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WHY DOES THE UNITED STATES PAY, BY FAR, THE HIGHEST PRICES IN THE WORLD FOR PRESCRIPTION DRUGS?

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED EIGHTEENTH CONGRESS

SECOND SESSION

ON

EXAMINING THE COST OF PRESCRIPTION DRUGS

FEBRUARY 8, 2024

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C O N T E N T S

STATEMENTS

THURSDAY, FEBRUARY 8, 2024

WHY DOES THE UNITED STATES PAY, BY FAR, THE HIGHEST PRICES IN THE WORLD FOR PRESCRIPTION DRUGS?

Thursday, February 8, 2024

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

The Committee met, pursuant to notice, at 10 a.m., in room 430, Dirksen Senate Office Building, Hon. Bernard Sanders, Chairman of the Committee, presiding.

Present: Senators Sanders [presiding], Murray, Casey, Baldwin, Murphy, Kaine, Hassan, Smith, Lujàn, Hickenlooper, Markey, Cassidy, Paul, Collins, Braun, Marshall, Romney, and Tuberville.

OPENING STATEMENT OF SENATOR SANDERS

The CHAIR. The Senate Committee on Health, Education, Labor, and Pensions will come to order. Today is a busy day. As we all know, a very important vote is going to be taking place and Republicans Democrats will be meeting in their caucuses. So, people are going to be coming in and out.

I also think that this hearing is important enough that we extend the time for questioning from the usual 5 minutes to 7 minutes, if that is okay with folks. Let me begin by welcoming the CEOs of Bristol-Myers Squibb, Chris—Chris Boerner. We thank you for being here. CEO of Merck, Robert Davis. We thank you for being here. And the CEO of Johnson & Johnson, Joaquin Duato, for being with us this morning, thanks very much.

There is a lot of discussion in our Nation about how divided our people are on many issues, and that is absolutely true. But on one of the most important issues facing our Country, the American people, whether they are Democrats, Republicans, Independents, Conservative, Progressive, could not be more united, and that is the need to substantially lower the outrageous price of prescription drugs in this country.

According to a recent poll, 82 percent of Americans say the cost of prescription drugs is too high and 73 percent say that the Government is not doing enough to regulate drug prices. As a Nation, we spend almost twice as much per capita on health care as do people of any other country—$13,000 for every man, woman, and child.

One of the reasons that we spend so much is the high cost of prescription drugs in our Country. The outrageous cost of prescription

drugs in America means that one out of four of our people go to the doctor, get a prescription, and they cannot afford to fill that prescription. How many die as a result of that, how many suffer unnecessarily, nobody knows. But my guess is it is in the millions, and I have talked to many of them in Vermont and around the country.

Meanwhile, our insurance premiums are much higher than they should be, and hospital costs are soaring because of the high cost of prescription drugs. Further, the cost of prescription drugs in this country is putting an enormous burden on taxpayers and seniors by raising the cost of Medicare and Medicaid. Medicare alone spends at least $135 billion a year on prescription drugs.

This is not only a personal issue. It is an issue of the Federal budget. Meanwhile, as we pay by far the highest prices in the world for prescription drugs, 10 of the top pharmaceutical companies in America made over $110 billion in profits in 2022. They are doing phenomenally well while Americans cannot afford the cost of the medicine they need and the CEOs in general receive exorbitant compensation packages.

This morning, we are going to hear a lot from our CEO panelists about how high prices are not their fault, and that the PBMs are forcing Americans to pay much higher prices than they should be paying.

But let us be clear, in 2022, Johnson & Johnson made nearly $18 billion in profit, paid its CEO over $27 million in compensation, and spent over $17 billion on stock buybacks and dividends. That same year, Merck made $14.5 billion in profits, handed out over $7 billion in dividends in their—to their stockholders, and paid its CEO over $52 million in compensation.

Bristol-Myers Squibb made $8 billion in profits last year, while recently spending over $12 billion on stock buybacks and dividends and giving its CEO over $41 million in compensation. Now, why did a majority of Members of this Committee invite these three pharmaceutical CEOs to testify today?

The answer is pretty simple. Mr. Boerner, we will want you to explain to the American people why Bristol-Myers Squibb charges patients in our Country $7,100 a year for ELIQUIS, when that same exact product can be purchased for just $900 in Canada and $650 in France.

Mr. Duato, we are going to ask you why Johnson & Johnson charges Americans with arthritis $79,000 for STELARA, when that same exact product can be purchased for just $20,000 in Canada and just $12,000 in France. Mr. Davis, please tell us later why Merck—why Merck charges Americans with cancer $191,000 a year for KEYTRUDA, when that same product can be purchased for $112,000 in Canada and $91,000 in France.

Let's be clear, Johnson & Johnson, Merck, and Bristol-Myers Squibb are not just charging higher prices in the United States compared to other countries. They are also charging Americans much higher prices today than they did in the past even accounting for inflation.

From 2004 to 2008, the median price of innovative new drugs sold by these three companies was just $14,000, inflation accounted. From 2019 to 2023, where we are today, the median price of new drugs sold by these three companies was $238,000.

In other words, Americans are forced to pay higher and higher prices for the drugs they need to survive. And let's be clear, the overwhelming beneficiary of these high drug prices is the pharmaceutical industry.

How do we know that? Well, that is precisely what they tell their investors. According to their own shareholder reports, Bristol-Myers Squibb made $34 billion selling the blood thinner ELIQUIS in the United States, compared to just $22 billion in the rest of the world combined. Make their money in the United States.

In other words, the U.S. accounts for nearly two-thirds of all global sales of ELIQUIS. Not a single dollar of this revenue is going to PBMs. 100 percent of it is going through Bristol-Myers Squibb. Johnson & Johnson has reported to its shareholders that it made over $30 billion in revenue selling the arthritis drug STELARA in the United States since 2016, more than twice as much as the rest of the world combined.

Nothing to do with PBMs. Merck has reported to its shareholders that it made $43.4 billion selling the cancer drug KEYTRUDA in the United States, compared to $30 billion in the rest of the world combined.

Now, our CEO panelists from the drug companies will tell us this morning how much it costs to develop new drugs and how often the research that they undertake for new cures is not successful. And they are right. We appreciate that.

But what they have not told us in their written testimony is that 14 major pharmaceutical companies, including Johnson & Johnson and Merck, spent $87 billion more on stock buybacks and dividends over recent 10 year period than what they spent on research and development—more on stock buybacks and dividends than in research and development.

In fact, Bristol-Myers Squibb spent 3.2 billion more on stock buybacks and dividends in 2022 that it spent on research and development. Johnson & Johnson spent $46 billion more on stock buybacks and dividends than it spent on research and development since 2012.

In other words, these companies are spending more to enrich their own stockholders and CEOs than they are in finding new cures and new treatments. Now, the average American who hears all of this is asking a very simple question, how does all of this happen? What is going on? How could your companies charge us, in some cases, ten times more than they charge Canadians, people around the world for the same drug?

How did they get away with this when so many of our people cannot afford the high prices of the drugs that they need? How can it be uniquely among industrialized countries that these companies, not just these companies but the pharmaceutical industry in general, can raise prices any time they want to any level they

want—want to raise double prices, do it any way they want. How do they get away with all of that?

Here, in my view, is the answer. The U.S. Government does not regulate drug companies. With very few exceptions, the drug companies regulate the U.S. Government. That is the sad state of affairs in a corrupt political system. Over the past 25 years, the pharmaceutical industry, not just these companies, the entire industry, spent over $8.5 billion on lobbying and more than $745 million on campaign contributions.

Let me be fair here. I don't want to misspeak. They are bipartisan. They give to Republicans. They give to Democrats. I am especially impressed by the Pfizer drug company—Pfizer is not here this morning contributing $1 million to the Republican Party in Kentucky to expand its headquarters named after Republican leader Mitch McConnell.

But again, it is not just Republicans. It is Democrats as well. Unbelievable, this is an astounding fact. Last year, drug companies had over 1,800 well-paid lobbyist here in D.C. to make sure that Congress did their bidding. There are 535 Members of Congress and 1,800 well paid lobbyists, over three for every Member of Congress.

If you want to know why you are paying the highest prices in the world, America, that is why. Now, here is some good news in the midst of all that. We are beginning, beginning to take on the greed of the pharmaceutical industry.

As a result of the Inflation Reduction Act passed several years ago, Medicare for the first time ever is beginning to do what every major country on Earth does and what the Veterans Administration has been doing for over 30 years, and that is to negotiate the lower prices of drugs, including JANUVIA, STELARA, and ELIQUIS.

Let me conclude by saying this, I am proud of what this Committee up to this point has accomplished. Last year, as you will all remember, the CEO of Moderna committed during a HELP Committee hearing that his company would make certain that no one in America would have to pay for their vaccine out-of-pocket.

We appreciated that. In a separate health Committee hearing last May, the CEO of Eli Lilly committed that his company would not raise prices on existing insulin products after having, in fact, lowered them.

But let's be clear, much more needs to be done. I look forward to hearing from our CEO panelists this morning as to how they are going to go forward to substantially lower the cost of prescription drugs in this country.

Senator Cassidy, you are now recognized for your opening statement.

OPENING STATEMENT OF SENATOR CASSIDY

Senator CASSIDY. Thank you. Thank you, Chair Sanders. Let's just be clear, everybody on this panel cares about the high cost of prescription drugs and wants to work on real solutions to address this.

But it is also clear that this hearing is not about finding legislative solutions. It is kind of following a formula. Republicans—we publicly attack private—I don't but others, publicly attack private citizens for being successful under capitalism. We grossly oversimplify our problem and blame corporations.

We demand CEOs come before the Committee for public verbal stoning. We reject the offer to send top executives with subject matter expertise and responsibility regarding issues at hand, and threaten a subpoena when CEOs are suspicious that they won't get a fair shake. Hold the hearing, get sound bites, then pick another set of CEOs for a show trial, but we don't pass meaningful legislation.

That sounds familiar. That has been the hearing of Starbucks founder Howard Schultz, Moderna CEO Stephane Bancel, and now this hearing with the same formula. I would have gladly joined the Chair in explore exploring solutions to address the high cost of prescription drugs. I am a doc. I worked in a public hospital for the uninsured for 25 years. I did my best to get care to those who otherwise would not have received.

I am aware of this. I am also aware of the perverse incentives. The kind of like, my gosh, it shouldn't be high, but it is high. Bad actors game the system and we need solutions that benefit patients and improve access. But the majority was not interested in working with this side of the dais to hold a serious hearing to inform serious legislation.

They didn't seek Republican input. The goal was to haul you guys in, decry capitalism, and blame these corporations for the high cost of drug prices. Now, by the way, of course, drug companies play a role, and hopefully we will get answers today to legitimate questions about how drugs are priced.

But the problem is far greater and more complex than individual companies or even a set of companies within an ecosystem, which is incredibly complex. Why do Americans pay more for certain drugs than patients in other countries? To understand, we need to have a serious effort to navigate the network of perverse incentives throughout the health care system.

I lived in it for 25 years. I am very kind of aware of it. Taking a substantial look at insurance benefit design, price transparency, regulatory barriers, intellectual property barriers, the perverse effect Government discount programs have upon prices charged to commercial patients, etcetera.

One example, just to say again a little bit of complexity here. The 340B drug program resulted in a $54 billion in drug discounts in 2022, but we actually don't know if those discounts lowered prices for the patient who bought the drug.

There are reports that patients paid cash when the intermediary took the full price, even though 340B should have lowered it. That is a serious investigation being conducted by this side of the dais that the other side of the dais was not interested in participating in. That is an understanding of an ecosystem.

I understand there is no one more eloquent than Chair Sanders on Medicare for all, and we can cherry pick examples of how other

countries are doing something better. I can cherry pick the opposite. Canada is struggling—just to show you that there is a complexity here. Let me just take an example. Canada is struggling with specialty care.

In May of last year, the Canadian government began to send 4,800 Canadians from British Columbia to Washington State to "ensure people have faster access to life saving radiation treatment." They can afford their system because we are right next door.

Relatedly to this hearing into that, Alison Decliso, a Canadian woman paid for her own treatment in the United States after the provincial health authority in British Columbia denied her access to life saving chemotherapy.

Canada had a lower cost drug, SOLO. They didn't carry the chemotherapy, so she paid for it out of pocket in the United States so she could have lifesaving chemotherapy. The United States is not perfect, but if we cherry pick from other countries, we have to do a more thorough investigation to see, is there a balance there?

Now let's return to prescriptions. Canadians pay less than we do. Let's figure out why. But let's also point out the public health insurance in Canada only covers 21 percent of newly developed drugs.

Now, maybe that is a tradeoff, but I can tell you, you tell an American that they can't have access to a lifesaving court—a lifesaving drug, they are going to see you in court. They are going to sue, and they are going to say, I want that access.

The UK only covers 48 percent of newly available drugs. Americans just would not tolerate that. It is fair to say that Ms. Decliso, all those radiation treatment patients, are those not getting the newly developed lifesaving drugs as quickly might die in those countries that don't have access to the same treatments as do we in the U.S..

These are serious questions. One more time, I am a doc. I am aware of this, but we need to fully consider all these issues and then maybe bring you in at the end, but we will bring you in with a context which is complete as opposed to isolated. As I said at the start, it would be best if this were a genuine exercise.

I am so willing to do the work on this, as are my colleagues. We have shown that willingness on work on PBM reforms and generic drugs. And even though the Chair and I got off to a rocky start, we did some pretty good work on that, Mr. Chair. I think we got some good bipartisan legislation.

This Committee, I agree with you, can accomplish that. But I don't want the Committee to devolve into a CEO whack a mole, ends up with no serious legislation as a result. Further proof of what I consider the unserious and cynical nature of this hearing is that the minority asked the Chair to have a witness on the panel that could actually explore some of these issues side by side these CEOs.

That was turned down. We wanted an academic expert in drug pricing who could provide unbiased and substantial input to the issues at hand. Our witness was not allowed. He will be on the

next, but the way this works is this get all the publicity and the next one gets crickets.

We have not had that opportunity. And I will also point out we didn't split the majority of minority witnesses into different panels during several hearings, which promoted kind of labor union issues. I can think of no reason to not allow our witness to be here now except perhaps ruining the optics.

As I said at our last markup, what ends up being hollow messaging gives D.C. a bad reputation. Folks want real answers. They want relief from high prices. It is in part what we are going to hear today, but it will be separated from a context that would have made it a lot more productive.

If you are telling voters you are going to do something when you know at the get go you have no legislative solution which emerges, and that is why folks don't trust.

If we are just looking for a social media clip, then I suppose we have accomplished something, but let's make a difference for the people whom we represent—for those patients in hospitals who I once treated who otherwise would not have access to care.

We have the ability to craft meaningful legislation. Let's do it. With that, I yield.

The CHAIR. Thank you, Senator Cassidy. Our first witness will be Joaquin Duato, Chairman and CEO of Johnson & Johnson. Mr. Duato has served as Johnson & Johnson's Chairman since 2023, and Chief Executive Officer since 2022. Mr. Duato, thanks very much for being with us.

STATEMENT OF JOAQUIN DUATO, CHIEF EXECUTIVE OFFICER, JOHNSON & JOHNSON, NEW BRUNSWICK, NJ

Mr. DUATO. Chairman Sanders, Ranking Member Cassidy, and Members of the Committee, thank you for the opportunity to be here today.

Johnson & Johnson has collaborated with this Committee over several decades to advance health care solutions for patients, including on diversity in clinical trials, nursing and health care workforce, pandemic preparation, mental health, and regulatory pathways for novel cell and gene therapies.

I applaud this Committee for your commitment to such critical priorities. I have been with J&J for more than 35 years and have held roles in Europe and in the U.S.. I understand the global challenges and complexities of health care innovation and delivery, and today I look forward to discussing our approach to pricing and the work we do to advance health care for all Americans.

Fundamentally, our decisionmaking is guided by the values set forth on our credo, which states that our first responsibility is to the patients. Our drug pricing decisions reflect our commitment to bringing forward innovative medicines for patients today and for patients tomorrow.

First, our prices are based on the value our medicines bring to patients, the healthcare system, and society. We take into consideration that our medicines improve patient's quality of life and show revival rates, while often reducing health care costs. And for con-

text, in 2022, the average net price of our medicines declined for the sixth year in a row by 3.5 percentage points.

Over those 6 years, prices have declined by almost 20 percent, and the real inflation adjusted price decline was more than 40 percent. Second, we price our medicines to support patient access.

In 2022 alone, we paid $39 billion in rebate discounts and fees, almost 60 percent of the average list price of our drugs, with the intent that patients benefit from these substantial cost savings. We also support patient affordability and access by funding patient assistance programs.

In 2022, these programs helped more than 1 billion—1 million underinsured patients. And we donated $3.8 billion in free medicines, another support, to help patients with no insurance.

Finally, we price our medicines to meet our commitment to innovate and develop different novel medicines for patients. The investment required to do so is massive. The average cost of bringing a drug through clinical trials in our industry is more than $2 billion.

However, more than 90 percent of the drugs that enter clinical trials do not make it to patients. Consequently, our R&D investment is enormous and totally—totals near $78 billion since 2016.

Despite the tremendous investment required to bring drugs to patients, drug costs in the U.S. have not increased significantly as a percentage of total overall health care costs. In fact, the largest spending in the U.S. is about 14 percent of health care spending, slightly below the average for the rest of the world.

While total U.S. health care spending is higher than other developed nations, this spending allows American patients to receive cutting edge health care earlier than any other country in the world.

However, the burdensome co-pay obligations imposed in the U.S. are hard for patients to meet and undermine access and health equity. Remarkably, the GAO found that patient co-pay obligations often exceed payer costs for their drugs. This means that patients sometimes pay more for their medicines than their insurers.

Clearly, this part of the system is not working as intended. We support proposals to reconcile this inequity and to ensure patient access. As outlined in my testimony, Congress should stop middlemen from taking for themselves the assistance that pharmaceutical companies intend for patients.

Finally, it is essential that we reject the price caps and controls that exist in other countries which stunt innovation. Our nation's robust biopharmaceutical industry was created by policy choices that prioritized earlier patient access to breakthrough medicines and incentivized investment in medical innovation.

Thank you for the bipartisan efforts of this Committee and for the opportunity to engage in today's discussion. I look forward to your questions.

[The prepared statement of Mr. Duato follows.]

PREPARED STATEMENT OF JOAQUIN DUATO

Chairman Sanders, Ranking Member Cassidy, and Senators of the Committee, I am the Chief Executive Officer of Johnson & Johnson and the Chairman of the

Board of Directors, positions I assumed in January 2022 and 2023. I joined Johnson & Johnson in 1989, and for the first 13 years of my tenure, I held various executive positions with the company in Europe. Over my thirty-five years with the company, I have held roles in both our Innovative Medicine sector and MedTech sector. As I have practiced and witnessed throughout my career, Johnson & Johnson's decisionmaking is guided by the values set forth in Our Credo, first adopted in 1943, which states that our first responsibility is to the patients, doctors, nurses, parents, and all others who use our products and services. This responsibility extends to both the patients who need our innovative medicines today to treat some of the most challenging and life-threatening diseases, and to the patients of tomorrow, who need us to continue to research cures and treatments for the unmet medical needs that they will face in the future.

Johnson & Johnson has collaborated with this Committee over several decades to advance the important work of pursuing novel healthcare solutions that benefit patients. Our engagement with the Committee has contributed to the efforts to address the mental health crisis, modernize the biopharmaceutical and medical technology regulatory pathways, provide critical access to affordable medicines and medical technologies, examine frameworks for use of artificial intelligence in health, enhance diversity in clinical trials, ensure pandemic preparedness, and support frontline healthcare workers and their daily challenges. I have long admired this Committee's ability to find common ground and deliver solutions for patients. Having held roles in the United States and Europe, and as a dual citizen of the United States and Spain, I understand well the global challenges and complexities of healthcare innovation and delivery.

I am grateful for the opportunity to discuss these issues, and Our Credo values that shape Johnson & Johnson's approach to pricing for our innovative medicines. I look forward to sharing with you our perspectives on how we may collaborate to improve access to and affordability of medicines for all Americans, while continuing to bring to patients the life-changing and life-saving medicines that are the hallmark of American healthcare.

Introduction

Johnson & Johnson's drug pricing decisions integrate our commitment to bringing innovative therapies to the patients who need them today, and our dedication to continuous research, innovation, and development of the next generation of medicines across dozens of diseases for the patients of tomorrow.

In furtherance of those objectives, we price our therapies, first and foremost, based on the value that our therapies bring to patients, the healthcare system, and society. Johnson & Johnson focuses on developing transformational therapies that address challenging and complex unmet medical needs. Our drugs improve patients' quality of life and survival rates, while also reducing overall healthcare costs, for example, through fewer surgeries and hospital admissions. The pricing of our medicines reflects these important life-saving, life-enhancing, and financial benefits.

Second, we price our medicines to further our commitment to patient access. To that end, Johnson & Johnson pays significant rebates, discounts, and fees to pharmacy benefit managers (PBMs), payors, and other "middlemen" in the healthcare system. It is our intent in making those concessions that patients benefit from these cost savings, not these intermediaries. To foster an open dialog regarding the appropriate recipients of these savings—PBMs, payors, or patients—we started publishing information about our pricing 6 years ago in our annual Transparency Report, available online for all to review. As detailed in the most recent issue, the average net price of our medicines declined for the sixth year in a row, and cumulatively by almost 20 percent over that period. During that same timeframe, consumer prices rose by more than 20 percent, which equates to a decline in the real, inflation-adjusted pricing for our drugs of more than 40 percent. The decline in our average net price is due in large part to the increased amounts paid to these middlemen. In 2022 alone, our average net price declined by 3.5 percent, attributable to our payment of $39 billion in rebates, discounts, and fees to others in the healthcare system—constituting almost 60 percent of the average list price of our drugs.

In addition to these price reductions, Johnson & Johnson furthers patient access by funding patient assistance programs designed to help manage copay obligations and provide free medicines to underinsured patients. As the Transparency Report details, in 2022, these patient assistance programs helped more than one million underinsured patients access Johnson & Johnson therapies their doctors prescribed. We also donated $3.8 billion in free products and other financial support through

independent programs and foundations to help uninsured patients obtain the therapies they need.

Third, we price our products to allow us to meet our commitment to innovate and develop new and novel medicines for the patients of today and tomorrow. To do so, we must price our existing medicines at levels sufficient to cover the investment required to pursue the development of broad portfolios of new drug candidates. The requisite investment is massive, as the average cost of bringing a drug candidate through clinical trials to patients is $2.6 billion over 10 years, across the industry. Moreover, we must pursue numerous drug candidates on parallel tracks because, across the industry, approximately 90 percent of the drugs that enter clinical trials (and 92 percent of cancer drugs) fail before they can make it to market. Even after a drug is approved and reaches patients, only around 20 percent to 30 percent of new drugs recoup the significant investments necessary to bring them to market. Consequently, Johnson & Johnson's pharmaceutical research and development spending is enormous, with an investment of $77.7 billion since 2016, $11.6 billion in 2022, and $12 billion in 2023. To our knowledge, this is one of the largest annual investments in research and development made among any of our biopharmaceutical industry peers. Accordingly, we must price our drugs both to recover funds for the investments made and to allow us to continue these efforts—including investments in promising drug candidates that ultimately fail and therefore generate no revenue.

Despite the tremendous investment required to sustain the flow of new medicines, drug costs in the United States have not increased appreciably as a percentage of overall healthcare costs in over a decade. Moreover, the level of drug costs as a percentage of total healthcare spending in the United States is about 14 percent, slightly below the average for other major markets. In some instances, the prices of drugs in the United States are higher than in other countries—and so are the costs of other healthcare services in the United States. This spending allows patients in the United States to receive cutting-edge healthcare as compared to patients elsewhere in the world, including obtaining markedly earlier and broader access to breakthrough innovative medicines.

Conversely, there is one notable attribute of the U.S. healthcare system that differentiates it from other countries in a way that is detrimental to patients. The United States healthcare system alone imposes onerous copayment obligations on patients, which are becoming harder for patients to meet and are undermining access and health equity. There is broad agreement among experts and policymakers that the copayment obligations imposed by both government programs and private insurers is a primary reason for patients' failure to complete prescribed courses of drug therapy, even with regard to cancer and other life-threatening diseases. Remarkably, as the Government Accountability Office found when analyzing the most highly rebated Part D drugs, patients' copay obligations often exceed payors' net costs for those drugs because rebates and other incentives paid by manufacturers to payors are not passed on directly to patients. The diversion of those price reductions from patients to middlemen is one reason that copayment obligations are neither an equitable nor effective means for controlling drug prices. We support the following proposals that have been advanced to address this inequity and to ensure patients receive the full course of drugs prescribed by their physicians.

First, we agree that patient copayment obligations should be reduced. The imposition of lower caps on out-of-pocket costs for Medicare patients under the Inflation Reduction Act (IRA) is a good first step. But access problems remain across multiple markets. Policymakers should closely monitor the effect of these changes to ensure they improve patient access in practice and, in addition, consider ways to reduce cost sharing in the commercial market.

Second, Congress or the Centers for Medicare & Medicaid Services (CMS) should stop payors, PBMs, and their agents from taking for themselves the copayment assistance that Johnson & Johnson and other companies intend for patients by eliminating the economic incentive to do so. As 19 Senators recognized in a recent letter to CMS, certain payors and PBMs have been capturing for themselves the benefits of copay assistance by excluding the patient assistance payments when assessing whether patients have met the copayment caps imposed by law. The economic effect of these programs—with benign-sounding names like "accumulators," "maximizers," and "alternative funding programs"—is to divert the patient assistance from patients to payors. These programs should be barred, and patients should be allowed to receive the intended benefits of the assistance.

Third, Congress should require that PBMs and payors pass on to patients the rebates and other concessions they demand that manufacturers pay. Overall, in 2022,

almost 60 percent of the list price of our medicines went to rebates, discounts, and fees, in many cases as a result of the financial demands of payors and others in the healthcare system. While the amount of these concessions is significant and increasing each year, studies show that the majority of these amounts is retained by these intermediaries and not passed along to patients. No other healthcare system tolerates the diversion of discounts intended for patients to these middlemen.

Fourth, Johnson & Johnson supports pending legislation—such as the Pharmacy Benefit Manager Reform Act passed by this Committee last year—designed to address certain PBM practices that distort the healthcare delivery system by ensuring transparency to the payors that utilize PBM services. This legislation, especially if expanded to require delinking of PBM fees from list prices, would be an important step toward aligning incentives for lower net costs and improved patient access.

Finally, it is essential that the United States reject the price caps and controls that exist in other countries and serve to stunt innovation and deprive patients of life-saving medicines. Our nation's robust biopharmaceutical industry was created and fostered by deliberate policy choices that prioritized and incentivized investment in medical innovation in exchange for a period of patent and regulatory exclusivity that enables innovators to price at levels required to recoup their investments and reinvest in the future. As reflected in the Constitution, this nation's founders recognized as a fundamental tenet, and a cornerstone of a free and capitalistic economy, that the award of exclusivity promotes progress. We can only make the significant research and development investments we do because U.S. policy has respected manufacturers' patent rights and afforded periods of market exclusivity for innovations. Those exclusivity periods are limited and often curtailed because they run from the date of invention, not from the date of market entry, which can be years thereafter. Moreover, as part of the laudable social bargain, upon expiry of patent and regulatory exclusivities, generic drug and biosimilar manufacturers are legally authorized to rely upon and leverage the innovator's investment in safety and efficacy studies to bring competitive drugs to the market. That social bargain is one reason that—over time and on average—drug costs in the United States are only 14 percent of total healthcare costs, which is below the average for other major markets. We support policies that encourage other countries to do more to foster innovation, rather than misguided approaches that would result in the United States doing less. This is critical not only to the health of the United States, but also to our Nation's financial and national security.

The remainder of my testimony contains additional details regarding each of these important subjects.

Investment in Innovation Leads to Treatments and Cures

For more than a century, Johnson & Johnson has created breakthrough scientific innovations that address some of the nation's most important medical needs. We are proud of our proven history of pharmaceutical innovation. Since 2016, our total investments in pharmaceutical research and development have reached $77.7 billion. In 2022 alone, Johnson & Johnson committed $11.6 billion to the discovery and development of medicines. In 2023, we invested $12 billion in pharmaceutical research and development (and $15.1 billion in research and development across the company).

Since 2016, our investment in the next generation of transformative medicines resulted in eight new drugs approved by the Food and Drug Administration (FDA) and an additional fifty-two approvals for expanded indications or new product formulations. Johnson & Johnson may achieve eight more significant approvals by the FDA in 2024. These medicines, if approved, will offer treatments for serious diseases, including multiple myeloma and lung cancer. Johnson & Johnson has an additional 11 significant FDA regulatory submissions that are planned for later this year. In addition, we expect to obtain important data this year from eight Phase III trials and three Phase II trials, which will inform the clinical and regulatory strategy for these significant programs in our pipeline. These figures do not include our entire clinical development portfolio, nor the substantial investment in drug discovery, including internally, in incubator settings and in stand-alone companies.

These significant investments by Johnson & Johnson—and other innovators in the biopharmaceutical industry—have had dramatic effects on the lives of Americans: people live longer and achieve a better quality of life. From 1990 to 2015, biopharmaceutical drugs accounted for at least an estimated 35 percent of the increase in U.S. life expectancy. Over that same period, pharmaceuticals accounted for 76 percent of the mortality reduction achieved for HIV, 60 percent of mortality reduction in cerebrovascular disease, 60 percent of mortality reduction in malignant

breast tumors, 52 percent of mortality reduction in ischemic heart disease, and 27 percent of mortality reduction in colon, rectal, and related cancers.

The industry continues to invest in new and life-changing medicines. Across the healthcare sector, the biopharmaceutical industry's spending on research and development accounts for 75 percent of all U.S. investment in medical and health research and development. The biopharmaceutical industry has a robust pipeline of more than 8,000 medicines in clinical development, including more than 800 treatments and cures for diseases that disproportionately affect minority communities.

The medicines that the Committee has identified, and that we are discussing today, are illustrative of the benefits that Johnson & Johnson's investment in medical innovation brings to patients and their providers, and I would like to address each one briefly.

Stelara. Stelara is an innovative treatment for certain chronic and debilitating immune-related diseases. Stelara is approved for the treatment of adult patients with moderate to severe plaque psoriasis, active psoriatic arthritis, moderately to severely active Crohn's disease, and moderately to severely active ulcerative colitis, as well as the treatment of pediatric patients ages 6 years and older with moderate to severe plaque psoriasis and active psoriatic arthritis. These debilitating diseases can cause inflammation, ulcers, pain, bleeding, and serious complications in the intestines; painful itching, burning, and scaling of the skin; and painful swollen and tender joints. Patients living with Crohn's disease and ulcerative colitis are at increased risk for hospitalization and surgery, which both carry risks for patients and cost burdens for the healthcare system.

Stelara was the first significant therapeutic advancement over the prior generation of treatments, TNF-inhibitors. Stelara can have a significant positive impact on patients. For Crohn's disease, a majority of patients were in remission 1 year after responding to the initial treatment with Stelara.

Xarelto. Xarelto is a type of blood thinner called a direct oral anticoagulant that helps patients facing conditions that put them at risk of blood clots, which can lead to thrombotic events such as heart attacks, strokes, and pulmonary embolisms. Initially invented by Bayer in Germany, Johnson & Johnson partnered with Bayer to bring the medication to patients in the United States.

Xarelto is a therapeutic advancement over other blood thinners, such as warfarin. Xarelto's benefits include fewer food and drug interactions, easier standardized dosing, and the elimination of invasive and costly blood tests required with some other therapies. Medical treatment guidelines provide that direct oral anticoagulants, including Xarelto, are preferable to warfarin for certain serious conditions such as nonvalvular atrial fibrillation and venous thromboembolism. Moreover, in about half of its FDA-approved indications, Xarelto is the only approved direct oral anticoagulant.

Imbruvica. Imbruvica is a once-daily oral therapy for the treatment of chronic lymphocytic leukemia and other blood cancers, including small lymphocytic lymphoma and Waldenstrom's macroglobulinemia. It has helped evolve the standard of care for adult patients living with B-cell malignancies, who until about a decade ago had poor prognoses and had to rely largely on chemotherapy and chemoimmunotherapy as the main treatment options available. Imbruvica is the only medicine in its class that has demonstrated a statistically significant overall survival benefit in first-line chronic lymphocytic leukemia and an established safety profile gained through clinical studies, long term follow up, and safety monitoring.

Symtuza. Symtuza is the first complete, darunavir-based single-tablet regimen for the treatment of HIV in adults and children who weigh at least 40kg. Developed by Johnson & Johnson, in collaboration with Gilead Sciences, Inc., Symtuza combines the proven high barrier to resistance of darunavir with a formulation designed for improved tolerability and the convenience of a single-tablet regimen. Symtuza offers an important treatment option for patients. Symtuza has been studied and used in patients who have never been on medications to treat HIV, as well as in those patients who have previously been well controlled on HIV medications and are not known to have any viral resistance to the components of Symtuza.

Pharmaceutical Pricing and Access to Johnson & Johnson Medicines

Johnson & Johnson's approach to pharmaceutical pricing balances our commitment to bring innovative therapies to the patients who need them today, and our dedication to continuous research, innovation, and development of the next generation of medicines across dozens of diseases. We strive to understand and address the serious health problems of today and create the potential medicines of tomorrow.

In setting the prices of its drugs, Johnson & Johnson follows three guiding principles:

1. Value to patients, the healthcare system, and society. In setting drug prices, a primary consideration is the value that the drug brings to patients, the healthcare system, and society as a whole. For patients, these considerations can include improvements in health, an extended lifespan, and an improved quality of life—such as the ability to take a pill rather than travel to a health center for an infusion, or conversely, to take a long-acting, twice-yearly injection rather than a daily pill. For the healthcare system, pharmaceutical innovations can significantly reduce other costs, such as surgeries and hospital admissions.

2. Affordable access to medicines. Our approach to drug pricing reflects our commitment to making our innovations available to patients who need them. First, we negotiate with insurance companies—and the pharmacy benefit managers they engage to negotiate on their behalves—to encourage insurance plans to cover our medicines. These entities are gatekeepers to patients. We work with these companies to demonstrate the value that our products bring to their policyholders, and we engage in negotiations on discounts and rebates that reduce the costs for our drugs. Second, we seek to ensure that a patient's financial situation is not a barrier to access through a variety of programs and approaches that promote patient access. For example, Johnson & Johnson's Janssen CarePath patient support program provides options for underinsured patients with commercial or private health insurance through solutions like copay assistance and medications free of charge.

3. Investing in future cures and treatments. As demonstrated by our robust pipeline, Johnson & Johnson is dedicated to bringing the next generation of treatments and cures to patients. Drug development is costly and uncertain. Our approach to pricing therefore must include the ability to invest in innovation for the patients of tomorrow. Developing a new medicine requires, on average, a $2.6 billion investment over 10 years. Pharmaceutical pricing must allow for and fund research into potential innovations that ultimately fail. In fact, most promising drugs do not succeed, whether due to unacceptable side effects, limited efficacy, or other factors. Across the industry, approximately 90 percent of candidate medicines that show sufficient promise to warrant a Phase I clinical trial do not eventually result in a new FDA approval. This reality means that the revenue from only about 10 percent of all drugs investigated for therapeutic potential in clinical trials must fund the research and development of all failed drug candidates and the research and development of all innovative treatments and cures of tomorrow. Even more, only around 20 percent to 30 percent of new drugs recoup the significant investments needed to bring them through approval and to patients.

With this understanding of the framework for Johnson & Johnson drug pricing, it is essential to consider the significant and substantial rebates, discounts, and fees that reduce Johnson & Johnson's revenue and result in a much lower effective price of our medicines than may seem apparent from the list price of our drugs. Because pricing trends and the extent of the diversion of discounts and patient assistance away from patients are, unfortunately, hidden from the public by our Country's byzantine drug pricing system, Johnson & Johnson has committed to transparency in its drug pricing and has issued a transparency report every year since 2016.

In Johnson & Johnson's most recent Transparency Report, issued in mid–2023, the company reported that the actual price of its medicines had declined for the sixth year in a row. In 2022, the average net price of Johnson & Johnson's medicines declined 3.5 percent.

There is a striking gap between the list price of medicines—often misleadingly cited in the media and by some in Congress—and the actual amount that Johnson & Johnson receives for its medicines. In 2022, Johnson & Johnson recorded $39 billion in rebates, discounts, and fees to commercial insurers, government programs, and others in the healthcare system. Overall, in 2022, Johnson & Johnson received well under half of the list price of its medicines—almost 60 percent of the list price instead went to rebates, discounts, and fees, in many cases as a result of the financial demands of payors and others in the healthcare system.

These middlemen also put financial pressure on patients, as insurance companies have continued to impose higher deductibles, higher copays, and higher coinsurance requirements—even for patients who thought they were well insured. Nearly a quarter of Americans are now considered underinsured, meaning that they are open to significant financial risk from a healthcare necessity or find that the care they need is financially out of reach because of the requirements imposed by their insurance provider. Since 2014, commercially insured patients with deductibles have ex-

perienced a 50 percent increase in out-of-pocket costs for brand medications due to these tactics.

Johnson & Johnson has sought to address these challenges to access with a variety of robust patient assistance programs. For example, Johnson & Johnson's Janssen CarePath Program is a patient assistance program that supports eligible patients on commercial, employer sponsored, or government insurance, regardless of income. Patients with commercial insurance can apply to the program, which includes a number of solutions such as copay assistance and free product. In 2022, more than one million patients were helped with support provided by Johnson & Johnson's Janssen CarePath Program. Also in 2022, we donated $3.8 billion in free product and other financial support to the Johnson & Johnson Patient Assistance Foundation and other independent programs.

Commercial insurers and PBMs have responded to these programs with a variety of tactics designed to thwart manufacturers' patient assistance programs. For example, they impose prior authorization requirements and cost sharing models to control or restrict a patient's ability to access a medicine prescribed by a doctor. They impose exclusion lists that prevent a patient from accessing a prescribed medicine, given these are lists of products determined in the sole discretion of an insurer not to be covered. Exclusion lists have grown nearly 1000 percent since 2014 and now include more than 1,350 drugs.

PBMs' newest tactics are designed simply to divert manufacturers' patient assistance funds to their own pockets. These tactics have opaque names like "accumulators," "maximizers," and "alternative funding programs," but they share a common purpose of undermining manufacturers' access programs. As one example, PBMs improperly inflate patients' copay amounts to astronomical amounts and then seek "support" from the assistance programs for this inflated copay. The patients quicky exhaust the available support, and the assistance programs' funds are effectively diverted to the PBMs. Johnson & Johnson brought suit against a company leading this practice in 2022.

The medications we are addressing today exemplify our approach to pricing, the downward trajectory of our prices due to discounts and rebates, and our commitment to patient access. Stelara, for example, has experienced a declining price in six of the last 7 years, once rebates and discounts are included. From 2017 to 2023, the average yearly price decline for Stelara was 5.9 percent. Xarelto similarly experienced a declining price in six of the 7 years between 2017 and 2023.

Each of these medicines also exemplifies the support that Johnson & Johnson provides in our patient assistance programs. Under the benefits provided by Johnson & Johnson's Janssen CarePath Program, eligible patients can pay as little as $5 for each dose of Stelara, $10 per fill of Xarelto, $0 per prescription of Imbruvica, and $0 per prescription of Symtuza.

U.S. Policy Supports and Fosters Innovation

The robust biopharmaceutical industry in the United States—currently the world's leading investor in innovation and developer of breakthrough treatments and cures—did not occur by accident. Instead, it was intentionally created and fostered by the policy choices of this Committee, Congress more broadly, and the many generations of policymakers that preceded those of us here today. Through thoughtful policy choices reflected in bipartisan legislation, in many cases emanating from this Committee, the United States created a medical innovation environment that is unique in the world.

For example, in the 1990's, Congress enacted the Prescription Drug User Fee Act to ensure that the FDA had the resources needed to remain the world's leading drug review agency. The law provided the FDA with a new funding stream to ensure that the FDA could hire and train the staff needed to review drug applications with predictable timeframes. For many new drugs treating serious medical conditions, the statute and associated funding allow the FDA to perform priority review. Patients and their families who were waiting for help and hope in the face of difficult and worrying diagnoses were the great beneficiaries of these policies. This Committee has advanced reauthorizations of the program every 5 years since 1992, including most recently in 2022, to help ensure that critical new, safe, and effective medicines reach American patients as quickly as possible.

Moreover, when the country has confronted challenges in healthcare, it has repeatedly looked for ways to spur private sector research, development, investment, and innovation. For example, when faced with concerns that diseases affecting smaller patient populations were not receiving sufficient attention in medical re-

search, Congress enacted the Orphan Drug Act, which provided incentives such as market exclusivity and reduced taxes to spur investment in research and development. According to the National Organization for Rare Diseases, since the passage of the law, more than 7,000 rare diseases have been identified and more than 1,100 orphan indications for treatments have obtained FDA approval. Similarly, when families and pediatricians identified a need for more pediatric research, this Committee advanced the Best Pharmaceuticals for Children Act, which created an incentive of additional marketing exclusivity to innovators that voluntarily complete pediatric clinical studies. When Congress found that federally funded research grants were producing promising early stage research, but this research was not being developed into products that benefited the public, Congress enacted the Bayh-Dole Act, creating a path for private sector pharmaceutical companies to make the significant investments required to transform this early stage research into new medicines with the knowledge that privately developed intellectual property would be protected.

More recently, when the Nation and the world faced the threat of a global pandemic, Congress's actions supported the development of multiple Covid–19 vaccines in an unprecedented timeframe. It is no coincidence that the three leading vaccines developed most swiftly—Pfizer, Moderna, and Johnson & Johnson—were ultimately developed by U.S. companies. That result would not have been possible if the United States had made different policy choices along the way that stifled biopharmaceutical companies' investments in researching and developing innovative treatments and cures.

Against this backdrop, the country again faces policy choices, particularly in light of the Inflation Reduction Act. Unfortunately, that statute diverges from the decades of U.S. policies that helped create the robust biopharmaceutical industry that the Nation and its patients have come to expect. Instead of adhering to those principles and ensuring that companies that invest and succeed in discovering and developing innovative new treatments that benefit patients receive appropriate and time-limited protections for their innovations, the IRA forces Johnson & Johnson and other manufacturers to provide innovative, patent-protected inventions to the government on pricing terms that, by law, must be significantly below market-based prices. As a result, the IRA's pricing provisions will constrain medical innovation, limit patient access and choice, and negatively affect the overall quality of patient care. For that reason, last summer, Johnson & Johnson filed a lawsuit challenging the constitutionality of the statute, as did every other manufacturer with a drug subject to the IRA's pricing provisions. We recognize that not everyone agrees with our decision to challenge the law. That is their right, just as it is our right to challenge in court a law that we believe violates the Constitution, upends decades of U.S. policies that have made the United States the center of medical innovation, and will inflict long-lasting damage to the American people by discouraging investment in future innovations.

The unique strengths of the U.S. biopharmaceutical industry, driven by decades of U.S. policies specifically designed to foster the growth of that industry in order to support patients, are also the reason that comparisons between U.S. drug prices and prices abroad are particularly inapt. The United States is unique in the world in the policy choices it has made to spur innovation and invention. Although it is true that there are certain disadvantages associated with these policy choices, including that the United States pays a disproportionate share of the costs of such innovation, the upsides far outweigh the downsides.

Americans access new medicines years earlier than other nations, including other wealthy nations, and sometimes have access to medicines that are never available at all in other countries. One study found that patients in Europe wait 2 years longer, on average, for new cancer treatments than patients in the United States. Fully 85 percent of new medicines are available in the United States, more than any other country. New medicines launch first and fastest, on average, in the United States compared to other G20 countries. Where Germany, France, and the United Kingdom, on average, face delays between 11 and 20 months to access new medicines, new drugs are available in the United States within 4 months of global launch, on average.

Finally, much of the debate about drug pricing outside the United States uses deceptively selected figures that do not reflect the true nature of drug pricing in the United States and abroad. For example, some critics ignore that about 90 percent of prescriptions in the United States are filled with generic drugs and biosimilars that are often cheaper in the United States than abroad. Lower cost generic drugs and biosimilars are enabled by the research and development of innovative drugs, and as a result of this framework, the United States spends roughly the same share

of healthcare spending on medicines as other countries, on average. Additionally, some critics compare U.S. list prices of drugs—which do not reflect the discounts and rebates provided to middlemen—to the prices charged abroad.

Johnson & Johnson supports solutions to address affordability and access to our innovative therapies. Imposing arbitrary price constraints on U.S. drug manufacturers, however, will harm innovation and deprive American patients of life-saving and life-extending therapies.

On behalf of the dedicated Johnson & Johnson employees around the world who work tirelessly to bring innovative medicines to patients in need, thank you for the opportunity to engage in today's discussion. I look forward to your questions and comments.

The CHAIR. Thank you very much, Mr. Duato. Our next witness will be Robert Davis, Chairman and CEO of Merck.

Mr. Davis has served as Merck's Chairman since December 2022 and CEO since 2021. Thank you very much, Mr. Davis, for being here.

STATEMENT OF ROBERT DAVIS, CHIEF EXECUTIVE OFFICER, MERCK, RAHWAY, NJ

Mr. DAVIS. Chairman Sanders, Ranking Member Cassidy, and Members of the Committee, thank you for the opportunity to be here with you today.

As the CEO of Merck, I am here to offer concrete policy suggestions to address the barriers American patients may encounter as they attempt to access our medicines and the current pricing system, while also ensuring Merck may discover and develop the next generation of lifesaving medicines and vaccines.

Based in Rockaway, New Jersey, our company is one of the world's most advanced, research intensive biopharmaceutical companies—an organization at the forefront of providing innovative health solutions that advance the prevention and treatment of disease in people and animals.

I have worked in the health care industry for the entirety of my 34 year career. I joined Merck 10 years ago in large measure because the company was on the precipice of its first approval for KEYTRUDA, a revolutionary oncology treatment.

At the time, people close to me were battling cancer, and unfortunately, they were not able to benefit from this amazing discovery. Following that first approval, Merck has demonstrated the efficacy of KEYTRUDA in 39 indications and reached nearly 2 million patients, with many of the most widespread cancers afflicting Americans.

The impact of KEYTRUDA and other recent advances is difficult to overstate. With a recent American Cancer Society report finding that cancer mortality in the United States has fallen 33 percent from 1991 to 2021, representing an estimated 4 million Americans whose deaths have been averted, and our work continues as we advanced KEYTRUDA into even more tumor types and earlier stages of cancer.

Remarkable progress like this does not come cheaply. For KEYTRUDA alone, between 2011 and 2023, Merck has invested $46 billion in development, and we expect to invest another $18 billion into the 2030's.

Oncology is just one of Merck's many areas of discovery. Right now, we have nearly 20,000 researchers seeking breakthrough treatments for immune disorders, infectious diseases, Alzheimer's, and other ailments threatening the health of millions of people.

To advance this critical work, we have invested more than $159 billion in R&D since 2010, including $30 billion in 2023 alone, and have invested more than $10 billion in capital in the form of both investments in manufacturing and R&D over the last 5 years in the United States, creating more jobs for Americans.

We do not hesitate to make these investments because they are necessary to further Merck's mission to serve patients. At the same time, many Americans are struggling to afford health care, including prescription medicines, and we are eager to find solutions to these access and affordability challenges.

That is why we supported changes to the Medicare Part D program to create an out-of-pocket cap that allow beneficiaries to pay their cost over time. We have also publicly disclosed our U.S. pricing data, including the average rebates and discounts we provide.

In addition, we offer coupons and support a patient assistance program for those who cannot afford the medications they need. In the past 5 years, this program has helped nearly 800,000 patients to obtain Merck products free of charge, with an estimated value of $7.8 billion.

But the reality is that Merck's efforts alone are far from sufficient. They do not and cannot address the underlying systemic and structural issues underpinning our system. As more power and control has been concentrated into the ever smaller number of vertically consolidated players, their negotiating strength has increased dramatically.

In contracting with them, Merck continues to experience increasing pressure to provide even larger discounts, and the gap between list and net price continues to grow. And patients are not benefiting from the steep discounts we provide.

These problems could be addressed if other actors' revenue streams were de-linked from list prices, thereby removing incentives for the system to favor high list prices. This would also ensure that less value in the system flows to these middlemen who do not create these medicines, who do not discover, or develop, or manufacture them.

In addition, the substantial savings provided by Merck and other manufacturers should be required to be passed through to patients to lower their out-of-pocket costs. We firmly believe that reforms like these will create a drug pricing system that incentivizes the discovery of new and important medicines, while at the same time ensuring patients can afford those lifesaving medicines and innovations.

Future treatment breakthroughs hinge on what we do now. We must hold on to a U.S. pharmaceutical market that is free, competitive, and predictable. One that encourages and rewards investment, one that drives the American economy and creates jobs, and one that continues to deliver innovation and new treatment discoveries.

I am here today to pledge our support and cooperation in these efforts. Thank you for your time and your consideration of these important perspectives.

[The prepared statement of Mr. Davis follows.]

PREPARED STATEMENT OF ROBERT DAVIS

Chairman Sanders, Ranking Member Cassidy, and Members of the Committee, thank you for the opportunity to be here with you today.

As the CEO of Merck, I am here to share the steps we are taking to ensure that American patients can afford our medicines, explain the barriers to our efforts that we encounter in the current pricing and access system, and offer concrete policy suggestions to both address these barriers and ensure our Country continues to have the world's best climate for pharmaceutical innovation, so that Merck may discover and develop our next generation of lifesaving medicines and vaccines.

On behalf of everyone at Merck, I want to thank you for your interest in working to ensure that safe and effective medicines are broadly accessible to all Americans who need them. As people who go to work each day to help protect and improve the health of others, my Merck colleagues and I share your desire to make today's medicines more widely available—even as we work to discover tomorrow's best treatments.

At Merck, our mission is to use the power of leading-edge science to save and improve lives around the world. We develop and bring forward breakthrough medicines and vaccines and then make those treatments available to patients in the United States and worldwide. Based in Rahway, New Jersey, our company is one of the world's most advanced research-intensive biopharmaceutical companies, an organization at the forefront of providing innovative health solutions that advance the prevention and treatment of disease in people and animals.

With a focus on scientific discovery, our company exists to help solve the world's toughest medical challenges. Indeed, we have a long history of taking on urgent health needs, stretching back more than 130 years to Merck's founding in 1891. Over the decades, Merck has developed essential childhood vaccines; introduced the first protease inhibitor, which helped transform AIDS from a death sentence to a chronic disease; and developed the first statin, markedly reducing the negative health impacts of high cholesterol.

Merck's groundbreaking work on the treatment and prevention of cancer

Today, our journey of discovery continues. I have worked in the health care industry for the entirety of my 34-year career. I joined Merck 10 years ago in large measure because the company was on the precipice of its first approval for Keytruda, a novel programmed death receptor–1 (PD–1) inhibitor that had shown effectiveness in preventing cancer cells from suppressing the immune system. At the time, people close to me were battling cancer, and, unfortunately, they did not live long enough to benefit from this amazing discovery.

Following that first approval, Merck has demonstrated the efficacy of Keytruda in 39 indications, in 17 tumor types and 2 tumor-agnostic indications, and reached nearly 2 million patients battling many of the most widespread cancers afflicting Americans: non-small cell lung cancer, melanoma, head and neck cancer, and renal cell carcinoma. The impact of Keytruda and other recent treatment advances is difficult to overstate, with a recent American Cancer Society report finding that cancer mortality in the United States has fallen 33 percent from 1991 to 2021, representing an estimated 4 million Americans whose deaths have been averted.[1] And our work continues, as we advance Keytruda into even more tumor types and earlier stages of cancer.

Merck's breakthrough contributions in vaccine development have also played a critical role in the prevention of cancer. Our product Gardasil is the first-ever vaccine to guard against the human papillomavirus (HPV) that is the leading cause of nearly all cases of cervical cancer, which is the fourth most common cancer among women globally. A study of real world evidence published in the New England Journal of Medicine looking at Swedish girls and women between 10 and 30 years of age found a substantially reduced risk of invasive cervical cancer among those who

[1] Siegel RL, Giaquinto AN, Jemal A. Cancer statistics, 2024. CA: A Cancer J Clin. *https://doi.org/10.3322/caac.21820*. Published Jan. 17, 2024. Accessed Feb. 3, 2024.

had been fully vaccinated with Gardasil.[2] The American Cancer Society report found similar transformative public health outcomes in the United States, with a 65 percent decrease in cervical cancer rates in women in their early 20's, following the widespread adoption of HPV vaccines in the United States.[3]

These remarkable advances, and the others we are making in our many other oncology programs, have not come cheaply. Taking just Keytruda as an example, between 2011, when our focused Keytruda research program began, and 2023, Merck has invested $30 billion in our own internal clinical development efforts, $14 billion in research collaborations and acquisitions to further the study of Keytruda with other compounds, and $2 billion in capital expenditures to scale up our processes and facilities to manufacture the drug in large quantities. And we expect to invest another $18 billion in Keytruda clinical studies into the 2030's. This is likely now the largest and costliest pharmaceutical research and development program ever undertaken. Over 2,200 clinical trials have been publicly disclosed to study Keytruda alone and in conjunction with other compounds in pursuit of new lifesaving and life-extending applications for this revolutionary medicine.

Merck's substantial investments across our research and manufacturing efforts

Oncology is just one of Merck's many intense areas of discovery and development. Right now, we have nearly 20,000 researchers seeking breakthrough treatments for immune disorders, infectious diseases, Alzheimer's, cardiometabolic disease, and other ailments threatening the health of millions of people. To advance their critical work, we have invested more than $159 billion in research and development since 2010, including $30 billion in 2023 alone.

In support of these and other efforts, we are also making infrastructure investments, many of which are here in the United States. In fact, over the past 5 years, Merck has made capital investments across the United States totaling more than $10 billion, increasing our domestic capacity for R&D and manufacturing while creating hundreds of new jobs in our U.S. operations. For example, we've invested $3.6 billion in our Pennsylvania facilities since 2018, with plans to invest another $700 million this year. And in the past 5 years, we have invested $1.4 billion in our manufacturing facility in Elkton, Virginia—about 2 hours from here—to increase domestic production capacity for our Gardasil HPV vaccine.

We do not hesitate to make these investments because they are necessary to further Merck's mission: to serve patients—and not just the patients of today, but those who will need the new treatments and cures we have yet to discover. But we know that many Americans are struggling to afford health care, including prescription medicines, despite the best efforts of leaders in government, industry, academia, and the nonprofit community. Even though medicine costs are growing at the slowest rate in years, thanks in part to market competition, patients are too often being asked to pay more out-of-pocket for their medicines. And for some, that burden is simply too much to bear. As has often been observed, a lifesaving drug is not effective if the patient who needs that drug cannot afford it.

Thus, I am here today to share our perspective about the structural elements in our Country's complex system of pricing, distribution, and insurance that have impeded Merck's efforts to bring our medicines to the American patients who need them. And I would humbly ask for your help and partnership in addressing these obstacles.

Merck's efforts to address patient access challenges

Merck has worked hard to help patients overcome access and affordability challenges. That work continues. We believe our company and our industry have a duty to act responsibly in our pricing practices and contribute to affordability solutions. That is why we supported changes to the Medicare Part D program to create an out-of-pocket cap and allow beneficiaries to pay their costs over time. And we have a history and heritage of responsible pricing. We are also committed to transparency in our pricing practices. Merck publicly discloses U.S. pricing data, including the average rebates and discounts we provide across our U.S. product portfolio to payers such as insurance companies, pharmacy benefit managers (PBMs), and the government.

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[2] Lei J, Ploner A, Elfstrom E, et al. HPV Vaccination and the Risk of Invasive Cervical Cancer. N Engl J Med 2020; 383:1340–1348. DOI: 10.1056/NENMoa1917338.

[3] Siegel RL, Miller KD, Wagle NS, et al. Cancer statistics, 2023. CA: A Cancer J Clin. *https://doi.org/10.3322/caac.21763*. Published Jan. 12, 2023. Accessed Feb. 3, 2024.

We also have programs designed to help patients who cannot afford their medicines. To reduce patient out-of-pocket costs at the pharmacy counter, we provide coupons and other co-pay assistance for our products. Last year the value of this aid totaled $130 million. And through our support of a separate charitable organization that administers our patient assistance program, we provide free medicines to Americans of limited means who do not have insurance coverage or have some other hardship and cannot otherwise obtain their prescribed medications. In the past 5 years, this program has helped nearly 800,000 patients to obtain Merck medicines or vaccines free of charge, with an estimated value of $7.8 billion.

Structural challenges and Merck's suggested improvements for the U.S. system

But the reality is that Merck's efforts alone are far from sufficient. They do not and cannot address the underlying systemic and structural issues underpinning our system, which do not allow patients to benefit from the substantial discounts that manufacturers are providing on the medications they sell.

As more power and control has been consolidated into an ever-smaller number of vertically consolidated players, their negotiating strength has increased dramatically. In Merck's efforts to contract with them, we continue to experience increasing pressure to provide even larger discounts, and the gap between list and net price continues to grow. But patients are not benefiting from the discounts being negotiated by PBMs. Instead, their insurers often base their cost-sharing on the list price, even when PBMs and insurance companies are paying a heavily discounted fraction of that price.

Our diabetes treatment Januvia is a great example of this phenomenon. Today, the weighted average net price for Januvia represents a 90 percent discount off its list price; with the price of Januvia being 33 percent lower than its price when we launched it in 2006. This is, in part, a result of significant discounts and rebates in a highly competitive market over the years. But these discounts and rebates are not being passed along to patients in a way that reduces their out-of-pocket costs.

Simply reducing our list prices is not a solution because patients often experience reduced access to their drugs when they are either not included on or are dropped from PBM and plan formularies. For example, in 2016, Merck introduced our Hepatitis C medicine, Zepatier, at a list price 42 percent below that of the standard of care at the time. Yet, we had difficulty getting plans and PBMs to add the product to their formularies. The situation did not improve in July 2018, when we further reduced the list price by 60 percent and found no increased uptake. More recent efforts by other manufacturers to offer products with lower lists prices have resulted in similarly poor PBM and plan coverage compared to their high list price competitors. Thus, lower list prices can result in reduced access for patients.

Rather than passing the steep savings they obtain through to patients to lower their out-of-pocket costs at the pharmacy counter, we understand that insurance plans retain them to cover overhead costs and reduce insurance premiums for all their insureds. When they do this, rather than reducing medicine costs for those that need them, it means sick people end up effectively subsidizing healthy people. This dynamic is contrary to the basic idea of insurance, which should use the premiums of healthy people to help fund the care of those who are struggling. This is yet another way in which our current system is fundamentally flawed.

From 2010 through 2023, Merck's annual average net price increase across our U.S. portfolio has been in the low-to mid-single digits. In 2017, our average net price actually declined nearly 2 percent. In 2022, the average discount for our medicines and vaccines was 40 percent off the list price. This money is flowing in part to middlemen, not to the innovative manufacturers that would reinvest that money to find tomorrow's cures. And, by and large, patients did not receive the financial benefits of these substantial discounts. Instead, their out-of-pocket costs continue to rise.

Though the issues I have described are complex and impossible for one company—or even the pharmaceutical industry collectively—to address, legislative solutions may not be difficult to implement. If Congress were to *require that other actors' revenue streams be delinked from the list price of a medicine,* it would remove incentives for the system to favor high list prices. This would also ensure that less of the value in the system flows to these middlemen, who did not discover, develop, or produce the medicines for which they contract.

Another critically important fix is to *require that the substantial savings provided by Merck and other manufacturers be passed through to patients to lower their out-of-pocket costs at the pharmacy counter, rather than allowing insurance plans to re-*

tain them. Reforms like these are necessary and will help provide long-term solutions for patients' out-of-pocket costs and ensure they can take advantage of the full breadth of innovative medicines available to keep them healthy and alleviate their suffering.

We firmly believe that it is possible to have a drug pricing system that incentivizes the discovery of new and important medicines and at the same time ensures patients can afford those lifesaving innovations. But reform of our current system is desperately needed to ensure that patients in the United States continue to have the greatest access, to the best medicines, faster than anywhere else in the world. I would encourage you to support legislative or administrative remedies that would address these systemic problems.

Fostering innovation alongside patient access solutions

These are exciting times in the biopharmaceutical industry and the wider world of health care. Decades of research investment are producing discoveries of increasing promise and impact. Life-threatening diseases like cancer are being conquered. Patients are living longer, healthier lives, even with serious conditions.

But let me be very clear: today's investments drive tomorrow's discoveries of breakthrough treatments. If we disrupt an ecosystem that incentivizes robust investments in research, we put at risk not only the foundation of American leadership in pharmaceutical development but also the health and lives of countless people who would have benefited from future discoveries.

We do not have to go down that path. In fact, we have examples of efforts that are already working. For instance, the Medicare Part D program facilitates actual negotiation, effectively holding down costs and broadening patient access without threatening to injure or destroy the innovation ecosystem that fosters future treatment breakthroughs.

The most important positive contributions Merck makes in the world—impacting economies, health care systems, and the well-being of countless patients and their families—are pharmaceutical innovations that save and improve lives. Achieving such innovations requires us to invest billions of dollars a year in the often unsung work of thousands of brilliant researchers sitting at lab benches and striving, with all they have, to create transformative breakthroughs.

The odds are stacked against these scientists, but they keep trying, and we keep investing. Even with all the advantages of modern technology, discoveries are few and far between. And, even among those discoveries that spark clinical trials, nine out of ten compounds will fail.

Of course, our Country needs to contain health care costs and reduce out-of-pocket costs to patients. And Merck is committed to being part of the solution. But we must pursue greater affordability and accessibility for medicines—and health care more broadly—in ways that preserve and strengthen our innovation ecosystem across academia, smaller biotech firms, larger pharmaceutical companies, government agencies, insurers, providers, and other stakeholders.

Ultimately, I believe we need to work together across these stakeholders to overcome the access and affordability challenges faced by today's patients without damaging our ability to innovate and discover new treatments for tomorrow's patients. Future treatment breakthroughs hinge on what we do now. We must hold onto a U.S. pharmaceutical market that is free, competitive, and predictable, one that encourages and rewards investment, one that drives the American economy and creates jobs, and one that continues to deliver innovation and new treatment discoveries.

I am here today to pledge our support and cooperation in this effort and other measures to help Americans live longer, healthier lives with improved access to effective and affordable drug treatments, and in ways that protect incentives for future innovation.

Thank you for your time and your consideration of these perspectives, and thank you again for the opportunity to share them with you today.

[SUMMARY STATEMENT OF ROBERT DAVIS]

Summary

Merck's mission is to use the power of leading-edge science to save and improve lives around the world.

Merck conducts groundbreaking work to treat and prevent cancer.

Keytruda treats cancer in 39 indications, including 17 tumor types and 2 tumor-agnostic indications.

- Since 2011, Merck has invested: $30 billion in internal clinical development; $14 billion in research collaborations and acquisitions; $2 billion in capital expenditures for Keytruda alone.
- We expect to invest another $18 billion in clinical studies into the 2030's.

Merck has made substantial investments across our research and manufacturing efforts.

Merck is making infrastructure investments in the United States. In the past 5 years we invested:

- $3.6 billion in Pennsylvania, with an additional $700 million expected this year.
- $1.4 billion in Elkton, Virginia.
- More than $10 billion total across the United States, creating hundreds of new jobs.

Merck works to address patient access challenges.

We have a duty to act responsibly in pricing practices and contribute to affordability solutions. We:

- Supported changes to the Medicare Part D program to create an out-of-pocket cap and to allow beneficiaries to pay their costs over time.
- Publicly disclose U.S. pricing data, including the average rebates and discounts we provide.
- Provide coupons and other co-pay assistance for our products, totaling $130 million last year.
- Created a patient assistance program providing nearly 800,000 people with an estimated value of $7.8 billion.

Structural challenges increase prices for patients.

The savings Merck provides to PBMs and insurers are not passed on to patients.

- Payors retain the savings to cover overhead and reduce insurance premiums for their insured.
- Sick people end up effectively subsidizing the healthy, contrary to the basic idea of insurance.
- When list prices are reduced, medicines are dropped from formularies, limiting patient access.

Merck has a history of cost reductions.

- From 2010 through 2023, Merck's annual average net price increase across our U.S. portfolio has been in the low-to mid-single digits.
- In 2017, our average net price actually declined nearly 2 percent.
- In 2022, the average discount for our medicines and vaccines was 40 percent off the list price.
- Unfortunately, middlemen absorbed some of the benefits from this price reduction—benefits that should have gone to patients.

Merck urges Congress to consider the following solutions:

- Require that other actors' revenue streams be delinked from the list price of a medicine, which would reduce incentives for the system to favor high list prices.
- Require that substantial savings provided by Merck and other manufactures be passed through to patients to lower their out-of-pocket costs at the pharmacy counter, rather than allowing insurance plans to retain them.

The CHAIR. Thank you very much, Mr. Davis. Our third witness will be Chris Boerner, CEO, Bristol-Myers Squibb. Dr. Boerner has served as CEO of Bristol-Myers Squibb since November 2023. Thanks for being here, Mr. Boerner.

STATEMENT OF CHRIS BOERNER, CHIEF EXECUTIVE OFFICER, BRISTOL MYERS SQUIBB, PRINCETON, NJ

Mr. BOERNER. Chairman Sanders, Ranking Member Cassidy, and Members of the Committee, thank you for having me here today. I am proud to be representing Bristol-Myers Squibb, an American company that is committed to transforming patients' lives through science.

I have spent more than 20 years in this industry, the majority in smaller, science driven biotechnology companies. I joined BMS because we have a similar focus on driving leading edge scientific innovation, and our scale allows us to bring more medicines to more patients faster.

To help illustrate the type of work that we have been doing for more than 150 years at BMS, let me provide two illustrations of how our innovative medicines have helped patients and provided tangible benefits to society. Our work in HIV/AIDS transformed this disease from a death sentence into a chronic condition.

Similarly, our pioneering immuno-oncology treatments, OPDIVO and YERVOY, harness the body's immune system to fight cancer and have contributed significantly to improved outcomes across a number of tumors, including metastatic melanoma, where the combination of these two medicines has changed the median life expectancy from less than 9 months to over 6 years. I am proud that our record of innovation continues today.

We have invested more than $65 billion in research and development over the past decade. This has resulted in truly novel and transformational medicines, like Camzyos in cardiovascular disease, our cell therapy platform in cancer, and we are working toward bringing to patients the first medicine for the treatment of schizophrenia in 30 years.

These medicines are but a few examples of the innovation that results from an American health care system that not only accounts for the majority of new medicines launched each year, but also one that delivers those medicines to U.S. patients faster than anywhere else in the world. This isn't by chance.

The United States has built a health care system that prioritizes patient and physician choice, as well as the broad and rapid availability of cutting edge medicines. This is in stark contrast to many systems outside of the United States, which while they may deliver lower prices, carry an often overlooked tradeoff, that patients often wait longer for new medicines that are sometimes never approved or reimbursed.

For example, Canadian patients have access to approximately half of the medicines available in the United States, and patients in other countries face a similar reality. Despite its benefits, we know our American system is far from perfect.

Patients bear the brunt of a complex U.S. system that results in increasing health care costs and a lack of affordability. We have to make the system work better for them. After all, innovation that does not make it to patients is no innovation at all.

While prescription medicines account for a relatively small portion of overall health care spending, we believe we have an important role to play in prioritizing the development of medicines that will bring savings to the health care system, and as an industry, we should set a higher bar for doing just that.

Similarly, we have a role to play in addressing affordability and stand ready to partner with Congress and others to address this issue for patients in a holistic manner. But in developing those solutions, we should not abandon our system for one that denies U.S. patients the broad and rapid access to vital medicines that they appreciate today.

We support policies that lower patient out-of-pocket costs without ultimately harming innovation. The need to strike this balance should not be abstract. I expect many of us in this room have lost a loved one to cancer or another devastating disease.

In my case, it was one of my best friends and it happened as he awaited a medicine that I believe could have saved his life. This is an almost daily reminder to me that making patients wait for weeks, months, or years can be the difference between life and death.

Thank you again for having me here today. On behalf of BMS and the more than 30,000 employees who share my passion for delivering new medicines for patients, I look forward to answering your questions.

[The prepared statement of Mr. Boerner follows.]

PREPARED STATEMENT OF CHRIS BOERNER

Chairman Sanders, Ranking Member Cassidy, and Members of the Committee, thank you for the opportunity to testify today on behalf of Bristol Myers Squibb ("BMS"). I appreciate the chance to speak about BMS's groundbreaking work and efforts to enhance access to our innovative medicines for patients. I am proud to testify on behalf of a company that is committed to transforming patients' lives through science.

At BMS, our mission is to discover, develop, and deliver medicines that help patients prevail over serious diseases. Our record of innovation has changed the outlook for countless patients. Groundbreaking BMS therapies helped transform HIV/AIDS from a death sentence into a chronic condition. Today, our medicines allow people with heart disease, cancer, diabetes, and autoimmune disorders to live longer and healthier lives.

We are not content, however, to rest on our more than 150-year legacy of scientific innovation and are dedicated to developing the next generation of breakthroughs. We are pushing the boundaries of science to treat debilitating diseases, such as cancer, Alzheimer's, and multiple sclerosis, where unmet needs remain. As we look ahead, we are focused on introducing novel treatments in areas we know best: oncology, hematology, immunology, cardiovascular disease, and neuroscience.

We are also focused on increasing access to our medicines. Patients in the United States get new medicines sooner than any other country in the world. That's a significant benefit. But we recognize that patients must be able to afford our medicines to achieve the clinical outcomes those medicines bring. BMS has long worked to enhance access to our innovative medicines for patients, while maintaining an environment that enables investments in cutting-edge science to deliver life-changing treatments, and we remain committed to working with Congress to do so.

Our commitment reaches beyond our medicines. BMS supports programs, initiatives, and organizations that improve health, broaden research opportunities, bolster STEM education, and bring essential human services to our communities. We also promote health equity and strive to increase access to life-saving medicines for populations disproportionately affected by serious diseases. From 2020 to 2023, BMS provided more than $118 million in grants and donations to non-profit organizations and independent medical educational partners for more than 750 health equity projects.

Having spent more than two decades in the biopharmaceutical industry, I joined BMS 9 years ago because of its dedication to improving the lives of patients. I became CEO in November 2023 and am honored to be leading this great company through its next chapter.

During my tenure, I have developed a deep admiration and respect for the over 30,000 dedicated BMS employees in the United States and around the world who harness their intellect, expertise, hard work, and passion on behalf of the patients we serve. From our scientists in the lab, to our manufacturing teams in our facilities, to our patient outreach teams in the field, I am proud to work alongside my BMS colleagues, who are dedicated to creating and delivering life-changing medicines to patients in need.

BMS's Emphasis on Expanding Patient Access

The United States has built a healthcare system that prioritizes the important role of patient choice and broad, rapid availability of cutting-edge medicines. Patients and their physicians in this country have access to more unique medicines than in any other country. This access is critically important because different medicines can have different side effects or safety profiles, different mechanisms of action, and different efficacies at stages of disease, such that the leading or most obvious therapy may not be the most appropriate. By providing physicians in the United States with more options, we give them the ability to choose the best treatment for their patients and offer potentially better outcomes.

Despite the many benefits of the United States system, we acknowledge that patient affordability is a significant issue. It is also one of the least understood. The United States has a unique and complex healthcare landscape, replete with conflicting pressures and perverse incentives driving the system. Many of these factors exert strong influence on patient access and the price patients actually pay for their medicines.

Manufacturers give significant rebates, discounts, and payments to intermediaries between us and patients in the pharmaceutical supply chain. BMS has provided these intermediaries with over $96 billion dollars of rebates, price concessions, and other discounts and fees over the last 5 years across our portfolio. But patients are not seeing the financial benefits of the sizable discounts because intermediaries are not required to pass on discounts to patients when they fill their prescriptions at the pharmacy counter.

Additionally, the United States healthcare system has not yet evolved to account for the economic benefits of highly specialized innovative medicines that contribute substantial value to patients and the system. For example, a patient on the right medicine may avoid serious or life-threatening medical interventions. This in turn also provides cost savings to the healthcare system by reducing expensive and high-burden hospital stays and conserving capacity.

We share your concerns about what patients pay for prescription medications, and we appreciate your work to examine this key public policy issue. It is our collective—and critical—— responsibility to ensure that patients receive the medicines they need. BMS invests billions in patient support programs with that objective in mind. Although patient support programs are an imperfect solution to these challenges, I am proud of our efforts to help patients access our medicines. Over the past 5 years, we have spent more than $2.5 billion on copayment assistance for commercially insured patients, helping patients receive medicines such as Eliquis, which treats and prevents blood clots. We broadened our existing patient support programs to help eligible patients in the United States without health insurance due to pandemic-related job loss.

We also contribute to organizations that help support patients in need. For instance, over the last 5 years, BMS donated over $12 billion in free medicines to the Bristol Myers Squibb Patient Assistance Foundation. The Foundation is an independent organization that promotes health equity and improved health outcomes for populations disproportionately affected by serious diseases. It supports community-

based programs that promote cancer awareness, screening, and care among high-risk populations. In addition, BMS made cash donations to independent charitable organizations to support patients in the United States.

BMS also supports comprehensive efforts across the continuum of care, including projects to train community health workers and patient navigators to help underserved patients navigate the healthcare system. In March 2023, we announced $10 million in grants to be made that year to 17 United States organizations that address social determinants of health. These grants support organizations striving to improve health in the United States, including through healthcare access and literacy and by integrating social care and healthcare to reduce health disparities.

BMS's Commitment to Bringing More Innovative Medicines to Patients Through Research and Development

We are proud to have a promising pipeline of innovative medicines that will allow us to continue delivering cutting-edge treatments to patients. BMS is investing in leading scientific programs, including in our core areas of oncology, hematology, immunology, cardiovascular disease, and neuroscience. Over the past 10 years, BMS devoted over $65 billion—more than 21 percent of our total revenue—to research and development ("R&D").[1] In 2022, we conducted more than 460 clinical trials.

In fact, our investment in R&D as a percentage of total revenue consistently ranks among the highest of any large company in any industry globally. In the 2023 EU Industrial Research and Development Investment Scoreboard, BMS ranked 15th for total R&D spending among all companies worldwide.

Our investment in R&D has resulted in vastly improved outcomes for patients. For example, BMS is a pioneer in the field of immuno-oncology through the development of three medicines: Yervoy, Opdivo, and Opdualag. Prior to the development and introduction of immuno-oncology treatments for metastatic melanoma, outcomes were generally quite poor, with a median life expectancy of only 6 to 9 months after diagnosis. Today, thanks to these therapies, survival rates have significantly improved among patients with metastatic melanoma. Long-term follow-up studies have demonstrated a median life expectancy of over 6 years with the combination of Opdivo and Yervoy.

Our investment of over $65 billion in R&D over the past decade is fueling the next wave of new treatments for areas of high unmet need. Our R&D pipeline includes potential treatments across a range of platforms, including those that harness the frontiers of genomics to translate that knowledge into gene therapies, cell therapies, RNA oligonucleotides, and other novel modalities. With our CAR T cell therapies, for example, we can now target cancer with a type of immunotherapy that works with a patient's own immune system by reprogramming their T cells. With a single treatment, CAR T cell therapy has been effective at producing durable responses in patients where other treatment options stopped working. BMS is the only company with two cell therapies approved against two distinct targets, and we are pursuing opportunities to bring them to more patients who may benefit.

Overall, we have more than 45 novel compounds in development, with more than 40 disease areas under study. We are conducting late-stage studies for medications to treat various solid tumors, multiple myeloma, Crohn's disease, lupus, and atrial fibrillation. And we are leveraging our expertise in protein homeostasis, immunology, and inflammation to tackle neurological and neuromuscular diseases with new approaches.

Our R&D efforts are not limited to discovering new compounds. We are constantly researching how we can use existing products to provide additional benefits to more patients through new indications and formulations. We are currently running and partnering with other innovators in more than 15 late-stage studies involving existing products.

Our commitment to innovation and to patients also includes establishing strategic partnerships with other biotechnology leaders and acquiring companies that benefit from our global scale and expertise to bring medicines to patients faster. We offer deep scientific leadership, resources, and abilities to invest in research and development programs and highly developed commercial, manufacturing, and supply chain operations. This global scale and range of expertise enables us to reach the greatest number of patients worldwide. Our recently announced plans to acquire RayzeBio and Karuna Therapeutics demonstrate this commitment. We are excited about the potential of Karuna's KarXT, a late-stage developmental medicine with a novel

[1] Based on non-GAAP calculations.

mechanism of action aimed at schizophrenia and other psychological disorders. If approved, KarXT would represent the first new pharmacological approach to treating schizophrenia in several decades.

R&D is complex and resource-intensive, often lasting 14 years or more for a particular compound. Results are far from guaranteed. In fact, the majority of our R&D efforts do not result in a medicine that we can deliver to patients. For instance, last year we had to discontinue two late-stage clinical trials into which we had invested multiple years and many millions of dollars. One was a phase-three trial that evaluated one of our existing medicines, Opdualag, for treating colorectal cancer. We invested more than $80 million and devoted thousands of hours of employee time to this research, which ultimately failed. In another case, after more than 6 years of research, we had to end a study evaluating a combination of our medicines, Opdivo and Yervoy, for advanced treatment of renal cell carcinoma. We invested over $130 million in that study alone.

Because we pursue a wide range of possibilities on the cutting edge of science, we know that some of our research will not culminate in new treatments. Failures are an inevitable part of the process by which we develop new treatments, and we learn from them along the way. Our successes allow us to try. Those successes are a critical engine in our ability to continue to invest in new medicines, allowing the United States to lead the world in bringing new treatments to patients.

The Disadvantages of International Pricing Systems

Rules and regulations regarding the pricing of medicines vary widely by country. Some countries, such as Canada, the U.K., Germany, France, and Japan, essentially allow the government to set pharmaceutical prices. In effect, governments in those countries make choices for patients—choices that often result in patients having access to fewer innovative medicines, and waiting much longer for new medicines as compared to patients in the United States. These delays can be attributed to a variety of factors, including waiting for the government to complete reimbursement assessments, challenges with subpopulation coverage, or a failure to appropriately value innovation.

In Canada and most European Union countries, the government regulates the pricing of a new medicine at launch through some combination of clinical and economic assessments, price negotiations, and international reference pricing. Prices are often reevaluated and further controlled after a medication has been introduced. Patients pay a significant price for these pricing schemes in the form of delays to access. For example, only about 45 percent of new medicines available globally have been introduced in Canada—compared to 85 percent in the United States. In France, Italy, and Japan, this figure is below 55 percent. The United States launched 94 percent of new cancer medicines from 2012 through 2021, while the same figure for the average OECD country was 49 percent. These figures are startling, reflecting dramatic differences in access to medicines around the world.

Patients outside the United States also often face longer wait times and obstacles before getting the medicines they need. According to a report published last week by the United States Department of Health and Human Services, medicines launch in the United States an average of 1 year before they launch in other major OECD markets. Other studies found that on average, there is an 11-month delay from a medicine's first launch globally to its availability and reimbursement in Germany, a 17-month delay in Japan, a 27-month delay in the U.K., and a staggering 52-month delay in Canada. Patients with multiple myeloma in the U.K. waited 4 years after the United States launch for BMS's medicine, Revlimid—a medicine that significantly improves outcomes. Canadian patients did not gain access to Opdivo and Yervoy for melanoma until more than 3.5 years after patients in the United States. Patients in Spain, Japan, Denmark, Australia, and other countries are still waiting for access to Camzyos, the first new treatment in decades for obstructive hypertrophic cardiomyopathy, which was approved in the United States in 2022.

By contrast, the United States is generally first in the world for launching new medicines, and patients usually benefit from access to new medicines within days of regulatory approval. The United States healthcare system has allowed Americans to have access to more new innovative medicines sooner than any other country.

This access generally translates into better outcomes to save and extend lives. For example, while it is challenging to precisely quantify and compare across different countries the impact of delayed access to anticancer therapy on survival outcomes, there is broad agreement that prompt access to effective treatments is a fundamental necessity, and it yields positive outcomes on patients, healthcare systems, and society in general. These outcomes include: lower mortality and avoidable

deaths; gains in quality of life for patients, family members, and caregivers; lower healthcare costs; and avoidance in loss of productive employment for patients and caregivers, ultimately lowering costs to the national economy.

BMS's Value-Focused Pricing Philosophy

We believe the prices of our medicines should reflect their benefit to patients, healthcare providers, payers, and society—both at launch and in future years. Guided by this belief, we price our medicines based on three primary factors, including aligning to the value of scientific innovation, investment into research and development, and our ability to provide rapid and sustainable access for patients, among other considerations. That means we look at longevity gains, clinical outcomes, and quality of life, as well as economic impact and productivity gains generated by a healthy population with more options to treat illnesses. We also consider our ability to sustain our research and development investment and to work with payers to secure access, so patients can have coverage for our medicines when needed.

Our product Eliquis, an oral medicine that inhibits a key blood-clotting protein, provides a good example of our approach to pricing. Over the past few years, Eliquis has become the standard of care for decreasing blood clot formation in patients—it is prescribed millions of times each year, and is the most prescribed branded medicine in Medicare Part D. However, it ranked 540th in Medicare spending per patient in 2021. Eliquis can lower the risk of a stroke and prevent deep vein thrombosis and embolism, and it is commonly used to prevent blood clots following certain surgeries. Because Eliquis can help prevent very serious medical conditions that require hospitalization or other expensive medical treatments, numerous studies have demonstrated that Eliquis provides substantial savings to our healthcare system, such as reduced hospitalization and institutional costs. Without the benefits of Eliquis, many patients would have substantially worse medical outcomes, and the healthcare system would face dramatically higher costs. For every 100,000 patients, we estimate that Eliquis offers patients and healthcare systems a $4.9 billion consumer surplus over older, generic products. This value to patients and to the entire United States healthcare system is reflected in the price of this medicine.

Path Forward

The United States healthcare system prioritizes patient choice and access in a way other healthcare systems do not, but it is far from perfect. The system is mired in complexities and incentives that frustrate our efforts to meet patients' medical needs. These hurdles range from complex rebates, to high copays and deductibles, to Federal rules that restrict our ability to assist patients in Federal healthcare programs. I welcome the opportunity to work with your Committee and others in Congress to resolve these issues in our healthcare system. Ensuring access to medicines involves more than just the companies that discover and develop them—it requires the active engagement of the entire ecosystem of governments, payers, healthcare providers, pharmacies, and hospitals. BMS supports policies that remove barriers and perverse incentives in the system and focus on patient out-of-pocket costs. We believe we can do this without harming innovation. BMS stands ready to work with Congress to address affordability and eliminate barriers in the system that fail to pass discounts and rebates to patients, but this cannot be done in a vacuum. The measures we support include: expanding value-based contracting for which there are regulatory impediments today; incentivizing competition and production of biosimilars and generics to ensure a steady supply in the United States; and passing rebates on to patients at the pharmacy counter to address the incentives in a complex system that drive up list prices.

As BMS continues to strive to enhance patient access, we are also committed to ensuring that we have the resources to fund cutting-edge R&D and to attract the private capital needed to do so. We also believe that policymakers should adopt and defend policies that promote innovation. Government policy should encourage innovators to take big risks and invest substantial sums, by promising a return on those efforts for a reasonable period of time. Such policies are the reason that the United States is a leader globally in medical innovations and developing new therapies. At BMS, we are eager to continue driving these efforts.

Again, I am proud to speak here today on behalf of BMS, where we believe patients in the United States should not be deprived of their choice to access the best, most recent technologies and advancements in medicine. I look forward to answering your questions about how we can meaningfully address healthcare costs and patient access.

The CHAIR. Mr. Boerner, thank you very much. Before I begin the first round of questions, let me remind our witnesses that while the HELP Committee does not swear in our witnesses as a general rule, Federal law at 18 U.S. Code Section 1001 prohibits knowingly and willingly making any fraudulent statement to the Senate regardless of whether a person is under oath.

I would also say, in response to many of your testimonies, we are aware of the many important lifesaving drugs that your companies have produced, and that is extraordinarily important, I think, is all of those drugs mean nothing to anybody who cannot afford it, and that is what we are dealing with today, that millions and millions of our people cannot afford the outrageously high cost of prescription drugs in this country.

Now, my time and the time of all of the Members is limited, so we are going to just—I am going to ask—so my time is limited, so I am going to start by asking all of you a number of questions and I would appreciate it if you could respond with a yes or no answer.

It turns out that a dysfunctional and extraordinarily expensive healthcare system, hundreds of thousands of Americans have gone to GoFundMe in order to raise money to pay for their health care needs and for their prescription drugs.

Let me ask Mr. Davis if I might, have you ever searched on GoFundMe for your cancer drug, KEYTRUDA?

Mr. DAVIS. No, I have not.

The CHAIR. Okay. We have, I and my staff have, and we have found over 500 stories of people trying to raise funds to pay for their cancer treatments.

One of those stories is a woman named Rebecca, a school lunch lady from Nebraska with two kids who died of cancer after setting up a GoFundMe page because she could not afford to pay for KEYTRUDA.

Rebecca had raised $4,000 on her GoFundMe page but said the cost of KEYTRUDA on a cancer treatment was $25,000 for an infusion every 3 weeks. Mr. Davis, and please yes or no, is it true that the list price of KEYTRUDA is $191,000 a year in the United States?

Mr. DAVIS. That is close to being true, yes.

The CHAIR. Thank you. Is it true that same exact drug can be purchased in Canada for $112,000 a year, and $44,000 a year in Japan?

Mr. DAVIS. Generally, yes.

The CHAIR. Mr. Davis, even though the price of KEYTRUDA is one quarter of the price in Japan compared to the United States, does your company, does Merck make a profit selling KEYTRUDA in Japan?

Mr. DAVIS. We do.

The CHAIR. What I understand is you make a profit selling KEYTRUDA in Japan for one quarter of the price that you sell it for in the United States. My question to you is a pretty simple one. Will you commit to lowering the price of KEYTRUDA in the United States to the price of Japan?

Mr. DAVIS. Well, Senator, I think—first, I acknowledge the prices in the United States are higher than they are in many of the countries you said, and not for all drugs, but for many drugs.

That is the reality we face. But I think it is also important to point out that you get access in the United States faster and more than anywhere in the world. We have 39 indications for KEYTRUDA across 17 tumor types in the United States. If you look across Europe, it is in the 20's.

If you look across Japan, it is in that number or a little bit less. So, there is a reason why the prices are different, and we need to be careful because we are also seeing in those markets that they are unwilling to support the innovation and we are very hardly—working hard to try to get them to understand the need to help funding the innovation we have——

The CHAIR. I apologize for cutting you off.

Mr. DAVIS. That is fine.

The CHAIR. There are two other witnesses—but I did want to make this point.

Again, we all appreciate the breakthrough and important drugs that you and other companies have produced that save lives. No debate about that.

But I do want to point out that after all is said and done, and after all the money we spend on the prescription drugs and health care in general, the life expectancy in Japan is 9 years longer than it is in the United States. Senator Cassidy talked about Canada. Life expectancy in Canada is 6 years longer than the United States.

Life expectancy in Portugal is 6 years longer. Life expectancy in the UK is 4 years longer. Let me ask the last question to Mr. Davis, because I understand that you made $52 million in total compensation in 2022.

Will you commit to not accepting a single dollar more in compensation until there is not a single GoFundMe page for KEYTRUDA?

Mr. DAVIS. Well, I can tell you at Merck we are very much sensitive to what is happening with patients. That is why we have very important patient assistance programs.

We commented on the fact that we have over 800,000 patients benefiting where we provide free drug for those who can't afford it, as well as other assistance programs that help with co-pay and other.

We are very committed as a company to doing what we need to do to try to help alleviate the challenges patients face that you are focusing on, and that is my focus as the CEO.

The CHAIR. Thank you. Mr. Boerner with Bristol-Myers Squibb, Carolyn from Florida says that she cannot afford ELIQUIS, and so she will, "stop taking it, though I need it to prevent the risk of having a stroke."

Mr. Boerner, again yes and no please, the list price of ELIQUIS is $7,100 a year in the United States. Dr. Melissa Barber, an expert at Yale University, has estimated that it cost just $18 to man-

ufacture a year's supply of ELIQUIS. $7,100 what we pay, $1,800 to manufacture.

Is it true that the same exact drug, ELIQUIS, can be purchased in Canada for $900 a year?

Mr. BOERNER. Senator, that is roughly correct.

The CHAIR. Let me ask you this, even at 13 percent of the cost in the United States, does Bristol-Myers make a profit selling ELIQUIS for $900 a year in Canada?

Mr. BOERNER. Senator, we do make a profit.

The CHAIR. All right. So, you are selling the product for 13 percent of what—in Canada of what we pay in the United States.

Obviously, you sell it there because you make money. So, Mr. Boerner, will you commit today that Bristol-Myers Squibb will reduce the list price of ELIQUIS in the United States to the price that you charge in Canada, where you make a profit?

Mr. BOERNER. Senator, we can't make that commitment primarily because the prices in these two countries have very different systems that prioritize very different things.

In Canada, medicines are generally made less available, and it takes oftentimes considerably longer for those medicines to be available. On average, roughly——

The CHAIR. I apologize—I do apologize. Just life expectancy in Canada is 6 years longer than it is in the United States. Mr. Boerner, your company spent over $12 billion on stock buybacks in 2022. Given that reality, can you tell Carolyn why you can't lower the price of ELIQUIS?

Mr. BOERNER. First, Senator, let me say no patient should have to go through the types of choices that the patient you just described go through. It is our commitment to continue to bring down the price of medicines in the U.S., and I would love the opportunity to bring down the price of ELIQUIS in the U.S..

Our net price, is what we are compensated, have actually over the last 5 years declined. At that same time, the list prices have increased. Why is that? Because of the complexity of this system and the billions of dollars in rebates that we have provided to intermediaries that unfortunately do not go to lowering the price of medicines like the patient you just described.

The CHAIR. Again, I apologize. I want to get very briefly to Mr. Duato, who is with Johnson & Johnson. Mr. Duato, is it true that the list price of STELARA is $79,000 here in the U.S.? Is that roughly right?

Mr. DUATO. It is roughly right, but it is also true that the average discount of STELARA in the U.S. is 70 percent.

The CHAIR. All of that, and we have dealt with PBMs, and we are going to get to that I am sure in—this morning. Is it true that while charging $79,000 in the United States, that the exact same product is sold in Spain for $18,000?

Mr. DUATO. I don't know the price in Spain. I can tell you that the average discount in the U.S. is 70 percent. So, the price that you quote, it is 30 percent of that.

The CHAIR. Okay. Mr. Duato, is it true that it costs less than $15 a year to manufacturers STELARA?

Mr. DUATO. The manufacturing cost is only a component that goes into our pricing. When we price our medicines, we are looking at the value that the medicine brings to the healthcare system. Our ability to continue to invest in research.

We invested $15 billion last year. And also, we look at affordability. The average copay, if they use our copay assistance programs in the U.S., for a patient using STELARA, it is $10 to $15 per month.

The CHAIR. I apologize. I am over my time. I am going to give Senator Cassidy the same time that I had.

Senator CASSIDY. Thank you all. Mr. Duato, the—in 2021, Janssen constructed an exclusionary contract with their PBMs to protect REMICADE, their blockbuster drug, a treatment for ulcerative colitis. Very familiar with it. A wonderful drug. Changed the outcome for people with UC.

But this deal protected REMICADE from competition by new biosimilar, Inflectra, which was launched at a 16 percent lower cost than REMICADE. Now, I understand this is confidential in terms of the settlement with the courts but—and by the way, let me just say this involves a rebate wall.

For the sake of those who are watching, a rebate wall is an anticompetitive tool which can be used to restrict a competitor's entry into a formulary. A manufacturer would offer more significant rebates to a health plan through a PBM for access to the formulary contingent upon the PBM blocking a biosimilar.

Now, we have been discussing the promise of biosimilars to lower the cost in a market oriented, competitive way. So, we are not going to have Government regulation, we have got to have a market situation, and the market would be a biosimilar, but this sort of arrangement blocked the biosimilar from entering.

In the full support of a market oriented approach, do any of your current contracts employ rebate walls to prevent lower cost biosimilars from formulary access?

Mr. DUATO. We welcome biosimilars and generics. We believe it is an integral part of the system.

As a matter of fact, in the U.S., 90 percent of the prescriptions are biosimilars and generics, and that is one of the reasons pharmaceutical expenses have remained flat or increased single digit during the last years.

We believe that biosimilars and generic foster patient access, and we care deeply about that. And we don't——

Senator CASSIDY. But let me ask because my specific question, do any of your current contracts employ rebate walls?

Mr. DUATO. Our current contracts do not employ any technique to avoid biosimilars and generics to have uptick in the market.

Senator CASSIDY. Okay. Thank you. Now, I think at least two of you, maybe all three of you, are working on gene therapy. I have been concerned that we don't really know how we are going to price those.

I think one of the concerns is that there will not be a market for us to lower the cost of an initial gene therapy, which are incredible. It is amazing the lifetime of benefit that gene therapy can create. But I was speaking to a medical director of Medicaid CMO, and he was telling me that the pharmaceutical costs related to Medicaid is now 35 percent were formerly it was like 25 or 30 percent.

He says this is being driven by gene therapy. And when sickle cell comes widely spread, it is going to—I don't know how it is going to be priced, but my state has a lot of sicklers. I don't know how my state is going to be able to afford giving it to everybody who should have access.

Very concisely, how are we going to show restraint on the price of some of these new gene therapies, which already is driving up Medicaid? So again, 35 percent of Medicaid is now pharmaceutical cost. Mr. Boerner, I will start with you.

Mr. BOERNER. Senator. We actually don't work in gene therapy——

Senator CASSIDY. Oh, then let me go to Davis. Mr. Davis.

Mr. DAVIS. We actually do not work in gene therapy.

Senator CASSIDY. Oh, I thought I saw you at a press release that you all were doing so. You had a vector or something.

Mr. DAVIS. No, we are—well, we are doing some very basic research, but we have nothing in advanced stages.

Senator CASSIDY. Mr. Duato.

Mr. DUATO. We do have a gene therapy served for treating inherited retinal diseases. And we support legislation in order to be able to do value based contracts in the case of gene therapy. So, we welcome legislation in order to be able to have value based contracts.

Senator CASSIDY. That is a really—that is good. Value based contract will be important, but it still doesn't address the opening cost. Because of the opening cost of sky high, you still—you see where I am going with that.

Now, what would you give to us who believe in markets, a solution to an opening price that would be so much it would be difficult for society to afford the gene therapy. And I can put in any other drug, but let's just start with gene therapy.

Mr. DUATO. We have to look at the value of these therapies and the fact that gene therapy for inherited retinal diseases may affect only less than 1,000 people in the world. So, we have to understand that.

You can rest assured that if we are fortunate enough to bring the solution that people that have diseases that can lead to blindness, we will sit down and evaluate very thoroughly our pricing in order to make sure that patients, all patients that need this therapy, are able to afford it.

Senator CASSIDY. I think I recall a couple of years ago there was a study that was shown, respected, and you probably know it better than I, that $2 million for gene therapy for ultra-rare diseases was a reasonable sort of—it would cover the cost. It would create the incentive to produce more.

That would be for the ultra-rare, where presumably you wouldn't have the ability to produce more. You know, obviously, the more you produce, you get a little bit extra profit. You know where I am going with that. So, but that shows restraint, if you will, on the behalf of the manufacturer.

Now we want to create incentive, but we want to be able to provide access, and without access, it is as if the drug has never been invented. So, is there any other thoughts you have on how society, if that is ultra-rare, $2 million, presumably.

If it is not ultra-rare, it would be less. How can we have a market oriented approach to this? Because I truly am concerned about the ability of a Medicaid program to be able to afford some of these gene therapies.

Mr. DUATO. We care deeply about our medicines getting to the patients that are need it, especially in these, as you have mentioned, ultra-rare diseases that have therapy can have life changing consequences.

We will always sit down and make sure that the way we price is reflective of the value of the medicine, but also importantly, it enables affordability, and it makes it possible that every patient that needs it in America, can get it.

Senator CASSIDY. Now, the affordability though, we are defining affordability for the patient. So, if Medicaid covers it, it is by definition affordable for the patient, or if the insurance does. But then that doesn't necessarily make it affordable for society. And society has got to pay for it.

Obviously Medicaid is taking more and more of a state's budget and frankly, more and more the Federal budget. I am not sure there is an answer there but let me just challenge you because we want market oriented solutions.

We want to create incentives so that good companies like the three of you and others are making these new things. But if my state goes bankrupt paying for a new gene therapy, then my state's—the taxpayer, we all are tough—in a tough shape.

Let me just go to one more thing. There is evidence that pharmaceutical companies will do lifecycle management kind of to prolong the sort of exclusivity of a drug. And some have argued that actually defeats innovation because as opposed to making profit from innovation, you can make profit from lifecycle management. Any thoughts about that, Mr. Boerner?

Mr. BOERNER. Senator, I think lifecycle management, if you think about the extension of new indications for a product, is incredibly important to really being able to deliver additional benefits to patients.

Obviously, the patents associated with any product will dictate when a generic enters. We have been in favor of a robust generic entry primarily because our focus is on innovative products.

But think, for example, in cancer where typically you start the treatment of cancer very late in disease, learn more about how the drug works, show it is safe, but ultimately you can bring that into early stage cancer, where you have the potential to potentially cure patients.

Now, that takes quite a bit of time, but that is an example of a lifecycle management where you are actually showing the true potential of a medicine. I would hate for us to cutoff the opportunity to show those benefits.

At the same time, we should be, as an industry, welcoming of generic competition, because ultimately our focus as a company is to take resources as we get close to generic entry and focus those resources on the next wave of new product innovation, which is where I think we ultimately want to go for patients.

Senator CASSIDY. Mr. Davis, you have got 20 seconds. How would you do it?

Mr. DAVIS. Well, the short answer is, as I look at it, one, we very much support generic drugs and biosimilar drugs. I think it is the core of how our system works. We have a period where we are protected.

We are able to recoup our investment, and then society benefits in perpetuity beyond that. As we look at life cycle management, we always are asking, are we bringing value to the patient? I will give you a live example.

If you look at KEYTRUDA. KEYTRUDA now, as I mentioned, is in 39 indications across 17 tumor types. It is revolutionizing the care of patients facing cancer. The reality of it is still only 30 percent of people show overall response.

As great as it is, patients are still suffering. And what we are doing is investing in combination therapies to be able to extend and go beyond that 30 percent, which means much better benefit and value to the patients that will—that ultimately use those drugs.

Senator CASSIDY. Thank you.

The CHAIR. Senator Murphy.

Senator MURPHY. Thank you very much, Mr. Chairman. Thank you for holding this really important hearing. Mr. Duato, looking at your arthritis drug, and we have talked already a little in this hearing about the difference in price between the United States and other countries.

Annual cost around $80,000 in the United States, $20,000 in Canada, $12,000 in France. Are the prices that you receive from a country like Canada or France, which look to me to be about one quarter of the price that you get from the United States, are those prices covering your costs?

Mr. DUATO. Yes they do. To clarify, Senator, the price in the U.S. is discounted by 70 percent. So, the appropriate comparison would be $25,000 in the case of STELARA, if you are considering that price.

Senator MURPHY. Are the prices you are receiving from these other countries, so let's say France—but I will give you the benefit of your argument. France is still 20—it is still 50 percent of the U.S. cost that you are claiming. Are those countries' prices covering your costs?

Mr. DUATO. They do. The difference is that, for example, in Canada, which was the first country you quoted, STELARA, which is mainly indicated for inflammatory bowel disease, Crohn's disease,

and ulcerative colitis, not for arthritis, is not just reimbursed in the public system.

Canadian patients that want to access STELARA, they cannot do it in the public system because 8 years, 8 years later is not yet reimbursed there.

Senator MURPHY. You don't identify any free rider syndrome today in which the United States is paying higher prices, allowing other nations to receive lower prices?

Mr. DUATO. I agree with you that the prices in the U.S. are generally higher for medicines, more aligned than what you are describing, as the rest of the healthcare system prices are.

The percentage of pharmaceutical expenses over the total healthcare expenses in the U.S. is 14 percent, and that is lower than most of the advanced economies. The real difference is that in the U.S., patients get access to therapy, lifesaving therapy years before they do in the countries that you mentioned.

Senator MURPHY. If the United States were to restrict the prices we paid, would that create a different negotiating dynamic in countries that right now, for instance, are paying 50 percent of what the United States pays? Would it allow you in your negotiations to get higher prices from other nations that right now are paying far less than the United States?

Mr. DUATO. We believe that price caps are not the way that innovation is going to be fostered. We have worked with the United States Trade Department and with U.S. embassies around the world to try to reject the price caps that some countries, as the one you to mentioned, impose.

We welcome the support of the U.S. Government in avoiding that these Governments that are ultimately imposing price caps on those that are not benefiting their patients neither.

Senator MURPHY. What do you say to Americans who look at the way that you allocate revenue and wonder why, in your case for instance, you are spending $6 billion on stock buybacks, $11 billion on dividends, and $14 billion on research and development.

You spend all of your advertising time talking about the research and development spend, but I think most Americans would be pretty surprised, given how much the industry talks about research and development, that you are actually spending more money shelling out money to investors and buying back stock than you are on research and development.

What do you say to folks who look at that and come to the conclusion that you care much more about keeping your investors happy and keeping your executives happy than you do in researching and development the next class of drugs that is going to help regular Americans?

Mr. DUATO. We care deeply about patients, Senator, and we care deeply about being able to discover the next medicines that are going to address major problems like Alzheimer's. What we——

Senator MURPHY. But explain to me how you justify that division of dividends and stock buybacks versus research development. You could just choose instead of using $6 billion to buy back stock to put that into more research and development, but you don't.

Mr. DUATO. Our level of R&D investment in the 2-years that referred to the $6 billion program buyback, which were 2022 and 2023, is six times higher.

In that period, we invested $30 billion in R&D and $6 billion in stock buybacks. So, we spent six times more in developing cures for patients than we did in the stock buyback.

Senator MURPHY. Well, I am looking at 2022 profits and spending by Johnson & Johnson, and it shows me $11 billion in dividends, $6 billion in stock buybacks, $45 million in executive compensation, and $14 billion in research and development.

Can you understand—let me ask a different question, do you understand that one of my constituents in Connecticut would look at those numbers and think that you care more about padding the pockets of the folks that work for you and invest in you than in research and development?

Mr. DUATO. Our priority is investing in R&D. We have spent $77 billion since 2016. And yes, we have to pay dividends because it is the only way that the company can remain operational and sustainable.

Otherwise, if we are not operational and sustainable, we are not able to do—fulfill our mission of developing medicine for patients and making them affordable.

Senator MURPHY. Mr. Boerner, you talked in your testimony about, the United States has a health care system that prioritizes the important role of patient choice.

I just want to present you with the case of one of my constituents and ask you about the choices that she faces. So, I have a constituent who needs ELIQUIS. This is a blood thinner that is critical to her survival.

She has priced the Medicare plan that gets her the best possible price. And that price is $350 a month. The average Social Security benefit in Connecticut is about $1,700 a month. And of course, somebody who is on ELIQUIS is likely on other drugs as well.

Here is her choice. Her choice is to pay the $350 and go without food or pay her rent late, or not take the drug and risk heart attack or stroke. Is that the choice you are talking about when you refer to a health care system that prioritizes the important role of choice?

Mr. BOERNER. Senator, absolutely not. And in fact, I would say on behalf of all of our employees at Bristol-Myers Squibb, that is a choice no patient should have to make.

Senator MURPHY. But she makes it. She makes it because you have chosen to price a drug at a point that is not affordable.

Mr. DUATO. Senator, we have priced ELIQUIS in the U.S., in our in our estimation—in fact, we try to do this for all of our medicines, consistent with the value it brings. And we are very happy with the fact that ELIQUIS is the leading anti-stroke drug——

Senator MURPHY. Why not take—why not—you put $8 billion into stock buybacks. Why not do $4 billion and instead take the rest of the money and bring the price of the drug down?

The CHAIR. I am going to keep people to seven.

Senator Tuberville.

Senator TUBERVILLE. Thank you, Mr. Chairman. Thanks for being here today. It is pretty well known where our Chairman stands on this—his worldwide view. Pretty clear that he believes you guys are setting drug prices and it is all about corporate greed.

I am a true believer of capitalism. I believe that we have the best health care system in the world. Problem is we have got the Federal Government involved in it and it is not implemented the way probably it should be. That being said, I just got a few questions here on a couple of things.

Mr. Davis, can you explain to me something, the Biden administration has two huge priorities, dictate prices of prescription drugs, specifically small molecule drugs, and cure cancer. Can you walk me through how those priorities might be in direct contradiction of each other?

Mr. DAVIS. Well, Senator, I think what you are referring to is what is called the pill penalty——

Senator TUBERVILLE. That is correct.

Mr. DAVIS. Underneath the IRA. And what that does is effectively—it says that at 9 years, post your first approval, your price for your drug will be negotiated, and if it is a small molecule—it is $13, if it is a large.

The issue that raises is that it disfavors small molecule development. And the reality of it is if you look across the majority of cancer treatments, they are still small molecules. And, as Chris pointed out earlier, the development of cancer drugs usually starts in a phase starting at the very, most sickest patient, the last stage of disease, and then you work forward into earlier stages of disease where in fact you can start to maybe talk about cure.

To do those studies in early stage disease, often called adjuvant or neoadjuvant care, and we have nine approvals in that space, those studies can take 7 to 9 years to do so. Obviously if at 9 years I have to significantly reduce the price of that drug to a point that it is potentially at basically no profit, my incentive to do those follow on studies is not there.

That is our worry that if you look at cancer care, you are going to see patients suffer because we can't get to really talking about cure, which is in earlier stages disease. I would also point out you didn't ask about Alzheimer's and neuroscience diseases, but most CNS diseases also require small molecules because large molecules, biologics can't penetrate the blood brain barrier.

We are disincentivizing some of the largest areas of sickness and chronic need in our society through that pill penalty you are referring to.

Senator TUBERVILLE. Thank you. Mr. Boerner, we hear a lot about how health care costs are ridiculous high. I think all of us would agree to that some degree. I want to peel back the onion here a little bit.

Today, we are being led to believe that these costs are due to corporate greed. I want to know if we are going to talk about some additional drivers of health care costs. When the Federal Govern-

ment dumped trillions into various industries during Covid, we upended our markets and drove prices through the roof.

You know, when I talked to health care folks back in Alabama, labor cost is one huge problem. But there are other costs, including supplies and raw materials. What impact are these having on the drug development and how drug cost?

Mr. BOERNER. Certainly, Senator, when we look at the cost bases for us doing what we do as a company, which is to bring forward new medicines for patients, we have to factor in all of those costs.

I will give you an example. In cellular therapy, which is really transforming very late line hematologic diseases. These are very complex medicines. You are taking patient cells, manufacturing them and re-engineering them to really target and hone in on cancer cells, and then you are inject them in the patients. This is really a first generation technology.

Unfortunately, it has very high labor costs because this is one that is very manual. It is a multi-step process to manufacture these products. There are transportation costs, their raw material costs.

All of those factors go into a cost of these first generation medicines. Now we are very focused on trying to innovate to get to a second and third generation quickly so we can bring those costs down, not only because it is important for us to be able to funnel additional research into development, but also so that we can bring ultimately the cost down to patients.

They are absolutely a factor, Senator.

Senator TUBERVILLE. Thank you. Mr. Duato, I am going to ask you this. With your accent and mine, we will probably have a tough time. But I know you are probably aware in 2021, you weren't CEO, I don't think, at that time, but the Biden administration announced a mandate that U.S. troops and personnel must take the Covid vaccine in order to serve in the military. Are you familiar with that?

Mr. DUATO. I am familiar, sir. Thank you.

Senator TUBERVILLE. Are you aware that more than 8,400 troops were kicked out of the military for declining to take the Covid vaccine? These were mostly young, healthy Americans for whom Covid risk was low. Are you aware of that?

Mr. DUATO. No, I was not aware of that, sir.

Senator TUBERVILLE. Thank you. Did you or did anyone at Johnson & Johnson encourage the Biden administration to mandate this Covid vaccine to the military? Are you familiar with that?

Mr. DUATO. We did not, sir.

Senator TUBERVILLE. Okay. How much did Johnson & Johnson benefit financially from the administration's military Covid vaccine mandate? Could you have any kind of guess to that?

Mr. DUATO. Our effort in the Covid vaccine that we collaborated with the Government, it was a time of a global emergency, so we thought that as a healthcare company that cares for patients we needed to collaborate with the U.S. Government on that, was entirely non-for-profit.

Senator TUBERVILLE. Do you think the soldiers who were expelled from the military was a right thing to do, and should they be reinstated?

Mr. DUATO. I was not aware of the situation, sir. I am not aware of these circumstances, so I cannot comment on that.

Senator TUBERVILLE. Thank you. Thank you, Mr. Chairman.

The CHAIR. Thank you, Senator.

Senator Murray.

Senator MURRAY. Thank you very much, Mr. Chairman. And thank you all for being here. We really appreciate it. I think we hear from our constituents constantly, and frighteningly, about the cost of some of the drugs that they take.

This is really an important hearing. And I continue to hear, as many have said, that sky-high drug costs are forcing many people, including in my home, State of Washington, to choose between filling their prescription and paying for other things they need, essentials like groceries or rent, and I often talk to people who are skipping their prescription altogether because they can't afford it and it puts their life at risk.

I really believe that Congress does need to do more here, I have for a long time, and I also think pharmaceutical companies need to do much more to put patients first. And that doesn't mean that private companies can't make a profit, and I think we all have a really sincere appreciation for the cutting edge research that happens at each of your companies.

But when you say you are in the business of saving lives and curing disease, you have to think about putting patients over profits, because, as we all know, lifesaving drugs don't do anyone any good if people can't afford them. So, I want to ask you about affordability. And I have heard the numbers. I was listening in my office.

Mr. Duato, your drug company makes product to treat arthritis, STELARA. It costs $79,000 annually here in the U.S., $12,000 in France. Mr. Davis, your company makes a drug to treat cancer, KEYTRUDA. You have been talking about it. Annually, the cost here is $191,000. $44,000 in Japan.

Mr. Boerner, your company makes a drug, ELIQUIS, to treat the risk of stroke that costs $7,100 in the year, and $770 in Germany. So, I mean, either you think that the same prescription drugs sold around the world work better here in America, or we are getting something more for it.

I mean, I don't think that is the case, but I wanted to ask each one of you, explain to us why it costs more in terms that we can tell our constituents and they understand. And, Mr. Duato, let me talk to you.

Mr. DUATO. We share your concerns about what patients have to pay at the pharmacy counter for medicines. In the case of STELARA that you mentioned, the net price in the U.S. is 70 percent lower than the price that you refer, so it would be $24,000. It is still higher than in France, but it is more aligned than here.

The difference is that patients with inflammatory bowel disease, which is the main indication with STELARA, were able to afford

STELARA years earlier than they did in other countries. As a matter of fact, in Canada, after 8 years that STELARA was approved, STELARA is not reimbursed in inflammatory bowel disease, nor in Crohn's disease, or ulcerative colitis.

What are we doing for that? We have strong patient assistance programs. A patient that has commercial insurance pays $10 to $15 a month for STELARA, and if they are not insured or underinsured, we have free medicine program. We distributed $3.9 billion in free drug in 2022.

Senator MURRAY. Mr. Davis.

Mr. DAVIS. If you look at KEYTRUDA and the example you are bringing up between the U.S. and Japan, first of all, like all of us, we are trying to focus on making sure that patients everywhere in the world get access to our medicines. Each market operates differently. Japan is a unique market in that the way they price their drugs, and we have been working hard to get this to change.

I think maybe we have successfully gotten some of it to change. Is that after you initially launched your drug, for every indication that comes afterwards, they treat it as a different drug. And in addition, if a competitor launches a drug, then you also still take a price decrease because of the competitor drug.

We are in a strange situation and one that is a very concerning situation to me in Japan, where in reality we as the most innovative, we have the most indications, we were driving the market fastest, we have by far the lowest discounted price in Japan, and the levels in Japan would not be sustainable to support the $46 billion, $40 billion we spent on KEYTRUDA.

We are working hard to help those markets and we could use Government help there to understand that we need to, across the globe, share in making sure we can invest to support innovation.

Senator MURRAY. What would Congress do that would make a difference to lower prices here?

Mr. DAVIS. I think. Well, on one hand it is a different question on lowering prices here. I think that is a question I am assuming we are going to get to, but this is, how do we focus on what is the really large discrepancy between the list price and the net price, which I believe we need to focus on is the out-of-pocket cost to the patient.

That is really the core. We need to address that. But in addition, we need to continue to work together on—we can work on trying to drive innovation clauses into trade agreements, we have had some success with that, to also help us in those markets outside the United States as well.

Senator MURRAY. Mr. Boerner.

Mr. BOERNER. Senator, there is no doubt that patients are going to pay less for our drug ELIQUIS, or frankly most of our drugs outside of the U.S. than in the U.S.. That, unfortunately, comes at a fairly significant cost for those patients outside of the U.S..

In Canada, patients will wait roughly three and a half to 4 years to get access to a medicine that is available in the U.S.. You see similar sort of stats in virtually every European country and in

Japan. What we can do more in the U.S. to do is try to bring out the pockets down—out-of-pocket costs down.

For ELIQUIS, for example, the average out-of-pocket is roughly $50, $55 in the U.S.. Most patients will pay less than $40. However, there are still patients for whom this drug is absolutely not affordable. That is not acceptable.

Medicare, in particular, is a space where we can't provide those types of copay support programs that we do in the commercial setting, so we would love to work with Congress on that. But probably the most important thing, and ELIQUIS is a great example of this that we can do, is try to bring down the list cost of ELIQUIS——

Senator MURRAY. Do you set the list price?

Mr. DUATO. We set the list price, but that lowest price for ELIQUIS is driven up by the incentives of intermediaries. And let me give you an example, order of magnitude. Over the last 5 years, we have, as a company, paid almost $100 billion in rebates and discounts to intermediaries.

The majority of those were on ELIQUIS. And our ability—that is unfortunately what patients pay is a co-pay on that list price. We would love to work with Congress to bring that down.

The CHAIR. Senator Marshall.

Senator MARSHALL. All right. Thank you, Mr. Chairman. Mr. Boerner, I will start with you. Bristol Myers makes this new miracle drug, ELIQUIS, relatively a miracle drug.

When I was in residency treating patients, I was using Coumadin—Heparin and then Coumadin. It might take three or 4 days to get someone heparnized, and then we switch them over to Coumadin.

They might be in the hospital for 10 or 14 days. So, in its own right, ELIQUIS saves money. It saves that length in the hospital and prevents hospitalizations as well. So, I want to point that out.

As we think—talk about rationing care, we have discussed how we are rationing care in foreign countries. But I want you to speak about rationing care in this country. How do PBMs ration care when they take a drug like ELIQUIS and don't allow it on their formulary? Does that ever happen?

Mr. BOERNER. Senator, I am glad you raised that point. We have had absolutely that case happen on multiple drugs. We have had it happen on ELIQUIS. We have had it happen where when we have not been able to reach an agreement with an intermediary on a rebate, that they have taken ELIQUIS off of formulary.

When that happens, those patients no longer have access to ELIQUIS and they have to go on to another branded or in many cases, they may go on to Warfarin, as you say. ELIQUIS is the No. 1 product in the oral anticoagulant space——

Senator MARSHALL. Okay, so I am going to—sorry. So, they have to go back to Warfarin, the Coumadin, the drug that I was using in medical school in the 1980's. A drug with significant complications.

Hassle factor, the patient has to go get blood testing done maybe twice a week as well. But with your drug the miracle, one of the

miracle parts of it is that a, they don't bleed into their brains anymore. And two, they don't have to go get their blood testing done once a week as well.

It is a huge amount of innovation. And it is just—it amazes me how much power these PBMs have obtained. Let's go to Mr. Davis next.

I want to talk about de-linking. And you have, at the time, a pretty—a miracle drug of your own to treat diabetes with. And there is a list price. How much of that—what percentage of that list price does typically Merck get at the end of the day?

Mr. DAVIS. Senator, if you look at JANUVIA, which is the drug you were speaking to, the list price is $6,900.

Senator MARSHALL. Per year?

Mr. DAVIS. Per year, for Merck. We recognize $690 on that drug per year.

Senator MARSHALL. Of the list price, you are only getting 10 percent.

Mr. DAVIS. It is a 90 percent discount.

Senator MARSHALL. 90 percent discount. Where does the rest of that money go?

Mr. DAVIS. Into the middlemen. Into the system as a whole.

Senator MARSHALL. If we had the time and the energy and a chalkboard, would you be able to explain to me and show me all the little places that goes?

Mr. DAVIS. I could, but I think you appreciate it is highly complex and so complex that at times even learned people who play in the space can't understand it.

Senator MARSHALL. Well certainly, I can't explain it, and that is my point. Is it is so nontransparent, we don't know where this money is going, but certainly, we know that pharmacy benefit managers are taking $0.50 to $0.75 of that dollar, and you are only getting 10 percent of it.

I would like to know where the rest of it goes. Then I will go back to Mr. Boerner. Similarly, with your drug, with ELIQUIS, what type of—what percent of that list price do you think that you all are taking home?

Mr. BOERNER. Senator, it is a relatively smaller percentage. As I mentioned before, we have paid over the last 5 years about $100 billion in rebates and discounts, and the majority of that go to one product and that is ELIQUIS.

Senator MARSHALL. Okay. Go back to Mr. Davis. Let's talk about, you all have an antiviral drug that has been approved. How many drugs did you go down—when Covid hit, you were trying to develop multiple drugs. How many have made it across the finish line? What did you spend on R&D as you look at those all together?

Mr. DAVIS. Yes, so we—when the COVID situation hit, we drove two—or four key programs, two in vaccines, two in antivirals. Only one of those succeeded, which is the drug LAGEVRIO. The total spend across those four programs is a little over $2.5 billion.

Senator MARSHALL. You spent $2.5 billion. You got one across the finish line, an antiviral. Is that being used in the United States?

Mr. DAVIS. Very little. It has emergency use authorization. It never got to full approval. And so, we are actually seeing it being used much more outside the United States.

Senator MARSHALL. In actuality, you spent $2.5 billion and got nonsignificant market share in the United States despite that. Mr. Duato, I will talk to you for a second.

In my 25 years taking care of patients, we were always able to find a solution for their drugs that they needed, 340B programs, rebates. There is always exceptions to the rules, but what type of efforts has J&J made to work with 340B programs and to help some of these people that need help?

Mr. DUATO. Thank you, sir. We care deeply about patient affordability, but also we care about the sustainability of the rural hospitals and the small hospitals that take care of patients that are underserved.

We believe that the 340B program, it is an important program to support those hospitals and we are fully, fully looking forward to collaborate with them in any way we can to support patient access on those hospitals.

Senator MARSHALL. I am going to point out once again, it is just not rural hospitals, it is our community health centers are taking great advantage of the 340B program as well, trying to make sure that every patient in America has access to primary care—true affordable access to primary care, plus having access to affordable drugs as well.

I might make a couple quick points. The people of Kansas sent me here to save Medicare. To save Medicare, I need a miracle drug to treat Alzheimer's. It seems to me that Americans bear the burden of most of the R&D in this world, and other countries benefit from it.

That impacts the price in many ways as well. Mr. Davis, am I wrong? Why does it feel like to me that Americans are feeling most of the brunt of the R&D cost, or is that not accurate? I don't know.

Mr. DAVIS. Well, I think, Senator, it gets down to, as you look across the globe, different markets and I appreciate what the U.S. does. I think the U.S. favors innovation. It values it. It values access for our patients, fast access, most access. Many markets around the world don't do that.

What they focus on more is their budget and how do they meet those budget needs, and we appreciate the budgetary constraints that everyone faces. But as a result of that, often patients aren't getting access to meds. They don't get them as fast, which we have commented on today, and it is harder to see how you can support the innovation we need to do in that situation.

The CHAIR. Thank you. Senator Baldwin.

Senator Casey.

Senator CASEY. Thanks so much, Senator Baldwin, for allowing me to jump ahead. Mr. Chairman, thanks for the hearing. I want to start with a sense of what I hear back home.

When I talk to people in Pennsylvania, and a lot of your companies have a lot of interest in Pennsylvania, I hear over and over again this problem, the cost of prescription drugs, is like a bag of heavy rocks.

It is when been people have been carrying this around their shoulders every day, year after year, and they are tired of it. And they don't believe that any player in this is doing enough.

I think most Pennsylvanians are happy that I could vote for a bill in 2022 that allowed Medicare to negotiate for lower prescription drug costs and that we could cap the cost of insulin $35 bucks a month for Medicare Part D beneficiaries. They are happy that we could cap the out-of-pocket cost.

That will go into effect about a year from now. But they are not happy—they are not satisfied that even Congress is doing enough, House or Senate, or either party. But they are certainly not happy with the level of work that you have put into this. Look, I hear all this talk about rebates and cost reductions you are trying to put in place, but it is not cutting back home.

When I talk to people that see what PBMs are doing, they know that they are not meeting the obligation that they would expect them to. So, there is no question that your companies and big pharmaceutical companies are playing a role in this. You bear a measure of responsibility in this.

I wanted to ask you a couple questions about that. First and foremost, tell me what concrete steps, very specific steps, that each of you are taking and your companies are taking to make sure that we can get these costs down. And even by way of repetition, you may have already said it.

I'm not worried about you repeating yourself, but we need to know specifically what you are doing to lowering costs so that no one, especially someone who needs a lifesaving intervention, a lifesaving treatment, is going to be denied that solely, solely because of cost. And I will start on the left, Mr. Duato, going left to right.

Mr. DUATO. Thank you, Senator Cassidy. We absolutely want to be part of the solution. We understand that co-pay obligations for U.S. patients are burdensome, and it does create health inequities.

What are we doing for that? We have a very extensive patient assistance program that, for commercial patients, enables them to be able to pay low co-pays, $5 to $15 per month. We supported more than 1 million patients in 2022 with our copay assistance programs. If a patient is underinsured or not insured, we provide free drug.

We gave $3.9 billion in free drug in 2022. But I think we can do more, and we can work together in order to lower out-of-pocket costs for patients even in Medicare, as you mentioned, because that is a real need that we are committed, all our employees are committed in order to make sure that our medicines get to the patients that did deserve it.

Senator CASEY. Mr. Davis.

Mr. DAVIS. Well, Senator, very much like J&J, we have tiered levels of patient assistance programs because we want to make sure that patients who need our drugs can access them. If you have insurance but you fall below certain means where you are not able to handle your copay, we will give copay assistance to those patients through a program we run.

If you are someone who doesn't have insurance, is not able to qualify for Government programs, we have a patient assistance program that basically provides the drugs for free. So, we are very much focused on this and making sure that we can do everything we can, and we are investing a lot of money on it.

But something I would like to add, because I think it is important to the discussion. We are focusing on prices today, but we also need to think about innovation as a way to fix the problem. And something we are focusing on as a company is a new technology called micro cyclic peptides that allow us to potentially take what historically has been large molecules difficult to make, expensive drugs difficult to deliver, and we are starting to show the capability to convert those into cheaper, small molecule forms, oral forms.

If we are able to do that, we have one in late stage development now called an oral PCSK9, which is for heart disease. But we are looking to do that for others. We are investing millions, billions behind that effort.

I think we need to also think about how can innovation solve the problem. We need to address the price challenges today. We have to lower out-of-pocket costs. But innovation ultimately is what is going to help us fix this.

Senator CASEY. Sir.

Mr. BOERNER. Senator, maybe I would highlight three things. First, we obviously have a very robust, on the commercial side, copay assistance program that brings out-of-pocket costs down in many cases for certainly our oral oncologists, for example, almost to zero.

They are complex at times, so we are working very hard to make those more universally available. That is step one. Step two, we would like to work with this Congress to find ways in which we could apply the same sort of programs in Medicare. There are some complexities.

We want to make sure we are not diverting from the use of generics, for example, but we think there are potential ways that we could do that, and we would love to explore those opportunities with Congress to bring out-of-pocket costs down for Medicare patients.

The second thing I would say is we are looking at doing more innovative work, innovative contracting work where we can. For example, if our drug works, we get paid. If it doesn't work, we get paid less and in some cases maybe even not get paid at all. There are technicalities in the U.S. that prohibit us from doing that more in the U.S..

We want to work to get those removed. The third thing, just building on what Rob was saying, is we do believe that innovation

plays a role here. Cellular therapy, while not gene therapy per the previous question, those are expensive therapies.

We have got to bring those costs down, and the way we will do that is we will innovate to the next generation, which hopefully is way less complex than what I described previously.

Senator CASEY. Well, I will be submitting some more follow-up questions for the record. Thank you, Mr. Chairman.

The CHAIR. Thank you.

Senator Paul.

Senator PAUL. I am not an apologist for big pharma. In fact, when corporations manipulate Government to their advantage, crony capitalism, I am an unfettered critic. But in defense of capitalism, I am a consistent, unapologetic advocate.

Milton Friedman once wrote that if you want to create a shortage of tomatoes, just pass a law that retailers can't sell tomatoes for more than $0.02. Instantly, you will have a tomato shortage. I might also add that is true of prescription drugs. Virtually every shortage of drugs that we have seen in the last few years involves price controls that drive out production of the drug.

One reason the United States leads in pharmaceutical innovation is because while the U.S. adhere to more—a more market based pricing and rewarded innovators, Europe adopted stringent price controls in the 1980's and 90's. It is not surprising that we lead the world in innovation and Europe does not.

But unfortunately, this Committee in this hearing is not here to celebrate American success. Instead, the majority drags us to conduct a show trial to harangue companies challenging the Inflation Reduction Act price controls in court.

They have simply brought forward people who question their partisan legislation. Ten years ago, the 5-year survival rate for patients diagnosed with advanced lung cancer was 5 percent—terrible. Since Merck introduced the cancer drug KEYTRUDA in 2014, the survival rate has grown nearly fourfold, 5 percent to 20 percent.

We should be celebrating that instead of castigating people and telling them how to run their business, and why are you buying your stock back. I have a friend with a genetic predisposition to cancer. He is alive today because of KEYTRUDA. We should be celebrating that. Johnson & Johnson's REMICADE was the first monoclonal antibody approved for treating chronic conditions like Crohn's disease and rheumatoid arthritis.

Since its approval, Remicade has revolutionized treatments for inflammatory disease, made remission a reality for patients with debilitating conditions, and paved the way for development of other autoimmune treatments. When I began in medicine, virtually all patients with rheumatoid arthritis you could see from a distance had crippling, disfiguring arthritis in their hands.

Now, today, it is rarely seen because of the advances of American companies under an American system that allowed profit to occur. In 1987, Merck pledged to donate the entire stock of its drug, Ivermectin, to those suffering from river blindness. Nearly 37 years later, Ivermectin Donation Program treats 300 million people an-

nually, with over 11 million treatments shipped to endemic countries.

This is charity, my friends, from capitalism. You don't get this under socialism because there is no profit under socialism. They have no money to give. They make extraordinary profits. Do they keep some of their investors? Yes, that is what they are supposed to do. But they also have some left over for charity and you don't get that under socialism.

Because of Merck's donation, seven countries eradicated the transmission of the No. 1 cause of blindness in the world. Pharmaceutical innovation has improved cancer rates, cured hepatitis C, doubled the life span of patients living with cystic fibrosis. It goes on and on.

We have tried price controls in general here. We did in the 1970's under a Republican President, under Nixon. It was a disaster, and it led to lines at the gas pump. It was an ultimate disaster. A study at the University of Chicago, found that 254 fewer drug approvals over the course of 18 years would happen under price controls.

Under communism, they knew this. Socialism, communism, and the economic system of socialism from price—it became a running joke. In Poland during the Soviet era there was a story of the guy who went to the store, he was looking for eggs, and he asked the clerk, is this a store with no eggs? And they said, no, this is a store with no toilet paper. The store with no eggs is across the street.

That is the story of socialism. That is the story of price controls. Scarcity and empty shells are the inevitable result of price controls. Those who understand and appreciate capitalism do not need a show trial to dupe them into forgetting that price controls have never worked and never will.

Let's get back to profitability. I don't think you guys did a very good job on answering this. Did you add into your estimate of whether it is profitable in Canada, whether or not it cost you $2.6 billion on average to develop it? You are talking about manufacturing costs. You are talking about how much it cost to make KEYTRUDA and how much you sell it for, and say you have a profit in Canada.

Do you think it would still be a profit, Mr. Davis, if you added in all the R&D, the $2.6 billion to get it through this system, all—the apparatus of your company and you divided all of that out for profitability, would it still be profitable in most of these other countries?

Mr. DAVIS. I have not done that analysis, but I would say that the profitability would be marginal at best.

Senator PAUL. Do you think you would have as much R&D if the whole world were Canada? Do you think you would be developing dozens of new drugs every year if the whole world were Canada?

Mr. DAVIS. No, I do not.

Senator PAUL. This is what we are arguing against, you know. Sure, you can make it for pennies now, but it didn't start that way. And then people were like, oh, my it costs so much in the beginning. That is capitalism. That is the way it works in capitalism. Joseph Schumpeter talked about this, and he said, this is an old

anecdote, but he said, the miracle of capitalism is not the queens have silk stockings, but that factory girls ultimately do.

But in the beginning only the queen has silk stockings. Rich people get stuff in the beginning. Rich people drive the innovation. The first calculators that came out, $300 for adding, subtracting, and dividing machine.

Now they are like pennies or free. But you have to allow the price to be higher in the beginning and the market brings it down as you have more widespread market. That is capitalism. We don't know what the correct price is. There is no moral price. There is no moral amount of profit.

There is no business of any of you all telling them how much stock to buy back. Their job is to make a profit. It is actually against the law for them not to maximize their profit. For you to sit in judgment of how much profit they should make and how they should run their companies, you know nothing of running companies.

You know, nobody up here, maybe some, but almost nobody up here has run big companies, billion dollar companies and you presume somehow to say you are going to tell these people how to run their company. List price versus net price. List price means absolutely nothing. I charged $1,800 for cataract surgery.

The Government paid me $600. Two-thirds of it, nobody stole that. It disappeared because it never existed. So, if I build $1 million in charges, I really was only building $300,000 because that is what I was getting paid. But because of the confusing nature of the system, the list price is much different than the net.

But to quote list price and then compare it to net price in other countries is completely and profoundly unfair. The list price means absolutely nothing. All of these fallacies need to be addressed before we begin haranguing American CEOs. Thank you.

The CHAIR. Thank you for your questioning.

Senator Hassan.

Senator HASSAN. Well, thank you, Mr. Chair.

The CHAIR. Senator Baldwin. I am sorry.

Senator HASSAN. She——

Senator BALDWIN. I yielded to Senator Casey.

Senator HASSAN. I know, but I was next——

The CHAIR. All right. Senator Hassan, go in then Senator Baldwin.

Senator HASSAN. Thank you. So, I just wanted to say, at the outset that the last time I checked, when a buyer and seller negotiate for a price, that is capitalism.

I wanted to talk with all three of our distinguished witnesses today, because one of the things that strikes me that we are struggling with is I think at various times in each one of your statements, you talked about your price reflecting the value of your product. And the thing is, human health and life is priceless.

If that is the metric here, you will always have an excuse for charging increasing prices for these lifesaving drugs. And what we are trying to do here is figure out how you can continue the innova-

tion that Senator Paul just so eloquently spoke about. I would suspect that every Member up here has a family member whose life has been saved by innovative medications are greatly improved.

But at the end of the day, we have to find a way to allow you all to innovate but also to make sure that the market here and the system here works for the very people whose lives you are helping to save.

I want to start with a question to you, Mr. Davis. While families in New Hampshire and across the country struggle to afford these lifesaving medications, pharmaceutical companies are doing everything that they can to keep their prices and their profits sky high. And I know you both talked about that not being the case, but let's just look at one thing here.

One way that companies do this is by filing dozens, even hundreds of frivolous patents that lock in their exclusive right to sell their drug for decades.

By playing games like this with the patent system, companies block low cost alternatives like generics from coming to market. Mr. Davis, the list price for Merck's cancer medication, KEYTRUDA is, as we have talked about, $190,000 per year. Can you tell us how many patents have been filed on this medication?

Mr. DAVIS. I don't have the exact number, but I would focus you on probably the most important patents, which are the composition of matter patents. In addition to that, the formulation and manufacturing patents.

There is one suite of composition of matter patents that we have and those are what allow us to continue to have exclusivity.

Senator HASSAN. Well, I don't think it would surprise you to learn that I do know how many patents you currently have. It is 168. This is what this looks like. Sheet after sheet after sheet.

Patent office records show that not only do you have 168, but half of them relate to the process Merck uses to manufacture the drug, not the way that the drug is used to treat patients. Merck is using patent gimmicks and loopholes to delay other companies from selling lower cost versions of this medication, all while raising the price of KEYTRUDA in the U.S. year after year.

It would be good if Merck would just stop blocking patient access to low cost medications by using the patent system in this way. It is clear that Merck and other pharmaceutical companies, you are not alone, won't stop abusing the patent system to keep their prices high.

It is clear we also need to take action on that. And that is something we can do. Senator Braun and I have a bill called the Medication Affordability and Patent Integrity Act, which would help break up these patent rules. And I would urge my colleagues on both sides of the aisle to support that.

Now, Mr. Duato, in your testimony, you mentioned that Johnson & Johnson provides financial assistance to uninsured patients in the United States. However, the barriers to access these programs are unreasonably high.

For an expensive medication like your company's arthritis drug, STELARA, what does a patient have to do to get assistance from the Johnson & Johnson program?

Mr. DUATO. Thank you. We care deeply about patient access, and we put a lot of work in developing well and wide patient assistance programs. And we have mechanisms for patients to connect with us via—mechanisms like a website called Johnson Care Path, in which patients can access patient assistance. We supported 1.1 million people with patient copay assistance last year.

Senator HASSAN. Well, let me just talk a little bit about that. The initial application, which I have here, is six pages long, and it requires pages of additional documents for income verification.

In the fine print, this document even requires the patient to consent to a credit report check and other financial disclosures. Mr. Duato, everyone on this dais wants you to charge a fair price for your company's medications.

But if someone does need assistance paying for their medication, this process has to be streamlined and easily available to anyone who qualifies. So, I would urge you to look personally at this application.

When somebody is dealing with a serious illness, the last thing they need to do is read the fine print and decide that they have to disclose a credit report, the relevance of which kind of escapes me. Mr. Boerner and Mr. Duato, we could also increase competition by making it easier for generic drugs to get approved.

Mr. Boerner let's turn to the BMS stroke prevention drug ELIQUIS. The list price, as we have talked about, is $7,100 per year. How many generics of this drug could a patient in the United States get at the pharmacy today?

Mr. BOERNER. Senator, in the U.S., there are not yet generics available.

Senator HASSAN. Right. There are zero generic versions of ELIQUIS available to patients, even though the original patents on the medication began to sunset in 2019. Because your company has sued to block two approved generics from the U.S. market until 2028 at the earliest, isn't that right?

Mr. BOERNER. Senator, we have allowed for generic entry in 2028. That is correct.

Senator HASSAN. Right. So, we have two generics ready to go. Your original patent is well past expired, but you still are actively trying to prevent generics from coming to market.

Mr. Duato, the list price of Johnson & Johnson's autoimmune arthritis medication STELARA is nearly $80,000 annually. Similar to ELIQUIS, there are currently zero low cost biosimilar versions of STELARA available to U.S. patients. There are zero biosimilars for STELARA available in the United States today because Johnson & Johnson has also sued to delay the launch of a low cost biosimilar drug.

We need—you know, you have all talked about the need to have speed of access—and Mr. Chairman, I am wrapping right up.

Speed of access getting drugs to market, but then you are actively working to block the less expensive biosimilars and generics to come to market, and that is something we should address. Thank you, Mr. Chair.

The CHAIR. Senator Romney.

Senator ROMNEY. Thank you, Mr. Chairman. And I appreciate these executives taking time away from your responsibilities at your respective companies to be here and to inform us, and in some cases, to get berated by us and give us an opportunity to pontificate on our various topics, which I am about to do.

One is that I fully concur with Mr. Paul or Senator Paul indicated just a moment ago, Rand Paul, and that is that a free enterprise system works marvelously. And I know we keep asking you what are you doing to try and reduce the prices of your products?

The answer is that is not what happens in free enterprise and capitalism. I hope it doesn't come as a shock to my colleagues. In capitalism, if you are running an enterprise where you have a fiduciary responsibility to your owners, you try and get as high a price as you can. That is what you try and do.

You try and make as much profit as you can. That is how free enterprise works. You think Chevrolet sits back and says, gosh, how could we get the price of the Chevrolet down? No, it is like, how high price can I get and maximize the profit for my shareholder? What price does McDonald's charge for a sandwich?

As high a price as they can get. But the amazing thing about free enterprise is that someone figured out that if everybody does that and you have competition among all the players, that somehow the prices come down, and the quality goes up, and the access to the product is broader. It is the marvel, it doesn't seem to make a lot of sense, but it is the marvel of capitalism.

Now, obviously wise companies say, well, you don't just raise prices to the roof and do things that are going to harm your credibility and the trust in the marketplace, and have your employees not want to work there because they are going to figure they are working for bad people. So wise enterprises don't just do all the things I just mentioned.

They also say we are going to do other things and care for the poor and care for people who want to come work in our company. We do those things too. But recognize free enterprise is about enterprises battling each other with higher prices in many cases, and then they get pushed out by people who develop new products and put them out of business. It is how it works.

But let me turn to—and I know, as Senator Paul indicated, there are some who would like price controls. There are some who would like socialized medicine. And it is like, have you seen what that produces? It doesn't produce new drugs. It doesn't produce cures. It sounds great.

We are going to—price controls is just another name for capitalism—excuse me, socialism lite. Our system works, but there are ways to improve it. And I am very concerned that this disparity between list price and what you actually get paid is a problem.

I don't know why it is a problem or what we can do about it, but do you have PBMs and getting prices of discounts like this in other countries that you compete in? Yes, Mr. Boerner, yes.

Mr. BOERNER. Senator, we do not. This is a unique element of the U.S. health care system.

Senator ROMNEY. Is that true for you also, Mr. Davis?

Mr. DAVIS. That is true for us as well.

Senator ROMNEY. Mr. Duato, is that also true?

Mr. DUATO. This is unique. The inequity that exists in the U.S.. It is because of that we have higher out-of-pocket costs for patients than anywhere else in the developed world.

Senator ROMNEY. I hope we focus on this. We may not have the right bad guys here, all right. These are the guys developing cures and helping people solve diseases.

But we have something here they don't have in the rest of the world, these PBMs that want higher and higher prices because they get paid based on how high the list price is, because they get a percent of the list price.

I am not sure where all the money goes. Some of it goes back to patients, some goes to the companies if they are self-insured. I don't know where it all goes, but I think that is the issue.

Let me ask each of you, if you were in our shoes knowing what you know, what should we be doing to try and get the cost of products down to our—to the people in the country and to the country at large, to the Government that buys a lot of goods, a lot of drugs—what should we be focused on?

I know that you sell to PBMs, so you got to be careful not to step on their toes too hard because they might punish you. But what advice would you give us? What should we be looking at? Where is the problem in this mess? We will start here, Mr. Boerner.

Mr. BOERNER. Maybe three things I would offer, Senator. First, to the complexity that you just described, No. 1, dealing profits from intermediaries from the list price of the drug, and the rebates rather that are provided. If you could delink that, that would be important.

Alternatively, require that those rebates be passed on to lower out-of-pocket costs for patients. That is No. 1. No. 2, I firmly believe we have the ability to help lower out of patient cost in Medicare if we could provide the same types of copay support that we do on the commercial side to Medicare patients.

That would be a second thing. And the third thing, we have referenced it before, we do innovative contracting outside of the U.S. where we get paid if our product works. There are constraints on our ability to do that in the U.S.. I would like to see those removed. That would be very helpful.

Senator ROMNEY. Right. Thank you. Mr. Davis.

Mr. DAVIS. I would say that I—Chris, basically covered all of the things we would also look to do.

Senator ROMNEY. Great. Thank you. Mr. Duato.

Mr. DUATO. Yes. Three things. As Mr. Boerner, I would make sure that the rebates and discounts that we pay to PBMs go back

to patients to reduce out-of-pocket costs. I will make sure that as we are trying to do, and I know these Committee is looking into that, would delink the compensation of the PBMs from the list price. And finally, I would sit down to see what we can do to provide, a, patient assistance program for patients in Medicare Part D, but also look to further lower the out-of-pocket costs for patients that the IRA is bringing.

Senator ROMNEY. Thank you. You did mention the fact that the PBMs are largely owned by the insurance companies.

Senators, we think PBMs are going to be lowering our costs as an employer, let's say, and you hire a PBM to lower your cost. But it might lower your cost, but then it is passing on their profit to the insurance company. Is that a problem?

Is the fact that the PBMs are owned by the insurance companies, is that a problem here? Is that something we need to look at as well? Do any of you have any comment on that?

Mr. DUATO. The three PBMs are owned by the three largest insurance companies, and together they control about 80 percent of the market of the prescriptions in the U.S..

Senator ROMNEY. Yes. I am a big believer in free enterprise, as you can tell by my opening comments. At the same time, I am concerned that we have got some structures here that are anti-competitive and make markets less effective, and we probably ought to focus on some of those. Thank you. I appreciate your testimony.

The CHAIR. Thank you.

Senator Baldwin.

Senator BALDWIN. Thank you. It has been very interesting to listen to the back and forth.

Senator Romney, your points about support of the free market, but understanding that there are times when there is market failures.

We also have an obligation, I think, to oversee because our Committee with the—along with the Finance Committee, oversee and the need to have good stewardship of Medicare and Medicare dollars.

But the point that Senator Romney just made about basically, I don't know—I can't follow the dollars and it is complex, is a real issue. I want to start just by sharing some of my constituents' struggles.

I have a constituent who literally turns down the heat in the winter, because that is how she is able to afford the prescription drug she needs for her wellness. There are choices that people are making. People are rationing their medication. People are forgoing their medication because of affordability.

I think we need more transparency. And I think we need more transparency to inform the policies that we adopt. I was pleased this last May that this Committee advanced my bipartisan Fair Drug Pricing Act, which I lead with Senator Braun.

Our bill would require basic transparency from your companies at any juncture in which you want to raise the price, list price of

a prescription drug by more than a certain amount, a certain percentage.

Asking questions like, what is the cost to manufacture the product? What do you invest in R&D, something we really support? How much are you spending on marketing and advertising? What are you doing in terms of stock buybacks? Is there excessive executive compensation?

I agree that we also have to have that transparency within the PBMs. I remember, under the last President, when we were having our confirmation hearing for the—his Secretary—Secretary Azar, who came out of the pharmaceutical industry, and I shared with him a letter from a constituent who has two diabetic sons who is talking about the costs every month, not just the insulin, but the test strips, etcetera.

I said, what do I tell this, dad about the high cost, which had just by the way, increased significantly. And he just responded, it is complicated. I can't tell my constituent, well we can't address this because it is complicated. I remember, when—this is years ago now when the EpiPen doubled in price overnight, went from $100 basically to $200.

My constituents certainly told me what a burden that was. I asked if you could show me—follow the money, a chart, follow the money. Nobody could. We need additional transparency to inform our policies.

Mr. Duato, the price of STELARA in the U.S. is $79,000 a year. And by the way, in Wisconsin, the median household income is $72,000. Your company has made twice as much selling this arthritis treatment in the U.S. than it did in the rest of the world combined. This is going back to 2016.

Under the Fair Drug Pricing Act, you would need to account for this exceptionally high cost. So, just to look at one component of what I am talking about, how much does Johnson & Johnson spend on marketing and advertising for this particular drug?

Mr. DUATO. Senator, thank you for the question. We publish every year since 6 years ago a report that we call it transparency report, and we explain our pricing practices and we give transparency also to the different intermediaries that play into the model. We disclose our advertising expenses and our R&D expenses.

What I can tell you is that in 2022, which was the last year that our report was published and is available, we spent double in R&D, 110 percent more in R&D that we did in sales and marketing.

Senator BALDWIN. Do you know what that dollar figure is for sales——

Mr. DUATO. I don't have it on my hand, but I will be sure to follow-up with you to bring it to you. But it was double the amount in R&D than we did to spend in sales and marketing.

Senator BALDWIN. Well, let's look at, Mr. Boerner, the price of ELIQUIS is—in the U.S. has increased by $4,000 since its launch. In other countries, the cost of this drug is decreasing. How much did your company spend on R&D last year?

Mr. BOERNER. Our company spent just over $9 billion last year on R&D.

Senator BALDWIN. Then how much did your company spend on stock buybacks, dividends, and executive compensation last year?

Mr. BOERNER. I don't have that exact figure, Senator. But we——

Senator BALDWIN. Does $12.7 billion sound right from the health study?

Mr. BOERNER. That is roughly correct.

Senator BALDWIN. Okay. For the first time, thanks to the Inflation Reduction Act, Medicare will negotiate the price of drugs, including ELIQUIS and STELARA, and this is really welcomed news for families in Wisconsin.

But the truth is, it is really not enough, and my constituents should not be forced to decide if they should turn the heat on in winter or buy the medication they need, all while companies are raking in literally tens of millions of dollars or billions. We have more work to do.

The CHAIR. Thank you.

Senator Collins.

Senator COLLINS. Thank you very much, Mr. Chairman. I think all of us could agree that when a doctor prescribes said needed medication, that cost should not be an insurmountable barrier to the patient using it.

Yet for more than half of the adults in my state, according to a survey, it is a barrier. They are worried about affording the cost of prescription drugs. And in the last year, nearly one out of three Maine adults reported skipping a dose of medicine, cutting pills in half, or not filling a prescription because of cost.

I talked to a young woman with type 1 diabetes who, after she aged out of her parents' insurance, started cutting back on her insulin. She ended up in the emergency room and was gravely ill because of that.

She felt she just couldn't afford it and took a very unwise chance. So, this is a huge problem. But another aspect of this discussion is that many new medications represent true breakthroughs, disease modifying therapies, or even cures. And the other part is that literally billions of dollars are invested in developing drugs that end up to not be successful. I think we have to balance all of these concerns.

These new drugs often cost more, but they have the potential to reduce the number of unnecessary hospitalizations that lead to better patient outcomes. They may be worth it for disorders like Alzheimer's.

The breakthrough drugs can help keep patients healthier and active longer, benefiting society as well as their families. For example, I heard of a patient being diagnosed with mild cognitive impairment early enough that the patient was able to benefit from the newly available treatment and actually returned to the workforce.

That is quite an accomplishment. Now, last year, the Chairman criticized this particular company for a list price of $26,500 per

year, even after the company, in a really unprecedented fashion, issued a lengthy analysis of the process by which they arrived at the price. Still, sticker shock around list prices and speculative claims that certain therapies will bankrupt the Medicare program have contributed to restrictive coverage policies, patient confusion, and limited uptake.

I would like, Mr. Davis, you to discuss how we can balance the need to have affordable medications without hampering innovation, and how access to the next—what would be the impact on access to the next generation of medications if price controls like those in Europe are implemented? How do you see a solution to the balance between affordability and innovation?

Mr. DAVIS. Yes. Senator, thank you for the question. You know, I would start with at Merck and what are the principles we apply when we think about how we price drugs, because I think it also gets to some of the other questions that have been asked about what stops you from just raising your price.

I can tell you that, as a company, and this goes back to the core of who we are over 130 years and is truly the purpose we live by, and that is we look at several elements. We look at what is the benefit to the patient. But equally we do look at what is the benefit of the cost to the system. We look at access and affordability.

I can tell you, for instance, when we launched KEYTRUDA, we launched at parity to market price, even though we knew we had a better product, in part because we wanted to ensure access.

We look at all of that, and then we look at what does it take to absorb the cost of all the failed drugs. We know 90 percent of all drugs we will bring into the clinic fail. The reality of it is the drugs that make it have to fund that failure. In the case of Merck, it is just interesting, I think, to point out.

Since 2014, the minority of drugs we have launched have actually even returned their cost of R&D. The minority—I am sorry, the majority have not returned their cost of R&D. So, it means that when you do get the rare drug that succeeds, it has to help cover that. So that is what we are facing in the system.

But as we look at how can we fix this, I think we have to get to the out-of-pocket costs and we have to find a way to really drive that down, and then continue to find ways to bring better access through the types of access programs we have all talked about here, whether it is through patient assistance programs, copay assistance, all of the ways we can help the individual person address that affordability challenge, which we all know someone who has faced that, and I don't want to see anyone face that.

Senator COLLINS. NIH provides a lot of assistance in the research that—and sometimes partners with pharmaceutical companies. How is the fact that there has been Federal help, for example, in the development of the Covid vaccines, how does that factor into the pricing?

Mr. DAVIS. Well and obviously, as we look at the system, the ecosystem we live in, it is important to understand that all players are important. So, the role of NIH is important.

But the NIH basically does the basic research, if you will. They provide the lock but they don't have the key. We provide the key. We take that basic research. We sculpt it into a molecule.

We are able to say, now that we know a target of disease to go after, how do we do it? And then we spend our resources in the most expensive part of the development and the riskiest part, which is the clinical development, to ensure safety and efficacy, to bring the drug to market. So, we need all players in the ecosystem——

Senator KAINE. If I could ask you to start to wrap up for Senator Smith——

Mr. DAVIS. Yes. And it is important that we do that. And so, I think as you look in the Covid vaccine situation, we didn't have—we did not receive any Federal funding for what we did. We spent all of our own resources at risk.

We commented, it was $2.5 billion. We did that at risk. But one of the programs we did do, LAGEVRIO, did have some basis from the NIH, and they were compensated for that.

Senator KAINE. On behalf of the Chairman, Senator Smith.

Senator SMITH. Thank you, Mr. Chair. Thanks to all of you for being with us here today. I appreciate it. I am going to start with you, Mr. Davis. Could you tell us how much Merck spends on advertising every year?

Mr. DAVIS. If you look in the United States, our direct to consumer advertising is about $350 million.

Senator SMITH. Then also direct to medical providers?

Mr. DAVIS. I don't have that. I wouldn't know that. We can come back to you on that one.

Senator SMITH. Okay. I think it is approximately $2 billion overall is what I think—is what—worldwide. That is worldwide number. Pardon me for that.

Mr. DAVIS. I don't recognize that number, but we can come back to you.

Senator SMITH. Okay. okay. And so one thing I bet most of us on this panel could agree with is that nobody likes that advertising. Doctors don't like it. Patients don't like it. Apparent—I know that the American Medical Association has called for a ban on direct to consumer advertising.

Could you just address this issue? And I think it is also true that you sued to prevent regulations that would require you to disclose the list prices in that advertising. Could you address that?

Mr. DAVIS. Yes, I am happy to do that, Senator. So, direct consumer advertising serves an important purpose.

There has been studies that have shown that it drives better adherence. It drives patients to understand the use of their medications. And it overall will bring benefits to the health system. I do believe there is a valid educational piece to direct to consumer advertising.

I also believe we need to be full and fair and transparent in helping people understand the cost of drugs. The reason we brought suit, the one you are referring to, was our concern that the specific

request that was in that was that you show the list price of the drug.

Our concern, based on all the conversations we have had here this morning, is that can often be very misleading, and in fact, could cause patients not to seek the drug when in reality, take JANUVIA as an example.

If we put on an advertisement that it is $6,900, when in reality, if you take the total in the system, it is $690, I would hate to think someone doesn't show up to get that medicine because they don't understand the price.

What we supported instead, which is what we do today, in all of our directing consumer advertising, we drive you to a site that gives our list price, it gives all of the rebates we provide so that you can see it, and we get further information and education.

We think that is a more effective tool and a more accurate tool to stop the misperceptions that exist. That is why we raised that concern.

Senator SMITH. One of the things that I think is really confusing for patients is to try to figure out what—you know, how much things cost in the health system overall, including in prescription medications.

Let me just ask you, I am going to ask you about this, Dr. Boerner, how much would acute myeloid leukemia patient, how much would that patient pay every month for your drug IDHIFA, the cancer treatment. That if let's say they had a 20 percent coinsurance responsibility.

Mr. BOERNER. Senator, I don't have that exact figure off the top of my head. What I can say is that for most of our world oncologic drugs, we are able on the commercial side to bring copays down to a very low amount and in many cases to zero.

Now, to a point that was raised earlier, we have to do more to make that more widely available and an easier process to actually get into those programs, and we are working on that.

We have been doing that since I became CEO in November, and that is something we are committed to. And again, I would like to be able to provide that same benefit on the Medicare side.

Senator SMITH. But if you have a list price that is—and I get what you all are saying about the list price is just the list price. That isn't necessarily what people pay. But if you have a list price and then you have a co-insurance responsibility that is a percentage of the list price, that could still be quite a significant amount of money. I mean, I think it could be in this case $6,800 a month for this medication.

Mr. BOERNER. Senator, what you are pointing out is absolutely why we believe we have got to also look at ways to bring that list price down.

We have been discussing at length this sort of the complexity the intermediaries play in this system that lead to incentives to drive those list prices up.

But unquestionably, because out-of-pocket costs and co-insurance, for example, are typically tied to that list price, we have to find ways to bring that list price down.

Senator SMITH. Well, I would agree with that. I think that is a really significant issue, particularly as I think some of my colleagues have pointed out that when you get to these patient assistance programs, they are quite confusing and hard to navigate through.

I think that, sometimes that is only available if you have commercial insurance. And if you don't have commercial insurance, then you could really be flat out of luck.

Mr. BOERNER. Senator, that is correct. And in fact, I reference that since I became CEO, one of the things we have done on the commercial side is really begun to look at how many hoops do patients have to go through to get access to these copay support programs?

You know, we have provided $2.5 billion in copay support programs over the last 5 years as a company, provided $12 billion in free product. But we have got to make it easier and more universally available for commercial patients to get access to that.

Again, there are some constraints to us being able to provide those services on the Medicare side. There is some very legitimate concerns to providing those on the Medicare side, because you don't want to obviously be diverting patients from, for example, generic products onto these as a result of the—onto branded products as a result of this, but we would love to work with Members of Congress to find ways to do this constructively.

Senator SMITH. Is it true that the cost of those patient assistance programs, you can then turn around and deduct on your taxes, to lower your tax liability?

Mr. BOERNER. Senator, I don't know the answer to that, but I can follow-up.

Senator SMITH. Okay. I want to get at the question—I just have a minute left and so let me see if I can do this really quickly.

One of the challenges that we have are some pretty—often pretty severe shortages in medications. And I have heard so many stories about this from Minnesota folks who, they have a preferred treatment for a disease and then the drug is not available.

I want to ask you all—I will just, I will cut to the chase on this, Senator Collins and Senator Murkowski and I have a piece of legislation that would require reporting of supply chain disruptions that could lead to shortages in medications, and I would like to know whether you all would support that concept to help people understand where these shortages are and where the route chemicals for their medications are coming from.

Mr. DUATO. We work—excuse me, we work very closely with the drug shortage office at the FDA, and we are constantly doing all efforts to dual source the entire supply chain of our medicines so there is no discontinuation in our supply.

Mr. DAVIS. I am not familiar with the specifics of the bill, but I would say in general, the more we can continue to help understand what are the shortages, we should address that.

But I think we got to get at the fundamental issues of why do we have a shortage in the first place. I can tell you in our example, we make a drug called——

Senator KAINE. Again, you are over time. So, could you take those answers for the record, Senator Smith?

Senator SMITH. I would be happy to, Senator Kaine.

Senator KAINE. Great. On behalf of the Chair, Senator Braun.

Senator BRAUN. Thank you. I am going to start with Mr. Davis. What would your definition of a free market be?

Mr. DAVIS. One where you are able to bring goods, and if those goods bring value and the system sees value in them, you are able to bring those at a value you think is fair and reasonable and negotiate with the other sides, in a world where you have free competition.

Senator BRAUN. So right there you said negotiate. Most free markets are typified by this. And I would like y'all to listen to this because I think the big challenge, if I were in your seat running your companies, is that it is not a free market.

A free market means you have got a lot of choices, you have got vibrant competition, no barriers to entry, and you have got an engaged consumer. Now, do any of those apply to your business?

Mr. DAVIS. I think all of those apply. But I think one thing we need to understand in our—in the way our business functions, for a period of time, we have exclusivity. That is during the patent protection period. Thereafter—and in that period, we must reap a return on the investments we make to fund the R&D we do. Thereafter, drugs are freely available and there is total competition in that space.

Senator BRAUN. But yet you would sue to keep transparency in terms of what the consumer price would be or the list price, or you do things like tweak patents. That doesn't happen anywhere else. And you are not alone there. Hospitals and insurance companies do all this stuff behind closed doors as well.

I would think if I were in your shoes, you have got maybe a few years before—so none of that stuff really applies to you guys as I listed it. You might try to spin it that way, but it is not the case. I fixed it in my own business back in, oh, probably 15, 16 years ago by creating health care consumers, by trying to avoid the system through wellness and prevention, which you don't hear much about.

But when you do need it, it has got to be there where you have got a lot of options. And I understand you are a little different in terms of the R&D that goes into it. Then many years ago, you created a monster called the PBM that now is sucking all kinds of money out of the market.

Why can't you fix that in terms of doing alternative ways that would just smother the market with transparency and get it into a different channel of distribution? You got a guy like Mark Cuban that is trying to start a company, Cost Plus.

You are going to probably need to find things like that or you are going to be appearing more often here, and it is going to be where

you are going to be regulated like a utility would be. Because in my opinion, you operate more like an unregulated utility kind of cloak yourselves behind free enterprise, and now it is up to 18, 19 percent of our GDP. Something has got to give.

Senator Sanders talked earlier about things costing 10 percent to 25 percent overseas, and I think I heard the excuse was, well they have price controls. Well, I think I would be smart enough to know that sooner or later that will occur here. It is going to be up to the industry to fix it, and you are probably just 15 to 20 percent of the problem.

You could fix the part that you get the most heat for by maybe trying to get more customers like the business Mark Cuban is putting out there that is based upon transparency. If not, you are going to get all the people that don't own health care businesses finally saying, we are not going to pay through the private side, the insurance system, three to four times what it costs through Government.

I will let you complete the logical chain. You are going to have Government as your business partner. So, why would you persist in a paradigm that looks like you are going to be headed toward what you definitely don't want, and that is doing more business with the Federal Government? Mr. Davis.

Mr. DAVIS. Well, I don't want to speculate on the system as a whole. I think what I focus on is what do we need to do to drive the mission of our company, which is in the near term, bring access and affordability.

Make sure that when we bring affordability, we don't sacrifice access. Often patients lose access when we try to address affordability. And that we fund innovation. And that is—whatever ultimately we come to as a solution, if we can protect those elements, I think we will both help patients of today and we can make——

Senator BRAUN. Have you ever looked at having some other system of distribution, like almost any other manufacturer would have when you make something? You do a pretty good job making the pill.

You completely default on how it gets from where you make it to who uses it. You are putting independent pharmacies out of business because the PBMs and other kind of peculiarities in the industry.

Have you thought about, at least in the place where most people confront the health care system with a prescription, about trying to restructure that, smother it with transparency and options to where people can get their stuff, and then apply that to biologics and the entirety of a spectrum, and don't tweak the patents and try to preserve a broken system.

Mr. DAVIS. Yes. So, we have considered should we look at going direct.

The reality of it is, as a single company, when you have now today three PBMs controlling 80 percent of the lives in this country, the ability to do that takes a portfolio of characteristics that we don't currently have.

I don't believe any one company can do that. That is why we continue to believe we need free market, but we——

Senator BRAUN. I bet if you collectively got together with the other drug companies and encouraged others like a Cost Plus that Mark Cuban has done to where you are going—I think you have got it under your control not to perpetuate a bad situation that was created by you. I mean, you make it.

You don't have to necessarily use PBMs. Why don't you encourage an alternative structure? At least show us that you are wanting to compete. Because all I can tell you is that if you don't take it—take the bull by the horns, do something different, you are going to be like all other countries.

You are going to be dealing with the Federal Government as a regulated entity, and I think we could lose some things. But in the meantime, Senator Sanders pointed it out, it costs a lot more here, the health care outcomes are better there, and pharma, hospitals, and insurance better figure it out before it is too late.

The CHAIR. Senator Hickenlooper.

Senator HICKENLOOPER. First, I will echo what Senator Braun said. Second, I will thank each of you for taking the time. And I know how busy you are, and I appreciate you coming in and answering questions.

You know, I grew up like most of us, I think, looking at our pharmaceutical companies as treasures, as companies that America could be rightfully proud of as innovators. But that is slipping away.

When I am back in Colorado, I hear much—let's just be generous—let's be gracious and say a wider diversity of opinion. According to a recent YouGov survey, more than a third of Americans report that cost has prevented them from filling a prescription they need.

A separate Kaiser Family Foundation poll, this one just from last year, said that 83 percent of Americans rated profits made by pharmaceutical companies as the overwhelming contributing factor to the high cost of prescription drugs.

You have all talked about the R&D, the innovation, which there could be no question about that, but what is the value of these cutting edge drugs and therapies if so many people can't afford them?

I think that widespread belief that Americans feel your companies are too focused on profits, it damages your credibility and I think the culture of your businesses and the culture of your customers.

I want to see how you feel about that in terms of the importance of people believing in your mission again, or believing as strongly that you are good leaders of the mission. Why don't we start with you, Mr. Duato.

Mr. DUATO. Thank you, Senator. I can assure you that the 50,000 employees of Johnson & Johnson in the U.S. wake up every day thinking what they can do for patients, and I can represent proudly that sentiment.

What can we do to address the real inequity that exists in the U.S., which is that seniors and patients that need the medicines the most pay higher out-of-pocket costs. In my view, that is the real problem.

There are other things that are positive in the U.S. healthcare system, like the access to breakthrough, cutting edge treatments earlier than any other country in the world, but it is true, we have a real inequity there.

I think we have to work together in order to address that inequity, and there is multiple ways that we can work on that. One is to make sure that——

Senator HICKENLOOPER. Just give me one, because I want to make sure—I have got a couple more questions.

Mr. DUATO. One is to make sure that the discounts and rebates, we paid $39 billion in 2022, that we pay to the middleman, are passed to the patients, so we can lower the out-of-pocket costs.

Senator HICKENLOOPER. Got it. That is a good one.

Mr. DAVIS. Senator, I appreciate the question. And I can tell you at Merck, we have lived by the statement our founder put out, that medicines are for the patients not for the profits. But so long as we have remember that, the profits follow.

It really says we can both do good and do well for our shareholders together. And there is a balance. And I think what you are talking about is where is the balance? And we are always trying to find that balance.

I am very much focused on it as the CEO of the company, because the legacy of Merck, the pride of our 70,000 employees and what we do matters to me, and a strong belief in the mission of the company.

It is why I came to the company, and it is why I am in this industry. So, we are very committed to that. But I do think the challenge we continue to face is the structural issues in the system that are creating the problem.

Senator HICKENLOOPER. We have heard that. I get it.

Mr. DAVIS. Yes.

Mr. BOERNER. Senator, the challenge that we are facing in this Committee today and what we have been discussing is, how do we ensure affordability today without sacrificing tomorrow's innovation? That is what we were focused on.

We have got to make sure we do what you have heard from all of us, are bringing highly innovative medicines to patients, but we also have to do a better job of ensuring that we are bringing drugs like ELIQUIS to market, which save the health care system money.

For every 100,000 patients on ELIQUIS, we estimate we save the health care system $5 billion. We have got to place a high bar on the medicines we bring to patients and stick by that as an industry.

Senator HICKENLOOPER. All right. Well, and I appreciate that. And I do—health is so precious to people that they will pay almost anything if it is serious, so that in a funny way, sometimes we see

increasing costs based on that calculus of how much money we are avoiding, which I think can be a false pathway sometimes.

But certainly, as a user of ELIQUIS and grateful recognizing what the old system was and how better ELIQUIS is, I salute that. The higher cost and the lower cost in other countries, you have all answered that.

I understand there is some price setting there. But I think the solution—I mean, we are paying double. Even when you take out the PBMs and the list price from the net price, we are paying double what Europe or Canada and Australia are paying, and somehow that has got to be a negotiation that the rest of the world probably has to pay more, and you guys are going to have to figure out a way to do that.

I am not saying it is easy, but it is one of those things. I want to—it is one of those things we have to address as a country and as an industry. I want to ask, earlier there is some mention of river blindness, of issues in underserved countries.

I want to see if each of you have a—just a quick example of something where your company has gone in there, obviously we have heard about Merck, but done something in a country like that where it really was philanthropic.

Mr. DUATO. Thank you, thank you. We dedicate billions of dollars every year to treat diseases that do not have an economic counterpart. For example, one of the diseases that we have contributed to its treatment and eradication is intestinal worms.

You know, we donate billions of pills every year in order to treat intestinal worms. We have programs to support frontline health care workers in the developing world that have supported more than a million frontline healthcare workers.

We develop a medicine for multidrug resistant tuberculosis, which is widely used in every single protocol and which we are not enforcing our patents as we speak. So, we have made significant contributions.

Senator HICKENLOOPER. That is impressive, but we most people don't know about that stuff. Mr. Davis.

Mr. DAVIS. Well, you mentioned Dymethazine donation, where we have $4.6 billion. I would add another one we did. You know, recently—and we were very focused on COVID now, we forget about Ebola and the scourge of Ebola that hit in 2014, 2016, in Western Africa.

We actually—and no profit to us, developed an Ebola vaccine. Have distributed that, continue to distribute that drug to address that devastating disease.

Senator HICKENLOOPER. Mr. Boerner.

Mr. BOERNER. Senator, we had as a reference to large presence in HIV, and I am incredibly proud that in the late 90's, our foundation worked with governments and local communities to set up the core infrastructure to deliver HIV medicines to sub-Saharan Africa, focusing on children.

The President of Botswana recently congratulated the—or thanked the BMX Foundation for saving a generation from extinc-

tion, his words. We are now leveraging that same infrastructure, partnering with Baylor College of Medicine, to reverse something in childhood cancer——

The CHAIR. Mr. Boerner, thank you. I am sorry. His time has expired. Apologize.

Senator HICKENLOOPER. Anyway, thank you all. And I think those stories need to get out. But we also have to solve this issue of the price disparity.

The CHAIR. Senator Kaine.

Senator KAINE. Thank you. Since I have 7 minutes, I am going to do 2 minutes to celebrate innovation and then 5 minutes to go after the cost question.

On the innovation side, there is an article that came out in the Health Affairs Journal in September 2020, and I would like to put it in the record, Contributions of Public Health, Pharmaceuticals, and other Medical Care to U.S. Life Expectancy Changes, 1990 to 2015.

[The following information can be found on page 110 in Additional Material.]

Senator KAINE. The article looked at the fact that between 1990 and 2015, life expectancy in the U.S. increased by 3.3 years, and the authors of the researchers and authors of the study were able to say 44 percent of that increase was because of public health measures, 35 percent of the increase was attributable to pharmaceutical innovation, and 13 percent of the increase was attributable to other improvements in medical care, with 7 percent unknown.

But the fact that pharmaceuticals led to more than a third of that increase in life expectancy is something that we need to acknowledge as a context to this discussion.

In a Virginia example—Mr. Davis, you will know this example very well. In Elkton, Virginia, there is a plant that produces GARDASIL, which your company developed and began to market in the mid 2000's—2006, 2007.

It is a vaccine against a virus, the HPV virus, that create—that leads to a lot of cancers, especially cervical cancer and other as well. And that has just been revolutionary in terms of cervical cancer.

We were one of the first states to put a vaccine mandate in place for HPV vaccine, and cervical cancer among vaccinated populations has dropped 70 plus percent just in the last 15 years. I mean, it is truly remarkable.

I have been to that plant, and I know how proud people are to work there and believe that they have been at the vanguard of a revolution that has helped so many Americans, but people all around the world. So, that is the good side.

Okay, now we got to get to the reality for the hearing which is, people here still pay too much out of pocket. Together with my colleagues here who voted for the Inflation Reduction Act, we said for a long time that we ought to be negotiating on prescription drug prices and we did it. And it passed by only one vote in the Senate.

Each of us who voted for it, we were the deciding vote. And I know not everybody likes that, but it is working. We put the cap, the out of pocket cost cap on seniors under Medicare.

We did the $35 insulin for seniors on the Medicare. And thank goodness that sent such a strong market signal that many of the companies that were reducing insulin cost to $35 a month said, we will just do it for not just Medicare patients, but others. And they wouldn't have done that had we not taking that step in the IRA.

But there is more that we can do. And I really want to focus on one thing, because I think it is just right before us. This Committee took strong bipartisan action about 9 months ago on this PBM reform bill that is sitting on the floor of the Senate right now.

I don't expect you to be the masters of all the details of that bill, but if we were to pass a meaningful PBM reform bill—and much of the conversation today has been about this weird difference between list prices and actual net prices.

If we were able to pass a meaningful PBM reform bill, what would that do to the cost that American patients are paying out of pocket for pharmaceuticals? Please, and I will ask each of you to address that. Mr. Duato.

Mr. DUATO. Thank you. Thank you, Senator, and thank you for recognizing the value for patients of pharmaceutical innovation.

If we were able to pass meaningful reform, meaning a reform that would delink the revenues of the PBMs and insurance companies from the list price, and that would pass rebates and discounts to the patients, I would anticipate two things. One, it would affect list prices.

Two, it would significantly reduce the out-of-pocket cost for the patients. So, I welcome the bipartisan efforts of this Committee to go through PBM reform. It is a linchpin of lowering the cost for patients.

Senator KAINE. Mr. Davis.

Mr. DAVIS. Yes. You know, I also believe that in the provisions that are in the bill, at least some of the big ones around transparency and also de-linking are definitely steps in the right direction. I think we need them.

There are a lot of what we have all been focusing on in our testimony and in the question and answers, and I do think it will—it can benefit patients if we move in that direction, so I am very supportive of what you are trying to do.

Senator KAINE. Mr. Boerner.

Mr. BOERNER. Senator, if we could do that and we could reduce the significant amount that we are paying in rebates to intermediaries who are not passing those rebates on to lower out-of-pocket costs, speaking on behalf of Bristol-Myers Squibb, we could work almost immediately to begin to bring down list prices, and I would welcome the opportunity to work with this Committee to do that.

Senator KAINE. Well, I know that in conversations with the Chair, the intent is to move on that bill pretty soon, potentially

with some other health items as well. And I think that the opportunity is right before us.

That bill passed out of Committee overwhelmingly bipartisan. I think it was an 18 to 3 vote, and that tells us that we would have some amendment on the floor. The de-linking provision was not in the bill.

The Chair and Ranking were supportive of the concept, but at the time we marked it up, the CBO hadn't given us the score, and so we agreed that we would wait on that until we got on the floor. But the CBO has now scored the de-linking bill that Senators Marshall, Capito, Braun, and I, and Tester have co-sponsored, and the CBO says that it would save about $650 million over 10 years.

That is in addition to the savings for patients. So, I know we would try, hopefully on the floor to add that in. My colleagues have all talked about the reality of what they hear from constituents, and I hear the same thing.

I know, I think the complexity of the system and the fact that list price is different than net price, and the fact that we have rebates, "rebates," that never show up in people's pockets. And you have programs to try to assist folks who can't afford medicines, but they have a six page application form, and both a sticker price might scare them off or a six page application might scare them off.

We just have to simplify this and cut out a lot of the middlemen in this instance. I have long said to the Chair that I am very concerned about PBMs because we might fight with you about whether you are researching enough or should your research be more than your stock buybacks.

PBMs aren't doing a single bit of research. They are not producing a single product. And yet, they seem to me to be the ones that are scooping up the most of money that is just sloshing through the system right now, so I hope we can address that soon. Thank you, Mr. Chair.

The CHAIR. Senator Luj̀an.

Senator LUJÀN. Thank you, Mr. Chairman. Thank you to everyone who is here today. Biosimilar competition is one way to drive down drug costs for patients and increase access. Would you all agree with that?

Mr. DAVIS. Yes.

Mr. DUATO. Yes.

Mr. BOERNER. Yes.

Senator LUJÀN. I appreciate that. Now, one of the concerns I have is we often see competition stifled in this particular area with biosimilars.

The concern that I have is tactics and delay that lead to entry of the lower cost biosimilar drugs keep patients from often having a choice, but also being able to afford their prescription drugs.

Now, Mr. Davis, yes or no, will you commit to not blocking other drugmakers from entering the market when the primary patent on KEYTRUDA expires?

Mr. DAVIS. Well, Senator, at Merck—and we do believe that biosimilar competition and generic competition is core to the system.

We need the patent protection, and then we need a robust biosimilar and generic market.

I can tell you that, when the composition of matter patents expire on our drug KEYTRUDA, I fully expect, and I will not try to stop a biosimilar IV version of KEYTRUDA coming on to the marketplace.

Senator LUJÀN. Is that a yes?

Mr. DAVIS. That is a yes.

Senator LUJÀN. I appreciate that. Mr. Boerner, yes or no, will you commit to not blocking other drugmakers from entering the market when your primary patent on ELIQUIS expires?

Mr. BOERNER. Senator, we have a number of patents on ELIQUIS, and we have certainly anticipated that when the patents that are most relevant for that product expire, we will have generic competition in this case, not biosimilar, but generic competition, and that would be around 2028.

Senator LUJÀN. When the primary patent expires on ELIQUIS, will you commit to not blocking other drugmakers from entering the market?

Mr. BOERNER. Senator, I don't—I am not a patent attorney, so I am not entirely——

Senator LUJÀN. You are the CEO.

Mr. BOERNER. Senator, I would say that when the most important, the most relevant patents expire on ELIQUIS, we will welcome generic competition.

Senator LUJÀN. Is that a yes or no?

Mr. BOERNER. That is a yes, Senator.

Senator LUJÀN. Mr. Boerner, I have the same question on OPDIVO. Yes or no, will you commit to not blocking other drugmakers from entering the market when your primary patent expires?

Mr. BOERNER. When the most relevant patents for OPDIVO expire, we would fully expect biosimilars to enter the market.

Senator LUJÀN. Your answer is yes when—the words you are using are relevant patents, not the primary patent. Is that the clarification that I can—?

Mr. BOERNER. Yes, Senator. I am just not certain exactly what the most—what you are referring to is the primary patent, but when we—when those patents expire, we welcome generic company.

Senator LUJÀN. First patent, primary, the initial one. The one that was filed when you got this drug done. Look, I am not a lawyer. I am not a CEO. I don't work at all. If I am not using the wrong words, please help me a little bit. You know what I am talking about here.

Mr. BOERNER. Yes. When the composition—generally it is when the composition of matter patent expires.

Senator LUJÀN. That doesn't sound like a yes. I hear what you are saying. I am going to move on. Mr. Duato, we know that J&J

entered into settlement agreements to delay the launch of some STELARA biosimilars in 2025.

This will prevent competition in the drug market and Medicare negotiation, the way I read it. Will you commit to lowering the price of STELARA in 2025?

Mr. DUATO. Senator, thank you for the question. I anticipate that the price of STELARA will actually be lower in 2025, as it has been lowering during the past decade. The path of STELARA has been a steady decline in the net prices, and I anticipate that the biosimilars in 2025 will further decrease the price of STELARA.

Senator LUJÀN. Are you answering yes to my question?

Mr. DUATO. Yes.

Senator LUJÀN. I appreciate that. Now, we have heard over and over that Medicare drug pricing negotiations will kill innovation.

Mr. Boerner, I want to get a few things clear. Yes or no, is it BMS's position as stated in its lawsuit against the Health and Human Services that, "the IRA's real victim is innovation, and in turn, the millions of patients who are counting on the pharmaceutical industry to develop new therapies, will save lives, and improve health and well-being."

Mr. BOERNER. Senator, we have serious concerns about elements of IRA, specifically the fact that this isn't an actual negotiation. We obviously like some elements of IRA, notably the out-of-pocket costs, but——

Senator LUJÀN. I appreciate that, but do you stand by this statement that was filed in the lawsuit to the United States Health and Human Services Department?

Mr. BOERNER. We have very serious concerns about the implication of IRA——

Senator LUJÀN. Do you stand by this statement?

Mr. BOERNER. Yes, sir.

Senator LUJÀN. Yes or no, is it also true that you said in your Q4 earnings call, "we see a legacy portfolio of well-established products facing headwinds such as IRA." Through this portfolio—"or though this portfolio is declining, it is expected to continue to generate strong cash-flows to enable investment in our future growth drivers." Do you stand by that?

Mr. BOERNER. Yes. We actually have a legacy product portfolio that will continue to provide the necessary funds to innovate and bring the next wave of innovation to market, yes, Senator.

Senator LUJÀN. Based on that, can I interpret that cash-flows were generated even though the IRA went to place, and they are sufficient to support new innovations, as was reported to the investors?

Mr. BOERNER. Senator, we don't yet have IRA having been fully implemented negotiation. That process is ongoing. But we are generating cash-flows off of our existing products to fund innovation, sir.

Senator LUJÀN. The statement in the same filing to Health and Human Services, what that case said, this portfolio—though the portfolio is declining, it is expected to continue to generate strong

cash-flows to enable investment in our future growth drivers. So, is it generating cash?

Mr. BOERNER. Our legacy portfolio products is continuing to generate cash, yes, sir.

Senator LUJÀN. So even in the face of IRA, you are generating cash?

Mr. BOERNER. Again, Senator, we haven't actually finished negotiation yet on our first drug, which is——

Senator LUJÀN. I will move on. I appreciate that very much. This is one of—look, I grew up on a small farm in Northern New Mexico. When a cow does its business in the barn, there is a pile of stuff I have got to go clean. That is what it is. It is manure. It has other a lot of other languages, but that is what it is.

I don't understand why this is so complex. The people in the room make these darn things so complex when no one understands them. I am beside myself, Mr. Chairman, that when a question was asked, can you break down where the money goes in this particular drug?

The answer is, well, it is complicated. We don't know. I am hoping it is included in the filings for investors that people know where the money—well, I will follow-up with more questions.

I have several, Mr. Chairman, but you all, help me and other laymen across the country and around the world to be able to understand what the heck is going on. You all have some good lawyers.

Maybe 1 day I will go to law school and try to get a gig with one of you. I don't know, but this is just frustrating. Thanks, Mr. Chairman.

The CHAIR. Senator Markey.

Senator MARKEY. Thank you, Mr. Chairman, very much. Research is medicine's field of dreams from which we harvest to the indings to give hope to families that a cure can be found for the disease which has been running through their family's history. That is what it is all about. That is what we all hope for.

That is what I represent in Boston, in Kendall Square, two miles from my house, and I have been for 47 years in Congress trying to help that industry to be able to grow and to be able to get the resources from NIH, all the resources to make the breakthroughs, to give hope to ordinary families, like my father who drove a truck for the Hood Milk Company.

The companies have done great work over the years, but that funding, which I was on the Health Committee in these—in the House for 36.5 years, and I fought very hard for NIH funding, and those NIH dollars delivered results. For example, between 2010 and 2016, every drug approved by the FDA was in some way based on biomedical research funded by the NIH.

My father, the truck driver at the Hood Milk Company one mile from Kendall Square, he paid his taxes to make sure that the funding would go to NIH so that research could be made in order to make the breakthroughs that would help him and help his families.

Merck's former president, and you have already quoted him, Mr. Davis, he said we never try to forget that medicine is for the peo-

ple—you know, my father—it is not for the profits. And Merck's website states that this philosophy is embraced by their leaders and the employees to this day.

FDA approved the cancer drug KEYTRUDA in 2014, based on NIH research that my father helped to pay for as a truck driver at the Hood Milk Company. And last year, the list price was $191,000 for this cancer drug that helps patients with lung cancer and other cancers, $191,000 a year.

The annual meeting and proxy statement of 2023, says that it brought in $21 billion in revenue for the company, and it was driving key growth for Merck's business. And at the same time, patients are also straining under insurance premiums, struggling to afford this drug, taking on debt, or skipping treatments altogether.

Merck has now filed a 168 patents on this cancer drug, KEYTRUDA. And as we know from this early discussion when we discuss this, we can be talking about primary patents or secondary patents.

What I heard earlier was that the witnesses in general just want all the secondary patents to also be exhausted. Now, to a very large extent, of course, 168 patents then bring at least 168 lawyers into the room.

How do we use this patent in order to thwart another smaller company, hundreds of smaller companies from now making the breakthroughs that advance even further the breakthroughs, innovating, discovering. 168 new patents extend further, using lawyers, you know the time at which there can be a lower price drug made available to people so that they can get the treatment, which they need for lung cancer.

Yes, we believe in competition, and we really believe in competition. In Massachusetts, we believe in Darwinian paranoia inducing competition. But when there is a monopoly on a drug, which is the key drug, there is no competition.

There is no paranoia if 168 patents just extend and extend the ability to have new companies, smaller companies, smarter, new scientists to make the additional breakthroughs. And that is the play. We understand the play.

That is how lawyers get into it, not scientists. You keep the lawyers, keep the smarter new 25 year old out with the new insight just by extending and extending. I do believe in research.

Adam Smith hated monopolies. It was the No. 1 thing he hated the most, monopolies. And so, in this particular instance, my father died from lung cancer. And my father was—drove a truck. So, the list price for KEYTRUDA is more than his entire pension. That is what he got from the Hood Milk Company.

One year of his entire pension would have paid for 1 year, and he died from lung cancer. And I don't think that Judge Merck really intended that, that would be what the result of research, ultimately did.

Mr. Davis, would it have been consistent with Judge Merck's philosophy to take research funded by my father's tax dollars, to invent a lifesaving lung cancer drug, charge him hundreds of thousands of dollars of his hard earned retirement for it, manipulate

the market using patent law to block out competition that could have brought in new scientists that could have improved it and lowered the cost, and as a result, the costs are unaffordable.

Then use the income you got from him to brag to your investors about the drug as a key growth area for your business. Do you think that is what Judge Merck intended when he had that high minded philosophy, which he used to describe Merck's——

The CHAIR. In 17 seconds.

[Laughter.]

Mr. DAVIS. Are you looking for the answer now?

Senator MARKEY. Yes.

Mr. DAVIS. Okay. Well, I would say, the quote was, medicine is for the patients, not for the profits. But so long as we remember that the profits have always followed.

What he was capturing was if you focus on bringing new medicines to benefit patients today and make sure you have an investment and a return to bring medicines for the future—because we are a biopharmaceutical research company.

Research is who we are. Innovation is the lifeblood of our company. Then we can deliver for the mission to the patients. And I can tell you at Merck, and I am very proud of this, we always put patients at the center, and we always look at ways to do that, and that will continue to be what we do.

I do think actually what we are doing is consistent because it allows us to be sustainable for the long term to deliver for patients into the future.

Senator MARKEY. I just think——

The CHAIR. Thank you.

Senator MARKEY. I just think it has turned into medicine for the shareholders and not medicine for the people like my father.

The CHAIR. Okay. Let me—that is the last line of questioning. So, let me thank our three panelists for being here today, and all the Senators who participated. We are now going to turn to our second panel. Thank you all very much, gentlemen.

Mr. DAVIS. Thank you very much.

Mr. BOERNER. Thank you.

The CHAIR. Thank you all very much for being here. We have three very knowledgeable guests, panelists, on prescription drugs and pricing.

Our first witness will be Peter Maybarduk, who is the Director of Access to Medicines Program at Public Citizen.

He is a lawyer who has advocated for stronger price regulation and stronger public health protections in patent law in the U.S. and around the world. Mr. Maybarduk, thanks very much for being with us.

STATEMENT OF PETER MAYBARDUK, J.D., ACCESS TO MEDICINES DIRECTOR, PUBLIC CITIZEN, WASHINGTON, DC

Mr. MAYBARDUK. Chairman Sanders, Ranking Member Cassidy, Members of the Committee, thank you. Public Citizen is a national

public interest organization. We have 500,000 members and supporters, and for 50 years we have advocated with success for health and consumer protections.

Drug prices are high because of monopoly power, leading to the rationing of treatment and preventable suffering. 1 in 3 Americans has failed to take medicine as prescribed due to cost. Like Louise Chisholm of Fort Worth, who tells us of Merck's diabetes drug, I need JANUVIA to control my blood sugar, but I can't afford it while on Social Security.

Robert Cherivano of Loveland, Colorado, and his wife both trying to afford J&J XARELTO, why do we have to pay so much? We are 90 and 81 on Social Security. Does anyone care about the elderly? Keith Clyburn, Lafayette, Louisiana, I am paying for ELIQUIS and other pricey meds from BMX. So, what do I do? I ration them so that I can eat and pay rent.

Patients for Affordable Drugs has compiled 34,000 such stories from people struggling to afford their medicine, and that is a tiny fraction, a mere sample of the heartbreaking problems out there.

High prices cost people their health. They can cost lives. They force impossible family budget decisions. We all pay for high prices, whether we are patients or not, whether out of pocket or through higher insurance premiums and wasted tax dollars. Medicare and Medicaid spent nearly $200 billion on prescription drugs last year.

Americans pay the highest prices in the world three times what other countries pay, and that is net prices not list, to the point of the last panel—three times more in net prices, the real prices. We also do the most to support research and development.

The world's largest biomedical research funder is a public funder, the National Institutes of Health, and we should be very proud of it, contributing more than $45 billion a year and laying groundwork for many, if not most, new medicines.

Plus, public support is now indispensable to the late stage development of 1 in 4 drugs also. We the people drive innovation together. So, Americans first pay for the research, then contribute to the development.

Then on top of it, when the drug comes to market pay the highest prices in the world. Other countries broadly negotiate prices to protect their people, but here, pharma has accrued tremendous influence in our politics, spending hundreds of millions a year in lobbying, outranking every other industry.

Now, our Government provides patent protection and exclusivity on medicines. In theory, this should support innovation. But in practice, drug corporations write the rules, extending monopoly power sometimes for decades, blocking competition far longer than this body intends.

Senators, it is not a market in the way that you may believe, respectfully. The corporations testifying here today claim any price relief would compromise their ability to invest in new medicines.

No, that framing erases the millions of Americans rationing treatment. It erases the tens of billions of dollars the tax taxpayers invest in R&D for real health priorities.

It erases the hundreds of billions of dollars the industry spends on self-enrichment. Last year, drugmakers selected for Medicare negotiation spent $10 billion more on stock buybacks, dividends, and executive compensation than they spent on R&D.

J&J and BMX each spent $3 billion more on these self-enriching activities. And over the prior decade, Merck's buybacks and dividends also exceed R&D by $3 billion. J&J spent an impressive $43 billion more on buybacks and dividends than R&D over this period. Of course, drugmakers do not set prices according to R&D costs.

Instead, the price of a patented drug is simply the most that we as a society are willing to pay to care for our sick and loved ones, where monopoly power blocks affordable alternatives, blocks market competition, and we have little choice.

Today, perhaps for the first time, our Country is making progress, challenging high prices and rationing, including through price negotiation, encountering price spikes, and we commend the Committee's attention to this problem. But the problem is getting worse, much worse, and more action is needed.

We should negotiate prices from the moment a drug hits market, not wait a decade as we are today, which cost taxpayers tens of billions of dollars. We support legislation before your Committee to strengthen market competition and transparency and accelerate generic entry. Ultimately, we will have to confront monopoly power.

That is the rotten foundation allowing drug makers to project influence, to game the law, and keep prices high.

Other real challenges, including providing patient assistance and challenging middlemen who take advantage, real problems, but these flow inevitably from the patent monopolies that make it so lucrative and so easy to rip off patients.

We can, we must do better for health, for access to medicines. Thank you for your time. Please count us with you in this fight.

[The prepared statement of Mr. Maybarduk follows.]

PREPARED STATEMENT OF PETER MAYBARDUK

CHAIRMAN SANDERS, RANKING MEMBER CASSIDY AND MEMBERS OF THE COMMITTEE,

Thank you for the opportunity to testify today on the high prices Americans pay for prescription drugs. I am Peter Maybarduk, Access to Medicines Director of Public Citizen. Public Citizen is a national public interest organization with more than 500,000 members and supporters. For more than 50 years, we have advocated for stronger health, safety and consumer protections; for corporate and government accountability; and in more recent years, for affordable access to essential medicines and biomedical technologies.

I. The Drug Pricing Crisis at the Hands of the Pharmaceutical Industry

This hearing unfolds against the backdrop of a drug pricing crisis in the United States. The Centers for Disease Control and Prevention's (CDC) data from 2021 shows approximately 9.2 million Americans aged18–64 are unable to take medications as prescribed due to costs.[1] 2023 Kaiser data on all adults shows that three in 10 Americans have not taken their medications as prescribed due to costs, 82 percent of Americans say the cost of prescription drugs is unreasonable, and 73 percent

[1] Laryssa Mykyta, and Robin A. Cohen, Centers for Disease Control and Prevention, National Center for Health Statistics, Characteristics of Adults Aged 18-64 Who Did Not Take Medication as Prescribed to Reduce Costs: United States, 2021, NCHS DATA BRIEF NO. 470 (June 2023).

say that the government is not doing enough to regulate drug prices.[2] People with disabilities are three times more likely not to take medications as prescribed due to cost barriers.[3]

Americans also confront the highest drug prices in the world, paying nearly three times more for the same drugs than other countries.[4] For the 20 top-selling drugs worldwide, drug corporations made more than $100 billion from sales to American patients in comparison to $57 billion from all other countries combined in 2020.[5] This pricing disparity is even more egregious considering significant taxpayer funded contributions to drug development. The taxpayer funded National Institutes of Health is the largest public funder of biomedical research in the world, investing nearly $45 billion in U.S. taxpayer dollars.[6] Much of this funding focuses on the foundational research on biological targets for drug action that drug development is based upon.[7] Further, recent estimates suggest that publicly supported research was critical to the late-stage development of one in four drugs.[8]

Drug pricing abuses also put an enormous strain on the coffers of public health programs, and consequently our tax dollars. Of the more than $400 billion spent on retail prescription drugs in 2022, almost $135 billion came from Medicare and $45 billion from Medicaid.[9]

Excessive drug prices and self-imposed rationing by American patients are the outgrowth of unregulated pharmaceutical monopoly power over drug prices. Prescription drug corporations receive government-granted patent protection on drug inventions and statutory exclusivities on medicines. In theory, this incentivizes innovation of new medicines, and it is critically important that we support research and development. But in practice, the rules have been written by or with the deep influence of drug corporations, to maximize their ability to extract rents from our healthcare system. Corporations extend their exclusive power over new drugs through an array of anticompetitive tactics to the detriment of American patients.[10] For example, many have abused the patent system to obtain subsequent patents over the same medicine with marginal differences or benefits to retain longer periods of exclusivity, sometimes decades.[11]

Pharmaceutical companies have exploited their monopoly power to accrue tremendous influence in our political system and protect their exceptional profits. The pharmaceutical industry expends hundreds of millions of dollars each year in lobbying efforts to advance its interests, outranking every other industry.[12] When Medicare Part D was established to cover prescription costs for seniors two decades ago, pharmaceutical companies successfully lobbied to deprive the program of the power to negotiate drug prices.[13] Federal law requires private insurers, Medicare,

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[2] Ashley Kirzinger, Alex Montero, Grace Sparks, Isabelle Valdes, & Liz Hamel, Public Opinion Prescription Drugs and Their Prices, KFF (Aug. 21, 2023), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/.

[3] Id. at 2.

[4] ANDREW W. MULCAHY, DANIEL SCHWAM & SUSAN L. LOVEJOY, RAND, INTERNATIONAL PRESCRIPTION DRUG PRICE COMPARISONS: ESTIMATES USING 2022 DATA (2024), *https://aspe.hhs.gov/sites/default/files/documents/277371265a705c356c968977e87446ae/international-price-comparisons.pdf*

[5] RICK CLAYPOOL & ZAIN RIZVI, UNITED WE SPEND: FOR 20 TOP-SELLING DRUGS WORLDWIDE, BIG PHARMA REVENUE FROM U.S. SALES COMBINED EXCEEDED REVENUE FROM THE REST OF THE WORLD (Sept. 30, 2021).

[6] National Institutes of Health, Serving Society, Direct Economic Contributions, IMPACT OF NIH RESEARCH, *https://www.nih.gov/about-nih/what-we-do/impact-nih-research/serving-society/direct-economic-contributions* (last visited Feb. 1, 2024).

[7] Ekaterina Galkina, Jennifer M. Beierlein, Navleen Surjit Khanuja, and Fred D. Ledley, Contribution of NIH funding to new drug approvals 2010—2016, 115 PNAS 2329 (2017).

[8] Rahul H. Nayak, Jerry Avorn, & Aaron S. Kesselheim, Public sector financial support for late stage discovery of new drugs in the United States: cohort study, 367 BMJ l5766 (2019).

[9] NHE Fact, CMS.GOV, *https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet* (last visited Feb. 5, 2024).

[10] E.g., Aaron Kesselheim, Jerry Avorn, & Ameet Sarpatwari, The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform, 316 JAMA NETWORK 858 (2016).

[11] Other tactics they use to maintain their extraordinary pricing power over essential medicines include switching patients from branded medications with patent protection nearing expiry to new drugs with no added clinical benefit and longer patent protection. Drug corporations also pay generic companies to delay their competing products in order to extract more profits.

[12] Inci Sayki, Despite record Federal lobbying spending, the pharmaceutical and health product industry lost their biggest legislative bet in 2022, OPEN SECRETS (Feb. 2, 2023), *https://www.opensecrets.org/news/2023/02/despite-record-Federal-lobbying-spending-the-pharmaceutical-and-health-product-industry-lost-their-biggest-legislative-bet-in-2022/*.

[13] Amy Kapczynski, The Political Economy of Market Power in Pharmaceuticals, 48 J. HEALTH POL., POL'Y L. 215, 223 (2023).

and Medicaid to cover FDA approved drugs, which effectively provides a government mandate to buy companies' monopolized drugs with absent or weak measures to contain costs. [14]

Other countries employ cost-containing measures to protect their residents from drug pricing abuses, which is why the price of prescriptions drugs in the United States is so excessive by comparison. [15] Drug companies have been happy to benefit from a slew of U.S. Government actions and policies that have dramatically increased their profits in recent decades, but they balk at any attempt to implement drug pricing measures that already benefit wide swathes of the world.

Drugmakers' largely unregulated, and government-expanded, pricing power has rewarded them with exceptional profits. To protect these profits, pharma trade groups claim that any measure that could deliver drug pricing relief to Americans will restrict resources to invest in new medicines and help patients in the future. [16] That framing usefully erases the millions of Americans that currently self-ration their medicines and are harmed due to pricing abuses. It also erases the tens of billions of taxpayer dollars invested annually in research and development, and the hundreds of billions the industry spends on self-enrichment.

The Biden administration is making significant progress in addressing our Nation's drug pricing crisis through implementation of Medicare drug price negotiation, inflationary rebates, the cap on out-of-pocket costs for insulin at $35 per month for Medicare enrollees, the caps on annual out-of-pocket expenses for prescription drugs in the catastrophic phase of Medicare Part D that will be set at $2,000 next year, and other provisions of the Inflation Reduction Act. Bipartisan reforms which this Committee has considered and advanced can build on that progress. [17] However, far more is necessary to provide material relief to all patients facing unbearably high prescription drug prices, including people with private insurance and those without insurance. [18]

To highlight the need for stronger measures to deliver drug pricing relief to millions of Americans, this testimony focuses on the drug pricing abuses of Merck, Johnson & Johnson, and Bristol Myers Squibb. In our view, these corporations have taken advantage of weaknesses in our health system to price gouge Americans and used suspect patenting practices to unfairly extend their monopoly power.

II. Merck, Johnson & Johnson, and Bristol Myers Squibb Engage in Pricing Abuses of Life-Saving Medicines

Merck

Merck takes advantage of its monopoly power to excessively price its blockbuster drug, Keytruda, which treats many different cancer types, [19] and Januvia, a widely used drug to treat diabetes. [20] Additionally, Merck exploits its monopoly protections

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[14] Id.

[15] Id. at 223; Aaron Kesselheim, Jerry Avorn, & Ameet Sarpatwari, The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform, 316 JAMA NETWORK 858, 860 (2016).

[16] See PhRMA, States Can Help Patients Pay Less for Their Medicines, STATE POLICIES AND ISSUES, *https://phrma.org/en/States* (last visited Jan. 11, 2023); PhRMA, INFLATION REDUCTION ACT'S UNINTENDED CONSEQUENCES,*https://phrma.org/inflation-reduction*

[17] Specifically, Public Citizen supports legislation to promote generic competition and lower drug prices through taking on drug corporation citizen petition abuse and exclusivity "parking", clarifying the scope of orphan drug exclusivity, and providing greater transparency for generic applicants. Additionally, Public Citizen has supported bipartisan measures advanced through the Judiciary Committee that address pay-for-delay, product hopping and citizen petition abuses.

[18] Public Citizen also supports legislation to build on the Inflation Reduction Act, through expanding the number of drugs negotiated, who benefits from negotiated prices, and reducing and removing the negotiation delay periods currently mandated. Public Citizen has also supported legislation reducing the biologics exclusivity period to 5 years, in parity with that afforded small molecule drugs, and legislation to require reasonable pricing of federally——funded medical inventions. Public Citizen has repeatedly called on Congress to advance insulin access reform to ensure people without insurance and with private insurance can access affordable insulin. Public Citizen also strongly supports additional solutions to address patent thicketing suggested by the Initiative for Medicines, Access and Knowledge (I-MAK). See IMAK, ADDRESSING PATENT THICKETS TO IMPROVE COMPETITION AND LOWER PRESCRIPTION DRUG PRICES: A BLUEPRINT FOR REFORM (2023), *https://www.i-mak.org/wp-content/uploads/2023/12/Addressing-Patent-Thickets-Blueprint—2023.pdf).*

[19] I-MAK, OVERPATENTED, OVERPRICED: KEYTRUDA'S PATENT WALL 3 (2021).

[20] ASSISTANT SECRETARY FOR HEALTH AND PLANNING, HHS, INFLATION REDUCTION ACT RESEARCH SERIES: JANUVIA: MEDICARE ENROLLEE USE AND SPENDING

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to price gouge Americans on the federally funded COVID–19 treatment, Lagevrio, that cuts the risk of hospitalization.[21] For Keytruda and Januvia, Merck has been granted patent protection beyond their active ingredient or mechanism, which helps prolong its monopoly control over these drugs by deterring manufacturers from bringing more affordable alternatives to market.

Keytruda

First, Merck exploits its monopoly protections in Keytruda to price the drug outrageously. The price of Keytruda for just 3 weeks is over $11,000,[22] and some patients may need to adhere to Keytruda for one to 2 years.[23] The extraordinary list price of the drug, amounting to over $190,000 a year, means that insured patients routinely hit their out-of-pocket limits, which can be thousands of dollars every year.[24] In 2023, Merck made $25 billion off of Keytruda according to its latest filing with the Securities Exchange Commission.[25] Of the $18 billion in sales of the drug globally in the first 9 months of 2023, Merck extracted $11 billion in revenue from American patients.[26] Evidence suggests the price of Keytruda is not keyed to its research and development costs. Merck itself did not make the original research and development contributions critical to the drug's discovery: it obtained ownership of the drug, and many others, via a corporate acquisition in 2009 for $41 billion.[27] In just 2 years, Merck has more than made up for those costs with $46 billion in sales for the drug.[28]

Second, Merck appears to be engaging in patenting practices designed to unfairly extend exclusivity over this biologic drug to prevent more affordable biosimilars from coming to market.[29] The Initiative for Medicines, Access and Knowledge (I-MAK) found that 129 patent applications have been filed to cover Keytruda, and 50 percent of these applications were filed after the drug's FDA approval in 2014, cutting against claims that these patent applications furthered innovation incentives for the drug's discovery.[30] Fifty-three patent applications have been granted to date, and the primary patents covering the antibody that's considered the main component of the drug were filed in 2008 and will expire in 2028.[31]

The other patents protect, among other things, methods of producing the drug and its use to treat different cancer types.[32] But method of production patents are more critical to biologics like Keytruda than small molecule drugs because the techniques for producing these drugs are more challenging.[33] As such, it's more difficult for manufacturers to work around these patents to create more affordable biosimilar alternatives.[34] Additionally, once the mechanism of action is known for a biologic in addressing one condition, testing its use for other similar indications becomes obvious.[35] Therefore, obtaining multiple patents for different clinical indications for these drugs appears problematic. The secondary patents on Keytruda grant an additional 8 years of Merck's monopolistic pricing power over the drug, and as a con-

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(Nov. 13, 2023), *https://aspe.hhs.gov/reports/ira-research-series-Medicare-drug-price-negotiation-program*.

[21] Sharon Lerner, Merck Sells federally Financed Covid Pill to U.S. for 40 times What It Costs to Make, THE INTERCEPT (Oct. 5, 2021), *https://theintercept.com/2021/10/05/covid-pill-drug-pricing-merck-ridgeback/*.

[22] Cost Info and Financial Help, KEYTRUDA, *https://www.keytruda.com/financial-support/* Feb. 1, 2024).

[23] What Do I Need to Know About My Treatment Schedule?, STARTING KEYTRUDA (last visited Feb. 1, 2024).

[24] Bob Herman, The Keytruda Boom, AXIOS (Oct. 19, 2021), *https://www.axios.com/2021/10/29/keytruda-sales-merck-drug-prices*.

[25] MERCK & CO., INC., FORM 8-K, EXHIBIT 99.1 (Feb. 1, 2024), *https://www.sec.gov/ixviewer/ix.html'doc=/Archives/edgar/data/0000310158/000110465924009109/tm244517d1—8k.htm*.

[26] MERCK & CO., INC., FORM 10-Q FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2023, at 29, *https://www.sec.gov/ixviewer/ix.html'doc—/Archives/edgar*

[27] I-MAK, OVERPATENTED, OVERPRICED: KEYTRUDA'S PATENT WALL 3 (2021).

[28] MERCK & CO., INC., FORM 8-K, EXHIBIT 99.1 (Feb. 1, 2024), *https://www.sec.gov/ixviewer/ix.html'doc=/Archives/edgar/data/0000310158/000110465924009109/tm244517d1—8k.htm*.

[29] I-MAK, OVERPATENTED, OVERPRICED: KEYTRUDA'S PATENT WALL 5–6 (2021).

[30] Id. at 1.

[31] Id.

[32] Id. at 3.

[33] Id.

[34] Id.

[35] Id.

sequence of this exclusivity, it is estimated that Americans will spend $137 billion on Keytruda.[36]

In sum, Merck appears to be unfairly extending its exclusivity over Keytruda, which will cost American patients billions in the coming years, in light of the filing pattern of patent applications on Keytruda particularly after its FDA approval, and the granted patent protection to deter biosimilar competitors after the expiry of primary patents.

Januvia

Merck's pricing of Januvia, which treats diabetes, also exemplifies the pricing abuses rampant to the pharmaceutical industry. Merck charges Americans as much as $6,900 per year for Januvia, while the same drug can be purchased for $900 in Canada and $200 in France.[37] Medicare Part D spent more than $4 billion on just this one drug between June 2022 and May 2023,[38] and the drug has been selected by CMS for the first round of Medicare price negotiation. The drug on average costs Medicare nearly $5,000 annually per enrollee, with out-of-pocket costs amounting to more than $500 each year for enrollees who do not receive the low-income subsidy.[39] On Januvia, and the related product Janumet, Merck made $4.5 billion and $3.4 billion in 2022 and 2023, respectively.[40]

Merck has managed to extend its monopoly pricing power over Januvia through unfair patenting practices. Januvia was first approved by the FDA in 2006,[41] and the original patent covering Januvia's active ingredient, filed in 2002, expired in 2023.[42] Americans already should have access to lower cost generics. Indeed, Merck lost exclusivity for the drug in 2023 in Europe.[43] However, according to the FDA's Orange Book, one patent set to expire in 2027 stands in the way of low-cost generics for American patients.[44] That patent covers a specific salt form of the active ingredient created from a reaction with phosphoric acid.[45] According to Merck, innovating patents after the filing of the primary patent "enhance[s] the benefits and convenience of treatments for patients."[46]

The validity of the patent and Merck's argument that these secondary patents, at least for Januvia, benefit patients are belied by the litigation surrounding this patent. Although a district court ultimately upheld the patent based on technical legal rules, it noted that the earlier patent claimed salt forms of Januvia's active ingredient, and most egregiously, the earlier patent disclosed that a salt could be formed using phosphoric acid and even lists it as one of eight preferred acids for creating such salts.[47] The second patent simply covers the salt form product formed

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[36] Id. at 4.

[37] Bernie Sanders: U.S. Senator for Vermont, PREPARED REMARKS: Sanders Ahead of Vote to Subpoena CEOs to Testify on Outrageously High Prices of Prescription Drugs in America, PRESS RELEASES (Jan. 25, 2024), *https://www.sanders.senate.gov/press-releases/prepared-remarks-sanders-ahead-of-vote-to-subpoena-ceos-to-testify-on-outrageously* high-prices-of-prescription-drugs-in-america/.

[38] The White House, FACT SHEET: Biden-.Harris Administration Announces First Ten Drugs Selected for Medicare Price Negotiation, BRIEFING ROOM: STATEMENTS & RELEASES (Aug. 29, 2023), *https://www.whitehouse.gov/briefing-room/statements-releases/2023/08/29/fact-sheet-biden-harris-administration-announces-first-ten-drugs-selected-for-Medicare-price-negotiation/*.

[39] Id.

[40] MERCK & CO., INC., FORM 8-K, EXHIBIT 99.1 (Feb. 1, 2024), *https://www.sec.gov/ixviewer/ix.html'doc=/Archives/edgar/data/0000310158/000110465924009109/tm244517d1—8k.htm*.

[41] Merck Sharp & Dohme, LLC v. Mylan Pharm., No. 1:19CV101 4–5 (N.D.W. Va. Sep. 21, 2022); HIGHLIGHTS OF PRESCRIBING INFORMATION, *https://www.accessdata.fda.gov/drugsatfda—docs/label/2012/021995s019lbl.pdf* (last visited Jan. 29, 2024).

[42] Merck Sharp & Dohme, LLC v. Mylan Pharm., No. 1:19CV101 16–17 (N.D.W. Va. Sep. 21, 2022); U.S. Patent No. U.S. 6,699,871 Claim 17.

[43] MERCK & CO., INC., FORM 10-K, at 27 (Feb. 24 2023), *https://www.sec.GOV/ixviewer/ix.html'doc=/Archives/edgar/data/310158/000162828023005061/mrk–20221231.htm*.

[44] Product Details for NDA 021995, ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, *https://www.accessdata.fda.gov/scripts/cder/ob/results—product.cfm'Appl—Type=N&Appl—No=021995#23300* (last visited Feb. 2, 2024).

[45] Merck Sharp & Dohme, LLC v. Mylan Pharm., No. 1:19CV101 12–13, 77 (N.D.W. Va. Sep. 21, 2022).

[46] Andrew Seidman, How Merck extended its monopoly on a blockbuster diabetes drug, PHILADELPHIA INQUIRER (Dec. 20, 2023), *https://www.inquirer.com/business/merck-patent-januvia-Medicare-price-negotiations–20231220.html*.

[47] Merck Sharp & Dohme, LLC v. Mylan Pharm., No. 1:19CV101 73, 76–77 (N.D.W. Va. Sep. 21, 2022).

by a reaction of phosphoric acid with the active ingredient.[48] In essence, Merck was able to extend its monopolistic pricing power over Januvia by claiming something it had basically previously disclosed, and what many would consider an obvious variation of the active ingredient. Further, Merck's claim that there is some corollary benefit to patients that arises from its salt patent is contradicted by the record: to reject the generic manufacturer's challenge to the patent's validity, the district court found that the active ingredient by itself was fine and did not need to be reacted with a salt.[49]

Lagevrio

A 5-day-course of Lagevrio, which cuts the risk of hospitalization from COVID–19, costs $17.74 to produce, but Merck charged the Federal Government $712, or over 40 times more, for the drug in 2021.[50] The government had contracted with Merck to supply 1.7 million courses of treatment at this price for a total of $1.2 billion.[51] The pricing of Lagevrio was particularly egregious because the Federal Government invested an estimated $29–35 million in the development of the drug.[52] In 2023, Merck's sales of the drug brought in $1.4 billion, but in the previous year, Merck made nearly $6 billion off of the treatment.[53]

In sum, Merck has been engaging in excessive pricing abuses with respect to Keytruda, Januvia, and Lagevrio, which bring in billions every year for the company. Additionally, it has sought to extend its monopolistic pricing power over Keytruda and Januvia using patenting practices we should deem unfair.

Johnson & Johnson

Like Merck, Johnson & Johnson benefits from monopoly protections to price gouge American patients on vital medicines. These drugs include (1) Stelara, which helps treat psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis;[54] (2) Xarelto, which prevents and treats blood clots and reduces health risks for patients with coronary or peripheral heart disease, and is licensed for sale in the U.S. from Bayer AG;[55] and (3) Darzalex, which treats multiple myeloma.[56] Imbruvica is another possible example of Johnson & Johnson's drug pricing abuses. Johnson & Johnson commercializes Imbruvica, which treats blood cancers,[57] outside the United States and has co-exclusive rights with AbbVie to commercialize the drug in the United States, though AbbVie states it is "the principal in the end-customer product sales."[58] The companies share profits and losses equally from the commercialization

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[48] Id. at 12–13, 77.

[49] Id. at 85. The district court's reasoning may have been flawed, as it noted earlier that Merck had been motivated to find a salt form of the compound because it proved unsuitable for making pharmaceutical tablets and was unstable. Id. at 7. Even if this were true, this should have provided the motivation for a person to arrive at this salt version of the active ingredient, rendering the patent claim obvious and invalid.

[50] Sharon Lerner, Merck Sells federally Financed Covid Pill to U.S. for 40 times What It Costs to Make, THE INTERCEPT (Oct. 5, 2021), *https://theintercept.com/2021/10/05/covid-pill-drug-pricing-merck-ridgeback/*.

[51] Id.

[52] Id; Luis Gil Abinader, U.S. government rights in patents on Molnupiravir, based upon funding of R&D at Emory University, KNOWLEDGE ECOLOGY INTERNATIONAL BLOG (Oct. 4, 2021), *https://www.keionline.org/36648*.

[53] MERCK & CO., INC., FORM 8-K, EXHIBIT 99.1 (Feb. 1, 2024), *https://www.sec.gov/ixviewer/ix.html'doc=/Archives/edgar/data/0000310158/000110465924009109/tm244517d1—8k.htm*.

[54] ASSISTANT SECRETARY FOR HEALTH AND PLANNING, HHS, INFLATION REDUCTION ACT RESEARCH SERIES: STELARA: MEDICARE ENROLLEE USE AND SPENDING (Nov. 13, 2023), *https://aspe.hhs.gov/reports/ira-research-series-Medicare-drug-price-negotiation-program*.

[55] ASSISTANT SECRETARY FOR HEALTH AND PLANNING, HHS, INFLATION REDUCTION ACT RESEARCH SERIES: XARELTO: MEDICARE ENROLLEE USE AND SPENDING (Nov. 13, 2023), *https://aspe.hhs.gov/reports/ira-research-series-Medicare-drug-price-negotiation-program*; BAYER ANNUAL REPORT 2022 97 (2023), *https://www.bayer.com/en/investors/integrated-annual-reports*,

[56] DAVID RIND, FOLUSO AGBOOLA, DMITRIY NIKTIN, AVERY MCKENNA, EMILY NHAN, MATT SEIDNER, & STEVEN D. PEARSON, INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW, UNSUPPORTED PRICE INCREASE REPORT: UNSUPPORTED PRICE INCREASES OCCURRING IN 2022 10 (Dec. 11, 2023), UPI—2023—Report—121123.pdf (icer.org).

[57] ASSISTANT SECRETARY FOR HEALTH AND PLANNING, HHS, INFLATION REDUCTION ACT RESEARCH SERIES: IMBRUVICA: MEDICARE ENROLLEE USE AND SPENDING (Nov. 13, 2023), *https://aspe.hhs.gov/reports/ira-research-series-Medicare-drug-price-negotiation-program*.

[58] ABBVIE INC., FORM 10-K FOR THE FISCAL YEAR ENDED DECEMBER 31, 2022, at 66–67, *https://www.sec.gov/ixviewer/ix.html—doc—/Archives/edgar/*

of the drug.[59] Even if Johnson & Johnson does not ultimately control the prices of drugs in the United States, it profits equally from the abuses of its commercial partner.

Johnson & Johnson also benefits from unfair patenting practices extending exclusivity over Xarelto and Imbruvica, which will incur billions in costs to U.S. patients.

Stelara

Johnson & Johnson prices Stelara exorbitantly in comparison to other high-income markets. The drug is priced at $79,000 in the United States when it can be purchased for a fifth of the price in the United Kingdom.[60] Even considering rebates, the price of Stelara is between 28 percent–81 percent lower in Canada, Switzerland, Germany, Australia, the United Kingdom, France, and Australia.[61] In 2023, Johnson & Johnson made nearly $11 billion in sales from the drug, almost $7 billion of which came from U.S. patients.[62]

The drug has been selected for the first round of Medicare price negotiation, and between June 2022 and May 2023, Medicare Part D spent over $2.6 billion on the drug. Further, Stelara had incurred over $4,000 in out-of-pocket costs annually for enrollees who did not receive the low-income subsidy.

There is reason to believe that Johnson & Johnson has engaged in unfair patenting practices to maintain its monopoly power over Stelara. Hagens Berman filed a class action lawsuit on Dec. 7, 2023 for health benefit providers on the basis that Johnson & Johnson illegally delayed the entry of biosimilar competitors to Stelara.[63] Their complaint alleges that Johnson & Johnson defrauded the Patent and Trademark Office by intentionally misleading the examiner on the patentability of a subject patent in Stelara, purchased a manufacturer that had patents in the methods of producing biosimilar alternatives to Stelara, and used these fraudulently and unlawfully obtained patents to delay alternatives that would have been more affordable to patients.[64]

Darzalex

In 2022, the Institute for Clinical and Economic Review found that Johnson & Johnson's 6.8 percent price hike of Darzalex was unsupported by new clinical evidence, increasing spending by an estimated $248 million in the United States.[65] In 2023, Johnson & Johnson made nearly $10 billion on the drug, of which more than $5 billion derived from the U.S. market.[66]

Xarelto

Johnson & Johnson prices Xarelto at $542 for a 30-day supply, which is nearly $7,000 a year in the United States.[67] Even considering rebates, Xarelto is two to four times more expensive in the United States compared to Canada, Switzerland, Germany, Australia, the United Kingdom, in Canada, Switzerland, Germany, Aus-

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[59] Id.

[60] Bernie Sanders: U.S. Senator for Vermont, PREPARED REMARKS: Sanders Ahead of Vote to Subpoena CEOs to Testify on Outrageously High Prices of Prescription Drugs in America, PRESS RELEASES (Jan. 25, 2024), *https://www.sanders.senate.gov/press-releases/prepared-remarks-sanders-ahead-of-vote-to-subpoena-ceos-to-testify-on-outrageousl—high-prices-of-prescription-drugs-in-america/*; The White House, FACT SHEET: Biden-.Harris Administration Announces First Ten Drugs Selected for Medicare Price Negotiation, BRIEFING ROOM: STATEMENTS & RELEASES (Aug. 29, 2023), *https://www.whitehouse.gov/briefing-room/statements-releases/2023/08/29/fact-sheet-biden-harris-administration-announces-first-ten-drugs-selected-for-Medicare-price-negotiation/*.

[61] Evan D. Gumas, Paige Huffman, Irene Papanicolas, & Reginald D. Williams II, How Prices for the First 10 Drugs Up for U.S. Medicare Price Negotiations Compare Internationally, Controlling Health Care Costs, THE COMMOWEALTH FUND (Jan. 4, 2024), *https://www.commonwealthfund.org/publications/2024/jan/how-prices-first—10-drugs-Medicare-negotiations-compare-internationally*.

[62] JOHNSON & JOHNSON, FORM 8-K, EXHIBIT 99.2 (Jan. 23, 2024), *https://www.sec.gov/ixviewer/ix.html'doc—/Archives/edgar*.

[63] Stelara Antitrust, HAGENS BERMAN, *https://www.hbsslaw.com/cases/stelara-antitrust* (last visited Feb. 4, 2024).

[64] Id.

[65] DAVID RIND, FOLUSO AGBOOLA, DMITRIY NIKTIN, AVERY MCKENNA, EMILY NHAN, MATT SEIDNER, & STEVEN D. PEARSON, INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW, UNSUPPORTED PRICE INCREASE REPORT: UNSUPPORTED PRICE INCREASES OCCURRING IN 2022 10 (Dec. 11, 2023), UPI—2023—Report—121123.pdf (icer.org).

[66] Id.

[67] HOW MUCH SHOULD I EXPECT TO PAY FOR XARELTO?, *https://www.xarelto-us.com/cost* (last visited Feb. 3, 2024).

tralia, the United Kingdom, France, and Australia[68] Xarelto has been selected for the first round of Medicare price negotiation, and between June 2022 and May 2023, Medicare Part D spent over $6 billion on Xarelto, with over $600 in out-of-pocket costs per year for enrollees who did not receive the low-income subsidy.[69]

Johnson & Johnson benefits from the unfair patenting practices of another company to prolong its exclusive authority to price and sell Xarelto in the United States. Johnson & Johnson licenses Xarelto from Bayer AG, a German company that owns the patents in the drug.[70] Johnson & Johnson received FDA approval for Xarelto in 2011,[71] and the patent protection for two of three patents listed for the drug in the Orange Book expire in 2025.[72] But the protection of a third patent covering the 10 mg, 15 mg, and 20-mg tablets of the drug expires in 2034.[73] Bayer AG describes that the patents covering the active ingredient of Xarelto in the U.S. expire in 2025.[74] Thus, the secondary patent expiring in 2034 for the drug prolongs Johnson & Johnson's monopolistic pricing power over these Xarelto tablets by almost a decade in excess of the protection afforded by the primary patents. This secondary patent appears to be a significant barrier to generic entry, as Johnson & Johnson and Bayer are relying solely on this patent's claims in lawsuits seeking to prevent at least three, and likely more, manufacturers from selling generics of the 10, 15 and 20-mg doses of Xarelto.[75]

While the earlier patents cover the active ingredient, its combination with other substances to form the drug, the process of preparing the drug, a solid oral version of the drug, and its use for preventing or treating cardiovascular issues, the primary marginal benefit claimed by the later-expiring patent appears to be its protection over a once-daily tablet version of the drug.[76] Bayer itself states in its annual corporate statements that the patent covering 10, 15, and 20-mg once-daily tablets in Europe is set to expire in 2026.[77] If this patent survives litigation in the U.S., it will likely be another instance in which Americans are uniquely deprived of more affordable generic medications.

Imbruvica

Imbruvica was priced at over $180,000 in 2021, nearly double its launch price in 2013.[78] The net price of the drug is higher than in Switzerland, Germany, the United Kingdom, France, Canada, Japan, and Australia.[79] Excluding Switzerland, Imbruvica is priced two to four times more in the U.S. compared to these high-income nations.[80] In 2023, Johnson & Johnson made $3.26 billion in sales from the drug, with over $1 billion coming from U.S. patients.[81] Additionally, the drug has

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[68] Evan D. Gumas, Paige Huffman, Irene Papanicolas, & Reginald D. Williams II, How Prices for the First 10 Drugs Up for U.S. Medicare Price Negotiations Compare Internationally, Controlling Health Care Costs, THE COMMOWEALTH FUND (Jan. 4, 2024), *https://www.commonwealthfund.org/publications/2024/jan/how-prices-first—10-drugs-Medicare-negotiations-compare-internationally*.

[69] The White House, FACT SHEET: Biden-.Harris Administration Announces First Ten Drugs Selected for Medicare Price Negotiation, BRIEFING ROOM: STATEMENTS & RELEASES (Aug. 29, 2023), *https://www.whitehouse.gov/briefing-room/statements-releases/2023/08/29/fact-sheet-biden-harris-administration-announces-first-ten-drugs-selected-for-Medicare-price-negotiation/*.

[70] BAYER ANNUAL REPORT 2022 65 (2023), *https://www.bayer.com/sites/default/files/2023—02/Bayer-Annual-Report—2022.pdf*.

[71] Xarelto (rivaroxaban) 10 mg immediate release Tablets, DRUG APPROVAL PACKAGE, *https://www.accessdata.fda.gov/drugsatfda—docs/nda/2011/022406Orig1s000TOC.cfm* (last visited Jan. 29, 2024).

[72] Product Details for NDA 022406, Orange Book: Approved Drug Products With Therapeutic Equivalence Evaluations, *https://www.accessdata.fda.gov/scripts/cder/ob/results—product.cfm'Appl—Type=N&Appl—No—022406* (last visited Jan. 29, 2024).

[73] Id.

[74] Bayer Annual Report 2022 65 (2023), *https://www.bayer.com/sites/default/files/2023—02/Bayer-Annual-Report—2022.pdf*.

[75] JOhnson & Johnson, Form 10-K For The Fiscal Year Ended January 1, 2023, at 91–92, *https://www.sec.gov/ixviewer/ix.html'doc=/Archives/edgar/*. The patent's claims are likely barring the entry of even more generic manufacturers according to a more recent SEC filing. See Johnson & Johnson, Form 10-Q For The Quarterly Period Ended October 1, 2023, at 35, *https://www.sec.gov/ixviewer/ix.html'doc=/Archives/edgar/*

[76] Compare U.S. Patent No. U.S. 9,539,218 with U.S. 7,157,456 & U.S. 9.415,053.

[77] BAYER ANNUAL REPORT 2022 65 (2023), *https://www.bayer.com/sites/default/files/2023—02/Bayer-Annual-Report—2022.pdf*.

[78] U.S. House Of Representatives' Committee On Oversight & Reform, Staff Report: Drug Pricing Investigation: Abbvie—Humira And Imbruvica 3 (May 2021).

[79] Id.

[80] Id.

[81] Johnson & Johnson, FORM 8-K, EXHIBIT 99.2 (Jan. 23, 2024), *https://www.sec.gov/ixviewer/ix.html'doc=/Archives/edgar/*.

been selected for the first round of Medicare price negotiation, and Medicare Part D spent over 2.6 billion on the drug between June 2022 and May 2023.[82] Imbruvica exacted the highest financial toll on Medicare enrollees of the drugs selected for Medicare price negotiation, with an average annual out-of-pocket cost of $6,497 per enrollee who did not receive the low-income subsidy.[83] The price of Imbruvica is even more unreasonable in light of the preclinical research support from government and nonprofit sources that led to the drug's development and FDA approval, as described by Knowledge Ecology International.[84]

Like Xarelto, Johnson & Johnson profits from patent abuses on Imbruvica committed by its collaborator, AbbVie. There is a massive patent thicket depriving U.S. patients of more affordable alternatives of the drug, with 88 patents granted to date.[85] The House Oversight & Reform Committee reported that the initial patent in Imbruvica's active ingredient was filed in 2006 and was expected to expire in 2026.[86] Citing I-MAK, the Committee detailed how a "drip——feed" patent strategy was employed to prolong monopoly power over Imbruvica.[87] Under this strategy, multiple additional patents were filed covering aspects of Imbruvica that had already been disclosed in earlier patents but with more pecificity.[88] The sheer number of patents providing protection on the drug is designed to discourage generic competition against the drug. Even then, the Committee reports that nearly a dozen generic manufacturers sought FDA approval of generics, but most entered confidential agreements to delay generic entry until 2032, 6 years after the primary patent was expected to expire.[89]

In sum, Johnson & Johnson price gouges American patients on several critical medicines. Moreover, the unregulated drug pricing power of the company will be unfairly extended by abuses of the United States' patent system.

Bristol Myers Squibb

Bristol Myers Squibb, like Merck and Johnson & Johnson, has engaged in pricing abuses of several drugs to the detriment of American patients, including Breyanzi, a cell therapy for B-cell lymphoma; Pomalyst, which is used to treat multiple myeloma;[90] and Revlimid, which treats the same.[91] This is also true of (1) Abecma, a cell therapy for treating multiple myeloma, that BMS licensed from the company, 2seventy bio, and for which BMS shares profits and losses equally with its commercial partner, and (2) Eliquis, which is a small molecule drug used to prevent and treat blood clots, that BMS developed with Pfizer.[92] Profits and losses are largely shared equally by the companies on a global scale, but BMS "is the principal in the end customer product sales in the U.S., significant countries in Europe, as well as Canada, Australia, China, Japan and South Korea."[93]

Eliquis

Bristol Myers Squibb abuses its monopoly protections to charge Americans over $7,000 for Eliquis while pricing the same drug for just $900 in Canada and just

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[82] The White House, FACT SHEET: Biden-.Harris Administration Announces First Ten Drugs Selected for Medicare Price Negotiation, BRIEFING ROOM: STATEMENTS & RELEASES (Aug. 29, 2023), *https://www.whitehouse.gov/briefing-room/statements-releases/2023/08/29/fact-sheet-biden-harris-administration-announces-first-ten-drugs-selected-for-Medicare-price-negotiation/*.

[83] Assistant Secretary For Planning And Evaluation, Office Of Health Policy, Department Of Health And Human Services, Inflation Reduction Act Research Series—Medicare Enrollees' Use And Out-Of-Pocket Expenditures For Drugs Selected For Negotiation Under The Medicare Drug Price Negotiation Program 5 (Aug. 29, 2023), *https://aspe.hhs.gov/sites/default/files/documents/*.

[84] Arianna Schouten, Notes On The Preclinical Development Of Imbruvica (Ibrutinib) (2023), *https://www.keionline.org/wp-content/uploads/KEI-BN—2023—4.pdf*.

[85] I-MAK, Overpatented, Overpriced: Imbruvica's Patent Wall 2 (July 2020).

[86] Id.

[87] U.S. House Of Representatives' Committee On Oversight & Reform, Staff Report: Drug Pricing Investigation: Abbvie—Humira And Imbruvica 36 (May 2021).

[88] Id.

[89] Id. at 37.

[90] Bristol-Myers Squibb, Form 10-K For The Fiscal Year Ended December 31, 2022, at 2, *https://www.sec.gov/ixviewer/ix.html'doc/Archives/edgar*

[91] Id. at 3.

[92] Assistant Secretary For Health And Planning, Hhs, Inflation Reduction Act Research Series: Eliquis: Medicare Enrollee Use And Spending (Nov. 13, 2023), *https://aspe.hhs.gov/reports/ira-research-series-Medicare-drug-price-negotiation-program*; Bristol-Myers Squibb, Form 10-K For The Fiscal Year Ended December 31, 2022, At 77. *https://www.sec.gov/ixviewer/ix.html-doc/Archives/edgar*.

[93] Id.

$650 in France.[94] Even with rebates, the price of Eliquis is between 35–70 percent lower in the high-income nations of Switzerland, Germany, the United Kingdom, France, Canada, Japan, and Australia.[95] Eliquis was selected for the first round of Medicare price negotiation. Between June 2022 and May 2023, Eliquis was the top spend among the 10 drugs selected for price negotiation, costing Medicare Part D over $16 billion.[96] Medicare enrollees who did not receive the low-income subsidy paid over $600 in annual out-of-pocket costs just for this one drug.[97]

Bristol Myers Squibb has sought to extend its monopoly protections over Eliquis using unjust patenting practices. Although generics received FDA approval in 2019,[98] none will come to market until 2026, with some alternatives prohibited until 2031 due to patent litigation and settlements.[99] The company's patent for the active ingredient of Eliquis was filed in September 2002, and was set to expire in February 2023.[100] But BMS received an extension of its patent term until November 2026 using a Federal law that can provide extensions for time lost in the premarket government approval process.[101]

On top of its extension on the primary patent, BMS and Pfizer obtained a patent on a pharmaceutical composition with a particular crystalline form of the active ingredient that expires in 2031.[102] In patent litigation, a generic manufacturer argued the claim was obvious because someone would have been motivated to develop the same claim based on what was known at the time. While American courts upheld the patent claim based on a finding that there was no need that would have motivated someone else to pursue this invention, the UK courts invalided the patent.[103] That court argued that it would have been obvious because someone in the field would have arrived at the invention, and if the court believed BMS's argument that there really was no need that would have driven the obvious invention, then the patent would have been invalid for lack of utility.[104] Ultimately, the patent appears

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[94] Bernie Sanders: U.S. Senator for Vermont, PREPARED REMARKS: Sanders Ahead of Vote to Subpoena CEOs to Testify on Outrageously High Prices of Prescription Drugs in America, PRESS RELEASES (Jan. 25, 2024), *https://www.sanders.senate.gov/press-releases/prepared-remarks-sanders-ahead-of-vote-to-subpoena-ceos-to-testify-on-outrageously—high-prices-of-prescription-drugs-in-america/*.

[95] Evan D. Gumas, Paige Huffman, Irene Papanicolas, & Reginald D. Williams II, How Prices for the First 10 Drugs Up for U.S. Medicare Price Negotiations Compare Internationally, Controlling Health Care Costs, THE COMMOWEALTH FUND (Jan. 4, 2024), *https://www.commonwealthfund.org/publications/2024/jan/how-prices-first—10-drugs-Medicare-negotiations-compare-internationally*.

[96] The White House, FACT SHEET: Biden-.Harris Administration Announces First Ten Drugs Selected for Medicare Price Negotiation, BRIEFING ROOM: STATEMENTS & RELEASES (Aug. 29, 2023), *https://www.whitehouse.gov/briefing-room/statements-releases/2023/08/29/fact-sheet-biden-harris-administration-announces-first-ten-drugs-selected-for-Medicare-price-negotiation/*.

[97] ASSISTANT SECRETARY FOR PLANNING AND EVALUATION, OFFICE OF HEALTH POLICY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, INFLATION REDUCTION ACT RESEARCH SERIES—MEDICARE ENROLLEES' USE AND OUT-OF-POCKET EXPENDITURES FOR DRUGS SELECTED FOR NEGOTIATION UNDER THE MEDICARE DRUG PRICE NEGOTIATION PROGRAM 5 (Aug. 29, 2023), *https://aspe.hhs.gov/sites/default/files/documents/9a34d00483a47aee03703bfc565ffee9/ASPE-IRA-Drug-Negotiation-Fact-Sheet—09-13-2023.pdf*.

[98] FDA approves first generics of Eliquis, NEWS RELEASE (Dec. 23, 2019), *https://www.fda.gov/news-events/press-announcements/fda-approves-first-generics-eliquis*.

[99] The Bristol-Myers Squibb-Pfizer Alliance is pleased with the U.S. District Court decision to uphold both the composition of matter (COM) patent (U.S. 6,967,208) and formulation patent (U.S. 9,326,945) covering Eliquis, PRESS RELEASE (Aug. 5, 2020), *https://news.bms.com/news/details/2020/The-Bristol-Myers-Squibb-Pfizer-Alliance-is-pleased-with-the-U.S.-District-Court-decision-to-uphold-both-the-composition-of-matter-COM-patent-U.S.*

[100] U.S. Patent No. U.S. 6,967,208.

[101] Applications for patent term extension and patent terms extended under 35 U.S.C. 156, UNITED STATES PATENT & TRADEMARK OFFICE, *https://www.uspto.gov/patents/laws/patent-term-extension/patent-terms-extended-under—35-usc-156* (last visited Feb. 5, 2024); Patent and Exclusivity for: N202155, ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, *https://www.accessdata.fda.gov/scripts/cder/ob/patent—info.cfm'Product—No—001&Appl—No=202155&Appl—type—N* (last visited Feb. 5, 2024).

[102] U.S Patent No. 9,326,945.

[103] Compare Bristol Myers Squibb Co. v. Aurobindo Pharma U.S. Inc., 477 F. Supp. 3d 306, 356 (D. Del. 2020) with Sandoz Limited & Teva Pharmaceutical Industries Limited v. Bristol Myers-Squibb Holdings Ireland Unlimited Company & Pfizer Inc., [2022] EWHC 1831 (Pat) (Mead, J.) at 48.

[104] Compare Bristol Myers Squibb Co. v. Aurobindo Pharma U.S. Inc., 477 F. Supp. 3d 306, 356 (D. Del. 2020) with Sandoz Limited & Teva Pharmaceutical Industries Limited v. Bristol Myers-Squibb Holdings Ireland Unlimited Company & Pfizer Inc., [2022] EWHC 1831 (Pat) (Mead, J.) at 48.

to have marginal value given that it was not addressed to a particular issue at the time, but the consequences of 5 years of additional monopoly power over the drug will be enormous. American patients will continue to face hundreds of dollars in out-of-pocket costs and the coffers of public programs will be stretched in the absence of lower cost generics.

Abecma & Breyanzi

The list prices of Bristol Myers Squibb's cell therapies, Abecma and Breyanzi, were $419,500 and $410,300 before BMS hiked the price of Abecma by almost $38,000 and Breyanzi by almost $37,000 in 2023; these spikes were among the nine highest list price increases of that year.[105] The therapies reached a combined $836 million in sales in 2023, with nearly 80 percent of the sales deriving from American patients.[106]

Pomalyst & Revlimid

In 2022, Bristol Myers Squibb hiked the price of its drugs for treating multiple myeloma. It hiked the wholesale acquisition price of Pomalyst by over $4,000, increasing its price to $94,845 for 100 capsules. The company also hiked the price of Revlimid by over $3,500, increasing its price for 100 capsules to $83,322.[107] These price hikes were among the nine highest for 2022 in terms of total dollar amount. In 2023, Revlimid made BMS over $6 billion in sales, of which over $5 billion was earned from the U.S. market.[108] That same year, Pomalyst's sales were $3.4 billion, of which $2.36 billion was earned from U.S. patients.[109]

Thus, Bristol Myers Squibb's pricing practices are yet another example of how drug corporations price gouge American patients. Further, Bristol Myers Squibb engages in patenting practices of marginal value that appear to be widespread in the pharmaceutical industry to extend monopoly control over drug prices and unfairly deprive U.S. patients of lower cost generics.

III. These Companies Spend Billions on Self-Enriching Activities, Often in Excess of Research and Development Expenses

All three companies have alleged that the Medicare price negotiation provisions of the Inflation Reduction Act would detract from the innovation of new life-saving medicines and sued to invalidate these measures.[110] But there is a wealth of evidence that contradicts claims that drug price regulation will impact the innovation of new medicines. First, experts, and even the Congressional Budget Office, conclude there is no connection between a drug's research and development cost and its future price.[111] Rather, the current price of drugs reflects the maximum that compa-

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[105] ASSISTANT SECRETARY FOR PLANNING AND EVALUATION, OFFICE OF HEALTH POLICY, HHS, ISSUE BRIEF: CHANGES IN THE LIST PRICES OF PRESCRIPTION DRUGS, 2017–2023 (Oct. 6, 2023), aspe-drug-price-tracking-brief.pdf (hhs.gov). Due to the opacity of drug pricing, it is difficult to discern the financial burden of this drug on the average patient. According to one source from 2021, a single dose of Abecma cost $419,500. See Eric Sagonowsky, Bristol's new myeloma CAR-T needs a hefty discount to be cost-effective, watchdogs say while endorsing GSK's Blenrep, FIERCE PHARMA (Apr. 7, 2021), *https://www.fiercepharma.com/pharma/bristol-s-new-myeloma-car-t-needs-a-big-discount-to-be-cost-effective-watchdogs-say-while*.

[106] BRISTOL MYERS SQUIBB, FORM 8-K, EXHIBIT 99.1 (Feb. 2, 2024), *https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar*.

[107] ASSISTANT SECRETARY FOR PLANNING AND EVALUATION, OFFICE OF HEALTH POLICY, HHS, ISSUE BRIEF: PRICE INCREASES FOR PRESCRIPTION DRUGS, 2016–2022, 2017–2023 (Sept. 30, 2023), Price Increases for Prescription Drugs, 2016–2022 (hhs.gov). Due to the lack of drug pricing transparency, it is difficult to determine the price for end users of the drug.

[108] BRISTOL MYERS SQUIBB, FORM 8-K, EXHIBIT 99.1 (Feb. 2, 2024), *https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/*

[109] Id.

[110] Complaint, Janssen Pharmaceutical Inc. v. Beccera et al., No. 3:23-cv–03818, para. 40. (D. N.J. July 18, 2023); The Inflation Reduction Act's Negative Impact on Patient-Focused Innovation, Value and Access, MERCK: COMPANY STATEMENT (June 6, 2023), *https://www.merck.com/news/the-inflation-reduction-acts-negative-impact-on-patient-focused-innovation-value-and-access/*; Impact of the inflation reduction act on innovative medicines for patients, BRISTOL MYERS SQUIBB (June 16, 2023), *https://www.bms.com/impact-of-the-inflation-reduction-act-on-innovative-medicines-for-patients.html*; Kevin Dunleavy, Johnson & Johnson becomes 4th drugmaker to file suit against IRA's drug price negotiations, FIERCE PHARMA (July 18, 2023), *https://www.fiercepharma.com/pharma/johnson-johnson-becomes—4th-big-pharma-file-suit-against-ira-drug-price-negotiations*.

[111] CONGRESSIONAL BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY (Aug. 2021) ("In CBO's assessment, current R&D spending

Continued

nies believe healthcare payers will pay for monopolized drugs with few if any adequate therapeutic alternatives.[112] More specifically, the Congressional Budget Office found that only 13 fewer drugs out of 1,300 (1 percent) would come to market over the next 30 years as a result of the Inflation Reduction Act.[113] Second, compared to the rest of the globe, the United States is an outlier that does little to protect its residents from the unfair pricing power of drug companies,[114] and bringing American policy into alignment with those of other countries, including other high-income peers, will not destroy the incentive to innovate new medicines. Finally, drug corporations spend in excess on executive compensation, share buybacks, and dividends which enrich their shareholders, cutting against the industry's mistaken impression that it is strapped for resources to research and develop new medicines.[115] For example, in just 2022, the manufacturers of the drugs selected for Medicare price negotiation spent $10 billion more on these self-enriching activities than research and development.[116]

Stock buybacks enrich investors by reducing the number of outstanding shares in a company. The fewer shares there are in investors' hands, the more each share is worth. When a company buys back and cancels 10 percent of its shares, that makes each share still held by an investor or insider rise in value, as it represents a greater claim on the company's earnings. Spending money this way allows companies to enrich shareholders silently, as well as the executives often paid in stock.[117] Stock buybacks are particularly problematic as they have historically increased stock value without raising taxable income, can provide a mistaken impression about the economic health of a company, and detract from more worthwhile investments in a company's own workers and productive capacity, such as research and development efforts. Dividends are another way of returning cash to investors. Each fiscal quarter, publicly traded companies typically issue fixed dividends to shareholders that rise when business is good and shrink or get suspended when business is bad.[118]

Looking at these self-enriching activities, Johnson & Johnson spent nearly $12 billion on dividends to shareholders, over $6 billion on stock buybacks, and $45 million on executive compensation in just the year 2022. In total, Johnson & Johnson spent nearly $18 billion on these self-enriching activities compared to $15 billion on research and development.[119] Similarly, Bristol Myers Squibb spent over $8 billion on stock buybacks, nearly $5 billion on dividends, and 48 million on executive compensation.[120] The company spent approximately $3 billion more on these self-enriching activities compared to research and development in 2022.[121] If we examine these spending patterns from 2012–2021, Johnson & Johnson spent $43 billion more

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does not influence the future prices of the drugs that result from that spending."); Aaron Kesselheim, Jerry Avorn, & Ameet Sarpatwari, The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform, 316 JAMA NETWORK 858 (2016); Vinay Prasad, Kevin De Jesus, Sham Mailankody, The high price of anticancer drugs: origins, implications, barriers, solutions, 14 NAT. REV. CLIN. ONC. 381 (2016).

[112] Aaron Kesselheim, Jerry Avorn, & Ameet Sarpatwari, The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform, 316 JAMA NETWORK 858 (2016).

[113] CONGRESSIONAL BUDGET OFFICE, ESTIMATED BUDGETARY EFFECTS OF PUBLIC LAW 117–169 (Sept. 7, 2022), *https://www.cbo.gov/system/files/2022—909/PL117—169—9—7—22.pdf*.

[114] Amy Kapczynski, The Political Economy of Market Power in Pharmaceuticals, 48 J. HEALTH POL., POL'Y & L. 215 (2023); S. Vincent Rajkumar, The high cost of prescription drugs: causes and solutions, 10 BLOOD & CANCER J. 381 (2020).

[115] Amy Kapczynski, The Political Economy of Market Power in Pharmaceuticals, 48 J. HEALTH POL., POL'Y & L. 215, 230 (2023) (citing Aaron Kesselheim & Jeffrey Avorn, Letting the Government Negotiate Drug Prices Won't Hurt Innovation, WASH. POST (Sept. 27, 2021), *https://www.washingtonpost.com/outlook/2021/09/22/drug-pricing-negotiation-biden-bill/*); U.S. HOUSE OF REPRESENTATIVES' COMMITTEE ON OVERSIGHT & REFORM, DRUG PRICING INVESTIGATION: INDUSTRY SPENDING ON BUYBACKS, DIVIDENDS, & EXECUTIVE COMPENSATION (July 2021).

[116] JISHIAN RAVINTHIRAN, PUBLIC CITIZEN & PROTECT OUR CARE, PROFITS OVER PATIENTS: SPENDING ON SELF-ENRICHMENT EXCEEDS RESEARCH AND DEVELOPMENT COSTS FOR MANY MANUFACTURERS OF IRA DRUGS (Jan. 18, 2024).

[117] PUBLIC CITIZEN, BAILOUT WATCH, FRIENDS OF THE EARTH, BIG OIL'S WARTIME BONUS 2 (2022).

[118] Id. at 8.

[119] JISHIAN RAVINTHIRAN, PUBLIC CITIZEN & PROTECT OUR CARE, PROFITS OVER PATIENTS: SPENDING ON SELF-ENRICHMENT EXCEEDS RESEARCH AND DEVELOPMENT COSTS FOR MANY MANUFACTURERS OF IRA DRUGS (Jan. 18, 2024).

[120] Id.

[121] Id.

on stock buybacks and dividends than research and development.[122] Similarly, Merck's spending on stock buybacks and dividends over this period exceeded its research and development costs by $3 billion.[123]

In sum, the spending patterns of all three companies belies their impression to the public that their profits are re-invested in research and development capacities; instead, they reallocate their profits mostly to the benefit of their shareholders and executives. As such, there is no necessary relationship between providing drug pricing relief for millions and harming resources for innovating new medicines.

Conclusion

Supermajorities of Americans want decisive government action to rein in the price gouging tactics of the pharmaceutical industry. And though most drug corporations have been happy to benefit from an array of government policies that have expanded their monopoly power over drugs to the detriment of patients, many now fiercely resist any efforts to deliver material drug pricing relief to millions of Americans. The drug pricing tactics of Johnson & Johnson, Merck, and Bristol Myers Squibb are representative of the broader exploitative practices endemic to the pharmaceutical industry. They use their monopoly control to price life-saving medicines excessively, and either pursue, or benefit from, additional patents of marginal value to extend their power to exorbitantly price drugs. This profiteering demands greater action from the Biden administration and Congress, which would not tangibly impact the innovation of new life-saving medicines.

[SUMMARY STATEMENT OF PETER MAYBARDUK]

Chairman Sanders, Ranking Member Cassidy and Members of the Committee.

Thank you for the opportunity to testify today on the high prices Americans pay for prescription drugs. Public Citizen is a national public interest organization with more than 500,000 members and supporters. For 50 years, we have advocated for stronger health, safety and consumer protections; for corporate and government accountability; and for affordable access to medicines.

Drug prices are high because of monopoly power, leading to treatment rationing and preventable suffering. Three in 10 Americans have not taken their medications as prescribed due to costs. Americans confront the highest drug prices in the world, paying nearly three times more for the same drugs than other countries. In 2020, for the 20 top-selling drugs worldwide, drug corporations made far more from U.S. sales than sales to all other countries combined ($101 billion to $57 billion). Drug pricing abuses drain the coffers of health programs. Of $400 billion spent on retail prescription drugs in 2022, $135 billion came from Medicare and $45 billion from Medicaid.

This pricing disparity is even more egregious considering taxpayer funded contributions to drug development. The world's largest biomedical research funder is a public funder, the National Institutes of Health, contributing more than $45 billion a year and laying groundwork for many if not most new medicines.

Our government grants patent protection and exclusivities on medicines. In theory, this should support innovation. In practice, drug corporations too often are writing the rules to extract maximum rents from taxpayers. In 2022; the manufacturers of the ten drugs selected for Medicare price negotiation spent $10 billion more on self-enriching activities—stock buybacks, dividends and CEO compensation—than on R&D. Drugmakers do not set prices according to R&D costs. The price of a patented drug is the most that we, as a society, are willing to pay to care for our sick and loved ones, where monopoly power blocks affordable alternatives and we have little choice.

Drugmakers extend their exclusive power over new drugs through anticompetitive tactics. Many have abused the patent system to obtain subsequent patents over the same medicine with marginal differences, sometimes for decades.13 The pharmaceutical industry has accrued tremendous influence in our political system, outranking every other industry in lobbying spending.

Today, perhaps for the first time, our Country is making progress challenging high prices and treatment rationing, including through price negotiations and coun-

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[122] WILLIAM LAZONICK & NER TULUM, INSTITUTE FOR NEW ECONOMIC THINKING, SICK WITH "SHAREHOLDER VALUE": U.S. PHARMA'S FINANCIALIZED BUSINESS MODEL DURING THE PANDEMIC (Dec. 6, 2022).

[123] Id.

tering price spikes, among other measures. We commend the Committee's attention to this problem. Far more is necessary.

Ultimately, we will have to confront monopoly power. That is the foundation allowing drugmakers to project influence, game the law and keep prices high. Other real challenges in medicine pricing and access, including secrecy, cost caps, patient assistance, and middlemen taking advantage, flow inexorably from the lucrative patent monopolies that make it so possible and so easy to rip off taxpayers. Thank you for your time, and please count us with you in the fight.

The CHAIR. Thank you. Our next witness will be Tahir Amin, CEO, Initiative for Medicines Access and Knowledge, a nonprofit organization working to address inequalities in how medicines are developed and distributed. Thanks very much for being with us.

STATEMENT OF TAHIR AMIN, LL.B., CHIEF EXECUTIVE OFFICER, INITIATIVE FOR MEDICINES, ACCESS & KNOWLEDGE, NEW YORK, NY

Mr. AMIN. Chairman Sanders, Ranking Member Cassidy, and Members of the Committee, it is my honor to be invited here to share with you a root cause of why the U.S. pays by far the highest prices in the world for prescription drugs. That root cause is how the pharmaceutical industry manipulates the patent system to lengthen patent protection and its market monopoly in order to block competition, all while increasing prices.

I qualify as a UK attorney in intellectual property, and I have been in the field for 30 years. I spent my first decade of my legal career practicing as an attorney at international law firms and for multinational companies, including American companies.

Through this work, I learned both the legal and business side of intellectual property and its importance to inventors, investors, and companies. I also learned how to use loopholes to game the system.

These loopholes enabled me to invent intellectual property rights so companies could obtain and maintain a monopoly in the market, while continuing to extract maximum profits. It was the reason why I co-founded IMAK and left the commercial world. America is in a severe drug pricing crisis.

More than one-third of Americans say they are not able to fill a prescription for medication because of its cost. Black Americans are most heavily impacted, as they are more likely to require medication for chronic conditions and earn less.

Now, prescription drug spending on retail and non-retail drugs is poised to grow 63 percent this decade to $917 billion, and branded prescription drugs, which are under patent protection, account for 84 percent of that spending.

These price hikes correspond with a dramatic increase in patenting activity in the pharmaceutical sector. Now, we have analyzed the top 10 selling drugs in the United States, and we have found a total of 1,429 patent applications have been filed as of 2022.

741 patents have been granted on these drugs. On average, that is, more than 140 patent applications filed per drug, and 74 patents granted per drug. That is 66 percent of those patents are filed after the drug is approved by the FDA.

Now, if we look at some of the drugs that are on the discussion today with the companies that were here, KEYTRUDA, Merck's ELIQUIS, STELARA, Johnson & Johnson, also IMBRUVICA, which is AbbVie, Johnson & Johnson.

Between them, there is a combined of 494 patent applications filed on them, of which 235 were granted patents. I just want to dig a little bit deeper into Merck and particularly Senate Lujàn's questioning of whether Merck would sort of allow biosimilar competition once the primary patent expires.

You have to remember, KEYTRUDA actually represents 47 percent of Merck's total pharmaceutical revenue. Now, as of June 2002, we have counted 180 patent applications, of which 78 are granted. They have patent protection at least until 2039, which is in total 37 years of patent protection since they filed their first patent, which is 2002. You are supposed to get a patent for 20 years, remember.

Market and media analysts a current reporting that we should see biosimilar competition in 2028, to Senator Lujàn's question. I put myself on record here today, we will not see biosimilar competition until 2034.

They will litigate the hell out of it, and they will use every cent that they can to kind of not leave $100 billion on the table, which is what those patents are worth to them.

All this talk of R&D and new indications, these patents are already disclosing the earlier patents that should be expiring in 2024. Bristol-Myers Squibb, same problem. Bristol-Myers has actually increased the price of ELIQUIS by 124 percent since its induction in 2012.

That is higher than the general rate of inflation. They have filed more patents here in the United States, 2.4 more times than in Europe. In fact, the patents that the CEO from BMX was talking about, the relevant patents, those were actually invalidated in Europe and that is why we have generic competition in Europe.

But those patents are actually preventing competition here in the United States and it is going to cost us $48 billion in branded ELIQUIS. So, this Committee should recognize that the use of patent thickets to extend the market monopoly period on a product is not a case of a few bad actors, it is endemic.

If you want to get to the heart of the problem, the first and most important thing Congress can do is solve the problem, is raise the bar for what classifies as an invention that deserves a patent. It is an enormous monopoly power that should—in the single hands of a drug maker, and we shouldn't leave it to the market and litigation to resolve these issues.

The patenting activity goes well beyond the time limits in monopoly that the Constitution required. Lawyers, exploit sophisticated legal marketing Jedi tricks that they use under the guise of innovation.

We need to actually not get sidetracked by this innovation talk. Most of these patents are tweaks deliberately for the financialization of profits, and that is what the pharmaceutical in-

dustry does today. I have been in the business, and I know what it is about. Thank you.

[The prepared statement of Mr. Amin follows.]

PREPARED STATEMENT OF TAHIR AMIN

Chairman Sanders, Ranking Member Cassidy, and Members of the Committee. It is my honor to be invited here to share with you a root cause of why the U.S. pays, by far, the highest prices in the world for prescriptions drugs. That root cause is how the pharmaceutical industry manipulates the patent system to lengthen patent protection and its market monopoly in order to block competition, all while increasing prices.

I. Introduction and Background

My name is Tahir Amin. I am a Founder and Chief Executive Officer of the Initiative for Medicines, Access & Knowledge, also known as I-MAK, a non-profit organization working to address structural inequities in how medicines are developed and distributed. We do not accept funding from branded or generic pharmaceutical companies.

I qualified as a UK attorney and have nearly 30 years of experience in the field of intellectual property. I have experience working with the intellectual property and patent systems of several countries in the world, including the U.S., both at the practice and policy level.

I spent the first decade of my legal career practicing as an attorney at international law firms and multinational companies securing and protecting intellectual property. Many of my clients were American companies, as was one of my employers during this time. Through this work, I learned both the legal and business side of intellectual property and its importance to inventors, investors and companies. I also learned how to use loopholes to game the system. These loopholes enabled me to "invent" intellectual property rights so companies could obtain and maintain a monopoly in the market, while continuing to extract maximum profits.

After a decade in private practice seeing how intellectual property rights—and especially patents—are often misused for commercial gain, I co-founded I-MAK to help restore integrity and to the patent system. For the past 15 years, I have worked alongside patients and advocates to remove unmerited patent rights that stand in the way of generic and biosimilar competition and keep life-saving medicines out of reach of the patients who need them.

I speak to you today as someone who has seen both sides of this issue.

II. The Link Between Patents and Drug Prices

America is in a drug pricing crisis. More than one-third of Americans say they have not filled a prescription for medication because of its cost.[1] Black Americans are most heavily impacted as they are more likely to require medication for chronic conditions, such as high blood pressure or diabetes, while having median incomes of nearly $30,000 less than white households.[2]

Prescription drug spending on retail and non-retail drugs is poised to grow 63 percent this decade, reaching $917 billion dollars.[3] This increase is fueled by spending on patent-protected branded drugs. While branded drugs make up just 8 percent of prescriptions versus 92 percent for generics, they account for 84 percent of all drug spending in the U.S. [4] Even after adjusting for general inflation, U.S. prescription drug spending increased by 76 percent from 2000 to 2017.

These price hikes correspond with a dramatic increase in patenting activity in the pharmaceutical sector.

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[1] YouGov, More than one-third of Americans have not filled a prescription because of cost, 10 March 2023, available at *https://today.yougov.com/health/articles/45388-americans-have-not-filled-prescription-price-poll*

[2] Protect Our Care, How High Drug Prices Hurt Black Americans, July 2021 available at *https://www.protectourcare.org/wp-content/uploads/2021/07/POC-Report-How-High-Drug-Prices-Hurt-Black—Americans—.pdf*

[3] Charles Roehrig and Ani Turner, Projections of the Non-Retail Prescription Drug Share of National Health Expenditures Report, Altarum, July 2022.

[4] The Use of Medicines in the U.S. 2022, The IQVIA Institute, 21 April 2022

It took 155 years for the USPTO to issue its first five million patents in 1991.[5] It has taken less than one fifth of that time for the USPTO to issue its next 6 million. This would suggest that over half of all inventions in the history of the U.S. patent system occurred in the last 30 years. But have we really become more inventive in the last 30 years, or have we just become better at "inventing" patents because our patent system is no longer stringent enough?

A similar picture emerges when we drill down into pharmaceutical patents specifically. The number of pharmaceutical patents granted in the U.S. more than doubled between 2005 (1,580 patents) and 2015 (3,742 patents).[6] But nearly 80 percent of the drugs—products based on small molecules—associated with new patents during this time were not for new drugs, but for existing ones.[7]

Our analysis for the top 10 selling drugs in the U.S. in 2021 alone revealed[8]:

- A total of 1,429 patent applications have been filed as of 2022;
- 741 patents have been granted on these drugs in total;
- On average, that is more than 140 patent applications filed per drug, and 74 patents granted per drug.
- On average, 66 percent of patents filed on these drugs are after the first approval for marketing by the U.S. Food and Drug Administration (FDA).
- On average 55 percent of the granted patents for these drugs were filed after FDA approval.
- Over four times as many patents were granted on these top 10 selling drugs in 2021 when compared to Europe.
- Keytruda (Merck), Eliquis (Bristol-Myers Squibb (BMS)/Pfizer), Stelara (Johnson & Johnson) and Imbruvica (AbbVie/Johnson & Johnson) were 4 of the top selling drugs in 2021. As of June 2022, these four drugs alone have had at least 494 patent applications filed on them, of which 235 were granted patents.
- Most of the patent applications (305) for these four drugs were filed after FDA approval.

A closer look at some of these best-selling drugs reveals the following.

Keytruda (Merck)

Merck's Keytruda belongs to a class of drugs known as immune checkpoint inhibitors used for cancer immunotherapy. It was first approved in September 2014. At the last count in July 2023, it has received an additional 35 FDA approvals across 16 different types of cancer.

Keytruda is projected to become the best-selling drug ever, taking over AbbVie's Humira. Its worldwide sales are forecasted to be $27.19 billion in 2024. In 2023, global sales for Keytruda were $25 billion, with $15 billion in the U.S. alone. Keytruda represented 47 percent of Merck's total pharmaceutical revenue in 2023.

As of June 2022, there are at least 180 patent applications and 78 granted patents covering Keytruda and its various indications. 61 percent of the 180 patent applications were filed after the first FDA approval for Keytruda in 2014.[9]

The first patent filed in relation to Keytruda was 2002. Based on our findings, the latest expiring patent for Keytruda will be in 2039, which will be 11 years after the key patents covering the drug are set expire (2028). In total, Merck currently has 37 years of patent protection for Keytruda (it is worth noting that patents are granted for 20 years for an invention). This protection includes

Market and media analysts are currently reporting that we could see biosimilar competition for Keytruda when the key patents on the drug expire in 2028 (often referred to as the patent cliff). Given the patent thicket that Merck has accumulated around Keytruda, I think that is wishful thinking. If we have learned any lessons from how AbbVie was able to extend its market monopoly on Humira for an addi-

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[5] *https://10millionpatents.uspto.gov/*

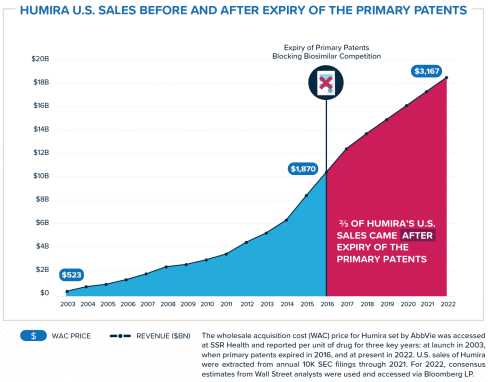
[6] Report—S&E indicators 2018—NSF—national science foundation. Science & Engineering Indicators 2018 Report. Accessed Oct. 31, 2023. *https://www.nsf.gov/statistics/2018/nsb20181/report/sections/invention-knowledge-transfer-and-innovation/invention—united-states-and-comparative-global-trends—uspto-patenting-activity*

[7] R Feldman. May your drug prices be evergreen. Journal of Law and the Biosciences, Volume 5, Issue 3, December 2018, Pages 590—647, *https://doi.org/10.1093/jlb/lsy022*

[8] I-MAK, Overpatented, Overpriced, September 2022 available at *https://www.i-mak.org/overpatented/* and *https://drugpatentbook.i—mak.org/*

[9] *https://drugpatentbook.i-mak.org/*

tional 7 years beyond its key patent and generate $102 billion in revenue alone in that period (which included continued price increases) because of its patent thicketing strategy (see Figure below [10]), then we can expect Merck to do the same. Based on an analysis of all Keytruda's patents, after all the patent litigation and settlements are done, we will be fortunate if we see biosimilars for Keytruda enter before 2034—roughly 6 years after the key patents expire. I also predict, as AbbVie did with Humira, that Merck will continue to increase prices for its branded Keytruda during the additional market monopoly period because of its extended patent protection. I do not see Merck leaving some $100 billion plus on the table, they will use whatever patents they have to litigate for every cent of it.



Imbruvica (AbbVie/Johnson & Johnson)

Imbruvica is a drug used to treat a variety of B cell cancers, including leukemia and lymphoma. It was first approved in 2013 and is approved by the FDA for several different indications.

The price of Imbruvica has increased by 108 percent in the U.S. since it was introduced in 2013, compared to a 30 percent general inflation increase in the same period. [11] Imbruvica's list price has increased nearly 32 percent in the U.S. in the past 5 years, from $431 in 2019 to $567 per capsule (70mg).

As of June 2022, AbbVie has filed 195 patent applications, of which 96 have been granted to date. That roughly works out to over one patent filed every month for the last 14 years. Over half of these patent applications were filed after Imbruvica received its first FDA approval. Currently, granted patents for Imbruvica give AbbVie patent protection for 29 years, until 2036—nine additional years beyond its original 20 years of patent protection.

Despite generic companies litigating AbbVie's patents, we have already seen six companies enter into patent settlement agreements. As a result of these agreements, competitors will delay introduction of generic versions of Imbruvica until 2032 and 2033. These 5 additional years of market monopoly because of extended patent protection could help AbbVie and Johnson & Johnson secure over $7 billion dollars in revenue.

Eliquis (Bristol Myers Squibb (BMS)/Pfizer)

Eliquis is an anticoagulant medication used to treat and prevent blood clots.

Sales for Eliquis in the U.S. increased by 10 percent to $8.6 billion in 2023. Eliquis accounts for 27 percent of BMS's sales in the U.S. The price of Eliquis has increased by 124 percent since its introduction in 2012 as compared to 31 percent general inflation increase during the same period. [12] In January this year, the list

[10] I-MAK, Overpatented, Overpriced, September 2022
[11] Noah Tong, Here are 25 Medicare Part D drugs that have skyrocketed in Price, Fierce Healthcare, 10 August 2023, available at *https://www.fiercehealthcare.com/payers/here-are-25-Medicare-part-d-drugs-have-skyrocketed-price*
[12] Ibid

price for Eliquis increased by 6 percent from the year before. This increase outpaced inflation and the annual price increases of the top 50 best selling drugs.

As of June 2022, BMS/Pfizer have filed at least 43 patent applications for the drug, of which 22 are granted. Sixteen of these patent applications were filed after FDA approval. There are 2.4 times more granted patents in the U.S. than in Europe. Generic versions of Eliquis entered some European countries in 2022 after several patents that would have extended the market monopoly period were found invalid.[13] However, in the U.S. these same patents were held valid after litigation and generic versions are not expected to enter until 2028. As a result of extended patent protection, generic versions will have entered Europe almost 6 years earlier than in the U.S. By our estimate, BMS/Pfizer will make $48 billion in revenue during this extended market monopoly period.[14]

III. Solutions to the Patent and Drug Pricing Problem

This Committee should recognize that the use of patent thickets to extend the market monopoly period on a product is not a case of a few bad actors. This is an endemic problem across the pharmaceutical industry.

If we want to get to the heart of addressing our National drug pricing crisis, the first and most important thing Congress can do to solve this problem is raise the bar for what gets patented. Over the last 30 years, more and more patents have been sought and granted for things that are not new inventions given what we know in the pharmaceutical sciences today.

For example, no reasonable researcher would call combining two existing drugs or switching dosages novel science by today's standards. And yet, drugmakers regularly get 20 years of patent protection for this commonly practiced knowledge.

In 1962, Senator Estes Kefauver of Tennessee said:

"If you want to tweak a drug, and you want to get another patent on it, the modified version has to be significantly better, therapeutically, for patients."[15]

A patent puts enormous monopoly power into the hands of a single drugmaker. That power should only be granted if the invention is original and materially better than what already exists. We cannot rely on the market and litigation to resolve these problems; they need to be addressed before a patent monopoly is granted in the first place.

IV. Conclusion

The Constitution grants Congress the power 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."

But patenting activity today goes well beyond the time limited monopoly intended by the Constitution. Today's patent system has become less an engine for real invention than a tool for companies and their lawyers to exploit using sophisticated legal and marketing Jedi tricks under

This is not an indictment of the pharmaceutical industry. Drugmakers and their armies of patent lawyers—people like me in my former life—are simply doing what the system incentives them to do, and what they are bound by their shareholders and clients to do.

But it is in Congress's power to end this perversion and restore integrity to the patent system. Instead of incentivising investment in minor modifications for the purposes of extending a patent, we need a system that incentives bold research—breakthroughs that are therapeutically better than existing alternatives and fill a real market need, not low-hanging fruit designed to maximize profits. Congress has the ability to return the patent system to what it was always intended to be: not a vehicle for unprecedented profits, but an engine for inventions that are truly original and unprecedented.

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[13] Amy Sandys, Court of Appeal confirms invalidity of Bristol-Myers Squibb apixaban patent, 9 May 2023, available at *https://www.juve-patent.com/cases/court-of-appeal-confirms-invalidity-of-bristol-myers-squibb-apixaban-patent/*

[14] I-MAK, Overpatented, Overpriced, September 2022

[15] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4101807/*

[SUMMARY STATEMENT OF TAHIR AMIN]

A root cause of why the U.S. pays, by far, the highest prices in the world is because of how the pharmaceutical industry manipulates the patent system to lengthen patent protection and its market monopoly.

I. The Link Between Patents and Drug Prices

Keytruda (Merck), Eliquis (Bristol-Myers Squibb (BMS)/Pfizer), Stelara (Johnson & Johnson) and Imbruvica (AbbVie/Johnson & Johnson) were 4 of the top selling drugs in 2021. As of June 2022, these four drugs alone have had at least 494 patent applications filed on them, of which 235 were granted patents. Most of the patent applications (305) for these four drugs were filed after FDA approval.

Keytruda (Merck)

There are at least 180 patent applications and 78 granted patents covering Keytruda and its various indications. 61 percent of the 180 patent applications were filed after the first FDA approval for Keytruda in 2014. Given the patent thicket that Merck has accumulated around Keytruda, we will be fortunate if we see biosimilars for Keytruda enter before 2034—roughly 6 years after the key patents expire (2028). During that extended monopoly period Merck will continue to increase prices and could pocket over $100 billion in sales.

Imbruvica (AbbVie/Johnson & Johnson)

AbbVie has filed 195 patent applications, of which 96 have been granted to date. As a result of patent litigation generic companies have entered settlements and will delay introduction of generic versions of Imbruvica until 2032 and 2033. These 5 additional years of market monopoly because of extended patent protection could help AbbVie and Johnson & Johnson secure over $7 billion dollars in revenue.

Eliquis (Bristol Myers Squibb (BMS)/Pfizer)

BMS/Pfizer have filed at least 43 patent applications for the drug, of which 22 are granted. There are 2.4 times more granted patents in the U.S. than in Europe. Generic versions of Eliquis entered some European countries in 2022 after several patents that would have extended the market monopoly period were found invalid. However, in the U.S. these same patents were held valid. after litigation and generic versions are not expected to enter until 2028. As a result of extended patent protection, generic versions will have entered Europe almost 6 years earlier than in the

U.S. BMS/Pfizer could make $48 billion in revenue during this extended market monopoly period.

II. Solutions to the Patent and Drug Pricing Problem

If we want to get to the heart of addressing our National drug pricing crisis, **the first and most important thing Congress can do to solve this problem is raise the bar for what classifies as an invention that deserves a patent.**

The CHAIR. Thank you very much.

Senator Cassidy.

Senator CASSIDY. Pleasure to introduce our witness, Darius Lakdawalla, currently the Quintiles Chair in Pharmaceutical Development Regulatory Innovation at University of Southern California Mann School of Pharmacy and Pharmaceutical Sciences.

He also serves as Director of Research for the USC Schaeffer Center for Health Policy and Economics, a partnership between the Mann School and the USC Price School of Public Policy.

He received his Ph.D. in economics from the University of Chicago as a renowned researcher and thought leader in health economics and health policy, which obviously impacts us today. Thank you, sir.

STATEMENT OF DARIUS LAKDAWALLA, PH.D., DIRECTOR, RESEARCH, UNIVERSITY OF SOUTHERN CALIFORNIA SCHAEFFER CENTER, LOS ANGELES, CA

Dr. LAKDAWALLA. Thank you. Chairman Sanders, Ranking Member Cassidy, and honorable Members of the Committee, thank you for the opportunity to testify today about drug prices and the assessment of medical technologies.

My name is Darius Lakdawalla. I am an Economist and a Professor at the USC Mann School of Pharmacy and Pharmaceutical Sciences and USC Price School of Public Policy. I am also the Director of Research at the USC Schaeffer Center for Health Policy and Economics. The opinions I offer today are my own and don't represent the views of the University of Southern California or the USC Schaeffer Center.

I would like to start with a story. In December 1984, a young boy from Indiana named Ryan White was diagnosed with AIDS, a result of a transfusion with infected blood. In the immediate wake of his passing in 1990, Congress passed the Ryan White Care Act, ensuring affordable care for HIV/AIDS patients.

The value of this program was fully realized 5 years later, when highly active antiretroviral therapy emerged as a lifesaving treatment for patients with HIV. Today, 9 out of 10 patients receiving care through the Ryan White Program enjoy viral load so low that they are no longer infectious.

Thanks to breakthrough medical innovation and to forward thinking public policy that made innovative HIV therapies affordable to many, HIV positive patients can now expect to live well into their 70's and beyond.

But increasing patient access through bold expansion of affordable care means little when there are no valuable cures or treatments to access, and breakthrough medical therapies provide little value if high cost sharing pushes them out of patients' reach. This is the fundamental tradeoff we are here to address today.

This tradeoff between innovation and affordability has played out in different approaches taken across the globe. There is little doubt that U.S. consumers access newer drugs sooner and more often than their overseas counterparts, and this increased access to the latest treatments matters.

Schaeffer Center research suggests that introducing European style pricing policies would ultimately reduce innovation and cost American consumers just over half a year of life expectancy, about what would be lost if all American surgeons suddenly forgot how to perform heart bypass surgery.

Yet there is no denying the sentiment that U.S. consumers unfairly pay higher drug prices than their peers overseas. The deteriorating accessibility of prescription drugs in recent years threatens to derail the access advantages and health gains American consumers have so far enjoyed and is one component of this growing sentiment.

Even patients with good insurance are struggling to access the therapies their doctors prescribe. Plans frequently employ coinsurance requirements and utilization management tools that severely

restrict access. These changes likely harm health, since the link between increasing out-of-pocket costs and worse patient adherence is well-established.

Surprisingly, coverage has deteriorated even while the average manufacturer net prices of brand drugs, the amount manufacturers receive after rebates and discounts, have declined in each of the last 5 years.

Shaeffer research analyzing the flow of money spent on insulin, found that while net prices fell by 31 percent, total expenditures remained nearly constant because intermediaries were pocketing the additional rebates and price concessions instead of passing them on to consumers.

Transparency and pricing throughout the pharmaceutical distribution system would be a major step toward ensuring that drug prices reflect the actual value provided to patients, and don't simply enrich intermediaries.

Rewarding drugs that do provide value promotes investment in the right kind of therapies and ensures good health will be increasingly within the reach of American patients for generations to come. Decades of economic research demonstrate that where innovators predict higher returns, innovative effort and discovery follow.

Outside the U.S., many countries adopt pricing approaches that either fail to measure value to patients or make it hard to predict future returns to innovation. The UK, Australia, and Canada employ relatively transparent and predictable methods that nonetheless rely on quality adjusted life years, which discriminate against vulnerable patients.

On the other hand, France and Germany avoid qualities and focus on rating clinical benefits in a way that often fails to correspond to the eventual price. These tradeoffs also underscore the risks of so-called reference pricing approaches that would tie American prices to those charged by other countries.

In so doing, Americans would be forced to live with the vagaries of pricing systems designed and implemented elsewhere around priorities that may differ from ours. Ultimately, the right policies for American patients need to focus on the affordability of good health.

Affordable and generous health insurance, transparent and predictable pricing, and an emphasis on value to patients provide the ingredients for a better approach that secures the health of American families now and for generations to come. Thank you very much.

[The prepared statement of Dr. Lakdawalla follows:]

PREPARED STATEMENT OF DARIUS LAKDAWALLA

Key Points:

- The challenge for public policy is to sustain the pace of medical innovation while ensuring that valuable new technologies remain affordable and accessible.
- The U.S. is by far the largest market for pharmaceuticals in the world and the engine of global pharmaceutical innovation. Other countries, in effect, free ride off the innovation stimulated by the American market.

- Despite stable or falling net prices paid to prescription drug manufacturers over the past decade, novel medicines lie increasingly beyond the financial reach of American patients.
- Blunt price controls are not the solution to the worsening affordability of prescription drugs or to global free-riding: Schaeffer Center research suggests that introducing European-style pricing policies would reduce Americans' life expectancy.
- Instead, aligning drug prices with the actual value provided to patients stimulates innovation that benefits patients and discourages innovation that does not.
- Legislation to increase drug price transparency, coupled with better information about value, can help payers and consumers spend their money wisely.
- Affordable and generous insurance for prescription drugs ensures that drugs remain within the financial reach of American families.

Chairman Sanders, Ranking Member Cassidy, and Honorable Members of the Committee, thank you for the opportunity to testify today about drug prices and the assessment of medical technologies.

My name is Darius Lakdawalla, and I am an economist, a professor at the USC Mann School of Pharmacy & Pharmaceutical Sciences and USC Price School of Public Policy, and the Director of Research at the USC Schaeffer Center for Health Policy & Economics. By way of background, I have been studying innovation in the health care sector for nearly three decades, I co-wrote the chapter in the *Handbook of Health Economics* on intellectual property and biomedical research, and I co-authored the book *Valuing Health* on modern methods for valuing medical technology. The opinions I offer today are my own and do not represent the views of the University of Southern California or the USC Schaeffer Center.

The Value of Innovation in Global Context

In December 1984, a young boy from Indiana named Ryan White was diagnosed with AIDS, as a result of a transfusion with infected blood. While his doctors gave him just 6 months to live, Ryan outlasted those predictions and lived six more years. In the immediate wake of his untimely passing in 1990, Congress passed the Ryan White Care Act, which has since ensured affordable care for generations of HIV/AIDS patients. While the Act played a critical role in the fight against HIV almost immediately, its full value would not be realized until 5 years after its passage, when highly active antiretroviral therapy (HAART) emerged as a life-saving treatment for patients with HIV. The Ryan White Care Act put effective medical care within reach for many HIV+ patients that would otherwise have gone without it, while medical innovation brought new forms of treatment that changed the lives of patients and their families. Today, *9 out of 10 patients* receiving care through the Ryan White program enjoy viral loads so low that they are no longer infectious. Thanks to breakthrough medical innovation, and to forward-thinking public policy that made it affordable to many, HIV+ patients treated with HAART in a timely fashion can now *expect to live* well into their 70's and beyond.

The case of HIV illustrates a pair of health policy truisms. Increasing patient access through bold expansion of affordable care means little when there are no valuable cures or treatments to access. At the same time, breakthrough medical therapies provide little value if high cost-sharing pushes them out of patients' reach. The challenge for public policy is to sustain the pace of medical innovation while ensuring that valuable new technologies remain affordable and accessible to the patients who need them.

At first blush, it may seem impossible to navigate the narrow straits between affordability and innovation. Medical innovation investment carries high risk that drives up the cost of discovery. Among investigational medicines that undergo human trials, *90 percent will fail to launch*. Pharmaceutical and medical device firms will undertake these costs only if they expect to recoup the cumulative costs of their investments and receive a reasonable rate of return. However, these returns on innovation must ultimately be paid by all Americans, through out-of-pocket payments, health insurance premiums, and taxes. In this respect, therefore, greater rewards for innovators lead to *more innovation* but less affordability. The converse is also true: bluntly lowering prices makes new medicines more affordable for today's patients, but limits innovation for future generations of patients.

This tradeoff between innovation and affordability has played out in the different approaches taken across the globe. There is little doubt that U.S. consumers access

newer drugs *sooner and more often* than their overseas counterparts. Academic research shows how this tendency results in more and earlier new drug launches in the U.S., and correspondingly *fewer and later launches* in other countries. Schaeffer Center research suggests that introducing European-style pricing policies would ultimately lower innovation and cost American consumers just over *half a year of life expectancy,* about what would be lost if American surgeons suddenly forgot how to perform heart bypass surgery. [1]

Meanwhile, academic research finds that the American healthcare system *performs better* than its European counterparts in treating disease. For example, American mortality rates from breast, colorectal, and prostate cancer have *fallen faster* than European rates. Indeed, an analysis of cancer care across 16 countries found countries where cancer spending has grown more rapidly have also experienced *faster declines* in cancer mortality rates. According to our research, where the U.S. lags is in the prevention of *chronic diseases* like heart disease, hypertension, and diabetes. Faster growth in American obesity appears to have played an outsized role in driving these differences. In short, America's relatively low life expectancy appears to be in spite of, not because of, its healthcare system.

Despite the good news, however, there is no denying the sentiment that U.S. consumers unfairly pay higher drug prices than their peers overseas. On the one hand, we cannot readily observe the actual extent of the difference between U.S. and overseas prices. Too often, price comparisons in the public discussion rely on U.S. list prices, which are easily accessible, but almost never reflect what is truly paid for a drug. While researchers have a rough idea of the *average discount paid in aggregate,* this provides little insight into the actual prices of specific drugs. Economic principles predict that volume will be higher on drugs offering higher discounts. Therefore, applying the average discount to the list price of every individual drug will overstate U.S. prices.

Nonetheless, economic principles *also predict* that U.S. prices probably are higher than prices overseas, even if we do not know by exactly how much. The culprit is the problem of "free-riding." The U.S. is by far the *largest market for pharmaceuticals* in the world. Smaller market countries have rational, self-interested incentives to pay lower prices, knowing that their small size allows them to save money without meaningfully reducing global pharmaceutical innovation. In effect, their lower reimbursements "free-ride" off the American market, which remains the engine of pharmaceutical innovation that benefits patients throughout the world.

Americans have understandably become frustrated by footing so much of the world's bill for innovation. Unfortunately, we have no reliable ways to coerce other countries to act against their own self-interest. And, while it may seem tempting to stop paying higher prices and to join with the free riders, the resulting slowdown in innovation would *harm American patients and their families most of all.* Fortunately, there are actions we can take to ensure that patients benefit from medical advances, today and in the future.

Ensuring Patient Access to Treatments: Net Prices Are Not the Problem

The deteriorating accessibility of prescription drugs in recent years threatens to derail the access advantages and health gains American consumers have so far enjoyed. Even patients with "good" insurance are struggling to access the therapies their doctors prescribe. Plans frequently impose *co-insurance requirements,* where patients pay a share of their drug's list price, exposing them to artificially inflated list prices even when drugs' true costs are much lower. Plans are also restricting access or denying it altogether for an increasing share of drug compounds. *Since 2012, the three largest pharmacy benefit managers have excluded a sharply increasing number of drugs from their formularies*—last year, each of them excluded from coverage more than 600 products. At the same time, the average manufacturer net prices of brand drugs—the amount manufacturers receive after rebates and discounts—have declined in *each of the last 5 years.*

If it is getting cheaper to buy these drugs from manufacturers, why are they growing harder for patients to access? Part of the answer can be seen in a *2021 analysis* of the flow of money spent on insulin. Between 2014 and 2018, net manufacturer prices for insulin fell by 31 percent, but the total expenditure per unit of insulin remained nearly constant. Growing discounts and concessions offered by manufacturers were not being passed on to patients or taxpayers in the form of

[1] Bypass surgery adds about 1.1 years of life to patients treated with it. The lifetime risk of cardiovascular disease is around 60 percent. Thus, even if every heart disease patient received bypass surgery, it would add just over half a year of life.

lower insulin expenditures. Instead, those savings were being pocketed by intermediaries in the pharmacy distribution system, including pharmacy benefit managers, pharmacies and wholesalers. Pending legislation aimed at increasing transparency in the distribution system will shed more light on the commercial practices that enable PBMs to divert savings like this and provide more insight into where our drug spending is going. Neither third-party payers nor consumers observe the net prices they themselves are paying for individual drugs. Even large self-insured employers *may be unable* to get simple answers about how much they are paying for a given drug, no matter how widely used. Transparency in pricing would be a major step toward ensuring that drug prices reflect the actual value provided to patients, and don't simply enrich intermediaries.

Some academics and Federal agencies have *asserted*[2]*2* that price transparency harms consumers, purportedly by providing a means for pharmaceutical firms to cooperate with each other in raising prices. This argument is specious. In the first place, there are no academic studies showing that pharmaceutical price transparency limits competition; the argument against transparency proceeds primarily by means of a flawed analogy to a 25 year-old *study* of the Danish ready-mix concrete industry. Moreover, the critique of price transparency rests on the quaint notion that confidential rebates yield vigorous price competition that benefits consumers. On the contrary, *our research* illustrates how confidential rebates explain why competition among branded drug companies is currently associated with higher-not-lower-list prices for drugs, and correspondingly higher costs for patients paying co-insurance for their medicines.

In addition to hitting American families in the pocketbook, higher out-of-pocket costs for drugs also harm health. The link between increasing out-of-pocket costs and patient adherence is *well-established.* USC Schaeffer Center research found that higher out-of-pocket burden corresponds with *lower patient utilization of insulin,* while other studies have found similar relationships between patient costs and adherence in *rheumatoid arthritis, breast cancer,* and *chronic kidney disease.* In addition, USC Schaeffer Center *research* demonstrated in the context of novel oral anticoagulants (NOACs) that prior authorization and step therapy restrictions in Part D plans harmed patient health. Patients in plans with more restrictions were less likely to use NOACs, had worse adherence when they did use NOACs, took longer to fill their initial NOAC prescription, and faced higher risk of mortality/stroke/transient ischemic attack. This research does not imply that every access restriction harms patient health. Rather, it highlights the need to evaluate the risks and benefits of access policies, just as we evaluate the risks and benefits of new medicines.

Sustaining Innovation for American Patients and their Families

Fortunately, reforms that promote patient access do not have to lower medical innovation. Indeed, *our research* shows that generous prescription drug insurance unlocks affordability and access for patients while still enabling sufficient rewards for innovation. This is not to say, however, that all innovation should be unquestioningly rewarded. The goal is to encourage innovations that benefit patients and their families, and to discourage those that do not. These goals can best be achieved when prices reflect value to patients.

Decades of economic research demonstrate that innovation follows pricing incentives. Where innovators *expect* higher returns, innovative effort and discovery *follow.* In contrast, innovators will avoid investing where they expect lower returns. As a result, aligning the price of every drug with the value it brings patients stimulates innovation that benefits patients and discourages innovation that does not. At a minimum, this requires a transparent and predictable approach to price-setting that rewards value. Predictability matters, because innovation investments follow what innovators expect prices will be, often many years in the future. Second, value must be measured in a way that holistically reflects what patients and their families care about. Doing otherwise stimulates the wrong kind of innovation.

Looking outside the U.S., many countries adopt pricing approaches that force a tradeoff between predictability and the holistic measurement of value. The United Kingdom, Australia, and Canada employ relatively *transparent* systems that set prices based on *three kinds of data:* the clinical benefits of the new drug, the expected economic benefit of the new drug, and the likely cost impact of the new drug. Even though prices are not determined in a purely formulaic manner, drugs are *more likely to be reimbursed* when their prices result in sufficient economic benefit,

[2] See page 362.

and vice-versa. And, since economic benefit is computed using a known mathematical framework, this approach results in more predictable pricing outcomes.

However, while these countries employ a more predictable approach, they also rely on old-fashioned methods of economic analysis—for instance traditional cost-effectiveness calculations using quality-adjusted life-years (QALYs). While many have correctly observed the ethical challenges posed by the discriminatory nature of QALYs, *our research* demonstrates that traditional QALYs also get the mathematics and economics of value assessment wrong for patients.

On the other side of the coin are countries like France and Germany, which recognize the *pitfalls* of traditional economic evaluation of new medicines. For the most part, these countries focus on clinical benefits as the main criterion for reimbursement decisions, rarely if ever attempting to form specific economic estimates of value. While these countries avoid flawed estimates of value, their approach compromises predictability. In contrast to economic evaluation, which is focused on estimating a monetary benefit, clinical evaluation typically considers many dimensions of health improvement without a clear and quantitative method for weighing these different dimensions against each other. For example, *one academic study* found that only 2 out of the 5 official criteria specified for clinical benefit in France are statistically associated with the official rating of clinical benefit. Moreover, even if estimated clinical benefits are predictable, their effect on prices may not be. Under the German system, which uses a very specific, *albeit complicated,* process for measuring clinical benefit, there remains *no clear quantitative relationship* between measured clinical benefit and negotiated prices.

These tradeoffs also underscore the risks of so-called "reference pricing" approaches that tie American prices to those charged by other countries. In so doing, Americans would be forced to live with the vagaries of pricing systems designed and implemented elsewhere, around priorities that may differ from ours. Moreover, *academic research* finds that bringing reference pricing to the U.S. would likely inflate overseas prices but leave U.S. prices largely unchanged. The net result will be little if any benefit for American families in the short-term, and some degree of harm to long-term medical innovation in the bargain.

Instead, aligning prices with value encourages innovators to invest in areas that patients value. Achieving this outcome requires *better information about value,* which is ironic because we already have an overload of certain kinds of information about value. Prescription drugs nearly always arrive to market with studies estimating their value, often many of them, and they frequently reach divergent conclusions. Instead of even more studies, payers and consumers need an objective review and translation of the evidence on value. This might not result in a single, incontrovertible estimate of economic value, but even a range of values, when objectively determined, would benefit the people and organizations ultimately footing the bill for prescription drugs. Better information about value, coupled with price transparency, helps ensure payers and consumers spend their money wisely.

While it is yet to be determined what the true impact of the Inflation Reduction Act (IRA) will be on biomedical innovation, there is *strong evidence* that cuts to *Medicare's pharmaceutical spending* will reduce discovery of new treatments as well as new uses for existing drugs. But *there are ways* to mitigate these adverse impacts. Most importantly, it is essential that Maximum Fair Price (MFP) determination hew to the principles of transparency and value to patients. Economic research provides transparent approaches that can be leveraged by CMS, and relying on economics no longer means relying on the old-fashioned QALY. For example, *one new value assessment method* based on research at the USC Schaeffer Center corrects the QALY's errors by recognizing the long-established principle that goods are more valuable to people who have less of them. Analogously, health improvements are more valuable for people with disabilities, terminal illness, or other severe disease. This approach comports with Federal law by avoiding value assessments that discriminate against vulnerable patients with disabilities or terminal illness.

Finally, *Medicare Part D's benefit design* also implicitly encourages high list prices. Part D insurers favor high list prices in part because they move patients more rapidly to the catastrophic phase of coverage, where Federal reinsurance payments await. While the IRA's Part D benefit redesign provisions may moderate these reinsurance-related incentives somewhat, other program features (such as an intense focus on premiums) suggest the upward pressure on list prices will continue absent other market changes.

Sustaining Affordable and Valuable Innovation

Ultimately, the right policies need to focus on the affordability of good health, not simply of health care. This is especially true for diseases with few or no treatment options. The least affordable drugs are those that have not yet been discovered. For example, in the days before the discovery of effective vaccines, freedom from the most devastating consequences of COVID–19 could not be bought at any price. To be sure, affordable and generous insurance for prescription drugs remains part of any solution, because today's medicines already put good health within reach for millions of Americans suffering from chronic disease. Making prices transparent and generating actionable information on value will help wring out wasteful spending that fails to benefit patients and their families. Finally, rewarding drugs that do provide value helps sustain innovation and ensures good health will be increasingly within the reach of Americans for generations to come.

[SUMMARY STATEMENT OF DARIUS LAKDAWALLA]

Ensuring Affordable and Valuable Pharmaceutical Innovation for Patients

Increasing patient access through bold expansion of affordable care means little when there are no valuable cures or treatments to access. At the same time, breakthrough medical therapies provide little value if high cost-sharing pushes them out of patients' reach.

This tradeoff between innovation and affordability has played out in the different approaches taken across the globe. There is little doubt that U.S. consumers access newer drugs *sooner and more* often than their overseas counterparts. And this increased access to the latest treatments matters. Schaeffer Center research suggests that introducing European-style pricing policies would ultimately reduce innovation and cost American consumers just over *half a year of life expectancy,* about what would be lost if American surgeons suddenly forgot how to perform heart bypass surgery.[1] Thus, even though other countries likely free-ride off the revenue generated in the American market, importing overseas pricing policies will harm the health of American families.

Nonetheless, the deteriorating accessibility of prescription drugs in recent years still threatens to derail the access advantages and health gains American consumers have so far enjoyed. Even patients with "good" insurance are struggling to access the therapies their doctors prescribe. An increasing number of plans frequently impose co-insurance requirements and exclude drugs from their formularies. These changes in the marketplace likely harm health, since the link between increasing out-of-pocket costs and patient adherence is *well-established.*

Surprisingly, coverage has deteriorated even while the average manufacturer net prices of brand drugs—the amount manufacturers receive after rebates and discounts—have declined in *each of the last 5 years.* Transparency in pricing throughout the pharmaceutical distribution system would be a major step toward ensuring that drug prices reflect the actual value provided to patients, and don't simply enrich intermediaries.

Rewarding drugs that do provide value helps sustain innovation and ensures good health will be increasingly within the reach of American patients for generations to come. Decades of economic research demonstrate that innovation follows pricing incentives. Where innovators *expect* higher returns, innovative effort and discovery *follow.* As a result, aligning the price of every drug with the value it brings to patients stimulates innovation that benefits patients and discourages innovation that does not.

Ultimately, the right policies need to focus on the affordability of good health, not simply of health care. The least affordable drugs are those that have not yet been discovered.

The CHAIR. Let me start the questioning by saying that I have heard some of my Republican colleagues talk about free market capitalism. Mr. Maybarduk, isn't the entire pharmaceutical industry based on Government granted monopoly power?

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[1] Bypass surgery adds about *1.1 years of life* to patients treated with it. The lifetime risk of cardiovascular disease is *around 60 percent.* Thus, even if every heart disease patient received bypass surgery, it would add just over half a year of life.

Mr. Amir, you may want to also speak to that. What does that have to do with free market capitalism if the Government is guaranteeing monopoly for many, many years?

Mr. MAYBARDUK. Well, precisely, Senator. Prices are high because drug makers have monopolies over products we can't just substitute. A patient can't just say, I will take this alternative. The patents block them from having affordable access. That is a monopoly, not a market system.

American taxpayers stand up to the world's largest and most productive funder of biomedical R&D at NIH. And it is we the people that fund the risk—we the people that support the risky early stage research that has led to such significant medical breakthroughs in the areas of mRNA, cancer, heart disease, gene therapy.

The CHAIR. In other words, the Government has played a very active role in the entire process. Mr. Amin, what about free market capitalism and monopolies?

Mr. AMIN. Well, I mean, it is—the Constitution grants Congress the power to promote the progress of science and useful laws, securing for limited times a right to their inventions. What we have now is a system where the patent system is not a limited time.

It is in a monopoly that gets extended, extended, extended. When we think about the free markets and the principles of capitalism, it is interesting Senator Paul mentioned Milton Friedman.

In fact, the neoliberals actually didn't like monopoly power, and they really did actually believe in the free market, but the fact that the intellectual property system, the patents has been corrupted by the modern pharmaceutical system to kind of extend those monopolies, actually goes against the principles of free market.

o, in a sense, they are not living up to the bargain of the free market.

The CHAIR. Okay. Mr. Lakdawalla, what do you think about free market capitalism and Government protection of monopolies?

Mr. MAYBARDUK. Thank you, Chairman. Well, truly free markets exist only on the whiteboard in my classroom at USC, first of all. But it is also true that without patent protection, there would be no innovation. That is a result that has been known in economics for centuries.

The real question is how do we balance patent protection, which induces innovation, against the value of new innovations and being able to broadcast them more widely after the end of a patent? And that tradeoff can be tricky, although in the case of pharmaceuticals, we have a useful instrument which is health insurance, and that allows patients to access drugs at much lower prices than what manufacturers receive even during the patent period.

That is an opportunity for us to expand accessibility even during the patent protection period.

The CHAIR. Thanks very much. My last question for all three of you is I believe you all heard the CEO's testimony in response to questions. What would you say, briefly, about their responses?

Did they in fact, effectively address the issue as to why we pay by far the highest prices in the world for prescription drugs, and

why one out of three people can't afford the medicine that doctors prescribe?

Mr. MAYBARDUK. Well, Senator, we heard some wild stuff up here this morning, including a lot of blaming middlemen for the problem of high prices. Look, drug makers' high prices are the whole reason that we have a middleman problem.

It is because we have exceedingly high prices at the outset that there is an attractive market for middlemen to enter. But the fish rots from the head. If you break up the market, if you look at where the revenue is, drug makers capture two-thirds, $323 billion. Pharmacy benefit managers are a small slice, $23 billion.

You can't fix the problem of the pharmaceutical industry by going off middlemen who are just trying to skim off the top. You have to get to the root of the problem, which is the monopoly power.

The CHAIR. Mr. Amin.

Mr. AMIN. I agree with what Peter says, and I would just add that some of the answers that these CEOs gave, for example, the Merck CEO about allowing biosimilar competition in when their primary patent ends, I believe that is not going to happen. I think if you look at all the patents that they have stacked up, they know what their game plan is.

You just have to look at what happened Humira and AbbVie. Similarly, I believe you just look at what is happening with these weight-loss drugs. We are looking at the patents on those now. These are potentially going to become $1 trillion drugs.

The CHAIR. Okay. Dr. Lakdula—Lakdawalla—pardon me for——

Dr. LAKDAWALLA. No problem. I think an important point that maybe is often missed is that net prices of pharmaceuticals have been falling for the past 10 years very consistently. CMS recently released its national health expenditure accounts data, and it confirms this fact as well. We have to reconcile that with rising costs for consumers.

I think intermediaries are actually playing a bigger role than it might appear. About $0.40 of every dollar spent on pharmaceuticals goes to intermediaries. And unlike pharmaceutical firms, they are not engaging in innovation that ultimately improves health.

The CHAIR. Thank you very much.

Senator Cassidy.

Senator CASSIDY. Thank you all. Mr. Maybarduk, I think it is made very persuasively—by the way, clearly, patents are part of the free market system, is the way that you protect intellectual property, and you incent creativity.

Now, whether it is being abused is another issue. And you mentioned the patent thickets, which is actually legislation sponsored by John Cornyn to do away with them. So, that is recognized. But I think without protection of intellectual property, we would not have this innovation. Now, why would you—why would you put the time into it?

Let's just make that point. But Mr. Maybarduk, Dr. Lakdawalla makes, I think, a persuasive point that without the profit incentive, you will not get the innovation. Are you disputing that?

Mr. MAYBARDUK. I am not.

Senator CASSIDY. You are just kind of—the degree of the profit taking, if you will. I will point out, by the way, that the three examples you gave seem to be all Medicare patients and there is legislation out there which will cap the out-of-pocket exposure to—for Medicare patients on these expensive drugs. I think it will be $2,000 in June 2025, and the catastrophic portion is going away now.

But Dr. Lakdawalla, that said, somebody is paying. Yes, insurance is making it more affordable. Medicaid is making it more affordable. Medicare is making it more affordable. I could go down, but somebody is paying. In my state, I was recently told that pharmaceutical costs for the Medicaid program are now 35 percent of the total. And so, yes, maybe we could do some value-based purchasing.

That is a lot of money, though. That is a huge program. That is not hospitals and doctors. It is a pharmaceutical cost. So, I think Mr. Mubarak would say, listen, they have got enough profit to innovate. What we are really talking about is more than the profit required to incent. Would you disagree with that?

Dr. LAKDAWALLA. Well, I think the question is really how much—whether we want to decrease profits or not. And we know that whenever you decrease profits, you get less innovation.

The research that we have done gets exactly that question. If you were to reduce prices and profits, what would the net result be? You would certainly save money, but you would also lead to fewer new drug discoveries and——

Senator CASSIDY. Are we at the sweet spot now, or could we do something to make drugs a little bit more affordable to the Medicaid program, for example? Because I am looking at this gene therapy and obviously how they are initially price is only based upon the restraint of the company.

But if you have a compelling gene therapy, they could almost name their price and it is going to be very difficult for a Medicaid program not to cover. So, but this could bankrupt taxpayers. So, thoughts on that?

Dr. LAKDAWALLA. Yes. So, I don't think we are at a spot where lowering prices makes us better off. But for gene therapies, I absolutely agree there is a significant problem. And the issue is that the prices are all paid upfront when there is the most uncertainty about whether the gene therapy is going to work in the long run.

Senator CASSIDY. Now, value-based purchasing could obviously play a role here. But if you do value based purchasing, you still have a—how do you negotiate the upfront cost? I come up with a drug for a gene therapy for sickle cell. I treated a lot of sicklers.

You want to treat them, and you charge $20 million a person. I can't believe they would get that, but you see, the only thing that would stop them from asking that may be the sticker shock. So, how do you negotiate that first out of the gate price?

Because I think that is a kind of a question that is kind of hanging out there. And you are the free market guy, so I would like your opinion. You are the whiteboard guy.

Dr. LAKDAWALLA. On the white board, yes. That is correct. It is actually not the case that you should negotiate the actual price upfront. Instead, a value based price would mean that the price will respond over time. So, imagine a situation where gene therapies were paid for in installments——

Senator CASSIDY. I get that. And believe me, I have written about that in Stat, if you ever wish to dig up something out of Stat behind a paywall. But it still means that if you have got an initial high price, no matter what your value-based purchasing arrangement is, it could still be something which society could not afford. What do you think of the German model? Dr. Baker, I think, came up with that in which there is—you know, you can ask whatever price you want for the first 2 years, but then after that, there is going to be some sort of negotiation based upon real world data.

Dr. LAKDAWALLA. Yes. I think the challenge with the German model is it is actually very hard to predict the outcomes. That if you look at the ratings that the Germans produce of the benefits of drugs, they are not well correlated with negotiated prices.

If I am an innovator trying to figure out what I am going to get paid in Germany, it is really hard. And if you can't predict your returns, then they are not going to work as financial incentives.

Senator CASSIDY. Mr. Amin, have you had a chance to evaluate the bill that is working its way through Judiciary Committee—it might be included in a year end package. It is to its effectiveness in addressing patent thickets. Yes, push your button——

Mr. AMIN. Senator Blumenthal and Cornyn's bill?

Senator CASSIDY. Yes.

Mr. MAYBARDUK. I think it will potentially cap the biologics patents that can be enforced to about 20. I have actually given some technical advice on that bill. I don't think it is going to resolve the problem.

Senator CASSIDY. You don't think it is going to resolve the problem?

Mr. MAYBARDUK. No.

Senator CASSIDY. I see. Okay. Well, thank you all. Very thoughtful.

The CHAIR. All right. Thank you all. Very good discussion. Appreciate you being here. That is the end of our hearing today, and I want to thank all of our witnesses for their participation.

For any Senators who wish to ask additional questions, questions for the record will be due in 10 business days, February 23rd at 5.00 p.m.. And finally, I ask unanimous consent to enter into the record three statements from stakeholder groups and experts about the cost of prescription drugs.

[The following information can be found on page 106 in Additional Material.]

The CHAIR. With that, the Committee stands adjourned. Thank you.

ADDITIONAL MATERIAL

FAMILIES USA,
WASHINGTON, DC 20005,
FEBRUARY 8, 2024.

Senator BERNIE SANDERS, Chairman
U.S. Senate Committee on Health, Education, Labor, and Pensions,
Dirksen Senate Office Building,
Washington, DC 20510.

DEAR MEMBERS OF THE HOUSE OF REPRESENTATIVES,

Chairman Sanders and Ranking Member Cassidy, on behalf of Families USA, we want to thank you for holding this important and timely hearing and offer our appreciation for lifting up the reality of high drug costs in the United States. It is well documented that the United States is paying significantly higher prices for prescription drugs compared to peer countries. A recent report from the Assistant Secretary for Planning and Evaluation (ASPE) at the Department of Health and Human Services (HHS) found that in 2022, across all brand name and generic drugs, families in America pay nearly three times as much as 33 Organization for Economic Cooperation and Development (OECD) countries.[1] And this gap is continuing to widen as drug prices in the U.S. continue to skyrocket. This problem can easily be traced directly back to failures in U.S. patent policy that incentivize big drug corporations to keep old drugs on the market and push out healthy competition, as well as these corporations' ability to price gouge year over year with no repercussions.

Congress and the Biden administration have taken meaningful steps to address high drug costs for Americans, importantly through enactment and implementation of the Medicare price negotiation program and inflationary rebates. It is essential that Congress build off this critical progress by taking additional steps to further address this uniquely American failure.

The Impact of High Drug Prices on Families

While high drug prices are a source of seemingly constant policy debate in Washington, DC, for millions of America's families, they are a painful and burdensome reality that often impacts their ability to meet basic necessities of life. For example, consumers facing increased drug costs report cutting back on key areas of their budget, such as buying food.[2] For some the choice is even more dire, with research showing that nearly three in ten adults—approximately 80 million people—in our Country have not taken required medicine as prescribed due to its costs.[3] Approximately one in five adults forgo essential medications altogether because they can't afford to fill their prescription in the first place.[4] The impact of being forced to make these decisions has on health is clear: medication nonadherence, such as rationing or skipping needed medication, causes an estimated 125,000 deaths a year.[5]

While people who need high-priced drugs often face the most significant financial pain from high and rising prices, the impact of the skyrocketing cost of drugs is widely felt beyond the pharmacy counter. Approximately 20 percent of health insurance premiums are driven by the rising cost of prescription drugs, which means as drug prices continue to rise so do premiums, deductibles, and other health care costs for all families—even those who are not taking prescription medications.[6]

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[1] "Comparing Prescription Drugs in the U.S. and Other Countries: Prices and Availability " *https://aspe.hhs.gov/reports/comparing-prescription-drugs*

[2] Gill, Lisa L. "How to Pay Less for Your Meds." Consumer Reports. April 5, 2018, *https://www.consumerreports.org/drug-prices/how-to-pay-less-for-your-meds/*

[3] Kirzinger, Ashley, Lunna Lopes, Bryan Wu, and Mollyann Brodie. "KFF Health Tracking Poll—February 2019: Prescription Drugs." The Henry J. Kaiser Family Foundation. March 01, 2019. *https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february—2019-prescription-drugs/*

[4] "Americans' Challenges with Health Care Costs" The Henry J. Kaiser Family Foundation, December 14 2021, *https://www.kff.org/health-costs/issue-brief/americans-challenges-with-health-care-costs/*

[5] Fred Kleinsinger. "The Unmet Challenge of Medication Nonadherence" National Library of Medicine. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6045499/*

[6] Kim Keck, "Six Ways We're Lowering Drug Prices," Blue Cross Blue Shield of America, March 3, 2022, *https://www.bcbs.com/the-health-of-america/articles/six-ways-were-lowering-drug-prices.*

Big Drug Corporations Abuse U.S. Patent System to Protect Profit and Limit Competition

The business model of big drug companies is rooted in exploitation. They take extreme steps to create a monopoly drug market and then abuse it for profit, including price gouging, protecting drug exclusivity through anticompetitive behavior, and increasing profits on old drugs rather than investing in new and innovative treatments to help our Nation's families.[7] Drug companies regularly deploy a barrage of tactics to extend their exclusivity periods, keep generics off the market, and maintain their market dominance.[8] Common examples include blanketing one drug with multiple and overlapping patents to create a "patent thicket" and "product hopping" a patent by making minor tweaks to existing drugs that typically confer no additional clinical benefit but allow for extended patent protections. In fact, the 10 top-selling drugs on the market today have been granted an average of 74 patents per drug, with an average of 140 patents filed for each of them.[9]

Once these big drug corporations have blocked other competitors, they are free to raise their drug's price year after year at shocking rates, even long after the drug's release. We see this problem across the drug market: Between July 2021 and July 2022, 1,216 drug products had price increases that were higher than the inflation rate (8.5 percent). Some drug prices increased by more than 500 percent.[10] These prices are not being justified by any additional benefits or effectiveness of that drug. In fact, one study of high-spend drugs showed that seven of the 10 drugs reviewed provided no additional clinical benefit relative to other available drugs.[11]

These abuses only occur because of the loopholes littered throughout the U.S. patent system and are major contributors to the uniquely high drug prices that American families face.

Proposed Legislation Could Address Corporate Pricing Abuses

Recently, Congress took important steps to systemically bring down drug prices and rein in the rate of skyrocketing price increases. The Inflation Reduction Act (IRA) of 2022 is landmark legislation that includes several key provisions to address the high prices that are a hallmark of the American experience with prescription medication. The recently passed reforms include giving Medicare the authority to negotiate the price of drugs, as well as penalties (through rebates) for big drug companies that raise the price of their drug higher than the rate of inflation. These are both foundational steps that change the incentives specific to the U.S. market that have led to these high drug costs.

Congress can build on this foundation to further rein in prescription drug costs and make health care more affordable for everyone in two key ways:

1. Extending the reforms in the IRA to apply to the commercial market to better protect all consumers from high and irrational drug costs. This includes allowing the commercial market to adopt Medicare's negotiated rates and extend the inflationary rebate to fight price gouging year over year in the commercial market.

2. Close loopholes that allow companies to create monopoly drug markets and prevent generics from coming to the market in a timely fashion. This includes ending patent abuses like patent thickets and product hopping, simplifying the generic approval process and ending pay for delay policies.

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[7] Bailey Reavis and Hazel Law, The Reality of Prescription Drug Innovation: Drug Manufacturers Limit Innovation to Protect Patents and Profits (Washington, DC: Families USA, August 2023), *https://familiesusa.org/wp-content/uploads/2023/08/Drug-Companies-Limit-Innovation-for-Profit—2.pdf*.

[8] Patricia Kelmar and Abe Scarr, The Cost of Prescription Drug Patent Abuse: How Drug Companies Abuse the Patent System and Demand Inflated Monopoly Prices in America (U.S. PIRG Education Fund, April 2023), *https://pirg.org/edfund/resources/the-cost-of-prescription-drug-patent-abuse/*

[9] Tahir Amin and David Mitchell, "Big Pharma's Patent Abuses Are Fueling the Drug Pricing Crisis," Time, February 24, 2023, *https://time.com/6257866/big-pharma-patent-abuse-drug-pricing—modifications*

[10] Bailey Reavis and Hazel Law, The Reality of Prescription Drug Innovation: Drug Manufacturers Limit Innovation to Protect Patents and Profits (Washington, DC: Families USA, August 2023), *https://familiesusa.org/wp-content/uploads/2023/08/Drug-Companies-Limit-Innovation-for-Profit—2.pdf*.

[11] Eliot Fishman, Our Broken Drug Pricing and Patent System Diverts Resources Away From Innovation and Into Mergers, Patent Gaming and Price Gouging (Washington, DC: Families USA, August 2021), *https://familiesusa.org/wp-content/uploads/2021/08/RX—2021—209—Innovation-Drug-Pricing-Issue-Brief.pdf*.

Conclusion

High and rising drug costs are a uniquely American problem and a major factor as to why health care affordability is an American crisis. Drug prices threaten the health and financial security of families and individuals in every state and community. Big drug companies abuse the patent system, delay the entry of generic drugs, and price gouge to support their greed while families and individuals go into medical debt, ration or skip medications, and have to choose between filling their prescription or filling their fridge. Even those not taking prescription drugs are left with difficult financial decisions due to rising insurance premiums, higher deductibles, and stagnant wages—all of which can be tied back to rising drug costs. This cannot be allowed to continue. We appreciate the important work of this Committee to address these concerns and look forward to continuing to work with you to ensure all families can achieve affordable health and health care.

Dear Members of the House of Representatives,

As organizations representing patients and consumers, we write in opposition to H.R. 485, the so-called Protecting Health Care for All Patients Act of 2023. This bill claims to protect people from discrimination but would in fact result in harm to patients if enacted into law.

There is no single factor more important in arriving at an appropriate price for a new drug than the value to patients. *It is axiomatic that to stimulate and reward innovative new drug development, we should pay more for high-value drugs and less for low-value drugs. Put another way, we want drugs with high clinical effectiveness against the disease or condition they target and with a low burden of undesirable side effects or toxicities.*

Patients in this country—especially those with disabilities—need a reliable system for evaluating the value of a medicine. Comparative Effectiveness Research (CER) can clearly and transparently assess the value of drugs in order to both inform patient decisionmaking and arrive at appropriate prices. Instead of prioritizing legislation that could lower prices, assess value, and improve health, the House Committee on Energy and Commerce advanced a version of H.R. 485 that would impose further limits on CER. If enacted, language referring to "similar measures" in the current version of the bill would *introduce ambiguity* across the health sector that could invite lengthy lawsuits from an industry eager to stop any efforts to constrain its ability to set prices as high as it wants for any drug—regardless of the drug's value. This is not a new fight. Powerful drug companies have fought to block CER for years with the single goal of preventing policymakers and payers from scrutinizing value in order to rein in prices.

If the leaders of this bill truly wish to protect people with disabilities from discrimination, they would instead advance legislation to address our drug price system at its core given that high drug prices disproportionately harm people living with disabilities, chronic conditions, and low-income communities. In fact, a recent study found thatpeople living with disabilities were about three times more likely to ration medications as those without a disability. High drug prices also disproportionately impact people of color. Big drug companies exacerbate health inequities and inflict harm by charging prices as high as the market will bear, untethered from the value of a drug and at the expense of people's lives and livelihoods.

To be clear, we emphatically support measures that protect people with disabilities, the elderly, and those with chronic or terminal illness from analytical tools that are discriminatory. Due to concerns about the use of the Quality Adjusted Life Year (or QALY), we believe its use should be prohibited in Federal programs. But we must also preserve the ability of our Nation to employ other measures that value all lives equally, such as the Equal Value of Life Years Gained (evLYG). Unfortunately, the leaders of the bill have rejected amendments that would ban QALYs while preserving non-discriminatory tools to assess value. So in the interests of patients, consumers, employers, taxpayers, and all Americans who pay for health care and prescription drugs and who need and want high value, innovative treatments, we urge a no vote on H.R. 485 in its current form.

Signed,

ACA Consumer Advocacy

AFL–CIO

AFSCME

Alliance for Retired Americans

Center for Popular Democracy Action
Citizen Action/Illinois
CT Health Policy Project
Communities United
Health GAP
Labor Campaign for Single Payer
Lower Drug Prices Now
MomsRising
Oregonizers
Patients For Affordable Drugs Now
People's Action
Protect Our Care
Public Citizen
Salud y Fàrmacos
Social Security Works
Spaces in Action
Unite HERE International Union
Universities Allied For Essential Medicines
VOCAL-NY

PUBLIC HEALTH

By Jason D. Buxbaum, Michael E. Chernew, A. Mark Fendrick, and David M. Cutler

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Contributions Of Public Health, Pharmaceuticals, And Other Medical Care To US Life Expectancy Changes, 1990-2015

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David M. Cutler is the Otto Eckstein Professor of Applied Economics in the Department of Economics at Harvard University and a research associate at the National Bureau of Economic Research, in Cambridge, Massachusetts.

ABSTRACT Life expectancy in the US increased 3.3 years between 1990 and 2015, but the drivers of this increase are not well understood. We used vital statistics data and cause-deletion analysis to identify the conditions most responsible for changing life expectancy and quantified how public health, pharmaceuticals, other (nonpharmaceutical) medical care, and other/unknown factors contributed to the improvement. We found that twelve conditions most responsible for changing life expectancy explained 2.9 years of net improvement (85 percent of the total). Ischemic heart disease was the largest positive contributor to life expectancy, and accidental poisoning or drug overdose was the largest negative contributor. Forty-four percent of improved life expectancy was attributable to public health, 35 percent was attributable to pharmaceuticals, 13 percent was attributable to other medical care, and −7 percent was attributable to other/unknown factors. Our findings emphasize the crucial role of public health advances, as well as pharmaceutical innovation, in explaining improving life expectancy.

Growth in medical spending consistently outpaces overall economic growth in the United States, prompting questions about the extent to which health care expenditures deliver value to justify their cost. If medical advances have contributed substantially to improved survival (life expectancy increased 3.3 years between 1990 and 2015), then growing investment in medical spending might be more palatable. The issue is particularly acute for pharmaceuticals, whose spending growth averaged 2.3 percentage points above growth in the rest of the health sector between 1990 and 2015.[1]

A recent synthesis estimated that a lack of modern medical care is directly responsible for 5–15 percent of premature mortality, with most premature mortality attributable to health-related behavior and social circumstances.[2] However, the impact of medical advances in explaining improving life expectancy over time has received somewhat less attention. One study estimated that half of all health improvements between 1960 and 2000 are due to medical care, although that estimation was extrapolated from a small number of conditions.[3] The difficulty is in part because medical care is difficult to evaluate as a whole. The determinants of health may shift within and across conditions over time, and many once-accepted scientific consensuses are later modified.

Even when one looks at a particular type of care, such as pharmaceuticals, the evidence of health impact is mixed. One recent study estimated that the expansion of cardiovascular medications led to a large reduction in heart disease mortality.[4] At the same time, evidence on the cost-effectiveness of anticancer agents varies greatly.[5,6] Further, excessive use of opioids has led to tens of thousands of deaths annually, contributing to flat or declining life expectancy between 2015 and 2017.

Given the salience of health care value in policy discussions, we sought to quantify the importance of medical care in total, and pharmaceutical treatments specifically, for recent changes in US life expectancy. We focused on 1990–2015 because some data sources used were unavailable for more recent years.

We began with vital statistics data to apportion improvements in mortality to various causes. For each of twelve causes responsible for life expectancy changes of 0.1 years or more, we reviewed the literature on the factors explaining mortality changes. We apportioned survival improvements into public health, pharmaceuticals, other (nonpharmaceutical) medical care, and a residual category comprising other or unknown factors. Aggregated results provide insight into the key drivers of increasing life expectancy between 1990 and 2015.

Study Data And Methods

CALCULATING CHANGES IN LIFE EXPECTANCY

▶ **DATA SOURCE:** Data on mortality by age and cause were obtained from the Centers for Disease Control and Prevention Wide-ranging Online Data for Epidemiologic Research (CDC WONDER) resource for 1990 through 2015. We identified causes using a hybrid of the National Center for Health Statistics' 113-cause-of-death and 39-cause-of-death classification systems. Details on our approach are in online appendix exhibits A1–A3.[7]

Although the 39-cause list is common in analyzing mortality, the level of aggregation is problematic with respect to some key conditions. For example, all accidents not caused by motor vehicles are grouped together. Accordingly, we conducted the analysis described here on both the 39- and 113-cause lists. We used the 39-cause list as our starting point, but we turned to the 113-cause list to avoid obscuring meaningful differences in trends among causes of death in overly broad categories, reduce the size of the "all other deaths" category, and group infant deaths together. Appendix exhibit A2 lists relevant *International Statistical Classification of Diseases and Related Health Problems*, Tenth Revision (ICD-10), codes.[7]

Data were available in *International Classification of Diseases*, Ninth Revision (ICD-9), for 1990–98 and ICD-10 for 1999–2015. ICD-9-to-ICD-10 comparability ratios were used to adjust pre-1999 death rates to form a consistent series and minimize potential bias associated with changes in coding practices (appendix exhibit A3).[7]

▶ **ESTIMATION:** Cause-deletion methods were employed to estimate the relative contribution of each condition to overall improvement in life expectancy at birth. This entailed starting with 1990 mortality rates and estimating sequentially the impact of changes in mortality for each condition on life expectancy at birth, holding other conditions at their 1990 mortality rates. The difference between life expectancy with and without the change for each condition is the life expectancy gain or loss attributable to that cause. For each cause studied in detail, we also examined mortality change in successive five-year intervals.

EXPLAINING LIFE EXPECTANCY CHANGES

We sought to apportion mortality changes for each cause of death associated with an increase or decrease in life expectancy of 0.1 years or more into the change attributable to public health, pharmaceuticals, and other medical care. We used multiple approaches because the most preferred method was not always possible (appendix exhibit A1, flowchart B).[7]

Whenever available, statistical models appearing in the peer-reviewed literature were used to explain changing mortality. Literature reviews were conducted to identify models using the union of the following Medical Subject Headings (MeSH) terms: "United States/epidemiology," "mortality/trends," and the condition name. On finding a relevant article, we consulted citations (a technique known as "snowballing") and used reverse citation look-up to identify related studies. We contacted subject-matter experts for guidance when we were unable to identify suitable sources through literature reviews. Some models were identified that did not cover the full period of interest. In these instances, we updated the model if the condition represented a large share of life expectancy change. Otherwise, we used the results available.

In some instances, we were unable to identify suitable existing condition-specific models. In those cases, we relied on alternative approaches to apportion mortality change among factors. These included the creation of new models, published surveys of physician opinion, and literature-informed judgements as to plausibility. Appendix exhibit A1 (flowchart C) depicts our approach in these cases.[7]

Public health was broadly defined as reductions in identifiable risk factors for injury or disease not classified in the three following categories: pharmaceuticals, which included opioids, biologics, and oncology agents among other agents; other (nonpharmaceutical) medical care, which included physician/hospital services such as cancer screenings, diagnostic testing, radiotherapy, and surgery; and a residual category for other/unknown factors. There may be overlaps among factors. For example, public health ef-

forts could lead to more cancer screenings, which could reduce mortality. Our primary analysis looked at the most proximal cause, so benefits would be attributed to medical care, not public health, in the previous example. We performed a sensitivity analysis to vary characterizations in areas with the greatest overlap of potential characterizations: overdoses, cancer screenings, and pregnancy terminations.

LIMITATIONS This approach had limitations. First, the attribution of responsibility for improved survival to public health, pharmaceuticals, and other medical care was constrained by the availability of literature and the need to impose subjective distinctions. It was also limited in that current knowledge may change over time. Second, the use of cause deletion required assuming that competing causes of death are independent from one another. This implies that the impact from any given cause may be misstated if the cause is strongly correlated with other causes. Third, life expectancy trends vary over time by race, ethnicity, education, geography, and other key dimensions, whereas this analysis is limited to overall trends. Fourth, coding changes over time, including the switch from ICD-9 to ICD-10, could affect findings (appendix exhibit A3).[7] Fifth, we examined life expectancy at birth. Results could differ with related metrics, such as average populationwide mortality rates. Sixth, morbidity changes may be equally important but were not included in our primary analysis. Seventh, the time period of the study predated the coronavirus disease 2019 (COVID-19) pandemic. Accordingly, COVID-19 was not analyzed as a unique cause of death.

Study Results

AGGREGATE CHANGES IN LIFE EXPECTANCY The cause-deletion methodology explained 3.3 years of improvement in life expectancy at birth for the modified list of 113 causes of death (appendix exhibit A4).[7] This corresponds with the observed change in life expectancy between 1990 and 2015. Exhibit 1 shows the contribution of each cause of death to changing life expectancy for the modified list of thirty-nine causes of death. Ischemic heart disease (1.76 years), lung cancer (0.34 years), and stroke (0.33 years) accounted for the greatest shares of improvement. Accidental poisoning or overdose (−0.32 years), dementia excluding Alzheimer disease (−0.19 years), and Alzheimer disease (−0.14 years) accounted for the greatest decrements in life expectancy.

Exhibit 2 shows causes of death that accounted for an increase or decrease in life expectancy of at least 0.1 years. Diseases of the circulatory system, cancers, and trauma (excluding suicide) accounted for 62 percent, 18 percent, and 9 percent of life expectancy improvement, respectively.

Public health improvements accounted for the largest part of mortality improvement overall.

Changes in life expectancy were generally continuous across five-year intervals (appendix exhibit A5).[7] Exceptions included ischemic heart disease, for which life expectancy increases slowed after 2005, and HIV, for which gains were concentrated in the 1995–2000 period. The negative impact of accidental poisoning or overdose on life expectancy also increased over time.

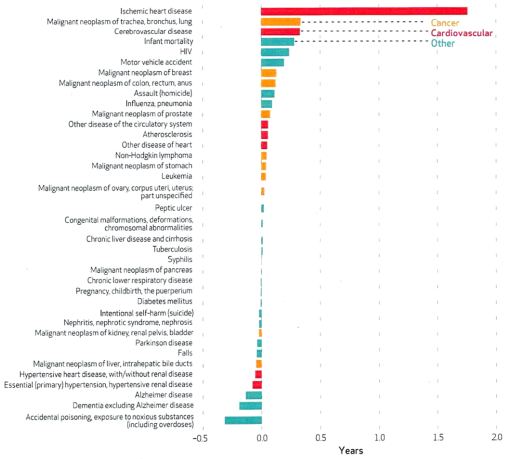
EXPLANATIONS FOR CHANGES IN LIFE EXPECTANCY Exhibit 3 attributes life expectancy increases to the impact of public health, pharmaceuticals, other medical care, and other/unexplained factors.

▶ **ISCHEMIC HEART DISEASE:** IMPACT is a validated statistical model that has been used in more than twenty countries to explain changes in death from heart disease over time.[3,8] We updated a 2019 version of the IMPACT model with 1990–2015 US-specific data to explain reductions in ischemic heart disease mortality.[8] Appendix exhibit A6 contains additional details.[7] The IMPACT model estimated that 52 percent of the decrease in mortality was attributable to pharmaceuticals and 7 percent was attributable to other medical care (exhibit 3).

The most important pharmaceutical treatments were care for hypertension and high cholesterol and, to a lesser extent, medications for secondary prevention after myocardial infarction and angina. With respect to other (nonpharmaceutical) medical care, rehabilitation and revascularization were of approximately comparable importance. Another 39 percent of mortality decline was attributed to improved public health not resulting from medications, principally reduced cholesterol and blood pressure. Although smoking decreased, benefits were partially offset by increases in body mass index and diabetes; we characterized these changes as public health. Approximately 2 percent of

EXHIBIT 1

Changes to US life expectancy, by cause of death, 1990–2015



SOURCE Authors' analysis of data from the National Vital Statistics System. **NOTES** Causes of death other than infant mortality exclude deaths for people younger than age one. See online appendix exhibits A1–A4 for further detail (see note 7 in text).

mortality improvement was not explained by the IMPACT model.

▶ **CEREBROVASCULAR DISEASE:** We updated a previously published cerebrovascular disease–specific extension of the IMPACT model to determine the causes of reduced cerebrovascular disease (appendix exhibit A7).[4,7] Sixty percent of reduced mortality was attributable to pharmaceuticals (including antihypertensives, statins, and anticoagulants), and 8 percent of reduced mortality was attributable to other medical care (carotid endarterectomies and rehabilitation). The remaining 32 percent of mortality reduction was attributed to unmodeled public health improvements, such as reduced smoking and hypertension not achieved through medical treatment.

▶ **LUNG, BRONCHUS, AND TRACHEA CANCER:** We did not identify any suitable existing models specific to lung, bronchus, and trachea cancer. We therefore used Surveillance, Epidemiology, and End Results Program data to create a new model (appendix exhibit A8).[7] Age-adjusted lung or bronchus cancer incidence fell 25 percent between 1990 and 2015, whereas mortality decreased 31 percent. Thus, decreasing incidence accounted for 81 percent of the decrease in mortality. Because smoking is the primary risk factor for lung cancer, we attributed 81 percent of reduced mortality to public health.

For these cancers, average five-year survival after diagnosis improved from 13 percent to 18 percent during 1990–2015. Stage migration has likely had only small impacts in lung cancer; screening was recommended only at the end of our study period, and symptomatic lung cancers

EXHIBIT 2

Top contributors to US life expectancy changes, by category, 1990–2015

Categories/causes of death	Years of life expectancy gained or lost	Contribution to overall life expectancy change (%)
Circulatory system		
Ischemic heart disease	1.76	53
Cerebrovascular diseases	0.33	10
Malignant neoplasms		
Malignant neoplasm of trachea, bronchus, lung	0.34	10
Malignant neoplasm of breast	0.13	4
Malignant neoplasm of colon, rectum, anus	0.12	4
Trauma		
Motor vehicle accident	0.19	6
Assault (homicide)	0.11	3
Neurological		
Alzheimer disease	−0.14	−4
Dementia, excluding Alzheimer disease	−0.19	−6
Other		
Infant mortality	0.28	8
HIV/AIDS	0.24	7
Accidental poisoning or overdose	−0.32	−9
Total	2.86	85

SOURCE Authors' analysis of data from the National Vital Statistics System. **NOTES** Limited to causes corresponding with increases or decreases of more than 0.1 years. See online appendix exhibits A1–A5 for further detail (see note 7 in text). Figures may differ from totals in text and table because of rounding.

generally grow rapidly. Further, there was little change in stage distribution of diagnosis; such changes accounted for only 4 percent of mortality reduction. We characterized this improvement as other/unknown.

Meta-analyses suggest a reduction in mortality risk of 13 percent in association with chemotherapy for treatment of non-small-cell lung cancer (roughly 80–90 percent of lung cancers). The share of patients with lung, bronchus, and trachea cancer receiving chemotherapy increased from 28 percent of known patients in 1990 to 40 percent in 2015. Even without accounting for advances in therapeutic effectiveness, increasing chemotherapy use accounted for 5 percent of reduced mortality. We attributed the residual mortality improvement (11 percent) to other nonpharmaceutical medical advances, such as improvements in surgery and radiotherapy.

▶ **BREAST CANCER:** We identified a 2018 Cancer Intervention and Surveillance Network article attributing reduced breast cancer mortality to advances in treatment and screening.[9] The article described findings from six models analyzing contributors to trends in breast cancer incidence and avoided mortality between 1975 and 2012. Averaging across models, 60 percent of improvement was attributable to medications, 31 percent of improvement was attributable to screenings, and 9 percent of improvement was unexplained (see appendix exhibit A9).[7]

▶ **COLORECTAL CANCER:** The Microsimulation Screening Analysis Cancer Intervention and Surveillance Network Colorectal Cancer Model has been used to estimate the source of longevity gains for colorectal cancer.[10,11] The most recent Microsimulation Screening Analysis results are from the period 1990–2000. The models were then used to forecast to 2015 under various scenarios. The "optimistic" scenario matched well with observed trends for the most important contributors to colorectal cancer incidence and mortality (appendix exhibit A10).[7] In this scenario, 27 percent of improved survival was attributable to pharmaceuticals (chemotherapy), 42 percent was attributable to medical care (cancer screening), and 31 percent was attributable to public health (especially decreased smoking).[10,11]

▶ **MOTOR VEHICLE ACCIDENTS:** Two studies in the traffic safety literature can be used to estimate the impact of medical care on motor vehicle accident fatalities. One study modeled traffic fatalities per 100,000 people at the state-year level as a function of automobile characteristics, road characteristics, and the White infant mortality rate for the state-year. The latter served as a proxy for the impact of medical technology.[12] We used this model to estimate the percentage of the time series change in motor vehicle accident fatalities attributable to medical advances (appendix exhibit A11).[7] The estimate suggests that improved medical care accounted for 10 percent of the reduction in motor vehicle traffic fatalities. We attributed the residual 90 percent to public health, such as improvements in vehicle safety.

A second model relates mortality for people in motor vehicle accidents to the receipt of high-level trauma care.[13] The study showed that the relative risk for death was 0.71 for people transported to a Level I or II trauma center compared with people transported to other locations. Using data on the share of people taken to Level I or II trauma centers over time implies that 10 percent of reduced motor vehicle accident fatalities were due to greater access to Level I or II trauma centers (appendix exhibit A11).[7] The alignment of results across models provided additional support for attributing 10 percent of reduced motor vehicle accident fatalities to other medical care and 90 percent to public health.

▶ **HOMICIDE:** We updated the approach used by Anthony Harris and colleagues in 2002 to estimate the contribution of medical care to reduced homicide.[14] These authors proposed that aggravated assaults be viewed as potential homicides where the outcome was not death. Change in the incidence of aggravated assault over time

EXHIBIT 3

Estimated impact of pharmaceuticals, other medical care, and public health on changes in US mortality, by cause of death, 1990–2015

Categories/ causes of death	Contribution to mortality reduction (%)	Contribution to mortality changes (%)				Comments
		Public health	Pharma-ceuticals	Other medical care	Other/ unexplained	
CIRCULATORY SYSTEM						
Ischemic heart disease	53	39	52	7	2	Most important pharmaceutical therapies: statins, antihypertensives Most important public health improvements: reductions in cholesterol, hypertension, and smoking
Cerebrovascular disease	10	32	60	8	—	Most important contributors: antihypertensives, statins, warfarin
MALIGNANT NEOPLASMS						
Malignant neoplasms of trachea, bronchus, lung	10	81	5	11	4	Reduced incidence of lung cancer used as proxy for public health factors
Malignant neoplasm of breast	4	—	60	31	9	Figures reflect 1990–2012 "Other medical care" reflects screening
Malignant neoplasm of colon, rectum, anus	4	31	27	42	—	Figures reflect experience (1990–2000) and projection (2000–15) "Other medical care" reflects screening
TRAUMA						
Motor vehicle accident	6	90	—	10	—	White infant mortality rate used as proxy for medical care Confirmatory findings from second model
Homicide	3	91	—	9	—	Aggravated assault rate used as proxy for nonmedical contributors to homicide
NEUROLOGICAL						
Alzheimer disease	–4	—	—	—	100	Possible changes in coding practices
Dementia, excluding Alzheimer disease	–6	—	—	—	100	Possible changes in coding practices
OTHER						
Infant mortality	8	39	21	20	20	See exhibit 4 and appendix exhibit A13[a]
HIV/AIDS	7	—	76	24	—	Figures reflect physician survey Confirmatory evidence from timing of HAART introduction
Accidental poisoning or overdose	–9	4	96	—	—	Includes deaths related to opioid crisis
TOTAL						
All causes	85	44	35	13	–7	

SOURCE Authors' analysis of data from the National Vital Statistics System and sources cited in text. **NOTES** Figures reflect 1990–2015 unless otherwise indicated. Figures may differ from totals in text and table because of rounding. HAART is highly active antiretroviral therapy. [a]See note 7 in text.

may thus be viewed as change in the risk for death from homicide not attributable to changes in the deadliness of the average aggravated assault, reporting patterns, or medical care.

According to federal Uniform Crime Reporting statistics, aggravated assaults fell by 44 percent between 1990 and 2015. During the same period, the homicide rate fell by 48 percent. The additional reduction in homicide deaths of 4 percentage points is 9 percent of the decline in homicides. Thus, we attributed 9 percent of reduced homicide mortality to medical care and the remaining 91 percent to public health. As with motor vehicle accidents, the medical care component was mostly nonpharmaceutical; we recorded it accordingly (exhibit 3).

▶ **ALZHEIMER DISEASE AND DEMENTIAS:** The reasons for underlying apparent increases in recorded mortality from Alzheimer disease and other dementias are unclear, as mortality trends were age adjusted. There are no established modifiable risk factors for Alzheimer disease, and the overall trend across known risk factors for non-Alzheimer dementia did not clearly worsen during 1990–2015 (appendix exhibit A12).[7]

There is generally "a blurred distinction between death with dementia and death from dementia."[15] Vital records–based estimates of

changes in dementia mortality may be particularly influenced by changes in disease awareness and place of death that took place between 1990 and 2015.[15] Given the absence of clear medical or public health explanations for the increases in dementia-related mortality, as well as the plausibility of changes in coding practices as the key explanatory factor, we attributed mortality increases to other/unexplained.

▸ **INFANT MORTALITY:** No comprehensive models to explain overall changes in infant mortality were identified. We therefore investigated the factors contributing to improved survival for the five conditions responsible for the greatest reductions in infant mortality between 1990 and 2015 (90 percent of the total; exhibit 4). Appendix exhibit A13 contains details.[7]

Reductions in sudden infant death syndrome accounted for 39 percent of all infant mortality gains. Sudden infant death syndrome–related improvements were attributed to advances in public health, particularly campaigns to prevent stomach sleeping in the 1990s. Reduced mortality from respiratory distress syndrome accounted for 23 percent of gains (exhibit 4). According to data from two neonatal hospital quality improvement collaboratives (appendix exhibits A13.1–A13.3),[7] the use of surfactant and antenatal steroids, both of which markedly reduce the risk for death among low-birthweight babies, increased sharply in the 1990s. We estimated that increasing use of these pharmaceuticals explained 89 percent of the observed respiratory distress syndrome mortality reduction. The large increase in life expectancy resulting from infant mortality reductions in the 1990–94 period is temporally consistent with advances associated with sudden infant death syndrome and respiratory distress syndrome (appendix exhibit A5, panel D).[7]

Fourteen percent of reduced infant mortality was a result of decreases in fatal congenital anomalies of the heart, most likely driven by nonpharmaceutical medical innovations. Eight percent of reduced infant mortality was attributed to reduced death from chromosomal anomalies. We attributed these reductions to increases in selective terminations and categorized them as other/unknown. Finally, 6 percent of reduced infant mortality was a result of reductions in lung-related congenital anomalies. There were important advances in surgery and diagnostic technique over our period of interest, particularly for diaphragmatic hernia repair, which we characterized as other medical care. Appendix exhibit 13.1 provides details and supporting references.[7]

Aggregating, we estimated that 39 percent of reduced infant mortality was attributable to public health, 21 percent to pharmaceuticals, and 20 percent to other medical care (exhibit 4).

▸ **HIV:** The literature review did not identify a suitable model to explain HIV mortality improvement. We therefore relied primarily on expert

EXHIBIT 4

Estimated impact of public health, pharmaceuticals, and other medical care on changes in US infant mortality, by cause of death, 1990–2015

		Contribution to mortality changes (%)				
Causes of death	**Contribution to mortality reduction (%)**	**Public health**	**Pharma-ceuticals**	**Other medical care**	**Other/ unexplained**	**Comments**
Sudden infant death syndrome	39	100	—	—	—	Spread of safe sleep practices Reductions in cigarette smoking among pregnant women
Respiratory distress syndrome	23	—	89	—	11	Increased use of surfactant and antenatal steroids in preterm births
Congenital anomalies of the heart	14	—	—	100	—	Interventional cardiac procedures and associated technology (for example, miniaturization of tools, increases in NICU access) Improved prenatal diagnosis
Chromosomal anomalies	8	—	—	—	100	Edwards and Patau syndromes are in this category Increases in prenatal screening and selective terminations
Congenital anomalies of the lung	6	—	—	100	—	Increasing use of diaphragmatic hernia repair
Other	10	—	—	—	100	Not investigated
Total		39	21	20	20	

SOURCE Authors' analysis of sources in online appendix exhibit A13 (see note 7 in text).

Our results suggest the importance of minimizing cost-related barriers to key preventive and chronic care services.

opinion, as reported in a survey of sixteen physicians specializing in the treatment of HIV.[16] Surveyed physicians estimated that pharmaceuticals accounted for 76 percent of reduced HIV morbidity and mortality between 1990 and 2015. Nonpharmaceutical medical technologies, such as diagnostic testing, accounted for nearly all the remainder. Responding physicians reported that other factors, including public health, accounted for only 0.3 percent of improvement.

Observed trends support these estimates. Seventy-one percent of the reduction in HIV-related deaths between the peak of the HIV/AIDS epidemic in 1994–95 and 2015 took place in 1996–97 (appendix exhibit A14), when highly active antiretroviral therapy first became widely available.[7,17] Similarly, Frank J. Palella Jr. and colleagues showed that protease inhibitors (an essential element of highly active antiretroviral therapy) reduced mortality by 70 percent for people with low CD4+ cell counts.[17]

The low estimate for net benefit from public health also appears reasonable. Male-to-male sexual contact is the most common mechanism of HIV transmission in the US. Risky sexual practices among men who have sex with men increased between 1992 and 2013.[18] Therefore, although transmissions might have increased faster but for public health efforts, it is unlikely that public health efforts contributed to improvements between 1990 and 2015.

▶ **ACCIDENTAL POISONING OR OVERDOSE:** We used vital statistics data to understand changes in the factors contributing to fatal accidental poisoning or overdose. Ninety-six percent of the increase in poisoning or overdose was attributable to increases in fatal prescription and nonprescription drug use, particularly opioids; the remaining component was attributable to other sources such as alcohol consumption (data not shown). The prescription drug component of opioid deaths is most readily characterized as pharmaceutical. The nonprescription component is somewhat more difficult, as it reflects the use of heroin and fentanyl. Evidence suggests that many people transitioned into these substances after prescription opioids were made more difficult to obtain.[19,20] Thus, we attributed these deaths to pharmaceuticals as well, even if some of the "technology" was related to the ability to supply illegal drugs.

SENSITIVITY ANALYSIS In the sensitivity analysis, we varied the characterization of three contributors to changing mortality: overdoses, cancer screenings, and selective pregnancy terminations for genetic anomalies (appendix exhibit A15).[7] Our overall findings were sensitive to reallocating opioid-related mortality from pharmaceuticals to public health (for example, lack of sufficient Food and Drug Administration and Drug Enforcement Administration oversight). In this alternative scenario, 35 percent of gains were due to public health gains and 44 percent of gains were due to pharmaceutical gains.

Discussion

We studied contributors to life expectancy changes for twelve conditions accounting for 2.9 years of improved life expectancy in the US between 1990 and 2015 (exhibit 2). We found great variation in the key drivers of mortality change across causes. In our primary analysis, 44 percent of improvement was attributable to public health, 13 percent was attributable to nonpharmaceutical medical care, and 35 percent was attributable to pharmaceuticals (exhibit 3). The share of survival deterioration attributed to pharmaceuticals (−9 percent) was outweighed by the share of improvement attributed to pharmaceuticals (44 percent) (based on authors' calculations of unrounded data from exhibit 3). There was also a residual of −7 percent attributable to other/unexplained factors.

In addition to heterogeneity in the drivers of mortality avoidance across conditions, there was heterogeneity in the extent to which improvements were attributable to new technologies versus greater diffusion of existing technologies. For example, the 1990s saw the introduction of highly active antiretroviral therapy and the widespread diffusion of statins, which were crucial to mortality reduction for HIV and ischemic heart disease, respectively. There were also increases in the use of surfactant and antenatal steroids, technologies that reduced infant mortality. However, reductions in life expectancy attributable to opioids underscore the potential for severe harm when technologies diffuse beyond appropriate populations.

We found additional heterogeneity in the pace of mortality reduction over time and across con-

ditions. Paralleling the work of Anne Case and Angus Deaton,[21] we observed a sharp slowdown in 2010–15 in improvement in ischemic heart disease mortality (appendix exhibit A5).[7] This change contrasts with trends for other causes of death, as well as longitudinal trends in heart disease–specific mortality in peer countries.[21] Explaining this slowdown requires further research.

We identified 3 percent of life expectancy gains as resulting from increases in breast and colorectal cancer screening (exhibit 3). The benefits of these screenings have been debated. For example, H. Gilbert Welch and colleagues argue that mammography and colorectal cancer screening have much smaller, if any, effects on overall mortality than on disease-specific mortality.[22] However, the most current reviews suggest reduced overall mortality in conjunction with these two types of screening, although estimates are not statistically significant.[23,24] In addition, the most recent screening modalities have not been fully evaluated (for example, colonoscopy instead of sigmoidoscopy).

Apart from screening, our models found that key gains in other (nonpharmaceutical) medical care included surgical care for adults with ischemic heart disease and stroke and for babies with congenital anomalies. Other nonpharmaceutical interventions were important for people with lung cancer.

Public health improvements accounted for the largest part of mortality improvement overall (44 percent), outranking any other driver analyzed (exhibit 3). This extends previous work suggesting that public health is the dominant determinant of longevity in general.[2] In our work, public health improvements were driven by increased adoption of risk reduction practices known before the 1990s, such as smoking reduction and seatbelt usage, as well as by important "low-tech" breakthroughs, such as awareness of the danger of stomach sleep for infants. Improved traffic safety was also a big contributor to improved health.

Our emphasis on public health and pharmaceuticals as the key drivers of reduced mortality is specific to 1990–2015. Had we studied the 1980s, other (nonpharmaceutical) medical care likely would have been assigned greater responsibility for improved outcomes, given the 250 percent growth in cardiovascular procedures over that decade[25] and the fact that statins only became available in the late 1980s. Had we studied only the years after 2010, our estimate of the net benefit of pharmaceuticals would have been reduced, given the acceleration of the opioid epidemic over this period. Even an analysis of the drivers of life expectancy change during 1990–2015 conducted some years from now might yield revised estimates as knowledge of the impacts of various interventions changes.

If we could translate knowledge from existing public health "wins" to areas with less success, longevity gains could be very large.

Our work sought to explain the reasons for mortality reduction and did not consider differing effects by race, ethnicity, geography, and education. Future work should address this important limitation. Future work should also consider the drivers of morbidity reduction. Global Burden of Disease Study data suggest that disability and mortality moved in tandem during 1990–2015 (appendix exhibit A16).[7] However, the extent to which the drivers of mortality reduction are also drivers of morbidity reduction is unclear, as we did not examine many of the conditions most responsible for reduced disability between 1990 and 2015 (including mental illness and visual impairment).

Policy Implications

Our findings have implications for the ongoing debate regarding the value of health care spending in general, and spending on pharmaceuticals specifically. Although our findings do not speak directly to the value of treating additional people with medications, they do underscore the central role of medications overall in explaining reduced mortality. Policy making on drug pricing should consider the implications of potential legislation across the full spectrum of conditions—both those where the societal return on drug investments is high and those where expected value is more ambiguous.

Our results also suggest the importance of minimizing cost-related barriers to key preventive and chronic care services. For example, coverage expansions through the Affordable Care Act have been associated with increases in early-stage cancer diagnoses[26] as well as increased use of heart disease medication.[27] For the in-

sured, elimination of cost sharing for primary prevention may have led to increases in cancer screenings.[26] Given substantial underuse of high-value care, longevity gains might have been larger if coverage gains had been more complete and if out-of-pocket spending for secondary preventive services had also been reduced. Expanding coverage and advancing value-based insurance design[28] therefore remain important needs.

Conclusion

Our results emphasize the need to build on existing public health successes. In recent decades, smoking has become much less prevalent and driving has become safer. Simultaneously, obesity has increased and opioid-related mortality has soared. It is not clear what most explains this mixed record: the intrinsic nature of the behaviors or the lack of appropriate interventions. If we could translate knowledge from existing public health "wins" to areas with less success, longevity gains could be very large. ■

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U.S. Senate Committee on Health, Education, Labor & Pensions (HELP)
428 Senate Dirksen Office Building
Washington, DC, 20510

February 5, 2024

Statement for the record for hearing Why Does the United States Pay, by Far, the Highest Prices in the World for Prescription Drugs?

Background:
I thank the Committee for their continued work in seeking to understand and address the problem of high drug prices in the United States.

I am a health economist based at Yale University. I completed my PhD at Harvard University in 2023 have served as a consultant on pharmaceutical issues for the World Health Organization (WHO), Médecins Sans Frontières (MSF), the Global Fund to Fight AIDS, Tuberculosis, and Malaria, and the World Bank. In September 2023 I testified before the House Committee on Energy and Commerce on *Legislative Proposals to Prevent and Respond to Generic Drug Shortages*. I represent only myself in this submission.

In this statement for the record, I will briefly outline the results of my research on the production costs of pharmaceuticals that the Committee may find useful in their investigation.

Summary of methods used to estimate the cost of production of medicines:
I have worked to develop and refine methods for estimating the cost of production of medicines since 2016. The core costing algorithm was commissioned by WHO for the Fair Pricing Forum in 2017,[1] and has since been expanded and further developed and applied to hundreds of medicines. The costing methods included herein have been extensively peer reviewed in a range of journals (*British Medical Journal (BMJ) Global Health, BMJ Open, Journal of Virus Eradication,* and *The Lancet Oncology*) and presented at numerous international conferences (International AIDS Society, European Society for Medical Oncology, and the European Society of Clinical Microbiology and Infectious Diseases). My co-authors and I have published cost estimates for all tablets/capsules and injectable medicines on the WHO Essential Medicines List (where permitted by available data),[2-3] insulin including insulin analogues,[4] HIV medicines and treatments for opportunistic infections,[5-6] direct-acting antivirals for hepatitis C,[7] cancer medicines,[8] and antihypertensive medicines.[9] Our 2018 *BMJ Global Health* paper was recently included as a reference for cost of production by Novartis researchers, giving us further confidence that our methods, developed in academic contexts, are also regarded as accurate within industry.[10]

Analysis

Sample selection: I include cost of production estimates for drugs (where permitted by available data) covered under Medicare Part D selected for negotiation as part of the Inflation Reduction Act. This sample of drugs was chosen as they were identified by CMS as significant cost drivers in Medicare expenditures, amounting to 20% of total Part D gross covered prescription costs.[11]

Table 1. Estimated cost of production for medicines subject to Medicare negotiation

		Cost (unit)		Cost (annual)	
Drug	**Unit**	**Estimated cost of production**	**NADAC**	**Estimated cost of production**	**NADAC**
Eliquis *apixaban*	5mg tablet	$0.02	$9.50	$18	$6935
Entresto *sacubitril / valsartan*	97mg/103mg tablet	$0.16	$11.00	$130	$8030
Farxiga *dapagliflozin*	10mg tablet	$0.04	$18.62	$16	$6796
Fiasp Flextouch *insulin aspart*	3 mL 100unit/mL disposable pen	$1.26	$107.13	$61	$5214
NovoLog FlexPen *insulin aspart*	3 mL 100unit/mL disposable pen	$1.26	$26.85	$61	$1307
Imbruvica *ibrutinib*	140mg capsule	$0.75	N/A	$1091	N/A
Januvia *sitagliptin*	100mg tablet	$0.06	$18.32	$23	$6687
Jardiance *empagliflozin*	10mg tablet	$0.04	$19.53	$16	$7128
Stelara *ustekinumab*	45 mg/0.5 mL in syringe	$2.82	$12,760	$12	$55,293
Xarelto *rivaroxaban*	20mg tablet	$0.03	$17.37	$12	$6340

In the interests of brevity for this submitted statement, I have submitted summary results. The methods are described in detail in the technical appendix and publications linked in the endnotes.

Should Committee members have further inquiries, including questions about cost of production methods and their application, I am available to support as may be helpful.

Sincerely,

Melissa Barber

Technical Appendix

1. Cost comparison to NADAC prices methodology

1.1 NADAC costs: National Average Drug Acquisition Cost. Most recent price reported as of 31 Jan 2024.

1.2 Many drugs have multiple indications. See Table A1 for assumptions about the indications and other considerations used in calculating annual treatment costs. Note: Unit costs are rounded to the second decimal point, but were not rounded in calculating annual costs.

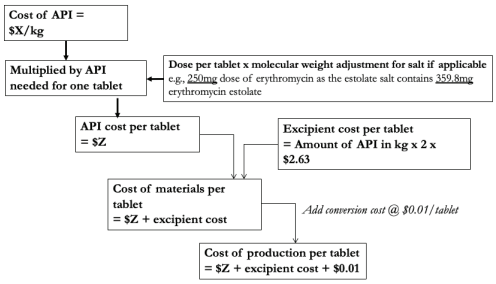
Table A1. Indication and treatment assumptions in calculating annual costs

Drug	Unit	Treatment regimen	Representative indication used for comparison (FDA label)	Notes / assumptions
Eliquis *apixaban*	5mg tablet	5mg x 2 daily	reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation	
Entresto *sacubitril / valsartan*	97mg/103mg tablet	97mg/103mg x 2 daily	to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal.	target maintenance dose as recommended in AHA/ACC/HFSA 2022 guidelines
Farxiga *dapagliflozin*	10mg tablet	10mg daily	adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	Typical dose
Fiasp Flextouch *insulin aspart*	3 mL 100unit/mL disposable pen	40 units/day	Improve glycemic control in adults with diabetes mellitus	WHO DDD 40 units/day
NovoLog FlexPen *insulin aspart*	3 mL 100unit/mL disposable pen	40 units/day	Improve glycemic control in adults with diabetes mellitus	WHO DDD 40 units/day
Imbruvica *ibrutinib*	140mg capsule	140mg x 4 daily	Mantle cell lymphoma (MCL) who have received at least one prior therapy	
Januvia *sitagliptin*	100mg tablet	100mg daily	adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	
Jardiance *empagliflozin*	10mg tablet	10mg daily	reduce the risk of cardiovascular death in adults with type 2 diabetes & established cardiovascular disease	
Stelara *ustekinumab*	45 mg/0.5 mL in syringe	45 mg/0.5 mL in syringe every 12 weeks	moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy.	Maintenance dose, assumed weight <100kg
Xarelto *rivaroxaban*	20mg tablet	20mg daily	reduce risk of stroke and systemic embolism in nonvalvular atrial fibrillation	

2. Cost of production methodology:

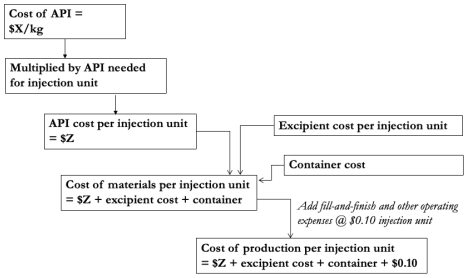
The costing algorithm includes costs of materials (active pharmaceutical ingredient, excipients), and formulation costs. This technical appendix briefly summarizes the methodologies of peer-reviewed publications to describe how different parameters were sourced. This summary is not comprehensive. Please see referenced publications and their supplementary appendices for a full description of data source, data cleaning algorithms, and costing considerations.

Figure A1. Cost of production algorithm for solid oral dosage formulations



Algorithm as published in Hill A, Barber MJ, Gotham D. Estimated costs of production and potential prices for the WHO Essential Medicines List. BMJ Global Health 2018; 0: e000571.

Figure A2. Cost of production algorithm for injectable formulations



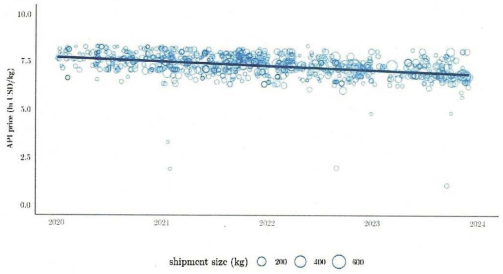
2.1 API cost

The price of active pharmaceutical ingredient (API) is the most important determinant in the cost of a production of a medicine. In order to identify shipments of API, a proprietary export/import database was searched for dates between Jan 2020 and Dec 2023, including import-export shipments from India, the United States, Mexico, Costa Rica, Panama, Bolivia, Brazil, Chile, Colombia, Ecuador, India, Paraguay, Peru, Uruguay, Venezuela, China, India, Indonesia, Pakistan, Sri Lanka, and the Philippines.[a] Data were not available for etanercept.

Data on shipments were manually cleaned to exclude shipments that did not represent genuine API, using criteria developed in peer-reviewed publications (e.g., shipments of working or reference standard, API with impurities, finished product, etc).[b] Outliers were defined as those with values higher than the third quartile plus 1.5 times the interquartile range, or lower than the first quartile minus 1.5 times the interquartile range, and were excluded. Weighted least-squares regression was used to fit linear models, with weights corresponding to shipment volume in kilograms. The outcome (unit cost) was log-transformed to reduce skew in the residuals. The predicted value on 1 December 2023 was used as the assumed average market price for API; we did not extrapolate beyond observed data.

Statistical analyses were performed and visualizations generated in *R* version 4.2.

Figure A1. Example of API cost data: rivaroxaban



2.2 Excipients

Excipients are ingredients other than the API that comprise a given formulation.

In general, specific weights of excipients for solid oral dosage formulations are not publicly available. The total proportion of finished product weight made up by excipient

[a] Not all import data sources available for all dates.

[b] See Appendix for details on approach to data cleaning, available here: https://gh.bmj.com/content/bmjgh/3/1/e000571/DC1/embed/inline-supplementary-material-1.pdf?download=true

is typically between 20% and 60%.[12] Table A2, below, shows typical costs of excipients used in solid oral formulations, and typical proportion of total finished pharmaceutical product (FPP) weight made up by each excipient.

Table A2. Costs of excipients used in solid oral formulations, and typical proportion of total FPP weight made up by each excipient.

	Typical weight as % of FPP weight		Cost per Kg (USD)	
Excipient	**Min**	**Max**	**Min**	**Max**
Sodium benzoate	1%	3%	$1.62	$2.19
Cellulose or microcrystalline cellulose	10%	60%	$2.00	$3.22
Talc	0.2%	2%	$2.00	$3.57
Sodium starch glycolate	1%	5%	$0.96	$4.93
Crospovidone	2%	5%	$3.03	$3.03
Lactose	5%	40%	$3.03	$3.77
Xylitol	5%	10%	$2.20	$5.75
Calcium phosphate, dibasic	5%	50%	$2.46	$5.70
Carboxymethylcellulose sodium	5%	25%	$3.25	$5.99
Starch, pregelatinised	5%	35%	$2.00	$9.00
Xanthan gum	5%	15%	$5.02	$7.44
Croscarmellose sodium	1%	5%	$6.56	$9.51
Methyl paraben	1%	2%	$11.50	$11.50
Povidone	5%	20%	$8.59	$17.11
Magnesium stearate	0.25%	4%	$4.30	$23.50
Potassium sorbate	0%	2%	$18.00	$37.00
Sodium lauryl sulfate	1%	2%	$36.00	$51.00
Aluminium oxide	0%	5%	N/A	N/A

Excipients composing the major part of FPP weight are in general very cheap – for example, cellulose, lactose, calcium phosphate, carboxymethylcellulose, pregelatinised starch. More expensive excipients, for example potassium sorbate, methyl paraben, and sodium lauryl sulfate, typically account for only a small proportion of the pill weight (<5%).

Using the data in the table above, and the assumption that excipients make up 50% of the FPP weight for tablets, we have calculated an average excipient cost of $2.63 per kilogram of FPP.

Excipients for injectable formulations were sourced from Niazi (2020) and/or regulatory submissions to FDA or EMA.[13][14]

1.3 Formulation costs

These are operating expenditures, minus API and excipients, needed to convert raw API into a FPP. Similar algorithms have been used and validated in previous studies.[15]

Multiple sources were consulted in order to inform a choice of assumed conversion cost per tablet/capsule. These are described individually below, summarized, and the final choice of assumed conversion cost is explained.

It is our view that, based on the values suggested by the available analyses, outlined above, the most plausible average conversion cost is between $0.005 and $0.01 for a solid oral dosage formulation. Of all the cost of production analyses identified (Table A3), it is only the Pinheiro et al study from Brazil in 2001 that has a per-unit estimate significantly greater than $0.01. We have set the assumed conversion cost in our generic price estimation algorithm at $0.01/tablet.

Table A3. Per-unit cost component values available from various analyses.

Report	Cost components included in estimate	Conversion cost per tablet
LOCOST/JSS (2004)[16]	Conversion cost not including depreciation of capital, distribution, but including quality control (testing) and packaging	$0.0016
Lowest-priced product in UK, South Africa, India (2016)	Cost per unit of lowest-priced solid oral formulation FPP	$0.0011–$0.0043
Chaudhuri et al (2015)[17]	Conversion cost including depreciation of capital and packaging, but not including sales and distribution	$0.0056
	Conversion cost including depreciation of capital and packaging, and including sales and distribution	$0.0105
Discussion by authors with large generic companies (2016)	Conversion cost including packaging, but not sales and distribution	$0.006
McKinsey & Company (2014)[18]	Total production costs, lowest-cost plants (not further specified)	$0.013
Pinheiro et al (2006, data from 2001)[19]	Conversion cost (direct and indirect costs)	$0.057
	Conversion cost (direct and indirect costs) plus operating margin	$0.101

Formulation costs for injectable products are described in *Estimation of cost-based prices for injectable medicines in the WHO Essential Medicines List, Production costs and potential prices for biosimilars of human insulin and insulin analogues,* and a publication in press.[3,4]

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[Whereupon, at 1:25 p.m., the hearing was adjourned.]

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