. The 340B program requires certain drug manufacturers to provide outpatient drugs to qualified medical care providers that serve the Nation's most vulnerable patient populations. However, it is questionable whether the benefits of the program are flowing to the intended vulnerable populations. Our report recommends that actions be taken to revert the 340B program back to its original intent.

Further, current insurance benefit designs for prescription drugs often expose consumers to considerable financial risk and can unfavorably affect patients' adherence to treatment regimens. Insurance plans should be modified to reduce the financial burden that patients and their families currently experience when they need costly prescription drugs. Limits should be placed on the total annual out-of-pocket costs paid by enrollees in Medicare plans that cover prescription drugs by removing the cost-sharing requirement for patients who reach the catastrophic coverage limit. Also, Congress should revise the Orphan Drug Act to achieve its original intent, by ensuring that drugs with orphan designation receive benefits only for the target rare disease (and not other indications), and getting rid of unnecessary sub-categories that can create artificial eligibility for orphan drug status.

Question 3. Do you believe that all companies who manufacture, distribute, provide drugs to patients, and pay for drugs should report more information about how their policies affect what patients pay for drugs? If so, what data would be most useful? How can we get the data necessary to understand the system without increasing costs? Are there unintended consequences that we should consider when looking at proposals to improve transparency? For example, if we were to add transparency around price increases, could that lead to higher drug prices, especially when a drug is first available?

Answer 3. The opaqueness of financial transactions among the participants in the biopharmaceutical supply chain makes it difficult to understand a system that is already complex. One way to improve transparency would be to require manufacturers to disclose detailed information on a drug-by-drug basis reflecting discounts given within the supply chain and discounts given directly to patients. Information about the prices paid at the end-stage of distribution in retail pharmacies or their mail-order counterparts and by hospitals, clinics, nursing homes, and other relevant organizations that purchase and directly administer drugs to patients would also need to be gathered. Logically, the difference between what the manufacturers report and what the final distributors (e.g., retail pharmacies, hospitals, doctor offices) report would indicate what has been retained in the intermediary system either as costs or profits. These data may provide clarity about the interactions—specifically the flow of funds and products—among the intermediaries of the biopharmaceutical supply chain, or they may point toward necessary regulation and additional data gathering from each participant in the biopharmaceutical supply chain. This proposed action would involve a sequential process of first gathering information at the two ends of the supply chain—manufacturers at one end and consumers at the other—with the understanding that more refined data may be needed later to completely understand how the biopharmaceutical supply chain operates.

With regard to transparency potentially increasing prices, the relevant data needed to conclusively answer this question of fundamental interest do not currently exist. This lack of clarity has led to numerous situations in which different participants in the supply chain point to other participants as the source of high and increasing prices. It is for this reason that the report recommends that the U.S. Congress should require disclosure of information on a quarterly basis at the National Drug Code level from:

- Insurance plans that cover prescription drugs about the average net prices paid for drugs, including patient cost sharing.

- Biopharmaceutical companies about average net volume of and prices for drugs across each sales channel, including discounts provided to pharmacy benefit managers and insurance plans. The U.S. Department of Health and Human Services should obtain, curate, and publicly report this collected information at the National Drug Code level on a quarterly basis.

The U.S. Department of Health and Human Services should conduct analyses of these data and inform relevant congressional committees. In addition, the Federal Trade Commission should examine these data to identify and act upon any anti-competitive practices in the market.

While there are indeed potential unintended consequences to be guarded against, these can be ameliorated by limiting access to some data to government entities and by seeking aggregated data rather than information pertaining to specific transactions.

SENATOR CASEY

Question 1. Approximately two-thirds of Medicare beneficiaries have two or more chronic medical conditions and almost half take five or more medications for those conditions. Many of these medically complex individuals are served by long-term care pharmacies, which provide prescription processing, dispensing and medication management. Services provided by long-term care pharmacies improve medication adherence and help prevent adverse events related to prescription mismanagement. What policies would help ensure older Americans and other individuals receiving care in long-term facilities continue to have access to the important services provided by these long-term care pharmacies?

Answer 1. While our report did not focus specifically on this segment of the population, it is clearly a critical portion of society with unique health needs. The Committee did consider affordability of medicines for various subpopulations (e.g., people who have Medicare, private insurance, or no form of health insurance). Ensuring high quality care for individuals in long-term facilities was the central subject of an influential 1986 Institute of Medicine report, Improving the Quality of Care in Nursing Homes, a topic that the National Academies could revisit, potentially incorporating the insights gained through our report on making medications affordable.

SENATOR WHITEHOUSE

Question 1. At the hearing, I identified three categories of pharmaceutical market: competitive markets, approved monopolies, and monopolies that are not approved. In this third category of "de facto" monopolies, companies, including some that aren't even in the pharmaceutical business, can buy a drug, add no value, and increase its price substantially. The National Academies report says, "there are situations where there is no agency with the definitive legislative authority to carry out certain recommendations." I believe this is one of those situations.

Answer 1. This indeed appears to be the case. A recent development, reported in the New York Times [1], about a hospital entering the generic drug manufacturing business signifies the truly dynamic nature of the biopharmaceutical landscape. In advance of any legislation to regulate "de facto" monopolies to protect the interests of patients, Congress could require relevant agencies to coordinate policy, investigation and enforcement activities. The relevant agencies would include FTC, DOJ, FDA, GAO and perhaps OMB.

Question 2. Are de facto monopolies a problem in the prescription drug market? If so, what are your recommendations for dealing with this problem? Where is regulatory authority over such monopolistic behavior presently located? Is it effective? Please include any specific additional authorities you would provide to government agencies to help solve this problem.

Answer 2. De facto monopolies are indeed a problem within the prescription drug market. When generics enter the market, the prices of the branded products frequently drop precipitously as the developer seeks to compete with the new, lower-cost entrants—or forfeit some or all of the market.

But there is a common practice in the biopharmaceutical industry that delays entry of generics into the market and thereby extends market exclusivity of branded products. This practice is commonly referred to as "pay-for-delay". Pay-for-delay agreements enable brand name drug manufacturers to engage in a contract or other arrangement with generic drug manufacturers, in essence, to refrain from chal-

[1] Abelson and Thomas, Fed Up With Drug Companies, Hospitals Decide to Start Their Own *https://www.nytimes.com/2018/01/18/health/drug-prices-hospitals.html—r—0*

lenging their patent exclusivity. In such agreements, the generic drug manufacturers delay marketing their drug products in exchange for some benefit, most often a monetary payment.

As discussed in Making Medicines Affordable, a 2013 Congressional Budget Office analysis found that it may take several competing generic companies to enter the market before the price of a competing drug significantly declines. Pay-for-delay agreements therefore keep drug prices higher than they would otherwise be if generic competitors were able to enter the market immediately.

The actions proposed in the report to address this problem include the following:

- The U.S. Department of Justice and the Federal Trade Commission should vigorously deter manufacturers from paying other producers for the delayed entry of generics and biosimilars into the market.
- The U.S. Department of Justice and the Federal Trade Commission should expand the enforcement of policies that preclude mergers and acquisitions among companies possessing significant competing generics and biosimilars in the absence of significant other competitors—either by preventing the mergers or acquisitions or by requiring divestiture of potentially competing drug products to independent entities.
- The U.S. Congress and the U.S. Food and Drug Administration should actively seek to reduce barriers to generic market entry and promote the expeditious entry of additional domestic and international providers of generics and biosimilars, particularly including those not marketed by the original patent holder.

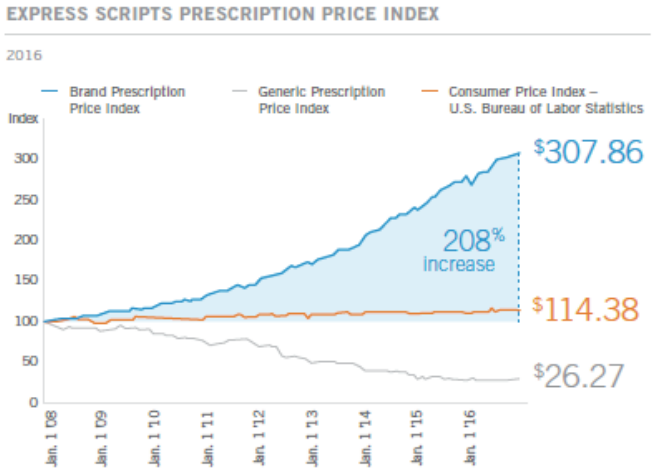
RESPONSE BY DAVID MITCHELL TO QUESTIONS FROM SENATOR ALEXANDER, SENATOR CASEY, AND SENATOR WHITEHOUSE

CHAIRMAN ALEXANDER

Question 1. Dr. Collins reaffirmed some of his breathtaking predictions in front of this Committee last week when testifying about the potential of 21st Century Cures. Those predictions include that: Scientists will find ways to identify Alzheimer's before symptoms appear as well as how to slow or even prevent the disease. Alzheimer's causes untold family grief and costs $259 billion a year. Doctors could rebuild a patient's heart using his or her own cells. This personalized heart would make transplant waiting lists and anti-rejection drugs obsolete. Drug companies will research, develop, get approved by FDA, and sell a Zika vaccine, a universal flu vaccine and an HIV/AIDS vaccine within the decade. Also, that companies will research, develop, get approved by FDA, and sell non-addictive pain medicines to help patients as we continue to battle the opioid crisis that kills 91 Americans every day. The National Academies report concludes that "There is little value in new drugs that patients cannot afford—and there is no value in drugs that do not exist." If the amount Americans spent on drugs last year went up 1.3 percent, I'd like to ask all of the witnesses how can we reduce that further and still get the biomedical miracles Dr. Collins has predicted?

Answer: First, it is important to clarify the increase in spending on drugs. Brand drug prices continue to rise dramatically. According to the investment bank Jefferies and Cowen, the biggest drug companies increased prices in January by almost 10 percent. For example, the world's top selling drug Humira already went up 9.7 percent this year. Amgen's drug Enbrel increased 9.7 percent. And after drawing condemnation from both sides of the aisle for its sham patent transfer, Allergan increased the price of Restasis by 9.5 percent.

What is constraining drug prices overall is deflation in generic drug prices. Here is a chart that makes the point:



Brand drug prices have increased more than 208 percent in the last 12 years, while generics have declined in price. Moreover, the 1.3 percent spending number cited in the Senator's question excludes drugs administered in hospitals and physician offices, which are among the most expensive specialty drugs.

To reduce spending further, we urge Congress to:

- End patent abuses which brand companies use to block competition.
- Require transparency from PBMs so we can see how much rebates and other price concessions are being used to defray patient costs vs how much are kept as profit for PBMs;
- Encourage disclosure from drug corporations so patients, taxpayers, and policymakers understand how they set prices. For example: how much are drug companies spending on research and innovation? How much for marketing and advertising? How much for manufacturing and distribution?
- Finally, Congress should give Medicare the power to negotiate with drug companies so it can use its purchasing leverage to negotiate for patients.

Question 2. What policies have already been enacted that you think need to be allowed to work, improved upon or revisited to address the broader policy questions or the discreet issues you think should be our focus?

Answer 2. None that I can think of.

SENATOR CASEY

Question 1. Approximately two-thirds of Medicare beneficiaries have two or more chronic medical conditions and almost half take five or more medications for those conditions. Many of these medically complex individuals are served by long-term care pharmacies, which provide prescription processing, dispensing and medication management. Services provided by long-term care pharmacies improve medication adherence and help prevent adverse events related to prescription mismanagement. What policies would help ensure older Americans and other individuals receiving care in long-term facilities continue to have access to the important services provided by these long-term care pharmacies?

Answer 1. I do not believe that this is a principal driver of increased prescription drug costs. The most effective way to lower drug prices is to curb the monopoly pricing power given to drug corporations and demand transparency from pharmacy benefit managers who run drug insurance programs.

The pharmaceutical industry is one of the most profitable in the world—averaging profits more than three times the average of the S&P 500. Drug corporations are spending 20–40 percent of their budgets on marketing. There is plenty of money available to lower prices, pay for research, and still deliver a good return for investors.

SENATOR WHITEHOUSE

Question 1. At the hearing, I identified three categories of pharmaceutical market: competitive markets, approved monopolies, and monopolies that are not approved. In this third category of "de facto" monopolies, companies, including some that aren't even in the pharmaceutical business, can buy a drug, add no value, and increase its price substantially. The National Academies report says, "there are situations where there is no agency with the definitive legislative authority to carry out certain recommendations." I believe this is one of those situations.

Answer 1. I agree. The FDA is trying to address this issue by encouraging development and approval of generics as a way to eliminate monopolies that are not approved. But congressional action is needed, particularly passage of the CREATES Act which would prevent brand manufactures from blocking generic competition.

Question 2. Are de facto monopolies a problem in the prescription drug market? If so, what are your recommendations for dealing with this problem? Where is regulatory authority over such monopolistic behavior presently located? Is it effective? Please include any specific additional authorities you would provide to government agencies to help solve this problem.

Answer 2. In addition to the actions referenced in Question 1, I think direct negotiation by Medicare could provide a countervailing market force to constrain these de facto monopolies. Congressional action is necessary on this front. We were pleased when candidate Trump called on Medicare to negotiate with drug companies to lower prices, but we are disappointed to see little movement on this issue. We urge Congress and the Administration to act expeditiously to fulfill the President's campaign pledge.

RESPONSE BY DOUGLAS HOLTZ-EAKIN TO QUESTIONS FROM SENATOR ALEXANDER, SENATOR CASEY, AND SENATOR WHITEHOUSE

CHAIRMAN ALEXANDER

Question 1. Dr. Collins reaffirmed some of his breathtaking predictions in front of this Committee last week when testifying about the potential of 21st Century Cures. Those predictions include that: Scientists will find ways to identify Alzheimer's before symptoms appear as well as how to slow or even prevent the disease. Alzheimer's causes untold family grief and costs $259 billion a year. Doctors could rebuild a patient's heart using his or her own cells. This personalized heart would make transplant waiting lists and anti-rejection drugs obsolete. Drug companies will research, develop, get approved by FDA, and sell a Zika vaccine, a universal flu vaccine and an HIV/AIDS vaccine within the decade. Also, that companies will research, develop, get approved by FDA, and sell non-addictive pain medicines to help patients as we continue to battle the opioid crisis that kills 91 Americans every day. The National Academies report concludes that "There is little value in new drugs that patients cannot afford—and there is no value in drugs that do not exist." If the amount Americans spent on drugs last year went up 1.3 percent, I'd like to ask all of the witnesses how can we reduce that further and still get the biomedical miracles Dr. Collins has predicted?

Answer 1. In the world of economics, there are tradeoffs. There is certainly a very real possibility that reductions in spending on pharmaceuticals will result in reduced investments in pharmaceutical R&D. Development of new treatments and cures is a risky business and companies must continue to be incentivized to take on that risk if we (society) want the possibility of reaping the rewards of that investment: access to better treatments and new cures. Wringing out all or even most of the profits will certainly lead to market exits. Conversely, high prices can encourage new entrants into the market bringing more choices and new treatments. Without the possibility of significant return on investment, companies will not be inclined to take on the risk that is more likely to result in failure and financial loss than not. Ninety percent of drugs that begin clinical trials do not make it to market, and the costs spent on those failed drugs must be included when considering the cost of developing a successful drug. The best estimate of this cost per successfully developed drug is nearly $2.7 billion. [1]

Further, it is important to consider an individual's treatment costs in totality, rather than focusing solely on the cost of a single piece of the patient's overall care. Evidence has shown that, in some instances, spending more on a prescription drug can actually lead to overall cost savings by reducing the need for hospital services

[1] *https://www.forbes.com/sites/matthewherper/2017/10/16/the-cost-of-developing-drugs-is-insane-a-paper-that-argued-otherwise-was-insanely bad/5ed4760f2d45*

by preventing the worsening of a condition or the onset of a new chronic conditioned. This phenomenon is common enough, in fact, that it can be seen in historical national health expenditure data—as spending on prescription drugs increased in the 1990's, spending on hospital services declined. [2]

That said, to think that every penny currently spent on medicines in the U.S. is absolutely necessary and that spending any less will halt all investment and innovation would be ridiculous. The question is "what is the tipping point?" and "where/how should those reductions be made?" The first steps should be reforming government programs and regulations that distort the market, reduce competition, and prohibit or inhibit the implementation of value-based payment models. Ensuring patients have access to greater choice, and that payers have the tools to incentivize use of high-value medicines is of the utmost importance.

Disallowing companies from taking advantage of rules to delay generic entry into the market is key to increasing access to more affordable options. Reforming and/or repealing government programs, such as the Medicaid Drug Rebate Program and the 340B Prescription Drug Discount Program, that distort the health care market will help to reduce costs across the board. Reforming regulations that are currently inhibiting more wide-spread use of value-based payments, such as anti-kickback statutes and prohibitions on communications regarding off-label uses and pre-market approvals would also help insurers be more prepared for new and expensive treatment options which would allow patients to access these new treatments sooner. Government programs and regulations are typically well-intentioned but often lead to unintended consequences or unforeseen roadblocks; Congress and the regulatory agencies must periodically review and adapt these regulations to match the needs of an ever-changing market.

Question 2. What policies have already been enacted that you think need to be allowed to work, improved upon or revisited to address the broader policy questions or the discreet issues you think should be our focus?

Answer 2. In the last year, the FDA has worked hard to improve the approval process and timeline, particularly for drugs currently with very limited or no competition, whether that be branded or generic single-source drugs, and including complex drugs and drug-device combinations. The FDA is working to stop abuse of evergreening rules that extend patent life and thus block generic drugs from entering the market, and the misuse of distribution restrictions in the name of safety which prevent generic manufacturers from obtaining drug samples necessary to the development of a generic version of a drug. These policies should produce positive results but it will take time for those results to come to fruition.

Bringing generic drugs to market more quickly helps reduce the price of a given drug dramatically, typically by an average of roughly 50 percent with just two generics. [3] Further, disallowing abusive uses of the patent and market exclusivity rules by brand-name drugs will help ensure that generic drugs are able to hit the market more quickly, as well.

Government regulations that have distorted the market and resulted in significant negative consequences in regard to prescription drug costs include the Medicaid Drug Rebate Program and the 340B Drug Discount Program. These programs have led to significant consolidation among health care providers, particularly through hospital acquisition of physician practices, providing hospitals with monopolistic power. Reforming these programs is important to rebalancing the private market forces that drive competition and push prices down.

Question 3. Do you believe that all companies who manufacture, distribute, provide drugs to patients, and pay for drugs should report more information about how their policies affect what patients pay for drugs? If so, what data would be most useful? How can we get the data necessary to understand the system without increasing costs? Are there unintended consequences that we should consider when looking at proposals to improve transparency? For example, if we were to add transparency around price increases, could that lead to higher drug prices, especially when a drug is first available?

Answer 3. Whenever Federal tax dollars are being spent on a good or service, it is important to ensure those dollars are being spent wisely, efficiently, and as intended. To that end, efforts to provide taxpayers and policymakers with information about how Federal dollars are being spent and where those dollars are ending up should be viewed as worthy of consideration. However, price transparency measures require thoughtful consideration in order to be effective without undermining the market's ability to function effectively. Striking this balance is difficult. Full disclo-

---

[2] *https://www.americanactionforum.org/research/understanding-pharmaceutical-drug-costs/*

[3] *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm*

sure of costs, rebates/discounts, etc. will almost guarantee all rebates and discounts (final expenditures) equalizing; companies will be unable to justify any price differences across populations. But to think that will result in all prices falling to the current lowest level is incredibly naive. Contracts between two private companies must remain exactly that—private. Congress must not undermine the sanctity of private contracts. Though, when one of the parties involved is taxpayers, the rules begin to change.

Regarding policies intended to reduce significant price increases, such a policy may deter price increases for drugs already on the market, but, as your question so mindfully suggests, such a policy already exists in the Medicaid Drug Rebate Program and it is known that this results in higher launch prices for new drugs. Further, Congress must be careful to not cause drug shortages. An exception would need to be provided for instances in which there is a supply chain failure that necessitates temporary increases in price in order to maintain necessary supply.

SENATOR CASEY

Question 1. Approximately two-thirds of Medicare beneficiaries have two or more chronic medical conditions and almost half take five or more medications for those conditions. Many of these medically complex individuals are served by long-term care pharmacies, which provide prescription processing, dispensing and medication management. Services provided by long-term care pharmacies improve medication adherence and help prevent adverse events related to prescription mismanagement. What policies would help ensure older Americans and other individuals receiving care in long-term facilities continue to have access to the important services provided by these long-term care pharmacies?

Answer 1. Medication management and treatment adherence is extremely important, particularly for elderly individuals who are more likely to be suffering from multiple chronic conditions. Keeping these individuals out of the hospital is vital to keeping them healthy and maintaining their medication regimen is often critical in meeting that goal. The services provided by long-term care pharmacies include ensuring a patients' multiple medicines will not counteract each other, educating patients about how and when to take their medicines in order to achieve best results, and supplying a long-term supply to reduce costs and inconveniences associated with more frequent refill needs. Any policies to limit the ability of long-term care facilities to provide these services must carefully consider the tradeoffs. In particular, the provisions of the recent proposed rule pertaining to Medicare Parts C and D for Plan Year 2019 which would reduce the required minimum prescription transition fill length in long-term care facilities from 90 days to 30—likely intended to reduce costs—may inadvertently result in missed dosages, and consequently, worsened health.

SENATOR WHITEHOUSE

Question 1. At the hearing, I identified three categories of pharmaceutical market: competitive markets, approved monopolies, and monopolies that are not approved. In this third category of "de facto" monopolies, companies, including some that aren't even in the pharmaceutical business, can buy a drug, add no value, and increase its price substantially. The National Academies report says, "there are situations where there is no agency with the definitive legislative authority to carry out certain recommendations." I believe this is one of those situations.

Are de facto monopolies a problem in the prescription drug market? If so, what are your recommendations for dealing with this problem? Where is regulatory authority over such monopolistic behavior presently located? Is it effective? Please include any specific additional authorities you would provide to government agencies to help solve this problem.

Answer 1. When a company is allowed to control a de facto monopoly, consumers are likely to suffer. Any abuse of this monopoly should be dealt with by the Federal Trade Commission (FTC). The FTC has a mandate to protect consumers from anticompetitive activity. Specifically, the FTC has the authority "to prevent unfair methods of competition, such as illegal anticompetitive agreements among competitors to increase prices or restrict supply, and illegal exclusionary or predatory practices."[4] In the pharmaceutical market this may include pay-for-delay deals, evergreening, REMS abuses, and mergers that will create a monopoly. The FTC should also have the authority to stop a sole provider of a certain drug from exploit-

[4] *https://www.ftc.gov/news-events/blogs/competition-matters/2015/05/antitrust-mailbag-what-can-ftc-do-about-prescription*

ing their monopolistic power and hiking the price of that drug to an exorbitant rate without any justification. If the FTC does not currently have the authority to prevent such abuses, Congress should provide it.

[Whereupon, at 12:03 p.m., the hearing was adjourned.]

○