

**UNSUSTAINABLE DRUG PRICES (PART III):
TESTIMONY FROM ABBVIE CEO RICHARD
GONZALEZ**

HEARING
BEFORE THE
COMMITTEE ON
OVERSIGHT AND REFORM
HOUSE OF REPRESENTATIVES
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- * Committee Staff Report on AbbVie: Humira and Imbruvica; submitted by Chairwoman Maloney.
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**UNSUSTAINABLE DRUG PRICES (PART III):
TESTIMONY FROM ABBVIE CEO RICHARD
GONZALEZ**

Tuesday, May 18, 2021

HOUSE OF REPRESENTATIVES,
COMMITTEE ON OVERSIGHT AND REFORM,
Washington, D.C.

The committee met, pursuant to notice, at 10:07 p.m., in room 2154, Rayburn Office Building, Hon. Carolyn Maloney [chairwoman of the committee] presiding.

Present: Representatives Maloney, Norton, Lynch, Cooper, Connolly, Raskin, Khanna, Mfume, Porter, Bush, Davis, Wasserman Schultz, Welch, Johnson, Sarbanes, Speier, Kelly, DeSaulnier, Gomez, Pressley, Comer, Jordan, Foxx, Hice, Grothman, Cloud, Gibbs, Higgins, Norman, Keller, Sessions, Biggs, Clyde, Mace, Franklin, LaTurner, Fallon, Herrell, and Donalds.

Chairwoman MALONEY. The committee will come to order.

Without objection, the chair is authorized to declare of the recess of the committee at any time.

I now recognize myself for an opening statement.

For more than two years, this committee has engaged in one of the most comprehensive and in-depth investigations of pharmaceutical pricing practices ever conducted by Congress. This investigation was launched by my predecessor, the late chairman, Elijah Cummings, and I have been proud to carry forward this critical work.

Last fall, the committee held two hearings with drug company CEOs and released five staff reports detailing our findings. This morning, we released a sixth staff report describing our findings on AbbVie, which sells two blockbuster drugs: Humira and Imbruvica. Our work has continued and confirmed what patients in this country have known for a long time: drug prices in the United States are unfair, unsustainable, and just plain wrong.

This investigation also reveals something even more distressing. Drug companies are actively targeting the U.S. for price increases while cutting prices in the rest of the world. They are doing this by taking advantage of flaws and loopholes in our system, most importantly, the law that prevents Medicare from negotiating directly with drug companies for lower prices. Finally, our investigation has revealed that the justifications the pharmaceutical industry offers for why they need to raise prices simply do not hold water.

Today we will hear from Richard Gonzalez, the CEO of AbbVie. We appreciate his attendance at today's hearing. Unfortunately,

this hearing was delayed because it took more than a year and the threat of a subpoena before AbbVie agreed to voluntarily comply with this committee's investigation.

AbbVie has repeatedly raised the prices of Humira, which is used to treat rheumatoid arthritis and other autoimmune diseases, and Imbruvica, a drug approved to treat different forms of cancer. AbbVie charges approximately \$77,000 a year for a year's supply of Humira. That is 470 percent more than when the drug was launched in 2003. Humira is the highest-grossing drug in the United States due, in large part, to these horrendous price increases. You see where it started out at \$500 for a syringe; it is now at \$2,984 just for a syringe. AbbVie and its partner, Janssen Biotech, charged even more, over \$181,000 for a year's supply of Imbruvica. That is 74 percent more than when the drug was launched in 2013. Experts estimate that by 2026, Imbruvica will be the fourth bestselling drug in the United States. These prices are outrageous and unfair.

Even more outrageous is that Americans are the only ones paying them. In 2015, a single syringe of Humira was priced over \$1,000 higher in the United States than in countries like Canada, Japan, Korea, and the United Kingdom. Even as AbbVie hikes its prices in the United States, it has actually been dropping its prices in other countries. In one internal presentation from 2016, AbbVie executives described this disparity as, and I quote, "positive price in the U.S. and negative price overseas." AbbVie's price increases have paid off for the company's bottom line. Last year alone, AbbVie collected \$16 billion in U.S. net revenue for Humira, and AbbVie and Janssen collected \$4.3 billion for Imbruvica. That is more than \$20 billion from American patients and taxpayers for just two drugs. And you see the massive pricing increase up to \$16 billion from \$200 million.

Our investigation also uncovered evidence that AbbVie has exploited the U.S. patent system and engaged in anti-competitive practices to extend its monopoly pricing. The committee has obtained internal documents showing that AbbVie's own executives projected its top-selling drug, Humira, would face competition from lower-priced versions of the drug, known as biosimilars, beginning in 2017. But AbbVie used legally questionable tactics to block lower-priced biosimilars from reaching American consumers until at least 2020. Those tactics made AbbVie a fortune, but cost Americans dearly. Based on these findings, I sent this letter to the FTC today, along with committee chairman of the Judiciary, Chairman Nadler, and Antitrust Subcommittee, Chairman Cicilline, asking for a formal inquiry into whether AbbVie's anti-competitive practices violated the law.

Finally, I want to emphasize that drug companies make essential lifesaving products. If the last year has taught us anything, it is that we are all indebted to the scientists who pioneer new cures, therapies, and vaccines, so we want drug companies to be successful. But abusive, unfair pricing and anti-competitive practices mean these medications are out of reach for too many Americans. And instead of investing in new innovations, drug companies, like AbbVie, are dedicating significant portions of their research budgets to coming up with new ways to suppress competitive products.

That means Americans are paying more, but we are getting less innovation. If we want to make a difference for patients and taxpayers, we need structural reforms like H.R. 3, which would finally allow Medicare to negotiate for lower drug prices like the rest of the world does. Congress must pass this commonsense reform and others so that patients and families can afford these prescriptions.

I want to close by playing statements from patients who want to share their experiences with us about these two drugs. Please watch.

[Video shown.]

Chairwoman MALONEY. These patients' stories show why we need immediate reform. We need to pass H.R. 3 this year to allow Medicare to negotiate lower drug prices for Americans like other foreign countries do. I thank these patients for their testimony, their very moving testimony, and I now recognize the distinguished ranking member, Mr. Comer, for an opening statement.

Mr. COMER. Mr. Comer. Thank you, Madam Chair. Over the past year, we have seen the massive importance of research and development in vaccines and treatments. Operation Warp Speed, one of the greatest public/private partnerships in American history, resulted in the Federal Government partnering with private companies to invest hundreds of millions of dollars to develop and manufacture COVID-19 vaccines. The result, despite constant vilification by the Democrats, was the fastest vaccine development in history with the first vaccine approved in less than 12 months from the first discovery of COVID-19. Since then, two more vaccines have been approved with two more awaiting approval by the FDA. In addition, there have been numerous pharmaceutical treatments and medical devices innovated to treat COVID-19. As a result of these vaccines and therapies, cases and fatalities have plummeted, and our Nation is on the road to recovery.

The catalyst behind these innovations have been intellectual property protections here in the United States. America's robust patent system enables enormous investments in the research and development of new medications, more generic drug competition, and new technologies to promote patient adherence. The research funded by these investments results in treatments and cures for countless diseases, enabling Americans to live longer and healthier lives. Yet today, the Democrats on this committee decry our country's intellectual property protections as the root of all evil in the pharmaceutical space. This is simply not true. Certainly there are companies that have abused our patent system, seeking hundreds of patents to prolong their ability to control the market for a particular treatment. But many seek patents simply to protect their intellectual property so they can recoup their investments.

While seeking hundreds of patents on a medication or vaccine is not illegal under our existing system, it can be anti-competitive and result in higher costs for patients. Republicans in the House and Senate have sought to right this wrong through legislation that would stop pharmaceutical companies that seek to abuse the patent system and extend their control of the market, and prevent the use of settlement agreement to pay generics to delay entry into the market. Democrats have instead proposed H.R. 3, a massive government takeover of the pharmaceutical market that would result

in significantly fewer treatments and vaccines from coming to market. We should not destroy the very system that has made the United States the world leader in medical innovation like our Democrat colleagues propose.

Republicans want to protect innovation and consumers. This Congress Republicans introduced H.R. 19, a collection of bipartisan reforms to prevent anti-competitive behavior in pharmaceutical markets, bring more generics to market, incentivize innovation and research, and require pharmaceutical rebates to be included at the point of sale so that patients receive the benefits instead of pharmacy benefit managers, or PBMs. While Democrats were impeaching this President, Republicans were working to decrease the cost of prescription drugs for all Americans. Now, nearly two years later, Democrats have nothing to show for it and are attempting to try to attack yet again another pharmaceutical company rather than help Americans across the country.

We must address rising prescription costs because high costs are hurting American families everywhere. Republicans presented a real plan to lower out-of-pocket costs and protect innovation for new treatments and cures. The American people need relief, but Speaker Pelosi has instead sought to pass a bipartisan plan and destroy intellectual property protection that our founding fathers even wanted. We must put people, not partisanship, first. I yield back the remainder of my time.

Chairwoman MALONEY. The gentleman yields back. I would now like to introduce our witnesses. Our first witness today is Dr. Aaron Kesselheim, who is an associate professor of medicine at Harvard Medical School. Dr. Kesselheim also testified at our committee's very first hearing on prescription drug prices back in January 2019. Then we will hear from Craig Garthwaite, who is the Herman Smith research professor in hospital and health services at the Kellogg School of Management at Northwestern University. Next, we will hear from Tahir Amin, who is the co-founder and co-executive director of the Initiative for Medicines, Access, and Knowledge. Finally, we will hear from Richard Gonzalez, who is the chairman and CEO of AbbVie.

The witnesses will be unmuted so we can swear them in. Please raise your right hands.

Do you swear and affirm that the testimony you are about to give is the truth, the whole truth, and nothing but the truth, so help you God?

[A chorus of ayes.]

Chairwoman MALONEY. Let the record show that the witnesses answered in the affirmative. Thank you.

And without objection your written statements will be made part of the record.

With that, Dr. Kesselheim, you are now recognized for your testimony. Dr. Kesselheim?

**STATEMENT OF AARON KESSELHEIM, M.D., ASSOCIATE
PROFESSOR OF MEDICINE, HARVARD MEDICAL SCHOOL**

Dr. KESSELHEIM. Chairman Maloney, Ranking Member Comer, members of the committee, I am honored to talk with you about curbing abuses by drug makers that take advantage of our market

exclusivity system for prescription drugs, raising the prices for these products and jeopardizing patient outcomes.

The idea behind our patent system, enshrined in the Constitution, is that a period of exclusivity enables innovators to profit from their creations, and then allows others to compete once that period is over to prevent a permanent monopoly. In the drug market, this dynamic is important since medications are costly to create and test for efficacy and safety. In the U.S., drugs are covered by patents on their active ingredient, and other Federal laws, like the Orphan Drug Act, provides special additional exclusivity for rare disease drugs for seven years, for biologics for 12 years, after approval. With all of these exclusivities, drugs routinely get an average of about 14-and-a-half years of market exclusivity, while biologics receive 21-and-a-half years. During this time, brand name drug manufacturers charge high prices. Alone in the industrialized world, the U.S. lets drug makers set the prices they choose for patented products. U.S. law then allows manufacturers to raise prices each year during market exclusivity, well beyond inflation. High prices lead patients to skip doses and worse health outcomes.

When market exclusivity ends, real competition is supposed to begin. Generics can quickly become the default prescription because they can be automatically interchanged, lowering prices 70, 80 percent or more. Biosimilars have been slow to enter the U.S., and none have yet been FDA certified as interchangeable, but we found that each biosimilar entrant reduces prices about 4 to 10 percent. This system has become subject to many abuses as brand name manufacturers try to delay effective competition. A common strategy is obtaining a thicket of dozens or even hundreds of patents. So-called secondary patents cover peripheral features of the drug, like intermediate compounds are methods of treatment. Tertiary patents cover the delivery mechanism, such as an injection pain or inhaler. The proportion of tertiary patents listed with the FDA tripled from 3 percent in 2000 to 9 percent in 2016. Some firms used this time to introduce new versions of their product with little or no clinical benefit for patients. For example, a firm might switch from a capsule to a patented tablet formulation that is not interchangeable.

Many secondary and tertiary patents are actually bad patents that lack novelty or cover only minor obvious changes to the drug. One analysis revealed that legal challenges seeking to overturn the primary patent succeeded only eight percent of the time, while challenges to secondary patents were successful 67 percent. But litigation to overturn improperly granted patents can take years and millions of dollars to complete, and in recent years, many generic and biosimilar manufacturers have settled litigation, agreeing with their brand-name counterparts to keep potentially bad patents in place and not introduce their FDA-approved competitors in exchange for financial benefits.

All of these issues can be observed with adalimumab, a drug acquired by what was then Abbott from a German company in 2000 before it reached the U.S. market in 2003. As the primary patent was set to expire in 2016, litigation with biosimilars over its thicket of patents led to settlements blocking U.S. market entry until

2023, although these products entered most U.S. countries in 2018, leading to billions of dollars in excess spending.

So what can you do? We need to protect and reward innovation, yet ensure timely competition after a reasonable period of market exclusivity. First, bad patents must be limited. Other patent offices around the world issue fewer bad patents by spending more time on review. In addition to granting more resources to the U.S. Patent Office, Congress should instruct it to develop new guidance on patenting standards so that trivial modifications would not be patented, while patents on novel innovations would remain. Another step would be to provide greater opportunity for administrative review prior to litigation via the already existing Patent Trial and Appeals Board. The PTAB should be required to review drug patents when they are listed with the FDA or are determined relevant to biosimilar approval.

You can also take steps to ensure that manufacturers cannot use other market exclusivity periods to delay competition. For example, the seven-year orphan drug exclusivity should be curtailed for drugs used in much larger populations after approval or that bring in substantial revenue. And the 12-year regulatory exclusivity provided for biologic drugs should be shortened to match small molecule drugs because biologic drugs have similar development times. Finally, you desperately need to pass H.R. 3 to give the government the power to evaluate the benefits of new drugs so that we can make clear which modifications greatly help patients and which are useless product hopping intended to extend exclusivity. The government should be able to negotiate prices so that we do not, as we do now, pay exorbitant prices for so-called new drugs with minor changes, but only pay for clinically meaningful innovation.

In conclusion, the drug exclusivity system was intended to provide a reasonable limited period after FDA approval during which brand-name manufacturers can earn fair, and even generous, revenues from their products. Strategies with adalimumab and other cases upset this balance and make it more lucrative for a drug company to invest in fending off competitors for decade-old products rather than coming up with important new discoveries. Ensuring that generic and biosimilar competition can occur in a timely fashion will have little detrimental effect on meaningful drug innovation, but would reduce overall healthcare spending, make medications more affordable, and promote improved patient outcomes.

Thank you very much.

Chairwoman MALONEY. Thank you. Mr. Garthwaite, you are now recognized for your testimony. Mr. Garthwaite?

STATEMENT OF CRAIG GARTHWAITE, HERMAN SMITH RESEARCH PROFESSOR IN HOSPITAL AND HEALTH SERVICES, KELLOGG SCHOOL OF MANAGEMENT AT NORTHWESTERN UNIVERSITY

Mr. GARTHWAITE. Thank you, Chairwoman Maloney, Ranking Member Comer, and members of the committee for inviting me to testify today about issues related to drug pricing in the United States.

As described in your opening statement, it is well known that the process of developing novel pharmaceutical products is expensive and risky. Innovative firms must make large, fixed, and sunk investments if they are to create the knowledge necessary to develop new drugs. The knowledge that results in this process is largely a public good. Absent government intervention, it would be hard for firms to protect that intellectual property and to stop competitors from copying their innovations and competing away any potential profits. Rational firms understand this eventuality, and absent such government intervention, they would be unwilling to invest in drug development. This would cause an economic condition known as “hold up” where valuable investments are simply not made.

To avoid hold up, governments provide various types of intellectual property protection that allow innovative firms a time-limited period of market exclusivity in which they can enjoy enhanced market power. In this way, innovation policy regarding prescription drugs involves a difficult tradeoff where we accept some amount of reduced access today in order to provide the incentive for firms to innovate and develop drugs for tomorrow. I don’t say this lightly. I fully understand that high prices can decrease access to potentially lifesaving medications, and we should consider policies, as I detail in my testimony, that limit that harm. But, frankly, there are no easy or simple answers here. Weakening existing intellectual property protections or using government power to set artificially low prices will decrease innovation and lead to its own access problems.

You see, while it is clearly true that patients today paying high prices can suffer decreased access to medication, we must also acknowledge that those patients do enjoy a significant benefit that should not be overlooked: there is an existing drug that can treat their condition. For those suffering from conditions where there are no treatments, there is no drug available at any price. When we only focus on access problems related to prices, we ignore this other fundamental lack of access. Simply because these missing innovations and their affected patients are harder to specifically identify and not available for photo opportunities doesn’t make them any less real. That said, we must remember that everything about the existing parameters of this tradeoff is simply a policy choice. There is nothing magical about our current 20-year patent length, and the very fact that this patent is constant across products, that it is constant across markets, suggests that it is not the result of some finely tuned calibration or economic model.

As the market changes, it is reasonable, as this committee is doing, to revisit our policies related to both access and innovation. In doing so, I would argue that we should focus on two broad areas as our goals. We should be focusing as a government on limiting welfare losses where possible while drugs are covered by patents, and ensuring that periods of market exclusivity are expressly time limited and followed by competition, and robust competition, from generic and biosimilar entrants. Welfare losses during periods of market exclusivity can be limited by both promoting competition between branded products and ensuring the continued operation of well-functioning insurance markets.

I outline several policies in my testimony that could accomplish these goals. These includes reforms, the Reinsurance Program in Part D, the buy and bill system for Part B, like “boy,” improving information disclosure on the flow of funds in the value chain, and perhaps, most important, but most interesting given the video at the start of the testimony, is decreasing owners’ cost-sharing for pharmaceuticals where the conversation there is as much about the price of the drug as it is about the insurance contract that we have, and particularly in Part D, an exceptionally poor insurance contract for many people buying expensive medications.

Once firms have reached the end of their period of market exclusivity, regulations should support the rapid and vigorous entry of competition. If market structures don’t allow for meaningful competition to emerge, there is a clear role for regulation to either create competitors or restrict pricing. When thinking about policies in the period of high prices being time limited, it is easy to recognize, given the other witnesses here today, that the committee is obviously concerned with the use and potential open use of patents. Often, critics of the existing intellectual property protection system will cite the sheer number of patents sought by pharmaceutical firms as evidence of nefarious behavior to deter entry. However, the number of patents is, at best, an incomplete metric. Our questions should be about the strength and the underlying validity of the patents, and not their sheer number.

Modern products involved meaningful intellectual property related not to just to the product, but its production, and also its additional uses in other medical conditions, and we should examine the process of granting these patents, up to and including more resources for the Patent and Trademark Office. Others have called for sweeping reforms in the form of price regulation or in the form of limiting paths to one per product. Those reforms are overbroad, and while I understand it is tempting to cave to sort of the crass calculus that we can increase access today and allow for more innovation going forward, that is not true. We will suffer less innovation if we lower the returns on drugs, and we should debate the nature of that reduced innovation in our policies.

Thank you very much for your time today.

Chairwoman MALONEY. Thank you. Mr. Amin, you are now recognized for your testimony. Mr. Amin?

STATEMENT OF TAHIR AMIN, CO-FOUNDER AND CO-EXECUTIVE DIRECTOR, INITIATIVE FOR MEDICINES, ACCESS, AND KNOWLEDGE

Mr. AMIN. Chairwoman Maloney, Ranking Member Comer, and members of the committee, it is my honor to testify before you today.

I spent the first decade of my legal career working as an attorney in the private sector securing and protecting IP. Many of my clients were American companies. I learned both the legal and business side of IP 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 IP, right, so companies could obtain and maintain a monopoly in the market, while continuing to extract maximum profit. I speak to you today as someone who has

seen both sides of the issue. I want to state up front this conversation is not about the death knell of innovation. It is about bringing equity to a system and about how well this system incentivizes genuine innovation.

Roughly 34 million American adults know at least one friend or family who died in the past five years because they could not afford treatment, and that figure is double for people of color. Sadly, that is not surprising. U.S. prescription drug spending has increased by 76 percent from 2000 to 2017. These price hikes correspond with a dramatic increase in patenting activity in the pharmaceutical sector. America not only has a drug pricing crisis, but it also has a drug patenting crisis.

Last week, the USPTO issued its 11 millionth patent. It took 155 years for the USPTO to issue its first 5 million patents in 1991. It has taken less than one-fifth of that time to issue the next 6 million. Have we really become more inventive in the last 30 years, or have we just gotten better at inventing patents because our patent system no longer is stringent enough? The number of pharmaceutical patents granted in the U.S. more than doubled between 2005 and 2015.

My organization has been analyzing the top 10 bestselling drugs in the U.S., and it found a total of 1,310 patent applications have been filed on these top 10 drugs, and 692 patents have been granted on these drugs in total. On average, that is 131 patent applications and nearly 70 granted patents per drug. On average, 63 percent of these patents are filed after the first approval for marketing, and that gives an average duration of patent protection covering these drugs monopoly period of 38 years. And between 2014 and 2019, on average, we have seen a 71 percent price increase on these drugs. Two of the best-selling drugs on this top 10 list belong to AbbVie: Humira and Imbruvica. AbbVie has filed an astonishing 422 patent applications on these drugs alone. Ninety percent of the 257 patent applications filed for Humira were filed after the drug was first approved in 2002, and it has amassed a record 130 granted patents for Humira, and 39 years of protection.

Despite litigation by nine different companies, patents settlement agreements have allowed AbbVie to keep competitors out of the U.S. market until 2023. Due to a lack of immediate competition, that means the U.S. will have spent an estimated \$77 billion before competition enters the market. Meanwhile, across the pond, competing biosimilar versions of Humira have already entered the European market, with prices dropping as much as 70 percent. A similar story with Imbruvica: 165 patent applications, and 88 have been granted so far. That is about one patent filed every month for the last 13 years. Granted, patents for Imbruvica give AbbVie a monopoly protection to 2030, nine years more than the usual 20-year period, and during that extended period, Americans will spend \$41 billion Humira and Imbruvica. And, again, generic companies have made settlement agreements.

One of the arguments you probably hear today AbbVie uses to justify this wall of patents is that the drug treats several different disease indications, but AbbVie has employed what I call the drip fee patent strategy for Humira and Imbruvica. The initial patents on these drugs are already disclosed and protect many of the indi-

cations, setting out a strategic roadmap for getting future patents. AbbVie recycled their claims in their original patents on these drugs over a decade later by making some minor changes, such as specifying the dosing or combining them with existing drugs. They will do so because this patent system allows it.

So how do we solve this problem? Well, before we get to the solutions, I want to just raise the point that Keytruda is about to trump Humira as the bestselling drug in the world in 2024. And the additional years that Keytruda potentially has already amassed is going to cost Americans an estimated \$137 billion. Today we are talking about Humira and Imbruvica, but if Congress fails to act, tomorrow we will be talking about Keytruda and another drug.

The solutions to the problem lie in raising the bar for what gets patented. Too many patents are granted that are too weak. We also need to change the incentives of the USPTO and the culture that is there. Basically, patents are granted to earn revenue, and we need to create a financial incentive that actually works outside of that. And also we need to reduce the prohibitive cost of challenging patents. American ingenuity is rightly a source of pride, and because of that, it is tempting to lionize the patent system. But patent activity today goes well beyond the limited time that the Constitution intended. Today's patent system had become less an engine for real invention than a tool for companies and their lawyers to exploit using legal and marketing Jedi tricks under the guise of innovation. And just because you invested money doesn't mean you have invented something.

Congress has the ability to return the patent system to what it has always intended to be, not a vehicle for unprecedented profits, but an engine for discoveries that are truly unprecedented. Thank you.

Chairwoman MALONEY. Thank you. Mr. Gonzalez, you are now recognized for your testimony. Mr. Gonzalez?

STATEMENT OF RICHARD GONZALEZ, CHAIRMAN OF THE BOARD AND CHIEF EXECUTIVE OFFICER, ABBVIE INC.

Mr. GONZALEZ. Chairwoman Maloney, Ranking Member Comey, and members of the committee, I am Richard Gonzalez. I am the Chief Executive Officer of AbbVie, a company with approximately 48,000 employees dedicated to developing new, innovative medicines for some of healthcare's most challenging diseases.

The global pandemic of the last year highlights the critical role that the biopharmaceutical industry plays in driving science and innovation to tackle the most significant diseases facing our society. Our industry invests over \$80 billion per year in research and development to meet those challenges, and our company alone has invested approximately \$50 billion since 2013, and has produced cures for diseases, like HCV, and therapies that are changing and prolonging the lives of patients suffering with cancer, rheumatoid arthritis, and other serious diseases. As we tackle the issues of drug pricing and access, it is important that we focus on what is working and what needs to change to make sure that patients get the medicines they need.

The United States has the most advanced healthcare system in the world. It doesn't ration care or restrict access to therapies, and

it is a leader in advancing science to provide cures to deadly diseases, like cancer. The United States is the most developed country when it comes to the use of generic drugs where over 90 percent of prescription volume are generic medicines with low out-of-pocket cost. Overall, most Americans have access to affordable medicines, and pharmaceutical companies, such as AbbVie, provide a number of forms of assistance for those who can't afford their medicines through co-pay support or free drug. The single largest patient group that lacks access to affordable medicines are standard Medicare Part D patients where the program design has put a significant cost burden on them. For these patients, reducing drug prices alone will not alleviate the challenge of access and affordability.

Last fall, the House Committee on Oversight and Reform held two days of hearings to examine the prices of prescription drugs, and certainly drug pricing is important, and the industry has taken steps to reduce drug pricing in recent years. In fact, since 2017, the overall contribution of price to AbbVie's business has been negative. In the category of what is working well here in the U.S., the Medicare Part D Program has been highly cost effective. The market-based structure encourages aggressive price discounts and have yielded significant savings to the government since the Part D Program was established. Despite a 70 percent increase in enrollment, the compounded annual growth rate in drug spending, adjusted for the increase in enrollees, is 1.8 percent, or roughly in line with inflation, and it has been basically flat since 2015. The aggressive price rebates negotiated by Medicare Part D plans have also kept patient monthly premiums flat at roughly \$33 since the program began in 2006. This data clearly demonstrates the overall cost effectiveness of the Part D Program.

So what is not working in Part D is that some patients must bear too much of the out-of-pocket costs, and there is no cap on drug spending. Unlike other commercial forms of insurance, Part D enrollees cannot access co-pay support. They cannot purchase insurance to defray these costs, and they must pay open-ended drug expenses. The average out-of-pocket cost is almost 100 times higher for a medicine like Humira than any other U.S. patient group. No other prescription drug insurance program puts so much cost burden on the patient.

We see the impact of the Part D design flaws most clearly in AbbVie's Patient Assistance Program where almost 40 percent of all Medicare Part D patients on Humira, or 1 out of 3, are seeking assistance and receiving free medicine. This stands in stark contrast to commercially insured Humira patients, where 1 out of 100 sought assistance from the AbbVie Patient Assistance Program. Medicare Part D patients' out-of-pocket cost is the single biggest issue when it comes to drug affordability. Additionally, while the overall costs in Part D is well controlled, government spending in the catastrophic phase is increasing the overall spending, and it is another area that needs to be addressed.

Industry, government, and healthcare plans should come together to significantly reduce out-of-pocket costs for patients and reapportion the cost in the catastrophic phase so that that spending will be well-controlled. Thank you.

Chairwoman MALONEY. And I now recognize myself for five minutes for questions.

AbbVie has raised the price of Humira 27 times since launching the drug. At the same time, AbbVie has actually lowered the price of this drug in the rest of the world. Mr. Gonzalez, has AbbVie been raising Humira prices in the United States while lowering them internationally?

Mr. GONZALEZ. Madam Chairwoman, the system that you described is how it actually does work. Certainly outside the U.S., there is always pressure on price, and prices do come down somewhat outside the U.S. once a product is launched, and in the U.S., we do have the ability to be able to raise prices. I think the key point will be what is the net price that companies like ours actually achieve, and what is done with the difference between gross and net pricing. I think that is an important debate that we should have.

Chairwoman MALONEY. Reclaiming my time. Well, AbbVie's internal documents prove that you did raise prices in the U.S. even while you were lowering them internationally. I want to put up Exhibit 23. This is an AbbVie board of directors presentation from 2016. Mr. Gonzalez, please turn to page 3 in the exhibit. The heading of this slide says, and I quote, "Humira Has Been Positive Price in the U.S. and Negative Price Overseas." In other words, AbbVie raised the price in the U.S., while lowering it in the rest of the world. This document also shows that the company had a plan to continue hiking the price of Humira in the U.S. for several more years. Mr. Gonzalez, please turn to page 10. This page shows that AbbVie planned to raise the price of Humira for Americans in 2016, 2017, 2018, 2019, and 2020, while cutting international prices each year. Mr. Gonzalez, did AbbVie actually go through with price increases on Americans during each of those years?

Mr. GONZALEZ. Madam Chairwoman, we would have had price increases on those years. That is a forward-looking, long-range planning document. I can't confirm for you whether or not it was those price increases. It is also important—

Chairwoman MALONEY. Well, reclaiming my time, the answer is "yes." AbbVie raised the price of Humira in the U.S. by even more than it originally planned. For example, instead of a 9.9 percent price increase for 2016, AbbVie actually raised the price by 18 percent that year alone. Let me turn to the second drug, Imbruvica. Mr. Gonzalez, is it true that AbbVie charges more for Imbruvica in the U.S. than in other countries?

Mr. GONZALEZ. Actually, Imbruvica is marketed through our partner outside the U.S., so I am not familiar with the pricing associated with Imbruvica outside the U.S.

Chairwoman MALONEY. Well, we looked at the data. I want to show you another graph comparing the list price of Imbruvica around the world in 2018. As you can see in this chart, Americans pay far more for this drug than people in other countries. This is unfair. In 2018, the price of a tablet of Imbruvica in the U.S. was roughly double the price charged in France, Germany, and the U.K. Medicare Part D provides prescription drug coverage to more than 45 million Americans, yet it is prohibited by law from negotiating lower prices on behalf of the patients it covers. Mr. Gonzalez, do

you know how much AbbVie made from Medicare in net sales of Humira and Imbruvica between 2014 and 2018?

Mr. GONZALEZ. It would have been approximately \$2.3 billion for Humira and approximately \$2.9 billion for Imbruvica.

Chairwoman MALONEY. Well, the documents we have, AbbVie's internal data shows that the company collected nearly \$12.5 billion, as in "B," from Medicare during this five-year period just for these two drugs alone, and this number accounts for any rebates that AbbVie paid to Medicare. No wonder AbbVie and the other drug makers target the U.S. for price increases. They know that, unlike the rest of the world, our Medicare program is prohibited from negotiating directly for lower prices. This data demonstrates clearly why Congress must pass H.R. 3 to grant Medicare the power to negotiate lower drug prices for patients. We must pass this bill this year.

I now yield to the distinguished ranking member, Mr. Comer.

Voice. No, Ms. Foxx.

Chairwoman MALONEY. No, Ms. Foxx? OK. Ms. Foxx, the distinguished gentlewoman from North Carolina, is now recognized.

Ms. FOXX. Thank you, Madam Chairman. My question is for Mr. Garthwaite. I want to relay a story from a recent report by the Information Technology and Innovation Foundation. "Scientists at Walter Reed conducted initial research and put out a request for a private company to work with them to develop a vaccine for the Zika virus. Sanofi was the only company to respond and reached an agreement with U.S. Army in June 2016. Upon learning of the agreement, Senator Bernie Sanders demanded that the Army require reasonable pricing language, also known as price controls, in the deal. In response, Sanofi noted, 'We can't undermine the price of a vaccine we haven't even made yet,' and said that it is premature to consider or predict Zika vaccine pricing at this early stage of development." Sanofi also noted the proposed license would require it to make royalty payments to the government, and its exclusive license would not prevent other companies from developing competing vaccines.

Following relentless media attacks, Sanofi announced it would not continue development of or seek a license to develop a vaccine. There is still no vaccine for the Zika virus. The taxpayers funded the research to identify the vaccine candidate, a private company agreed to take the risk of testing and manufacturing it, but this whole effort failed due to these progressive attacks. Thanks to these attacks, we may never know how many lives could have been spared by this vaccine. Mr. Garthwaite, if the threat of price controls on one potential product kills that innovation, what can happen if we threaten the entire industry with this type of socialist pricing like the one Democrats are proposing with H.R. 3?

Mr. GARTHWAITE. So I think the economic evidence is clear that if we are going to decrease the potential revenues of a product, we will see fewer investments in research and development. And so very large price increases, we would worry, would lead to declines in innovation. Your question gets at another point well. Well, how do we think about U.S. Government research into drugs and how that should affect pricing? I know there is a lot of concern, at times expressed by other members of the panel today, that the NIH re-

search shows up in the development of many drugs. And that is true because, in the example you gave, the NIH does a lot of basic science research, and that is what we want the government to do.

But given we spent the money to do that, we then want private firms to take that research up and be willing to invent or develop new products. If you put price controls or restrictions on it about specific returns or fair pricing clauses, or anything like that, you will likely decrease the take-up of government intervention or government research, and society is no better off. And that is why we want to think about our government investments here as complements to the research that is done by private risk capital, and because they are complements, we want people to use the NIH research as much as possible. And I worry that price regulations of the nature in H.R. 3, but also, broadly, conversation that the NIH should restrict the prices of products using their research, are going to decrease the returns we get on our investments in the NIH.

Ms. FOXX. Thank you very much. Mr. Gonzalez, in your opening statement, you described the competitive nature of the Medicare Part D program and how improvements to the program help seniors in my district lower their out-of-pocket costs. Now the Democrats are telling us that the only way forward on Part D is to have the government take it over and set prices so that the government can determine what medicines are worthwhile. Can you please help educate us on how the current Part D program is already a competitive market, and then how we need to improve it so that seniors are not facing higher costs?

Mr. GONZALEZ. I would tell you that in my experience, and I have got a tremendous amount of experience in this business, the Medicare Part D program is negotiated aggressively by the plans, and I will give you an example. Medicare for Humira gets a discount that is three percent higher, or a rebate that is three percent higher than the commercial side of the business. It gets that rebate despite the fact that it is roughly one-sixth the volume. Normally, when you think about discounting, a consumer that had six times the volume would get the lower price, but in this case, it is the opposite of that. The government is getting the lower price.

I would also tell you that if you look at the Medicare Part D plan, it is the structure of the plan that ultimately dictates the affordability issue for patients, and what I mean by that is this: you can take any other kind of patient in the United States, and, on average, they will pay for Humira around \$120 a year. A Medicare patient has to pay \$5,800 a year for Humira based on the structure of out-of-pocket costs, so, you know, an excessive amount. And you have to remember, these patients, on average, make \$28,000 a year, and there is no ability to be able to support or subsidize that out-of-pocket cost because of the anti-kickback laws.

So the only thing that we are left to do for a company like AbbVie, where we want patients to be able to get their drug, is we have a Patient Assistance Program where we provide drug for free, a full year of drug for free, for those patients who can't afford it, and we subsidize essentially the Medicare system. And think of it this way: for every 10 Medicare Humira patients, we are providing, free of charge, Humira to four of those patients.

Ms. FOXX. Thank you very much. Dr. Fauci has said—
Chairwoman MALONEY. Your time has expired. The gentlelady's time has expired.

Ms. FOXX. Thank you, Madam Chair.

Chairwoman MALONEY. The gentlewoman from the District of Columbia, Ms. Norton, you are now recognized for five minutes. Ms. Norton?

Ms. NORTON. Thank you, Madam Chair, for this important hearing. In 2003, Abbott Laboratories launched Humira at a price of \$522 per 40-milligram syringe, or just over \$6,200 annually. Over the course of the next decade, Abbott raised the price of Humira 13 times. By 2013—remember we started in 2003—a single 40-milligram syringe of the drug was priced at \$1,024, started at \$522. Now, that is nearly double what it was 10 years earlier. AbbVie spun off its own company in 2013, taking Humira with it. Mr. Gonzalez, that is when you became CEO. Isn't that correct?

Mr. GONZALEZ. Yes, that is correct.

Ms. NORTON. Since that time, the increases in Humira have only accelerated. I would like to show a graph, and I hope that that graph can be put up now, Madam Chair, showing the price of a 40-milligram syringe of Humira, how it has grown from 2003 to today, and there the graph is up for everyone to see. You will notice that price increases really ramped up after 2013, the year AbbVie spun off and the year you became CEO. AbbVie has raised the price of Humira 14 times in just eight years, and those price increases were not small. In just the 10 months between March 2015 and January 2016, AbbVie increased the price of Humira by a total of 30 percent. That is in about a year.

Today, the list price of a single 40-milligram syringe of Humira is \$2,984, 470 percent more than its price at launch. That means that a year's supply of Humira now costs over, and get this number, \$77,000. Internal data shows that Humira's net price, or the list price minus all rebates, discounts, and fees, have also increased over time. In fact, the net price increased by 110 percent, more than doubling between 2009 and 2018.

Dr. Kesselheim, what does this drastic increase in net price say to you about the role, if any, of rebates in driving up Humira's price over time?

Dr. KESSELHEIM. Well, it says to me that that drug price increases have increased both on a gross scale, both in terms of list prices and in terms of net prices, that rebates, while they might have increased over that time, definitely have not increased enough to offset the substantial price increases that AbbVie has been allowed to get away with.

Ms. NORTON. Thank you, Madam Chair. The data are clear. AbbVie's repeated price increases of Humira have had costs to our health system with millions of dollars, and are simply unsustainable going forward. Madam Chair, I believe we need structural reforms, like H.R. 3, if are going to bring any relief to patients about the price increases I have just offered in my questioning. I thank you, and I yield back.

Chairwoman MALONEY. Thank you. The gentlelady yields back, and I agree with her.

The gentleman from Georgia, Mr. Hice, is recognized for five minutes.

Mr. HICE. Thank you, Madam Chair. We just saw one of the greatest public-private partnerships in the history of our country, and it was led by President Trump's administration. Despite the villainization of Operation Warp Speed by Democrats, the Federal Government and private companies invested literally hundreds of millions of dollars to develop and manufacture COVID-19 vaccines, and candidates thereof, not knowing whether or not those attempts would be approved. The results was that the first vaccine was approved in less than 12 months from the discovery of COVID-19, and three vaccines were ultimately approved with others still waiting in line. And many are now actually praising Operation Warp Speed, and frankly, they are incorrectly giving the Biden administration accolades for the brevity of the program when, in fact, this current administration is absolutely not responsible for spearheading this whatsoever.

This past summer, the House Select Subcommittee on Coronavirus exhibited skepticism of Operation Warp Speed. In fact the Democratic member who chairs that particular subcommittee sent a letter to HHS Secretary Alex Azar regarding Operation Warp Speed, and he made this quote: "A lack of transparency in the development of a coronavirus vaccine, especially on an accelerated timeline, could contribute to the growth of anti-vaccination sentiment," end quote.

This type of rhetoric, frankly, nearly—and certainly could have, and it did, it undermined one of the greatest achievements, medically, in our country's history. And fortunately the Trump administration did not bow to that kind of outrageous posturing by the Democrats. But once again, our country demonstrated how incredible our people are, as our greatest minds literally came together, in one of the darkest times in recent history. But now the United States may again not—well, let me put it this way—now we might never again be a leader in pharmaceutical innovation like we were with Operation Warp Speed if the Biden administration continues to pander to some of its most progressive members, like he did in endorsing an intelligence property waiver to the World Trade Organization.

Listen to that. He supported and endorsed an intellectual property waiver. That is dangerous. That is thinking that is incomprehensible to me. Waiving intellectual property for COVID vaccines or any other type of medicine will make the United States and the world more reliant on countries like China and India for pharmaceuticals, and that is frightening when you look at and consider that their vaccines right now for COVID are far less effective than are ours. Frankly, it puts the future of drugs and vaccines that were created under a program like Operation Warp Speed at tremendous risk.

Then you have countries like South Africa and India. They would like a resolution that would force pharmaceutical companies to share their COVID vaccines and therapy IP with developing countries, so they fall right in line with this type of waiver endorsement.

And look, this is supported not only by our current administration. It is supported by other low-income countries, progressive groups, and more than 100 congressional Democrats right here, serving today.

Now why do these countries want to end patent protection? That question has got to be answered. Well, they say they want to expand access to vaccines, but access for lower-income countries is already available. There was an article in *The Wall Street Journal* in April, where Merck announced such a thing.

Fortunately we have some European countries and friends who are smart enough to realize the importance of intellectual property. In fact, German Chancellor Angela Merkel rejected this whole idea of waiving COVID vaccine patents, and she said, in the first place, it would not make more vaccines available, and it would weaken innovation in the future.

So, look. Madam Chair, I just think it is very important that we protect those who are innovative inventors of medications. Certainly those that abuse the rights we should deal with. But we have got to protect the ability for these—

Chairwoman MALONEY. The gentleman's time has expired.

Mr. HICE. I yield back.

Chairwoman MALONEY. The gentleman yields back. The gentleman from Tennessee, Mr. Cooper, is recognized for five minutes.

Mr. COOPER. Madam Chair, I pass at this time.

Chairwoman MALONEY. The gentleman passes. Hank Johnson is now recognized. Hank Johnson.

Mr. JOHNSON. Thank you, Madam Chair, and I want to thank you for holding this very important committee meeting. And Mr. Kesselheim, I would like to begin by addressing the frequent misconceptions that rebates provided to PBMs, or pharmacy benefit managers, are the cause of skyrocketing drug prices. Can you briefly explain what a rebate is?

Dr. KESSELHEIM. Sure. In the system we have in the U.S., the drug companies are free to set whatever price they want, and the negotiating tool that the payers use in our system is negotiating rebates that are provided, you know, as an exchange for placement of the drug on the formulary or different utilization management strategies being implemented or not. And so those rebates, you know, ultimately reduce the price for different drugs, by different amounts.

Mr. JOHNSON. OK. In testimony before the Senate in March, you noted that rebates, quote, "do not keep pace with list price increases," end quote. What does that mean to the everyday person who is just trying to afford their life-saving medication?

Dr. KESSELHEIM. Sure. Well, so first of all, over the last decade, overall drugs prices have increased by about 160 percent, at the list level, and they have increased at a net level by about 60 percent. So, both of those are much greater than the change in inflation over that same period of time.

But what that generally means to the individual person, a lot of people pay out-of-pocket costs that are based on the list prices that they experience, and that can mean a much higher out-of-pocket cost for individual patients. Increased net prices, though, also mean increased premiums that people pay for insurance overall, because

those prices are reflected as well in the premiums that you pay as well as the individual out-of-pocket costs.

Mr. JOHNSON. OK. So, I want to ask you about net price, or the amount a drug company collects after subtracting the rebates and discounts. If a drug's list price increases, and if those increases had, in fact, outpaced rebates, would you expect the net price of a drug to also increase over time? Yes or no.

Dr. KESSELHEIM. Yes.

Mr. JOHNSON. Thank you.

Mr. Gonzalez, I would like to turn to you. Your company provided data on the average net price of Humira between 2009 and 2018. I would like to display a graph created using this data, and this graph shows the annual net price for a weekly dose of Humira. Can we have that exhibit, please?

[Pause.]

Mr. JOHNSON. Well, I guess we are having some technical difficulties.

Chairwoman MALONEY. It is up. Mr. Johnson, it is up. We can all see the Humira Annual Net Price Bi-Weekly.

Mr. JOHNSON. OK. Mr. Gonzalez, as you can see, the net price of Humira increased every single year between 2009 and 2018. In fact, the net price of Humira increased by 110 percent. In the Medicare channel, Humira's net price increased even more, by 151 percent.

Dr. Kesselheim, what do these trends depict on this graph, or what do these trends depicted on this graph tell us about the rebates AbbVie was providing to PBMs during this time?

Dr. KESSELHEIM. Those rebates, although they may have been increasing, the list price increases were far beyond—were increasing at a rate far beyond those list price increases, so the net price is overall increasing.

Mr. JOHNSON. Mr. Gonzalez, the committee also received rebate data for your cancer drug, Imbruvica. In the Medicare and commercial channels, the rebates you gave to PBMs and insurance plans averaged between 4 and 11 percent. In contrast, you have raised the price of Imbruvica by 82 percent since it came to market. The data is clear. PBMs are not the primary driver of the dramatic price increases of AbbVie drugs. AbbVie is the primary driver of dramatic price increases.

Would you agree with that, Dr. Kesselheim?

Dr. KESSELHEIM. Yes, I would agree with that. Drugs prices are set by the pharmaceutical manufacturer, and, you know, PBMs and other insurers use rebates as a negotiating tool, and that helps reduce prices somewhat. But drug prices are generally set by the manufacturer.

Mr. JOHNSON. So, we should not allow pharmaceutical companies to distract us with the argument that PBMs are responsible for the explosive increases in drug prices. It is actually the pharmaceutical industry itself, correct?

Chairwoman MALONEY. The gentleman's time has expired. The gentleman's time has expired.

The gentleman from Wisconsin, Mr. Grothman, is now recognized for five minutes. Mr. Grothman.

Mr. GROTHMAN. Thank you. I am going to start off with Mr. Gonzalez. I am going to ask you a little bit about insulin and biosimilars. I have a bill that would transition to a BLA classification and require the FDA to regulate newly approved biologic insulin products as biosimilars, rather than brand-name biologics, which would get more of these products to market and presumably save people a lot of money if they need insulin.

There are rumors out there that your company would be opposed to that sort of thing. Could you comment on that?

Mr. GONZALEZ. Congressman, we are not in the insulin business. I would tell you it is not a market that I know a lot about, so I do not really have a point of view on it.

Mr. GROTHMAN. OK. I will ask Mr. Garthwaite. Do you have an opinion as to why it seems to be difficult to getting biosimilars to market for some competition in the insulin arena?

Mr. GARTHWAITE. I think that—so I do not know the specifics of your bill so I want to be careful about exactly how I answer this, but I think overall, if we are worried about getting biosimilars to market, I think we will want to think—and I detailed this in my testimony—a bit more about the relationship between rebates and market entry for biologic products, and the idea that we might think of the rules around rebating need to be different for biologic products than it is for small molecule. And this is primarily related to the fact that it is very hard for a new entrant to compete for the existing stock of patients that are medically stable on their product. And given that and given the way that exclusivity works for some of these rebates, it might be hard for new entrants to come in and be able to compete their way onto the formulary.

So I think that, in particular, rebate contracts for biologics that reference the rival, the potential new entrant, and say they cannot be on the same tier of the formulary as us, should be looked at by both Congress and antitrust authorities as a way to potentially increase entry.

Mr. GROTHMAN. Do either of our other two witnesses have anything to comment on the possibility of getting biosimilars to market to lower the price of insulin?

Dr. KESSELHEIM. Well, I would say I think it is extremely important to get biosimilars onto the market to lower the price of insulin, because what we really need for insulin is competition from more manufacturers and manufacturers—

Mr. GROTHMAN. I do not mean to cut you off, but could you tell me why, then, we do not do it? Why do you believe we do not do it, if it seems like such an obvious thing?

Dr. KESSELHEIM. Well, actually, until recently insulin had been regulated as a small molecule product and not as a biosimilar, although I think the FDA has switched that over in the last year, so that now you can actually get a follow-on insulin on the market through an abbreviated VLA. And so hopefully we will soon start to see insulin biosimilars on the market, and hopefully some of them will be interchangeable so that we can actually get real, meaningful competition to try to lower the prices of insulin biologic products.

I think, unfortunately, to this point, there have been, you know, problems with sort of getting—there has been litigation over insu-

lin patents, and a lot of patents have been issued on insulin pens and other peripheral aspects of the insulin product, which has made it challenging for potential biosimilar or competitor entrants to get in the market, and required a lot of litigation. And so now at least we have a regulatory pathway to make that happen, and so hopefully we will see that soon. But I agree with you that the fact that we have not seen it until now is a major flaw.

Mr. GROTHMAN. And I will ask you, why do you think that is?

Dr. KESSELHEIM. I think it is, again, a multifactorial reason. I think that, first of all, a lot of the insulin manufacturers have obtained patents on peripheral aspects of their products. Even though insulin itself has not changed much in the last couple of decades, there have been patents on the pens and delivery devices that have blocked entry of new products and led to litigation. And I think that is one aspect of it.

Mr. GROTHMAN. OK. I will ask one other question, a general question, for Garthwaite. It does alarm me that people in other countries pay so much less for drugs than this country, and just flat out, that should be wrong. Could you give me a quick summary as to how you feel we can get around that problem? I have a lot of sympathy with what, H.R. 3. I think it is kind of an extreme bill, but it seems ridiculous on its face that Americans have to pay so much more for drugs than other countries. Could you kind of respond?

Mr. GARTHWAITE. I agree also. I find that, as an American citizen, some combination of annoying and offensive that we pay so much for drugs and European countries do not. I think the real question, though, is why we would think that the European price is the correct price that we should be thinking about. They are choosing to free ride on the innovation caused by American profits. I think attempting to adopt European prices in the United States should be an abrogation of the responsibility of policymakers. If we want to push forward to have stronger negotiation on prices in the United States, I think that is a debate that we should have. But I certainly do not think that I would like us to see to simply adopt the policies of Paris, London, and Berlin, in the United States.

I think we also have to be honest that if we want to negotiate prices in that way we have got to be willing to say no to both existing and future innovation. And I want to be very clear. I am not saying we should have no conversation about reducing prices—

Chairwoman MALONEY. The gentleman's time has expired. Please wind up. The gentleman's time has expired.

Mr. GARTHWAITE. I just think we should be honest about the tradeoffs. Thank you, Chairwoman Maloney.

Chairwoman MALONEY. Thank you. The gentleman from Maryland, Mr. Raskin, is now recognized for five minutes. Mr. Raskin.

Mr. RASKIN. Madam Chair, thank you. You know, Congress passed the Orphan Drug Act in 1983 to promote the development of treatments for rare diseases, which were defined as conditions that affect 200,000 people or fewer than that, and Congress understood that certain diseases could affect a population so small in the country that Big Pharma would not see a financial incentive to invest in the research for developing therapies and cures for them.

The Orphan Drug Act intended to provide an incentive for companies to get into this research, most importantly by granting seven additional years of market exclusivity for drugs that have received what is known as the orphan designation.

Now, Dr. Kesselheim, is Humira the type of drug that Congress was envisioning when it passed the Orphan Drug Act?

Dr. KESSELHEIM. No. Humira is a blockbuster product that makes billions, tens of billions of dollars a year, and is extremely profitable. The Orphan Drug Act was initially designed to try to provide an incentive for companies to take up unprofitable products for extremely small patient populations.

Mr. RASKIN. In fact, it is the best-selling drug in the world.

Well, Mr. Gonzalez, Humira is approved to treat a painful skin condition called hidradenitis suppurativa, or HS for short. Your company has obtained an orphan drug designation to use Humira as a treatment for HS, right?

Mr. GONZALEZ. That is correct.

Mr. RASKIN. And would you have researched Humira as a treatment for HS if it were not for the Orphan Drug Act?

Mr. GONZALEZ. Certainly, the orphan designation, it qualified for it because it was less than 200,000 patients, and normally there is a faster regulatory path.

Mr. RASKIN. Well, let me just short-circuit to get to the right answer here. According to an internal memo from your company, from October 2008, obtained by the committee, you determined that the HS patient market would be profitable even without Orphan Drug Act incentives. Isn't that right?

Mr. GONZALEZ. That is correct.

Mr. RASKIN. Yes. So, despite internal evaluations that expanding into the HS market would already prove profitable, corporate executives still pursued the additional market exclusivity through the orphan drug designation. Mr. Gonzalez, your company applied for and received two separate orphan drug approvals for HS, one for moderate to severe HS, and another specifically for patients 12 years and older. Did you apply for both of these orphan approvals at the same time?

Mr. GONZALEZ. I don't know the answer to that.

Mr. RASKIN. Well, as I understand it, no, you did not. The first of these applications was approved in September 2015, the second approved in October 2018.

Dr. Kesselheim, why might AbbVie have delayed seeking the approval to treat HS in pediatric patients?

Dr. KESSELHEIM. Well, this seems like actually a common practice in the pharmaceutical industry called "salami slicing," in which companies try to slice up indications into small, discrete segments, to try to get as many different of these additional exclusivity protections as possible.

Mr. RASKIN. So, they enjoyed a 10-year period of exclusivity, and by spacing them out in this way they got three years longer than the seven years intended under the act. Due to the three-year delay, pediatric patients experiencing this painful skin condition were also possibly denied access to treatment due to insurance companies being less likely to reimburse the drug without formal approval.

So the company claims the commitment to bringing the best science and therapies to patients, but here we have a clear case in which they were actively choosing to delay patients' access to treatments and to block competitors, simply for the sake of increasing their profits. Congress must act immediately to put a stop to these anticompetitive behaviors, including abuses of the Orphan Drug Act. Do you agree with that, Mr. Kesselheim?

Dr. KESSELHEIM. I do.

Mr. RASKIN. And is this a question of one or two bad-apple companies, or are these structural problems that we are seeing throughout the entire sector?

Dr. KESSELHEIM. As I said, I think that the behavior and the tactics and strategies that you are seeing in the Humira and Imbruvica cases around the Orphan Drug Act but also around price increases and others, those are common practices, and I think we have also heard about them with respect to the Orphan Drug Act and abuses of the Orphan Drug Act in obtaining the Orphan Drug Act protections for drugs that do not deserve it.

You know, even one of the treatments for the pandemic, you know, transiently got orphan drug act protection at the beginning of the pandemic situation last year. So, I mean, I think that we see this all across the industry, and do think that it is time to reconsider trying to make the Orphan Drug Act apply to the drugs that it was originally intended to.

Mr. RASKIN. Well, thank you very much. We need structural change here, and I yield back to you, Madam Chair.

Chairwoman MALONEY. Thank you. The gentleman yields back. The gentleman from Ohio, Mr. Gibbs, is now recognized for five minutes.

Mr. GIBBS. Thank you, Madam Chair. First I want to mention, Madam Chair, I have a bipartisan bill, co-sponsored with Senator Tonko from New York, H.R. 4629, the Star Rating for Biosimilars Act. This bill would help amend—bipartisan, would require HHS to evaluate Medicare Advantage plans based on whether biosimilars are available to enrollees, and set new set measures for the current five-star rating. So I just wanted to bring that to your attention.

Mr. Garthwaite, you know, the other side of the aisle is talking about H.R. 3, how it needs to be passed, and one of my concerns I have is how they would price the drugs, and if they did not like what the drug companies priced the drugs there would be severe penalties. Do you think H.R. 3 would stifle innovation and research and development in this country if it were to pass?

Mr. GARTHWAITE. I think given the projections of what we see for the reduction in revenue that would result from H.R. 3, which, I should note, is the intended goal of the legislation, the economic evidence is clear that we would see reduced investments in innovation in the form of clinical trial activity by firms, and that is something we saw the reverse of when we founded Medicare Part D, and saw that the increase in market size led to an increase in innovation and research and development activities.

Mr. GIBBS. Mr. Gonzalez, would you concur that passage of H.R. 3—well, first let me say, Madam Chair, last Congress, former chairman Greg Walden from Oregon, introduced H.R. 19, that the

More Cures, Lower Costs Act, and I think it is going to be soon introduced again. I think we ought to take a serious look at that.

But Mr. Gonzalez, on H.R. 3, do you think it would stifle innovation and research and development in this country?

Mr. GONZALEZ. I think if you depress forward revenues it will definitely depress the ability to be able to do innovation. I think the CBO report that recently came out reinforced that point.

Mr. GIBBS. Also, Mr. Gonzalez, when you talk about 4 out of 10 your company subsidizes or makes drugs available free to patients that cannot afford them, is that in this country or is that overall?

Mr. GONZALEZ. No that is 4 out of 10 in the Medicare Part B plan.

Mr. GIBBS. OK. So what is happening in, say, in Europe, in the EU? The prices are lower, but is there subsidization not going on, or what is happening in the foreign countries then?

Mr. GONZALEZ. We donate some product, but I would say it is relatively limited in socialized medicine systems. We donate—

Mr. GIBBS. So let me stop you right there because I am using time here quickly. Is it safe to assume that a lot of our pricing, we are paying the whole cost for all the R&D and the rest of world isn't?

Mr. GONZALEZ. That is absolutely true.

Mr. GIBBS. I am going to yield my two minutes to you, Mr. Gonzalez, to answer any questions that maybe you did not have a chance to answer, from previous questions. I yield my time to you. Go ahead.

Mr. GONZALEZ. Well, I think I would like to highlight a couple of the points that were made earlier, with some specific information. There was a lot of discussion about what impact would the rebates really have on list price and net price. I will use Humira as an example, because it is the one that I think keeps coming up here.

If I look at Humira from 2017 to 2020, the gross price went up 7.9 percent. The net in the U.S. went up 2.6 percent. The difference between that was the increase in the rebates, so that gives you some feel for the rebate impact.

Now, having said that, managed care and PBMs aggressively negotiate for increased rebates, and those rebates, to my knowledge, are returned to the government in the form of lower costs or lower premiums back to the patient, the insurance premiums. I think I saw a report recently that said 99.6 percent of the rebate is returned to the government.

So it is a different way of getting a discount. When you negotiate for formulary position, as a company like ours, you are obviously trying to get that formulary position. You are negotiating what rebate you have to give in order to be able to get that. You are trying to capture a little bit of net positive impact to offset inflationary costs and increases in R&D.

And the other statistic that will give the committee, which I think is relevant, if you look at AbbVie since 2013, when we were formed, our net price impact was about 0.3 percent, on a compounded basis, or roughly \$62 million a year in net price. To give you a flavor for where does that go, we have increased R&D, on average, \$652 million per year.

So the short answer is, yes, to get that price we invest more than that in increases in R&D.

Mr. GIBBS. Thank you. I yield back.

Chairwoman MALONEY. Thank you. The gentleman from Virginia, Mr. Connolly, is now recognized for five minutes.

Mr. CONNOLLY. I thank the chairwoman. I thank you for this hearing.

Mr. Gonzalez, there are six companies with FDA approval to sell biosimilar versions of Humira. Is that correct?

Mr. GONZALEZ. I believe so.

Mr. CONNOLLY. Are there any of those biosimilars besides yours on the market here in the United States currently?

Mr. GONZALEZ. Congressman, we are not biosimilar, but I don't believe any of them are on the market.

Mr. CONNOLLY. Right. None. That is a little surprising, because in your own internal documents, obtained by the committee, your company anticipated lower priced biosimilars to enter the U.S. market no later than 2017, four years ago, as is demonstrated in page 9, Exhibit 14, in your materials. According to that slide, AbbVie expected three to five biosimilar competitors by 2017. In fact, the bottom of the slide identifies a few of those potential competitors by name—Amgen, for example. Amgen's biosimilar received FDA approval in 2016, five years ago. Rather than allowing Amgen's biosimilar to enter the market, however, AbbVie sued Amgen for patent infringement.

On September 28, 2017, AbbVie and Amgen entered into a settlement agreement, under which Amgen agreed not to enter the U.S. market until 2023.

Mr. Gonzalez, AbbVie's own assessment of the strength of its patent portfolio determined it could only prevent biosimilar entry until 2017, and Amgen presumably looked at the same patent portfolio. So why would Amgen agree to wait until 2023?

Mr. GONZALEZ. Congressman, I don't agree with the point of view that the assessment of our patent portfolio said we could only protect until 2017. This is planning document. It does an estimate at this point in time. I believe the documented was dated in 2014. So in 2014, the estimate was 2017. We updated that as we continued to move forward. Obviously, our patent portfolio played an important role in that.

Mr. CONNOLLY. Thank you, Mr. Gonzalez. I have limited time. Thank you. I am reminding you that you are under oath. During settlement negotiations with Amgen, was there any discussion of transferring any item of value, monetary or otherwise, to Amgen in exchange for staying off the market through 2023?

Mr. GONZALEZ. There was none, and they pay us royalties for our patent, when they come to market.

Mr. CONNOLLY. But you had other settlement agreements with other competitors, as the next chart shows. AbbVie how entered into a total of nine agreements with biosimilar manufacturers to stay off the market until 2023, six years after the entry date AbbVie projected, although you call that an internal planning document.

Let me ask you again. During any of these settlement agreements was there any discussion of AbbVie transferring any item of

value, including monetary value, to the competitors in exchange for staying off the U.S. market?

Mr. GONZALEZ. There was not. I think what it demonstrates is the value of our patent portfolio, and all of those competitors have agreed to pay royalties to access that patent portfolio.

Mr. CONNOLLY. So, during that same period, however, six biosimilars entered the European market in 2018, which reduced the price of Humira in Europe by as much as 80 percent. Why would the European market be so radically different with respect both to purported patent infringement and royalty payments, compared to that of the United States, where there is only you?

Mr. GONZALEZ. These are different patent portfolios around the world. The U.S. market has a set of patents that the U.S. Patent Office issues, and in the European system there are different patents.

Mr. CONNOLLY. According to your own internal projections, the U.S. would have saved \$19 billion, and instead U.S. patients will not have access to lower-priced biosimilars until 2023. Why would you account for the 80 percent difference in the price of Humira between Europe and the United States, other than lack of competition?

By the way, unlike what Ms. Foxx suggested, it clearly isn't about recouping R&D costs. It is about lack of competition in the market.

Mr. GONZALEZ. I think it is about two things. Obviously, we have invested \$16 billion in Humira, and we want to recoup that investment. The U.S. patent system is designed to give you a period of exclusivity, to be able to recover that investment.

The other thing that is important to remember is, like many industries but certain in this industry, the products that are on the market today pay for the products of the future. We invest roughly \$7 billion a year in research and development. It is the Humira's and the Imburvicas and these other products—

Chairwoman MALONEY. The gentleman's time has expired. Please wrap up. Thank you.

Mr. AMIN. Chairwoman Maloney, may I add something to this conversation, please?

Mr. CONNOLLY. With the indulgence of the chair.

Chairwoman MALONEY. Yes. Absolutely.

Mr. AMIN. Yes. I think it is important to recognize, I mean, Mr. Gonzalez talks about the planning document being 2014. By our findings, a number of our patents were filed after 2014. So obviously, the planning was to try and prevent the competition coming in, in 2017.

It is also worth noting that a number of the EU patents were actually revoked or withdrawn because they were not actually up to strength in order to get a patent in Europe. So despite what Mr. Gonzalez is saying about the U.S. patent giving a limited time of exclusivity, unfortunately I would say the U.S. patent system actually over sort of provides exclusivity in the sense that companies can easily get more patents, and it can keep filing patents well into a drug's life, and that is why we have settlement agreements. And by some litigation statistics, some 74 patents were thrown at com-

petitors and they just couldn't litigate through it. It was just impossible.

Mr. CONNOLLY. I thank the chair for her consideration, and I yield back.

Chairwoman MALONEY. The gentleman yields back. The gentleman from Louisiana, Mr. Higgins, is now recognized for five minutes. Mr. Higgins?

Mr. HIGGINS. Thank you, Madam Chair. Let me jump into H.R. 3 and just get it out of the way. In my opinion it is massive Federal overreach.

Professor Garthwaite, regarding development, affordability, and access to new treatments and cures, as someone who looks at this both from the medical and the business perspective, in your work at Northwestern, what concerns do you see in government overreach without private sector consideration or input as it impacts pharmaceutical prices in America?

Mr. GARTHWAITE. I worry that using the power of government to set prices and push them down—and we should be clear that H.R. 3 which is often described as negotiation—is not a negotiation. This is price-setting of drugs and we should call it what it is and then debate the sort of validity of that. I worry it is going to decrease innovation.

I do worry, as I detailed in my testimony, I worry about access. I worry about the ability of people to get access to drugs, today and in the future.

I think a lot of the conversation we are seeing today, in the hearing and about drugs, is about the cost-sharing that insurance is putting on people, much more than it is just about the price of the drug, and in particular, Medicare Part D, which has extremely onerous cost-sharing on patients.

Mr. HIGGINS. Agreed. Agreed, and thank you for your clarification. In the interest of time I am going to move on.

Mr. Gonzalez, I find myself very much aligned with my colleagues across the aisle, which I am hoping that my friends will market a calendar. You have been under tremendous pressure today, and, sir, it is about to get worse.

How can you defend American prices of pharmaceuticals overseas versus prices on drugs in the Nation that you love? You enjoy the protections and the benefits of America. You benefit from the Tax Cuts and Jobs Act that I worked very hard on and that my party pushed through. But your answers to the chair were evasive, at best, and appeared to be obviously written by attorneys.

Please just explain to America how the hell can you explain the prices overseas of the drugs you manufacture in America, develop in America, that are so much higher for American citizens and patients than they are overseas? As briefly as you can.

Mr. GONZALEZ. Congressman, it is an excellent point. The short answer is, outside the United States you have socialized health care systems. They ration care or they set price.

Mr. HIGGINS. Oh, but wait. Socialized health care. Let's talk about Europe. Thirty years ago, Europe was the center of the global pharmaceutical industry. In 1986, Europe led the United States spending on pharmaceutical research and development by 24 percent. After the imposition of socialized health care policies, they fell

behind, and by 2015, they were lagging United States by 40 percent. So you are right—socialist policies don't work. But you are an American company, making American money, and your market is global. American citizens should benefit from your love and commitment to the country wherein you live and work, good sir.

I am going to move on, because I am going to give you an opportunity to explain the patent modifications—the other gentleman referred to them as trivial modifications—and your company. You have been accused of threatening patent litigation. The claim basically is that your patent portfolio and the threat of patent litigation to see favorable settlements with biosimilar manufacturers, to delay their entry into the market. Explain to America how you can prove the legitimacy of your patents, please.

Mr. GONZALEZ. Our patents go through a rigorous process at the U.S. Patent Office that looks at prior obviousness. The Patent Office narrows claims to make sure they are not overly broad. And to the point that the other gentleman raised a few moments ago, what I would tell you is if you thought they were frivolous patents, we deal with patents all the time.

Mr. HIGGINS. Yes, they are frivolous. They are frivolous. Making minute changes to your product to extend your protection periods. We don't appreciate—look, I am no enemy of big business. I support freedoms, and you have the right to make your profit. You invest many billions to research and develop new pharmaceuticals, most of which never come to market. My research says that only 1 in 10 come to market. So you have the right to earn your honest profit.

But it is the question of whether or not it is an honest profit, sir, that I would extend. And Madam Chair, my time has expired, but thank you. God bless you for holding these continued hearings.

Chairwoman MALONEY. Thank you. Thank you. The gentleman yields back. The gentleman from California, Mr. Ro Khanna, is recognized for five minutes. Mr. Ro Khanna.

Mr. KHANNA. Thank you, Madam Chair, and I appreciated Congressman Higgins' questions in a bipartisan way, and I want to pick up there.

Mr. Gonzalez, can you tell us who invented the fully human monoclonal antibody?

Mr. GONZALEZ. It was invented as part of [inaudible], when we acquired [inaudible] back in two thousand and—

Mr. KHANNA. Do you know who it was?

Mr. GONZALEZ. No, I don't know.

Mr. KHANNA. You don't know who invented your biggest drug? It was Gregory Winter. Do you know who he is?

Mr. GONZALEZ. No.

Mr. KHANNA. He actually won the Nobel Prize in Chemistry for the invention. You know what he has to say about Humira? He said, "I must not be a very good businessperson, because I didn't make the billions. All the other people made the billions."

Now, you know, you stand here saying you are for all this innovation and you believe in innovation, and you don't even know who the Nobel Laureate was who invented the drug that you are profiting on. Isn't there some disconnect there?

Mr. GONZALEZ. We focus our attention on just trying to create new innovation that helps patients.

Mr. KHANNA. How can you say you are creating new innovations when you don't even know the Nobel Laureate who came up with the innovation for Humira? Doesn't that show that what you are really doing is business? I mean, let's just be honest about it, as opposed to thinking that you are doing an innovation, when you don't know the person who invented the drug that you are profiting on.

Let me ask you this. The patent that expired in 2016, obviously you have talked about extensive patent law, and you seem to understand what is needed. Can you explain two concepts and how you understand them, in terms of a new patent, and that is a novelty and non-obviousness? What does that mean to you? What does it mean for something to be novel and what does it mean for something to be non-obvious, as you understand it?

Mr. GONZALEZ. What I understand for non-obvious is that the Patent Office looks at the invention that you have, and they ask the question, someone skilled in the art, would they have thought of this as being obvious?

Mr. KHANNA. OK. Good. And how about a novelty?

Mr. GONZALEZ. Novelty I don't know that I could describe to you in as much detail.

Mr. KHANNA. Common sense, what would you think is novelty?

Mr. GONZALEZ. Common sense would be it is a novel theory, right? It is a novel approach.

Mr. KHANNA. You can't define a term with a term, but basically something new, right? Something that people haven't thought of.

So let me ask you this. One of the examples of the new patent you filed, that Congressman Higgins and others feel is frivolous—I am not going to characterize it but you have characterized it. I mean, one of the ideas was that you had Humira, and all these doctors were prescribing it, and on your own marketing material you had told them, "Here is the dose that you should prescribe it at." And then you file the patent to say that the dose that is on our marketing material, that we should have a patent on doctors prescribing that dose.

Now, by your own definition of what is non-obvious, you said if a skilled person in the art, in the craft, knows it, then it is obvious. It doesn't qualify as non-obvious. How would you say, under novel and non-obvious—I would like to give you the opportunity to explain to the country how saying a dose for Humira, at a particular amount that is on your marketing material that every doctor in the country is already doing, how getting a patent on that is non-obvious or novel?

Mr. GONZALEZ. Well, it is really the Patent Office that makes that determination, and as I was trying to say before—

Mr. KHANNA. No, no, I get that. I want to understand it. I mean, you are obviously the CEO. You said, "Let's go file a patent." You know, you may not have invented it, and you may not even know who won the Nobel Prize for the thing we're selling, but we'd like to claim that we didn't invent the therapy, but we want to get a patent on what we are putting on our marketing material for the dose. And you go and you say, "Go do it, lawyers."

So, what are you thinking about why that is the case? I mean, you wouldn't say, "Let's get a patent for our brochures and how we sell things." So, what made you think, oh, it would be great idea to get the patent. It is such a novel invention, a non-obvious invention on the dose. I just want to understand the thinking that goes on there.

Mr. GONZALEZ. We patent innovation that we believe is meaningful and that we invested to understand why it was meaningful innovation, and how—

Mr. KHANNA. So explain—in this case, what did you think was so meaningful and innovative about telling the Patent Office that a dose that every doctor is prescribing already and that is on your marketing brochure, that that should be patented?

Mr. GONZALEZ. Well, no—

Mr. KHANNA. What was the innovation? What do you think you should be up for the Nobel Prize for? I mean, what was the innovation there?

Mr. GONZALEZ. Well, I don't know that I would agree with the premise of what you said. I am certainly not an expert on every patent that we have in the company. I will be happy to follow back up with you.

Mr. KHANNA. Do you see, Mr. Gonzalez, what is galling, just at an intuitive level? It is that the people who are actually inventing this stuff—it is a brilliant invention. It is staggering, you know, that Mr. Winter deserved the Nobel Prize. You know, I am not smart enough. No one is that smart to come up with it. But then you sit here claiming that you are the fountain of innovation, that you are benefiting from billions of dollars for innovation. You don't even know who the person is who invented your drug, and you are unable to explain what is so novel about what you are getting patented. That is why there is outrage. I mean, can you understand that, just at a human level?

Chairwoman MALONEY. The gentleman's time has expired and his point is well taken. Thank you.

The gentleman from Texas, Mr. Sessions, is now recognized for five minutes.

Mr. SESSIONS. Madam Chairwoman, thank you very much. I would like to pick up perhaps where the gentleman just left off and further this line of questioning. Does your drug work, sir?

Mr. GONZALEZ. The drug works very effectively. It is approved across ten different indications. The only molecule of its type to be able to achieve that.

Mr. SESSIONS. Did you have to go through an FDA modeling of doing trials to get there?

Mr. GONZALEZ. Yes, hundreds of trials, clinical trials, including dosing trials which would have defined what dose worked in what indications.

Mr. SESSIONS. Did this take any money? I heard it took time, but did it take money?

Mr. GONZALEZ. We invested \$16 billion in Humira.

Mr. SESSIONS. \$16 billion. And when through the idea of this, did you have to purchase anything from the, quote, "inventor"?

Mr. GONZALEZ. We acquired the company that the inventor was originally working with.

Mr. SESSIONS. OK. So you are trying to take a model, spend \$16 billion, have it work, make it available. Now our chairwoman said earlier that the Federal Government was prohibited from negotiating the price, prohibited. I would like to disagree with that, but what does take place in negotiating a price that you have already sunk \$16 billion in?

Mr. GONZALEZ. Actually, the Federal Government, on average, gets the highest discount of any channel on Humira. The average discount on Humira is 64 percent, to the Federal Government.

Mr. SESSIONS. So you looked at \$16 billion and you put that over a model. You had a modeling, the number of people you felt like would be available, the number of things that would happen, and then you had to stretch out \$16 billion, and then gave the Federal Government this discount. Did they set the discount or did you?

Mr. GONZALEZ. In different channels they do it in different ways. But even in the Medicare Part D channel it is negotiated aggressively by the plans, on behalf of the Federal Government.

Mr. SESSIONS. So it was negotiated and you said, OK, we'll give you a 64 percent reduction.

Mr. GONZALEZ. On average, that is the reduction.

Mr. SESSIONS. On average. OK. If you had not done this, what would be the medical things that might be—I would call it a cost-benefit analysis, but what would the other answer in the marketplace be for people who would use this product if you were not there, and what is that general cost and outcome?

Mr. GONZALEZ. Well, there is a class of drugs that treats these types of diseases, so there are some alternatives that are available. One of the important things to remember in this class is patients are required, through their formulary, to fail lower-cost therapies before they get access to these therapies.

Mr. SESSIONS. So really, whoever the way the thing works is they start one, they go to the next, they go to the next. Presumptively it would work for a certain percent. And then you would get down to the percent that it did not work so well. You are the last chance. You are the alternative when there is no B option. You become the A option.

Mr. GONZALEZ. When alternative, lower-cost therapies have failed, biologics are the type of therapy those patients end up on.

Mr. SESSIONS. Now we saw, in the very beginning, the chairwoman very thoughtfully put several people up who indicated that they did need products that seemingly made their life better. Were they in reference to you?

Mr. GONZALEZ. Those patients were referring to our products. One of the things I would say is one of the things that we are very committed to in AbbVie is ensuring that there is a safety net in place to cover all patients who need our drugs, whether they can afford it or not. And we have a very extensive safety net in place, for uninsured, for Medicare Part D patients, for underinsured patients. And I say, as an example, an uninsured patient, we approve 99 percent of the applications we get, and an uninsured patient can get Humira for free, up to an income of \$388,000. So it is quite generous.

Mr. SESSIONS. I appreciate your time and thank you very much. Madam Chairman, I yield back my time.

Chairwoman MALONEY. Thank you. The gentleman from Illinois, Mr. Davidson, is recognized for five minutes.

Mr. DAVIDSON. Thank you, Madam Chairman, and let me just thank you for holding this very informative and important hearing.

Mr. Gonzalez, let me appreciate the fact that AbbVie has such a strong presence in the state of Illinois, where I live and where I come from. And I also want to appreciate the tremendous scientific achievements as well as the efforts toward diversification and the work that you have done to assist in making sure that we were able to fight the coronavirus.

But let me ask, a moment ago I heard you talk about the possibility of negotiating discounts, and, of course, I understand that pharmacy benefit managers are entities that negotiate the price of medication for insurance companies. Did I understand you to suggest that negotiation could be beneficial to insurance companies in terms of the prices that they would ultimately pay?

Mr. GONZALEZ. The way the system works is we compete for a formulary position, and as part of that negotiation we negotiate with the managed care organization, or the PBM, what discount or rebate we will provide to get on that formulary. So yes, there is a negotiation that occurs.

Mr. DAVIDSON. Would it be advantageous to the beneficiaries whose payments are made by governmental entities if negotiations took place for those groups of individuals?

Mr. GONZALEZ. I think that occurs, to a great extent, already, if I understand the question correctly.

Mr. DAVIDSON. It is my understanding that the government, the U.S. Government, CMS, that we are pretty much prohibited from negotiating drug prices. That has been my understanding.

But let me just ask you, I understand that AbbVie applied for far more patents with countries outside the United States than inside, or at the Patent Office in the U.S. Is there a reason for that differential?

Mr. GONZALEZ. There are countries all around the world where you can apply for patents. They have different approaches. And I would say the U.S. is the most rigorous and thorough area of patents, and tends to be the area where much of the innovation is originally created.

Mr. DAVIDSON. Dr. Garthwaite, let me ask you, because the case has been made for me that we are paying far too much for pharmaceutical drugs. I would say that means me, lots of other people, you. But we are also paying more than our counterparts in other countries. And not to suggest that any other country has reached a level of perfection.

Why do you think we are paying so much more than they are?

Mr. GARTHWAITE. Well, I think they are paying less because we are paying more. Small European countries, I think, have a lot more freedom to choose to not worry about how their individual price will affect innovation incentives, because they are fairly small. They are kind of agonistic in this conversation. No pharmaceutical manufacturer is really thinking about how much they can earn in England when they are deciding to make drugs, but they think very carefully about how much they can earn in the United States. And so one of the downsides about being one of the largest

global economies is that we have an outsized presence in the profits of a sector.

That said, also they have different patent rules around that, and I think, you know, what we should do is we should think about sort of how we want think about reforming our patent rules in the United States. I think there is a role for government to do that. Patents are, after all, a grant from the government to try to balance access and innovation. And so, we should think about reforms, including sort of reforms to the incentives, as Mr. Amin mentioned, the incentives of the patent examiners themselves. I think that we should be focusing on the Patent and Trademark Office in some ways more than we are on the private firms.

Chairwoman MALONEY. The gentleman's time has expired.

Mr. AMIN. May I just add a comment to this?

Chairwoman MALONEY. Who is speaking?

Mr. AMIN. Tahir Amin.

Chairwoman MALONEY. Very briefly. Very briefly.

Mr. AMIN. Yes. I would just say that, you know, having worked across 25 different countries on patent systems I would disagree that the U.S. patent system is the most rigorous. I think it is the easiest system to getting a patent. In fact, by some studies, one can never get a patent rejected in the United States, because you can keep refiling it over and over again until you get one. So, it is a war of attrition, and just to Craig Garthwaite's point, I agree that, you know, examiners are under an immense amount of pressure, and because of the incentive to keep granting we end up with more patents.

So, I kind of disagree with the contention that Mr. Gonzalez said that the U.S. has the most rigorous patent system.

Mr. DAVIDSON. Thank you, Madam Chairman, and I yield back.

Chairwoman MALONEY. Thank you. The gentleman from Pennsylvania, Mr. Keller, is recognized for five minutes.

Mr. KELLER. Thank you, Madam Chair. The U.S. has long been a global leader in pharmaceutical innovation, and I thank you for holding this hearing. Getting generic drugs to market as quickly as possible remains a priority for this committee and will help to bring down the cost of prescription drugs.

Professor Garthwaite, American companies have greatly contributed to the \$182 billion invested globally by the private industry into pharmaceutical research and development initiatives, generating roughly 30 FDA-approved drugs annually. Can you explain the relationship between investment and incentives in the pharmaceutical space?

Mr. GARTHWAITE. Yes. To develop a new product you have got to make a large, fixed sum in a risky investment. And so you are trying to make that investment with the idea that the potentially you will get intellectual property that would allow you to earn back sufficient revenues and expectation to justify that initial investment. That is the basic business tradeoff that we are thinking about here.

And so firms are acutely aware of the potential market size. I would note, though, that that is firms around the world. While the United States does have a very strong biopharma sector, firms around the world respond to the profits generated in the United States. And so we have great biotechnology companies in Europe.

We have an amazing emerging biotechnology for novel products coming out of Hong Kong and Shanghai. But all of it is driven by the same incentive, which is again that return on investment, and most of it is driven by the profits generated in the United States.

Mr. KELLER. How would price controls or forced negotiation as contained in H.R. 3 affect the price and availability of prescription drugs?

Mr. GARTHWAITE. I mean, it would. I think the goal of H.R. 3, and if you look at the CBO model is it would meaningfully reduce prices. The resulting knockdown above that would be a reduction in innovation. And we should have that debate as to what we think is going to be the acceptable level of tradeoff between access and innovation, or are there other ways, such as reforming our health insurance system to reduce onerous cost-sharing that we can decrease some of the reduced access when prices are high and still provide large innovation incentives.

I really would encourage the committee to look at this as not just a question of the price of the drug but a lot about the cost-sharing, particularly cost-sharing in government programs, which simply do not match the modern pharmaceutical market.

Mr. KELLER. Thank you for that. Another question, Mr. Garthwaite. Patents are critical for safeguarding intellectual property. However, the patent system can also add barriers to competition that would otherwise drive down drug prices. So do you have a suggestion on possible reforms to the patent system that would still incentivize innovation while also allowing for product variation?

Mr. GARTHWAITE. So I think we should look directly at the patent system. As I mentioned before, there are organizational incentives around how we fund it. It could be that what we want to do is think about funding it, about the number of patents maybe that apply or some other PDUFA-like structure but applied to the patent system.

I do think something that gets lost in the question here, though, is that we very much do want firms to invest resources for new uses for old drugs. These sort of secondary patents have been much maligned in this testimony. I am happy to see that a drug like Humira, that we have seen the number of indications that we have, we want to make sure that we maintain the incentives to get as much as we can out of the resources that society has spent to develop new products.

And so I don't think we should go to some type of system where there is one patent for every drug. That is a naive view of modern drug development. But we should have a rigorous review at the Patent and Trademark Office about whether things truly represent novel and non-obvious innovations.

Mr. KELLER. Thank you. As we begin to once again have discussions about Speaker Pelosi's drug pricing reform bill, H.R. 3, I would caution my colleagues that more price controls and government overreach in the pharmaceutical market will only stand to make prescription drugs more difficult for access.

I also look forward to discussing bipartisan pharmaceutical proposals such as the provisions in H.R. 19, the Lowest Cost, More

Cures Act, to get generic drugs to market faster, improve competition, and ensure Americans have access to affordable medicine.

Thank you, and I yield back.

Mr. AMIN. Chairwoman—

Chairwoman MALONEY. The gentlelady from Florida, Ms. Wasserman Schultz, is recognized for five minutes.

Ms. WASSERMAN SCHULTZ. Thank you, Madam Chair. AbbVie jointly markets its cancer drug, Imbruvica, with Janssen Biotech. Though the companies share decision-making authority and profits, AbbVie leads the drug's commercialization efforts in the United States.

Mr. Gonzalez, yes or no. Does commercialization include setting pricing in the U.S.

Mr. GONZALEZ. It does, yes.

Ms. WASSERMAN SCHULTZ. OK. Thank you. As a breast cancer survivor, the exceptionally high cost of cancer drugs is an issue where the policy is very personal for me. I want to put up on the screen a graph showing how the list price of Imbruvica has changed over time.

At its launch in 2013, Imbruvica was priced at about \$91 per tablet. As you can see, since just 2013, AbbVie has raised the price of the drug nine times. AbbVie took a 7.4 percent increase in each of the last two years, as millions of Americans were struggling financially because of the coronavirus pandemic. The current list price of Imbruvica is now at \$165 per tablet, and an annual course of treatment is priced at anywhere from \$181,000 to \$242,000 per patient, depending on how many tablets a patient takes daily.

Dr. Kesselheim, I would like your help dispelling two myths that pharmaceutical companies continually perpetuate about drug pricing. First, they insist, that no one actually pays the so-called list price of a drug or directly feels the impact of that price.

Dr. Kesselheim, very briefly, is that true?

Dr. KESSELHEIM. That is not true. Actually, we just published an article led by my colleague, Dr. Rome, here in my group, showing that when list prices go up, patients who have high deductibles or other kinds of limited insurance can feel substantial increases in prices.

Ms. WASSERMAN SCHULTZ. And isn't it true that uninsured patients pay the list price, patients' out-of-pocket costs are tied to the list price? I mean, my familiarity, the whole notion of cost-shifting is that when you go to the hospital and you are a patient that doesn't have coverage, you are charged the full list price. That cost-shifting occurs because those uninsured patients are unable to pay the price, and then the costs go up for all of us, and that would include the price of prescription drugs. Am I correct?

Dr. KESSELHEIM. Yes.

Ms. WASSERMAN SCHULTZ. OK. So drugs companies, very clearly, also claim that they are forced to raise prices because pharmacy benefit managers demand bigger and bigger rebates. They argue that while prices rise, their profits don't. But internal data obtained by the committee shows that the Imbruvica rebates AbbVie provided to Medicare and commercial plans from 2013 to 2018, range from just 4 percent to 11 percent. The data also showed that the annual net price of Imbruvica, the price of the drug after sub-

tracting all rebates, discounts, and fees, rose by approximately 60 percent.

Dr. Kesselheim, what does that demonstrate about whether rebates are driving AbbVie's price increases for Imbruvica?

Dr. KESSELHEIM. Right. AbbVie's price increases for Imbruvica are being set by AbbVie itself, and the reason that rebates are so low in this market is because we don't allow the government to negotiate drug prices based on their value, and, in fact, allow drug companies to set prices wherever they want. And if a drug company is trying to meet the needs, the sort of expectations of its shareholders or something, about its revenues, then it is going to do what it can by increasing prices on currently available drugs as much as it can.

Ms. WASSERMAN SCHULTZ. Thank you. So, despite what Big Pharma wants you to believe, they bear responsibility for our current crisis of cancer drug affordability. No one should be unable to afford life-saving medication, but 42 percent of cancer patients deplete their entire net worth—I have talked with countless of them—within the first two years of treatment, in part due to high drug prices.

We can have both innovative treatments and affordable prices, and we all deserve both. We shouldn't have to make the false choice. Congress should reject that false choice and act now to rein in the era of the greed of pharmaceutical companies. We have to make sure that if you are facing a life-or-death condition that you are not faced with having to bankrupt yourself in order to be able to afford to stay alive.

Thank you, Madam Chair, for the privilege of participating in this hearing, and I really commend your leadership in having it. I yield back.

Chairwoman MALONEY. The gentlelady yields back. The gentleman from Arizona, Mr. Biggs, is recognized for five minutes.

Mr. BIGGS. I thank the Chair and I thank the witnesses for being here today.

What we see is that many folks have observed this around the world, but other nations are free-riding on American consumers, particularly in the pharmaceutical area. But if we jump from the frying pan into the fire, this is, as one writer said this, and I am quoting from him now, "We would be jumping from the frying pan into the fire if we had European-type price controls that stifled innovation by pharmaceutical companies. Sure we would enjoy lower prices in the short run, but we would have fewer life-saving drugs in the future," and I close the quote.

This past year, we have seen the remarkable, innovative ability of American companies. Operation Warp Speed allows for the American people to receive three COVID-19 vaccines in less than a year. This achievement could not have been accomplished with world-leading American companies.

Mr. Garthwaite, what can Congress do to replicate the success of Operation Warp Speed for other diseases and cures?

Mr. GARTHWAITE. So I think we should be careful not to over-generalize from the success of Operation Warp Speed, which was really trying to address a very specific problem, where we have an

exact type of product we want to develop, and we are going to allocate massive government capital to do that.

I think that there are good and bad things about Operation Warp Speed. I do think that if we are going to give people public dollars, all the way up through clinical trials, like we did with Moderna, we should probably think more about some type of pricing clause, because that firm is not putting capital at risk, and so we should think more about those questions.

But I really caution against the idea that we would generalize from the attempt to address one specific problem to some type of use of government money to try and solve all drug development. The capital markets are really good at allocation money toward the most potential success, scientifically. Most modern drugs companies are using those small firms to do that early stage research, and I think how many NIH take up that drug development mantle would really fundamentally change the nature of that agency.

Mr. BIGGS. That is a great lesson to learn. I appreciate that, because I think I agree with everything you just said with regard to capital formation, et cetera. Anything regarding the regulatory side of things that we should learn?

Mr. GARTHWAITE. I think one thing that has been very nice about the FDA during this process is the degree to which they did try and stand up for rigorous review. I think there was a lot of worry at the start of Operation Warp Speed that there would be some type of political manipulation of the FDA or some pressure to not take science seriously to speed things up. And I do think the FDA has done a good job of trying to balance sort of access with regulatory review.

We need to believe in the produces, and the FDA solves an important asymmetric information problem where they validate the success of these products. I know we can quibble about how long certain reviews took, and people wanted them to be shorter. But I do think it is very good to see the FDA maintaining its place as a place for rigorous review.

Mr. BIGGS. Mr. Gonzalez, could you explain how price controls might prevent companies
[inaudible].

Mr. GONZALEZ. I think if you institute price controls or reference pricing you are going to drive down the amount of revenue going forward, and that is going to reduce the return on investment that you have in R&D. It was clearly laid out, in the CBO document, and I think it is accurate in the way it described it. So I think you would be trading off a short-term benefit for a long-term problem.

Mr. BIGGS. And so, Mr. Gonzalez, AbbVie has been able to grow Humira into one of the world's best-selling drugs, bringing in over \$136 billion since it went to market in 2003. Can you explain to us how that money has been reinvested at AbbVie into development of additional medications?

Mr. GONZALEZ. Absolutely. I mean, I think if you look at products like Humira, as I said before, the on-market products pay for the R&D of the future. We have invested \$48 billion in R&D since 2013, and out of that investment we have created a highly effective cure for HCD, we have created two cancer compounds that have improved survival rates in blood cancers significant, and now we

have now created two immunology assets that have demonstrated superiority to Humira, and they are in the process of being launched in the marketplace. All of those things help patients tremendously, and it is that on-market product revenue that pays for R&D going forward. The system can't work without that.

Mr. BIGGS. Thank you both. I appreciate the time, Madam Chair, and I yield back.

Chairwoman MALONEY. The gentleman yields back. The chair now recognizes one of the authors of H.R. 3, the gentleman from Vermont, Mr. Welch, who is now recognized for five minutes.

Mr. WELCH. Thank you, Madam Chair. Mr. Gonzalez, you have a business model, as does all pharma, that starts with patent protection provided by the Federal Government. Is that correct?

Mr. GONZALEZ. That is correct.

Mr. WELCH. And that is supposed to be a limited time, and you do everything in your power to extend it beyond the original grant. Is that correct?

Mr. GONZALEZ. We develop innovation, and if we believe that innovation is meaningful and worth enough, we—

Mr. WELCH. Well, the answer to that is yes, right? You did a memo when you were Executive Vice President, that was about 10 years ago, a little less, talking about, quote, "product enhancements," and those included things like changing the size of the needle. Correct?

Mr. GONZALEZ. That is correct.

Mr. WELCH. And you do constant analysis internally within the company to anticipate competition that may result in lower prices, or price competition. Correct?

Mr. GONZALEZ. What we do is we constantly look for ways that we can innovate a product to be able to protect and grow its position by making it a better product for patients.

Mr. WELCH. And what that means is extending patent protection and maintaining pricing power through the monopoly that a patent confers. Is that correct?

Mr. GONZALEZ. Yes, it can result in that, yes.

Mr. WELCH. All right. And when biosimilar competition was introduced in Europe, the price of your product, Humira, went down by 80 percent. Is that correct?

Mr. GONZALEZ. The average reduction in revenue is about 50 percent—48, I believe is the last number.

Mr. WELCH. So, the point here is competition works. Correct?

Mr. GONZALEZ. That is correct.

Mr. WELCH. And your pay, executive pay, is related, and has been for a period of time, to increasing revenues and hitting revenue targets. Is that correct?

Mr. GONZALEZ. We have a plan for what we believe our revenues are going to be in the following year—

Mr. WELCH. Right.

Mr. GONZALEZ [continuing]. And that is [inaudible] yes.

Mr. WELCH. The revenue is affected by the amount you sell and the price at which you sell it. Correct?

Mr. GONZALEZ. It is affected by that and then the cost, that you obviously incur in the business, such as increases in R&D.

Mr. WELCH. Well, let's just go through this. Immediately after that incentive plan came into effect, there were three major price increases, about 30 percent in one year for Humira. Is that correct? That is according to the documents that you provided to this committee.

Mr. GONZALEZ. If I look at AbbVie's price from 2017 forward, our net price was negative.

Mr. WELCH. 2013 is when this went into effect. The records you provided to this committee indicate that the compensation of the top executives increased. And, by the way, your income last year, or your compensation, was about \$24 million?

Mr. GONZALEZ. That is correct.

Mr. WELCH. And between 2013 and 2020, it was \$170 million?

Mr. GONZALEZ. I would have to add it, but let's—

Mr. WELCH. Well, it is a big number. And compensation for all of the top executives was about four hundred and, what, about 80 million dollars? Is that correct?

Mr. GONZALEZ. Probably averaged about \$60 million a year for the top five executives.

Mr. WELCH. All right. So, the bottom line here is that you had a system within AbbVie where executive compensation was tied to hitting revenue targets. Revenue targets were enhanced by increasing prices and sales. Correct?

Mr. GONZALEZ. Congressman, I don't agree with that. If you want to talk about a period of 2013 forward, then what I would tell you is net price for AbbVie, 2013 forward—

Mr. WELCH. Right, but let me reclaim my time. And the way you were able to do that is, one, reaching agreements with competitors that they didn't bring their product out; No. 2, shadow pricing with Amgen, with respect to their product, Enbrel; No. 3, patent thickets, filing for over 150 patents here when you only did for six in Europe; and in so-called enhancements, which were things that made virtually no difference to the patient, other than that they had to pay more to get a smaller needle.

So the business model here starts with the government providing a patent, the government providing payers, through Medicare and Medicaid, and then what I can see, rampant abuse on the part of your company to essentially extend that monopoly pricing power and abuse at the expense of patients. It has got to end. It has got to end. I yield back.

Chairwoman MALONEY. The gentleman yields back. The gentleman from Georgia, Mr. Clyde, is now recognized for five minutes. Mr. Clyde.

Mr. CLYDE. Thank you, Madam Chairwoman, for holding this important hearing today.

In the four-plus months that I have held office, one of the top issues to repeatedly arise in many of my meetings with constituents in Georgia's Ninth congressional District is the high cost of prescription drugs, many of which are lifesaving medicines. This is an issue that I think most all of us sitting on the committee have the desire to address. I strongly believe that we should be working to ensure patients have more choices when it comes to accessing lifesaving medications.

However, in achieving this goal, we must be very wary of any effort that looks to stifle innovation or to set prices, such as in the Democrats' proposed bill, H.R. 3, as the solution it puts forward would be detrimental to the efforts to lower costs and increase choices. Not only would the woes of H.R. 3 be felt by the big manufacturers, but I believe they would be felt by the small businesses and startups as well, and I am reasonably confident that would be the end result, because as a small businessman by trade, I fully understand how stifling it is to be strong-armed by Federal bureaucrats.

So I am determined to look for solutions that work, not only to bring transparency to the convoluted drug pricing space, but also to lower costs and to increase choices for patients.

So I have got a couple of questions here. My first question is for Mr. Gonzalez. Is AbbVie engaged in any early stage partnerships with smaller biotech companies—and I am not looking for names or anything like that, of the companies—and if you are, can you please elaborate a bit on how government price-setting, like what we see in H.R. 3, how government price-setting might impact your investments in those companies and those partnerships, sir?

Mr. GONZALEZ. We invest significantly in small biotech companies in partnership arrangements or other kinds of pro-licensing arrangements. I think the fundamental issue with something like price controls is it would take the riskiest area and it would make you much more hesitant to invest in those areas, but yet those are the areas that have the greatest opportunity to improve society, areas like new treatments for Alzheimer's, or treatments for Parkinson's disease, or better treatments for some of the solid tumors and cancer that we haven't been able to make significant improvements.

And so the tradeoff you are going to make is you are going to take these very high-risk areas and you are not going to invest as aggressively in there, because your risk is so high, but you can't get the return going forward. I think that is the significant tradeoff that we are going to have to deal with if we were to implement that kind of an approach.

Mr. CLYDE. OK. Thank you very much. I appreciate that. My next question is for Mr. Garthwaite. In your submitted testimony, you discussed the importance of, and I quote, "inefficient value-destroying policies." Would you consider the Biden administration's push to waive IP protections from COVID vaccines as a value-destroying policy, and if yes, could you elaborate a little bit, please?

Mr. GARTHWAITE. I have really strong concerns about waiving IP, and particularly waiving IP when we believe that products generate so much value that we need to make them more accessible to the world.

I think we need to find ways to increase manufacturing capacity, and I we need to find ways to give vaccines to the rest of the world, and I think right now the incentives of Pfizer or Moderna, given their ability to sell this vaccine to the world, are aligned well to try and increase that manufacturing capacity.

The thing I worry about is not the current pandemic. I worry about the next pandemic. In particular, I worry about one that is going to require perhaps a small molecule treatment or therapeutic

as opposed to a vaccine, where firms are going to be very hesitant to make the investments to jump into those markets, if what is going to ultimately happen is that they are going to have the intellectual property that they create transferred to other parties.

And so I really believe that instead of waiving IP, the U.S. Government can increase the incentives to bring vaccinations to the rest of the world, by either transferring vaccines that we currently have in storage or committing to pay high prices, even for vaccines throughout the developing world coming from the United States. It would be in our financial interest to pay for such vaccines.

Mr. CLYDE. OK. Thank you very much. I like that response. I think it is very dangerous that we would open the door to allowing China to not only steal years of knowledge and investments that these companies have made in mRNA technologies and production capabilities, but then to turn around and effectively assist them to profit off of it too.

With this concern in mind, and to add to what my good friend, Congressman Hice, has said earlier about waiving IP protections, I have added my name to a letter led by my good friend and fellow colleagues from Georgia, Congressman Buddy Carter, that expresses how waiving such IP protections is dangerous and not an efficient means to achieving the White House's goal of getting vaccines to those around the globe in a timely manner. As expressed in the letter, I think that focusing on the transportation chain would better achieve the objective and simultaneously preserve U.S. companies' intellectual property rights.

And with that, Madam Chair, I yield back.

Chairwoman MALONEY. The gentleman yields back, and the gentlewoman from California, Ms. Porter, is recognized for five minutes.

Ms. PORTER. Thank you. Mr. Gonzalez, you are the CEO of AbbVie, which makes the cancer drug Imbruvica. Do you know what the annual price of Imbruvica was for a patient taking the standard three pills per day in 2013?

Mr. GONZALEZ. One-hundred-thirty thousand dollars.

Ms. PORTER. OK. We had \$99,766. What about today for those same three pills?

Mr. GONZALEZ. I think it is \$169,000.

Ms. PORTER. We have \$181,000, but we can agree that there was a significant increase. Roughly, in a matter of eight years, AbbVie more than doubled the price.

Now, Mr. Gonzalez, how much money did AbbVie put directly into the research and development costs of Imbruvica before it hit the market in 2013?

Mr. GONZALEZ. We acquired Imbruvica when it was launched, so it would have been the company that we acquired—

Ms. PORTER. So, AbbVie—reclaiming my time—so AbbVie itself didn't spend any money to create Imbruvica. It was invented by a smaller company, Pharmacyclics, which you later acquired. Correct?

Mr. GONZALEZ. We paid \$21 billion for the company, correct.

Ms. PORTER. It was expensive to acquire them. So, you paid fair market value for Pharmacyclics, but AbbVie then doubled the price, presumably justified by its \$2.45 billion investment in R&D.

Are there fewer side effects for patients now than there were in 2013?

Mr. GONZALEZ. Well, we developed significant indications and expansions and other disease states—

Ms. PORTER. Are there fewer side effects, sir?

Mr. GONZALEZ. No. It has the same side effect profile.

Ms. PORTER. OK. Mr. Gonzalez, do people need less of this medicine, Imbruvica, to treat lymphoma now?

Mr. GONZALEZ. No.

Ms. PORTER. So, AbbVie took zero risk to develop this drug. You bought it approved for the market, knowing it would be profitable. You hiked the price to pay for R&D, but you haven't made the drug any better, even as you doubled the cost.

I wrote an entire report on what is essentially the Imbruvica story—Big Pharma gobbles up a small, innovative company, does nothing to improve the drug, but jacks up the price.

Now you told us that you spent \$2.54 billion for R&D for Imbruvica, even though the drug didn't get any better. Really, it was all for these innovations and indications, which are designed to keep competitors off the market and find new sales opportunities. So, I want to look at what other money AbbVie spent doing its business. You filed 165 patents for Imbruvica. You filed patents for Humira, other drugs, to keep competitors off the market. How much did you spend on litigation and settlements from 2013 to 2018?

Mr. GONZALEZ. Congresswoman, let me correct one thing that I think you just said. It is not true that we didn't invest in additional indications and additional diseases. As an example, we received approval after the development work of graph versus host disease. We also—

Ms. PORTER. Reclaiming my time. Mr. Gonzalez, how much did AbbVie spend on litigation and settlements from 2013 to 2018?

Mr. GONZALEZ. I don't have that number offhand. I will be happy to give it to you.

Ms. PORTER. OK. \$1.6 billion. \$2.45 billion on R&D, \$1.6 billion in litigation and settlements. What about marketing and advertising? How much does AbbVie spend on that?

Mr. GONZALEZ. Marketing and advertising, we spend about \$4 billion a year.

Ms. PORTER. Yep, \$4.71 billion. How about executive compensation, 2013 to 2018?

Mr. GONZALEZ. 2013 to 2018, it is probably, on average, about \$60 million a year.

Ms. PORTER. Try \$334 million on for size. Now how much did AbbVie spend on stock buybacks and dividends to enrich your shareholders from 2013 to 2018?

Mr. GONZALEZ. Stock buybacks, if you actually look at just pure stock buybacks it would be about \$13 billion.

Ms. PORTER. Stock buybacks and dividends is the question, sir.

Mr. GONZALEZ. Dividends, I would have to come back with a number for that over that period of time.

Ms. PORTER. \$50 billion. So, Mr. Gonzalez, you are spending all this money to make sure you make money, rather than spending money to invest in, develop drugs, and help patients with afford-

able, life-saving drugs. You lie to patients when you charge them twice as much for an unimproved drug, and then you lie to policymakers when you tell us that R&D justifies those price increases.

The Big Pharma fairy tale is one of groundbreaking R&D that justifies astronomical prices, but the pharma reality is that you spend most of your company's money, making money, for yourself and your shareholders. And the fact that you are not honest about this, with patients and with policymakers, that you are feeding us lies that we must pay astronomical prices to get innovative treatments is false. The American people, the patients, deserve so much better.

I yield back.

Chairwoman MALONEY. The gentlelady's time has expired. The gentleman from Kansas, Mr. LaTurner, is recognized for five minutes.

Mr. LATURNER. Madam Chairwoman, I thank you for holding this hearing which affords this committee the opportunity to help the American people understand why the U.S. is the world leader in medical innovation, why that leadership position in the world helps save countless lives during this pandemic, and continues to save lives every single day, and what advances the Trump administration and House Republicans have made in recent years to help bring down the high price of prescription drugs, speed generics to market, and reduce out-of-pocket costs.

While everyone on this committee can agree that Americans pay too much on certain prescription drugs, and they do, Democrats have been unwilling to work with Republicans on bipartisan solutions to help both bring down the high cost of drugs while simultaneously preserving U.S. medical innovation, the benefits of which have been on full display this past year like never before.

I hope this year will be different, with both Republicans and Democrats willing to work across the aisle and to do what is achievable—lowering the cost of some high-priced drugs while maintaining choice for Americans, and not harming robust R&D funding, which has spurred groundbreaking innovation in both vaccines and therapies for COVID-19.

Just like our national defense, the only safe place is first place, when it comes to our Nation's health care, especially as it pertains to the creation of vaccines and medical therapies. And this has never been truer than during this pandemic. In 2018, it is estimated that pharmaceutical companies spent \$169 billion globally on R&D, and an estimated \$182 billion in 2019. CBO has noted that R&D has increased among pharma firms just as it has to the industry as a whole, reaching 25 percent in 2017.

It is important to point out that the average spending on R&D across all industries is less than three percent, compared to 25 percent for the pharmaceutical industry. Why is this important? With less investment comes less innovation, which, in turn, leads to fewer new drugs. Europe used to lead the world in drug innovation, over 30 years ago, but government-imposed price controls led to less foreign R&D investment, which, in turn, led to U.S. worldwide leadership in the development of innovative life-saving treatments and cures, including three current COVID vaccines, with more on the way.

According to a White House Council of Economic Advisors report, under the Democratic legislative approach, H.R. 3, to price controls and a punishing excise tax on American medicines, Americans would be denied access to dozens of life-saving medicines over a 10-year period. But the result would be fewer saved lives and a reduction in the life expectancy for the average American. Unlike developed nations and Europe, such as the UK, where the citizens had access to only 60 percent of new medicines, Americans currently enjoy access to almost all new medical innovations and cures. This isn't by accident. And while I believe there is more than can and must be done in our effort to lower drug prices, I am confident that my constituents back home in Kansas are not interested in reducing choice and giving up access to life-saving drugs and therapies, especially for diseases such as cancer and hepatitis C.

I encourage Congress to focus on legislation that is both doable and helpful to the American people, and not jeopardize our free market system, which preserves innovation while ensuring access to the world's largest choice of affordable medications.

Now to questions. Mr. Gonzalez, I can't think of a time when the value of public-private partnerships in drug development has more evident to the general public. Even Dr. Fauci has said he can't think of a vaccine, even one in which the Federal Government has provided substantial resources, that was brought to the goal line without private industry. Yet some of the proposals being discussed today would substantially change the parameters of current IP protections in the U.S.

Is it wise to send innovators the clear message that the larger the health crisis, the less we will protect your IP?

Mr. GONZALEZ. No, it is not. IP is fundamental to this industry.

Mr. LATURNER. I appreciate that very much. Some of my Democrat friends, again for Mr. Gonzalez, believe the Federal Government should take over the pharmaceutical sector. While I strongly agree the price of drugs are too high in some instances and that Congress must do more in this area, can you speak to the role of the private capital and U.S. drug innovations, just more broadly?

Mr. GONZALEZ. Well, obviously we put a tremendous amount of capital at risk to be able to develop new, innovative medicines going forward, and that is built around the premise that you will have an opportunity to recoup that investment and continue to invest further in R&D to create additional cures as time goes on. That is fundamental to this industry, and I think we have seen the benefit of it. We have made tremendous progress in treating cancer, in curing HCV, with COVID vaccines. I mean, we see tremendous progress in this area, and I think if we put price controls in place that will damage the R&D in this industry.

Mr. LATURNER. Thank you. I appreciate it, Mr. Gonzalez, and all the conferees. I yield back, Madam Chairwoman.

Chairwoman MALONEY. The gentleman yields back. The gentlelady from California, Ms. Speier, is recognized for five minutes.

Ms. SPEIER. Thank you, Madam Chair. Let me, at the outset, make note of the fact that our colleagues on the Republican side have talked about this phenomenon of getting three vaccines in less than a year. It is a phenomenon, but it has everything to do

with the fact that the Federal Government negotiated the price of these drugs. So, let's not forget that in the course of this discussion.

I want to say, at the outset, that AbbVie is a [inaudible] my district, but I also feel a responsibility for their practices. And I want to make sure we continue to have innovation and medical advancement, but I also want to protect the consumers.

Humira has been on the market for 18 years, but it is still under patent protection. Mr. Gonzalez, I want to understand how AbbVie has managed to avoid competition for so long. First I would like to put up Exhibit 19, a presentation you delivered to investors in October 2015. As you look there, it shows that the actual ingredient for Humira expired on December 31, 2016. Am I reading that correctly?

Mr. GONZALEZ. That is correct in the U.S.

Ms. SPEIER. Had that been your only Humira patent, U.S. patients could have accessed lower-priced versions of Humira in 2017. As this slide shows, however, AbbVie filed for scores of additional patents on Humira, 22 patents on method or treatment, 14 patents on formulation, 24 patents on manufacturing, and 15 "other" patents. AbbVie successfully created what the title of the slide suggests, an entire estate of patent protection.

Now I understand your obligations is to your shareholders and not to the consumers, Mr. Gonzalez. But tell me, how much did you pay in taxes last year?

Mr. GONZALEZ. We paid about \$1 billion or \$6.4 billion since tax reform.

Ms. SPEIER. So \$1 billion in taxes last year. And your revenues that you generated last year were how much?

Mr. GONZALEZ. Approximately—well, taxable revenues over that same period of time, an easy way to think about it would be the \$6.4 billion, we had about \$21 billion of taxable revenues over that period of time.

Ms. SPEIER. \$21 billion. So that suggests you paid maybe 10 percent in taxes, if that.

But going back to your patent situation, you have now 256 patents for Humira, and they will not expire for a total 34 years since the launch. My question to Mr. Amin, you are the patent expert. Did AbbVie really need 256 separate and new patents? Did they have 256 new inventions related to Humira?

Mr. AMIN. Thank you, Congresswoman. Well, it is actually 257 applications of which, by our count, is 130 that have been granted. I believe there are probably more out there, but obfuscated in trying to actually find them. If you look at the initial patents, this roadmap

[inaudible], the new indications that are subsequently being patented later on in the lifecycle of the drug were already highlighted and protected in the initial patents that went off, expiring in 2016.

So, what we see is this system that the U.S. patent system encourages, is to these middle increments that the companies do. And this is not just AbbVie. This is every company, in order to extend their life and protection so that they can have another 8, 9, 10 years. We see it with Imbruvica, and we will probably see more

patents that are being filed as Imbruvica is actually entering its sort of eighth year on the market.

So, they don't need all these patents, but it is a great strategy to keep competition at bay.

Ms. SPEIER. So if you were to advise us on how we could just focus, narrowly, on patent abuse, could you just give me, in 39 seconds, what kinds of recommendations you would make to us?

Mr. AMIN. I would raise the bar for what it means to get a patent, so that we can actually really incentivize real discoveries and treatment. Because companies also get FDA exclusivity just for these little tweaks, an indication. But they are already getting awarded for that. The idea that they are going to stifle innovation is wrong.

So, my main call is that we should actually raise the bar in what would take to get a patent, and we have to improve examination [inaudible].

Ms. SPEIER. All right. Thank you very much. Madam Chair in my two seconds, just in my calculation, I guess what AbbVie paid was five percent in taxes last year, when most of us were paying 37 or 38 percent. I yield back.

Chairwoman MALONEY. The gentlelady yields back. I now recognize the gentlewoman from New Mexico, Ms. Herrell. She is now recognized for five minutes.

Ms. HERRELL. Thank you, Madam Chair, and thank you for having this hearing as well, and thank you to our panel. I just have a couple of questions for clarifying, and I will start with Mr. Gonzalez. I just wanted to ask you; how much involvement has the government had currently in price setting for your prescription drugs?

Mr. GONZALEZ. On behalf of the Medicare Part D plan that is negotiated by the plans, the insurance plans or managed care plans, on behalf of the government. Then the government obviously negotiates directly in areas like VA, DoD, TRICARE.

Ms. HERRELL. So, Mr. Gonzalez, then would that have a direct impact on what the consumers are paying for their prescriptions?

Mr. GONZALEZ. I am sorry. I didn't understand the question, Congresswoman.

Ms. HERRELL. Would that have a direct impact on what consumers are paying for their prescription drugs?

Mr. GONZALEZ. Negotiation is your question?

Ms. HERRELL. Yes. Would those have a direct impact on what we are paying for our prescriptions?

Mr. GONZALEZ. As I indicated, the government today does negotiate, and if you look at it, as an example, for Humira, the average discount for Humira across all the government channels is 64 percent. It is the highest discount by a significant margin, compared to any other part of the channel.

Ms. HERRELL. Right. So once the negotiations are done, that does impact the consumers' prices.

Mr. GONZALEZ. No, I think that is one of the challenges of the discussion today. The Medicare Part D system is relatively insensitive to the price of the drug.

Ms. HERRELL. So, Mr. Gonzalez, let me put it this way. Would it be better or worse for the consumer if there was less government involved in the price negotiation?

Mr. GONZALEZ. What I would say is it would be better for the Medicare Part D consumer or patient, in this case, if we work together to be able to restructure the out-of-pocket costs for those patients, because lowering the price alone will not allow you to get to a point where these patients can afford their medicines.

Ms. HERRELL. OK. Thank you. And Mr. Garthwaite, I just wanted to ask you a question. The Congressional Budget Office estimates that 38 fewer cures would be developed in the next 20 years if H.R. 3 became law. How does H.R. 3 stifle innovation?

Mr. GARTHWAITE. So the CBO modeling, we could spend a long time if you wanted, but you probably don't, talking about sort of positives and benefits of that model. But they are relating the fact that when you see this decrease in revenue, and expectation, firms like Mr. Gonzalez's and AbbVie are going to optimally reduce their investment in R&D to match the size of the potential market that is going to exist. We have lots of economic evidence that suggest the direction and the magnitude of that effect. A really big decrease in prices, like those proposed by H.R. 3, could have a fundamental effect on innovation, really depending upon how much prices are going to go down from that.

I know earlier that Representative Wasserman Schultz wanted to say that, you know, we have this ability to both, you know, cut prices and keep innovation at the same level, and I think that is really more hope than science. I think that the evidence is clear we will see a decrease in innovation, and instead of promising to people we will get the same of innovation, we should have an honest debate about how many drugs we are willing to give up if we are going to see prices go down. That would be a much more productive and a much more honest cost than these simple political promises.

Ms. HERRELL. Right. So then do you feel that under the Trump administration, headway was being made to lower prescription drug costs and help the availability or accessibility?

Mr. GARTHWAITE. I can't think of meaningful efforts that actually the Trump administration put into place that would have done that.

Ms. HERRELL. And so at the end of the day, with free markets, with collaboration, with both industry, government, and consumers, we can find a way to maybe revisit the standard Medicaid and Medicare Part D and help push the price down to consumers?

Mr. GARTHWAITE. I certainly think—I mean Medicaid, the price for consumers is not an issue, but Medicare Part D is certainly an insurance program that is crying out for reform. It creates the incentives to raise prices. It creates the incentives to generate more rebates so you can lower premiums for healthy customers, and it really takes advantage of its customers that require expensive medications. And I strongly encourage Congress to look at reforms in that sector.

Ms. HERRELL. OK. Just very quickly, Mr. Gonzalez, earlier you were asked about the 30 percent increases in that 10-month time period from March 2019 to January 2020. Can you help us understand why the significant increase?

Mr. GONZALEZ. Well, over that specific timeframe, I can't specifically talk about that, but what I would tell you is there are two drivers to this. And as I said a moment ago, if I look at the overall

impact of net price on AbbVie's business since 2013, it is very, very modest. It is 0.3 percent. If I look at even shorter periods of time, just in the U.S., as an example, the net price since 2017, in the U.S. only, it was 1.8 percent. So price is not contributing significantly to the overall performance of the company.

Now, many different factors drive the price. I would say increasing rebates plays a significant role. Rebates have increased significantly over that period of time.

Ms. HERRELL. Thank you. I yield back. Thank you, Madam Chair.

Chairwoman MALONEY. The gentlelady yields back. The gentlewoman from Missouri, Ms. Bush, is now recognized for five minutes.

Ms. BUSH. Thank you, Madam Chair, for convening this important hearing.

As a nurse, I repeatedly saw the devastating harms that outrageously high prescription drug prices had on my patients. I saw our health care system prioritize their profits over my patients. I saw drug manufacturers, like AbbVie, line their pockets with cash while my patients suffered. We can't continue to let Big Pharma keep getting rich on life-saving medicines that people need to survive. And we are talking about survival of humans.

Humira is currently the top-selling drug in the United States and the world. In 2020, Humira's U.S. net revenues were roughly double that of the second-highest-selling drug in the United States, which is Merck's cancer drug, Keytruda.

Mr. Gonzalez, what share of your company's overall sales revenues comes from Humira?

Mr. GONZALEZ. About 40 percent now.

Ms. BUSH. 40 percent now. OK. Thank you. According to an article published earlier year in the journal Nature, Humira accounts for nearly 60 percent of AbbVie's sales, what is documented there. Humira has delivered your company over \$170 billion in worldwide net revenue since launching in 2003. Two-thirds of that revenue, or \$107 billion, have come from the U.S. market alone, even though Humira is the top-selling drug in the world, due in large part to AbbVie's price increases for Humira. A study of prices from 2017, found that in the U.S. Humira is three times more expensive than the drug in Germany, and four times more expensive than in Switzerland.

Mr. Gonzalez, is there any difference between the brand drug here versus in different countries?

Mr. GONZALEZ. There is not a significant difference. They are manufactured in different kinds of facilities. A U.S. drug would be manufactured in an FDA-regulated facility, and a European drug may have been manufactured in a different facility that was not FDA regulated. But the general drug is the same.

Ms. BUSH. The general drug is the same. So the difference, if it matters, is what facility manufactured it that changes the price up three, four times.

Mr. GONZALEZ. No. I am sorry. I didn't mean for you to conclude that.

Ms. BUSH. OK.

Mr. GONZALEZ. What causes the differences in price is essentially socialized health care systems mandate what price you are allowed to sell the drug at, and as a manufacturer, you only have two choices. You either accept that price or you deny the population of that country the benefits of your medicine. And that is an impossible choice. Can you imagine a cancer drug, not providing the population of a country, that drug, because you don't like the price?

But that is the fundamental challenge with socialized medicine systems. And that does force the U.S. to pay far more of the innovation costs of our industry. That is a reality.

Ms. BUSH. So that is what it is. We are picking up the slack. I just feel like if you can sell the same exact drug elsewhere for a fraction of the price there is no reason that people should be forced to pay high prices here, such high prices.

But, you know, let me put up a graph on the screen, using data from AbbVie's SEC filing. This graph shows Humira's annual U.S. net revenue from 2003 to today. As the graph shows, each year AbbVie set a new record—each year, a new record for Humira revenue in the United States. The prices are staggering. On my own staff we have someone who used Humira for 6 years. His medications would have cost nearly \$1 million—for six years—if not for his insurance plan, and his family would have repeatedly gone bankrupt trying to keep them stable, because of your predatory pricing scheme, had he not been insured. The story is the same for AbbVie's other blockbusting drug, Imbruvica, which is jointly marketed with Janssen Biotech.

I would like to show another graph, showing the U.S. net revenue for Imbruvica. Since 2013, AbbVie and Janssen have together generated \$16 billion in net revenue from Imbruvica. More than one-quarter of this amount, or \$4.3 billion, came from sales in 2020 alone. During that period, AbbVie raised the price of the drug nine times—one, two, three, four, five, six, seven, eight, nine times.

Mr. Gonzalez, has the drug's efficacy dramatically improved nine times? If you could just yes or no answer that question for me.

Mr. GONZALEZ. The drug is basically the same drug.

Ms. BUSH. Thank you. We all want to incentivize the development of new medicines, we do, but there is a difference between turning a profit and profiteering off of patients and families all over the world.

Mr. Gonzalez, last question. Will you commit to lowering the price of Humira and Imbruvica in the United States? This is just a yes or no.

Mr. GONZALEZ. No, I can't commit to that. But if you will allow me one more minute. I think we were aligned in that we want to be part of the solution to lower costs, out-of-pocket costs, for patients. And what I would tell you is when I look at Medicare Part D, I will use Imbruvica as an example. To make Imbruvica affordable to patients on Medicare Part D, it is literally 50 times more out-of-pocket cost on Medicare Part D than any other insurance vehicle. To make it affordable under the current structure of Part D you would have to lower the price of Imbruvica by 98 percent—98 percent to make the out-of-pocket affordable for a patient.

What that tells you is the structure of Part D's out-of-pocket is not built for these kinds of medicines.

Chairwoman MALONEY. The gentlelady's time has expired. The gentleman from South Carolina, Mr. Norman, is now recognized for five minutes.

Mr. NORMAN. Thank you, Madam Chairman. Mr. Garthwaite, you know, pharmaceutical companies are paid based on a percentage of the list price. That means your middleman, your distributors, all of them make more money at the patient's expense. You know, insurance is supposed to help existing patients who are buying drugs, such as insulin, which has been around since the 1950's.

What common-sense solutions should we, as Members of Congress, do to try to bring down this cost?

Mr. GARTHWAITE. So I would encourage you to look at regulations around cost-sharing that require that it is based more on the net or the post-rebate price as opposed to just the list price.

I do think you are right that what we end up having is that when individuals purchase expensive medicines, which is again in the Part D program, it appears that part of the motivation of the plans is to generate high cost-sharing payments that they then don't necessarily capture as profits themselves or as the PBMs, but they use the lower premiums for the rest of the market, and that is effectively transferring resources from sick to healthy patients, and really unwinding some of the benefit of insurance, and certainly unwinding the idea of community rating that was very popular among policymakers and consumers, where you don't pay more for a pre-existing condition. And so I think we should look at things around not having cost-sharing tied to list prices.

I also think that you should look at improving the flow of information between plan sponsors and PBMs. I think the Senate Finance Committee report on insulin pricing was very interesting to read through on issues related to administrative fees and other non-rebate funds that are flowing between manufacturers and PBMs, and I think it would be important for everyone in the value chain to have a bit more information about the flow of funds so they can negotiate an effective set of prices, rebates, and formulary placements.

Mr. NORMAN. Would you agree that the first step would be getting the actual contracts that the PBMs have, getting the actual language so you could delve into it? Would you agree with that?

Mr. GARTHWAITE. I am concerned about the fact that there are such strong auditing requirements for plan sponsors, if they want to be able to look at the revenues that they are generating for the PBM. While there are obviously concerns about confidentiality, regulations around sort of who can be an auditor, how many contracts they can see, that the contracts are only allowed to be reviewed in paper, at the PBM facility, these are all things I think Congress could look into, in the spirit of improving information, because the market works best when information is common among the negotiating parties.

Mr. NORMAN. Well, I would like any solutions that you could get to help us do this. All of us, whether you are a Democrat or Republican, the price of drugs, particularly those that have been around for 70 years, that have not changed as far as improvements, we need to know and take action. I am really tired of just talking about it. The government is good at, you know, forming a com-

mittee to get another committee to talk about it, but anybody that, you know, has any kind of empathy really needs some direct things that we can do. So anything you can do, I would appreciate it.

Mr. Gonzalez, PBMs exclude certain drugs from the formularies in favor of other, you know, drugs that may be inferior, at best. What kind of actions like this have driven up drug prices, I guess, in the market as a whole, that you could cite?

Mr. GONZALEZ. Congressman, I mean, generally speaking, my experience with PBMs and managed care on formularies is that they try to design the plan in a way, the formulary in a way to be able to cover a broad set of patients. Humira is an example. We compete on formularies. Probably average number of competitive products on that formulary is nine or ten, and that gives enough flexibility to physicians to be able to alternate between different drugs to find the right drug for the patient, and in some cases maybe different delivery vehicles. Some are injectables. Some are orals.

So there is typically a fairly broad set of products that are available.

Mr. NORMAN. But you would agree, as far as trying to get a handle on PBMs and their formularies for pricing, we need to actually see the contracts that they are going by, to make the companies abide by. Would you agree?

Mr. GONZALEZ. Yes, I would agree with that.

Mr. NORMAN. OK. Madam Chairman, I yield back.

Chairwoman MALONEY. The gentleman yields back. The gentlewoman from Illinois, Ms. Kelly, you are now recognized for five minutes.

Ms. KELLY. Thank you, Madam Chair. One of Humira's competitors is Enbrel, an expensive brand name sold by Amgen. In a functional competitive market, you would expect companies to price their products below their competitors in order to gain market share. So in the case of AbbVie and Amgen, they would be expected to compete with each, and the result would be lower prices for Humira and Enbrel. Dr. Kesselheim, is that what we see in the pharmaceutical sector?

Dr. KESSELHEIM. Definitely not. The U.S. pharmaceutical sector, especially for brand name drugs, I mean, the idea behind patents and other regulatory exclusivities is to avoid a competitive market, you know, to allow these companies to price drugs at a very high level. So what we see, particularly with brand name competition, there is not substantial price lowering when new products hit the market in the U.S.

Ms. KELLY. Thank you. On the screen, I would like to put a graph prepared by committee staff, which shows AbbVie and Amgen's pricing for a year's course of Humira and Enbrel from 2003 to 2021. The lines are so close together, it is a little difficult to tell which is which. That is what shadow pricing looks like. For almost two decades, AbbVie and Amgen consistently followed each other's price increases. In that time, the price of Humira has increased 470 percent, and the price of Enbrel has increased 457 percent. According to internal company documents obtained by the committee, AbbVie viewed Amgen's price increases as cover for its own price increases.

Mr. Gonzalez, in 2012, you received an email from another company executive saying it was a “great weekend.” This email is Exhibit 9 in your packet, as I hope everyone can see. Mr. Gonzalez, did you view that as a good development when Amgen would raise the price of Enbrel, just out of curiosity?

Mr. GONZALEZ. Just give me one moment to read it.

Ms. KELLY. OK.

Mr. GONZALEZ. I essentially view this as someone sending me an email that just alerted me to the Enbrel price increase, and then saying, “have a great weekend.” I don’t tie those two together.

Ms. KELLY. OK. Do you believe Amgen’s price increases give AbbVie license to further increase the list of Humira?

Mr. GONZALEZ. No, but I think, Congresswoman, one of the things that does happen in this industry that is somewhat unique because of the way rebate pools work, is when a competitor raises their price, you don’t know what the rebate is that the competitor has. But what you do know is if you don’t raise your price, you will be at a disadvantage of how much rebate dollars you will be able to contribute. So you have seen that there has been some correlation between companies, but I think it is driven more by this phenomenon of how rebate pools work where you don’t want to put yourself at a competitive disadvantage because, you know—

Ms. KELLY. It does seem like increasing the price of Humira is exactly what happened. In July, you raised Humira’s price to \$26,632. Less than three weeks later, Amgen raised the price of Enbrel again. And AbbVie says, you know, they price their drugs are, “based on the value that those medicines bring to patients in the competitive environment.” But emails like this one uncovered by the committee’s investigation seem to demonstrate that that is not true.

And I just want to go back to my prior colleague. I am not trying to do things like that, but we need to come to some type of solution. This is ridiculous. As you have heard over and over, people have to choose, you know, between sometimes death, you know, if they can eat or not eat. You know, we all care, you know, about making sure that our citizens, people in the United States, you know, know can afford drugs, and we do have a problem, and I would think you think we have a problem, too, despite, you know, innovation and research and development. I mean, you have to believe there is a problem.

Mr. GONZALEZ. Congresswoman, I absolutely believe, especially in Medicare Part D, that there is a significant problem with the out-of-pocket cost approach for those patients. What I would tell you is we have tried to set up a broad safety net that ensures that any patient who needs our drug, regardless of their ability to pay, regardless of their ability to have insurance, can get our drug. And that doesn’t mean we don’t miss people, but I can tell you we cover the vast majority. We give away \$4.3 billion worth of drug every year. As I mentioned a few moments ago, 99 percent of uninsured people who come to us, we approve and give them free drug. And in the case of Humira, you can have an income as high as \$388,000 and still qualify for free Humira. We are subsidized—

Ms. KELLY. And with all the things that you guys are doing, there is still a problem, so we are still not doing something right,

which I will let other people ask about that because I am out of time. Thank you.

Ms. PORTER. [Presiding.] Thank you. The gentleman from Kentucky, Mr. Comer, is recognized for five minutes.

Mr. COMER. Thank you. My questions are for Professor Garthwaite. Despite the villainization of Operation Warp Speed by committee Democrats, the Federal Government and private companies invested hundreds of millions of dollars to develop and manufacture COVID-19 vaccine candidates, with no guarantee those vaccines would be approved. The result was the first vaccine was approved in less than 12 months from this discovery of COVID-19 and three vaccines approved to date. Would this have been done without private company investment and expertise?

Mr. GARTHWAITE. I think it is quite simple to say that we would not have gotten the vaccine as fast as we did without private company expertise, but I also think it is important and fair to note, and, honestly, since we also wouldn't have gotten it without strong involvement of the government money, both in terms of direct financing for some of the clinical trials in the case of Moderna, but also the advanced market commitments the Federal Government had that they would buy any product they did approve. That eliminated some of what we refer to as the market risk of developing a drug. And then the subsidizing of clinical trials eliminated some of the scientific risk of developing a drug.

Mr. COMER. But what could Congress do to build on the momentum of Operation Warp Speed to continue investing in treatments and vaccines for other diseases?

Mr. GARTHWAITE. This is a really great question actually. You know, a lot of us want to put the pandemic behind us. We have the vaccine. We are trying to move forward, I think, both in the United States and globally. We want to come to a solution for this. I think it would be a real shame if we squandered the sort of momentum and information we had about the importance of investing in vaccines, but also in other therapeutics related to anti-infectives. I think, in particular, if Congress wants to really work in this area, we need to come up with a solution for developing next generation antibiotics and how we want to fund the development of them and pay for their marketability.

We knew that prior to the pandemic, but I also want to note that the next global disease burden might not be a virus, right? It might be antibiotic-resistant bacteria. And I think we need to focus on really developing treatments for the next pandemic, but realize the next pandemic might look very different from COVID.

Mr. COMER. In today's innovation cycle, I believe less than 10 percent of drugs get approved. How much investment goes into each drug prior to seeking FDA approval?

Mr. GARTHWAITE. There is a wide range of estimates on sort of the cost of bringing a drug to market. I think the important thing to think about here is how we get drugs in the pharmaceutical market, and here I will disagree vehemently with Representative Porter on sort of how we think about the cycle of innovation here. We want, and I think there are lots of you, if we were at the Kellogg School and we were in a strategy class, I would be teaching companies to pay attention to what they are good at and do that.

Early stage companies are very good at developing innovative drugs. Later-stage companies are good at clinical trials, dealing with the FDA, sales and marketing. They all occupy a very valuable place in the supply chain along with the early stage research investments from the NIH. We need all of that to bring to market, and we have seen an increasing specialization in the pharmaceutical market, not because of some worry about anti-competitive practices, but really because we want those early stage companies to invest. That said, those early stage companies are often going to fail. They are going to go out of business. And so when you start to add up sort of what do we spend on R&D and you only look at the winners, the people whose drugs work, you are doing a disservice to this conversation. You also have to look at the losers.

Mr. COMER. OK. Thank you. My last question is for Mr. Gonzalez. AbbVie has received 130 patents on Humira and 88 patents on Imbruvica. These patterns include intellectual property related to the discovery, uses, improvements in manufacturing processes of these medications. Can you explain why so many patents are necessary for these drugs?

Mr. GONZALEZ. If you look at Humira, it is a classic example. We were approved for the first indication, rheumatoid arthritis, in 2013. Over the course of the next 14 years, we developed additional disease states and indications along the way. All of that took research and development, clinical trial, working out dosing, and all kinds of technical challenges, and we learned and invested in innovation along the way. We applied for patents. Whenever we have meaningful innovation, we apply for patents.

The other thing is, I think everyone gets somewhat hung up on the number of patents, and I would say that is partially a function of the Patent Office in the U.S. that tries to narrow patents so that they are not overly broad. So sometimes you will have an innovation, and they will say to you, that is five different things, go back and break them up into five different patents, so that is one of the things that causes a larger number of patents. But the more important thing is this: I can have one patent, and if no one can work around that patent, that is all it would take to extend the exclusivity of the product.

Real innovation is what ultimately gives you the ability to have value in a patent. If you have meaningless patents or they are frivolous patents, I can file an IPR at the Patent Office and have them re-review the patent, and they take down a large number of patents. It is not expensive. It is not hard to do. And ultimately, competitors did that with our portfolio, and we prevailed the vast majority of the times. You can litigate.

We work around patents all the time. If they are not foundational patents, you try to work around them. If you believe they are invalid, you invalidate them. You only pay royalties and license patents that you believe are fundamental to your ability to create the product. And what is very evident here is we have highly sophisticated companies, like Amgen, like Pfizer. They are just like AbbVie. They made a decision that it was worth licensing our patent portfolio and paying us a royalty. I can tell you, companies don't do that unless they believe those patents are valid and meaningful. We don't do it. And so I think that is the best validation

to the level of innovation and the importance of the portfolio. And in the U.S. system, if you create something that is inventive, you deserve the right to get protection. And remember one other thing. We licensed all biosimilar players 11 years before the last patent expired. We thought that—

Ms. PORTER. The gentleman's time has expired.

Mr. AMIN. Congresswoman, may I just intervene there?

Ms. PORTER. The gentleman from Maryland, Mr. Sarbanes, is recognized for five minutes.

Mr. SARBANES. Thank you, Madam Chair. I appreciate the opportunity. I want to take a moment to address an argument I keep hearing from the other side, that H.R. 3 and these other structural reforms that we are seeking would hurt future innovation. We all know that drug companies produce lifesaving therapies and vital medications. That is critical. But we also know that the current situation is untenable. That is what so much of the testimony we receive, the stories we hear from our constituents and families across the country, indicates.

Nearly 1 in 3 Americans say they are unable to take their medications as prescribed because of the cost. One out of 3. Innovative medications are worthless if people can't afford them. I mean, we have to keep that in mind. And drug manufacturers like AbbVie argue that current prices are necessary to drive innovation and discover new treatments, but that is not true. As the committee's investigation revealed, much of the research these companies are investing in isn't innovative. It is simply meant to preserve their pricing monopolies.

According to a 2017 report by the GAO, novel drugs, meaning those recognized by the FDA as meeting a previously unmet need or significantly advancing patient care or public health, only counted for 18 percent of all drug approvals between 2005 and 2016. It is important to note that after H.R. 3 passes, and it will pass, drug companies will still make a healthy profit. So, Dr. Kesselheim, help me out here. Do drug manufacturers still make money on their drugs abroad, despite the fact that these countries negotiate for lower prices?

Dr. KESSELHEIM. They absolutely do, and I agree with you. I think this is one of the big misperceptions I have heard throughout the day around H.R. 3. H.R. 3 is about trying to negotiate prices with respect to brand-name drugs better and to sort of more efficiently make the market in the United States work, try to ensure that if a drug is not a new or important drug, then we won't pay a high price for it. Right now, drug companies set prices at whatever level they want, and Medicare and Medicaid is required at some levels to pay those prices and don't have a good way of pushing back and negotiating prices.

For really important, useful new drugs for treating Alzheimer's disease, I think that under H.R. 3, we would still expect to pay a very high price that would make those drugs very profitable to the companies that bring them forward. I think what H.R. 3 will do is it will give the U.S., just like other countries do, the ability to negotiate up front and say, well, this drug is worth us paying a high price, and this drug is not worth us paying a high price. That is

what other countries do, and it is how they are able to lower prices on the drugs that they pay for, and that is not what we do.

Mr. SARBANES. Thanks. That is excellent. I mean, you are basically describing a value proposition here. If the value of that drug is worth paying for, the market is going to reflect that when Medicare goes into the market, the almighty market, to negotiate. That is all we are trying to accomplish here, what has been done in other places around the world. The other thing I will just mention, and you know this for sure, is that government research plays a huge role in drug development, so taxpayers are investors here. So taxpayers are investing on the front end a lot of the times when it comes to the trajectory of these medications and drugs, but then having to pay again on the back end exorbitantly because of all these maneuvers that the industry has managed to embrace.

So, I will just close with this, Madam Chair. I don't really expect Mr. Gonzalez or other pharmaceutical executives to behave any differently than they are. There is a profit-making incentive here that is guiding them. Sadly, the executive compensation is, as was, I think, laid bare by Congresswoman Porter, and Congressman Welch, and others, is operating to drive a lot of this behavior and conduct. There isn't a whole lot we can do about that. So, Mr. Gonzalez and others are going to behave the way they are. What we can do is what we are trying to do, which is to allow the Medicare program to negotiate on the price of drugs. It is the American thing to do, we ought to do. We ought to pass this bill. Thank you for the opportunity and for this hearing, and I yield back my time.

Chairwoman MALONEY. [Presiding.] The gentleman yields back. The gentleman from California, Mr. DeSaulnier, is recognized for five minutes.

Mr. DESAULNIER. Thank you, Madam Chairwoman, and thank you so much for this hearing. I feel your predecessor, Mr. Cummings', spirit in the room today. Mr. Gonzalez, I am a survivor of CLL. I have some of your product here. This product cost about \$15,000. My treatment for one pill a day costs about \$500. In Australia, it costs \$30. When I asked my oncology team why that was, they said it is because they can. It is upsetting to know in your business model that Americans subsidize people in other countries. I am obviously grateful for the research and development that kept me alive with this drug, but I would like to know how it came about and how sustainable it is.

And the No. 1 increase in bankruptcies for American citizens are because of medical bills. So, in addition to having to struggle with the co-pays on this product, people have to worry about losing their home or going into bankruptcy. And if the tradeoff there is for you and your executives to make more money, I think that is a question that the American public should be aware of, in addition to the fact of why are they subsidizing Australians in this instance.

But I want to ask you a few questions about Humira. In 2018, AbbVie began selling a high-concentration, citrate-free formulation of Humira, which you marketed as a reduced pain version of the drug in 2018. Is that correct? Yes or no, please.

Mr. GONZALEZ. That is correct.

Mr. DESAULNIER. Mr. Gonzalez, I want to put up a 2011 strategy presentation obtained by the committee. This is Exhibit 8 in your

materials, and if you turn to page 11, you will see it. This chart identifies the benefits of various research projects AbbVie was engaged in in the left column and benefits in the top one. For Humira's high-concentration formulation, the presentation identifies "biosimilar defense" as one of the benefits. Biosimilar defense, Mr. Gonzalez, is another way of saying you are protecting from competition, from biosimilars, getting into the marketplace. Is that an unfair characterization?

Mr. GONZALEZ. I am actually trying to read the page. You said page 8, correct?

Mr. DESAULNIER. No, I said Exhibit 8, page 11.

Mr. GONZALEZ. OK.

Mr. DESAULNIER. While you are looking for that, I am going to continue because I want to use all my five minutes.

Mr. GONZALEZ. I have it now.

Mr. DESAULNIER. And so that one, the question was biosimilar defense. That means, and I understand you have got an obligation to your shareholders in your investments. You are trying to defend against biosimilars getting into the market sooner than taking away profit share, correct?

Mr. GONZALEZ. I don't believe that that is what that means. What it means is we were working on a formulation which would reduce pain upon injection. There were multiple aspects of that, a smaller needle, high concentration, and removing the citrate buffer.

Mr. DESAULNIER. OK.

Mr. GONZALEZ. We believed that would be a differentiated product for patients.

Mr. DESAULNIER. I apologize for interrupting. It is the five-minute rule. I would love to take more time. Let's put up another slide, this time from a presentation to the board of directors in 2015. This is Exhibit 17, and it is the first slide and that is up. The presentation states, "Our defense strategy remains the same," and the second bullet below defending intellectual property says, "Gain approval, EU/US, of Humira high-concentration formulation." In both of these slides, there is no designation for reducing patients' pain. Now, earlier you confirmed that AbbVie introduced high-concentration formulation in 2018, correct?

Mr. GONZALEZ. Correct.

Mr. DESAULNIER. FDA approved it in 2015. Why did you wait three years to bring the product up after the FDA approved it?

Mr. GONZALEZ. Yes. I mean, we had to buildup the manufacturing capacity because it required a different manufacturing capacity. So we actually introduced it first in just pediatric patients because that is where the need was the greatest to reduce pains, and then we moved forward from that to be able to offer it in a more broad-scale market.

Mr. DESAULNIER. Some skeptics would say that the reason for the delay was to wait until biosimilar manufacturers had already invested significant resources in developing biosimilar versions of the original formulation, so you shifted patients to high-concentration formulation. This anti-competitive strategy is commonly referred to as product topping. Mr. Gonzalez, is that an unfair description of what was happening here?

Mr. GONZALEZ. I think it is an unfair description of what was happening here. To your point a moment ago, Congressman, when we launched in Europe, the majority of biosimilars had citrate-free, high-concentration products, so it is not like this did anything to inhibit their ability to do that. The second thing I would say is both products are still on the market in the United States, so that won't change any ability for a biosimilar to come to the marketplace. And ultimately we license, through our settlement agreements, all of the IP we have around high concentration and citrate free. So there is no difficulty for biosimilars to come forward in the marketplace with a prior license.

Mr. DESAULNIER. Mr. Gonzalez, I am going to interrupt you there, and, again, I apologize. Madam Chair, just before I yield back—

Mr. HIGGINS. Time.

Mr. DESAULNIER. Arbutimine, which I have spent a lot of time on, and I am happy that I was the founder of the Cancer Survivors Caucus, is—

Mr. HIGGINS. Time.

Mr. DESAULNIER [continuing]. We would just like to see your books to see how much money goes into innovation for research and development and how much of it goes into financial innovation. I yield back.

Chairwoman MALONEY. The gentleman's time has expired. The gentlelady from Massachusetts, Ms. Presley, is recognized for five minutes.

Ms. PRESSLEY. Thank you, Madam Chair. Patients taking AbbVie's No. 1 drug, Humira, are battling chronic joint inflammation, fatigue, and other painful symptoms of rheumatoid arthritis. Now, the ironic thing here is this medication is meant to help people, to alleviate their hurt and pain, but due to steady price increases, AbbVie is causing greater physical pain, mental hurt, and financial hardship as well. The cost of prescription drugs is causing strife and suffering for families across the Nation, and as fatigued as you may be by hearing these sobering, gut-wrenching accounts, people are even more fatigued by living them and experiencing them daily.

I have heard from people throughout my district who are forced to cut pills in half to make them last, people who are paying medication costs that are the equivalent of a college tuition, state college, and, at times, even exceeding that, heart-wrenching, unjust choices people are making simply to survive, and these individuals are not outliers. According to a 2013 research study from the University of North Carolina, 22 percent of individuals with arthritis were forced to spend less on basic necessities as a result of high drug prices, and 1 in 5 reported taking fewer medications than prescribed due to cost. Madam Chair, I would like to enter that 2013 research study from U of NC into the record.

Chairwoman MALONEY. Without objection.

Ms. PRESSLEY. Dr. Kesselheim, from your experience serving families in my district, the Massachusetts 7th, how can tradeoffs like these impact the patient's overall health?

Dr. KESSELHEIM. Oh, very substantially. I mean, I think a lot of patients struggle with high drug prices and, you know, come look-

ing for, you know, ways of trying to address those, you know, when they come into my office. And, you know, there are sometimes that I can send them to, you know, patient support groups, but a lot of times, unfortunately, they may not qualify or there may be a lot of hoops that they have to jump through, or those kind of, you know, charity, but charity only lasts for a certain amount of time and then it ends. So, you know, I think that this is a major issue, and it leads people to stop taking their medications or to, you know, have to make difficult decisions about other spending in their lives as well.

Ms. PRESSLEY. Thank you. Mr. Gonzalez, you know your company's pricing decisions have very real impacts on patients' lives. The committee reviewed approximately 400 complaints from patients and caregivers begging you to lower the price of Humira, yet your company repeatedly does the opposite and denies desperately needed relief for these patients. Although your primary patent expired in 2016, there is still no competition in the U.S. market. Now, according to documents the committee received as a part of our investigation, on page 9 of Exhibit 14, AbbVie executives predicted that Humira would have three to five biosimilar competitors in the U.S. by the first quarter of 2017. Mr. Gonzalez, did that prediction come to pass? Yes or no.

Mr. GONZALEZ. No.

Ms. PRESSLEY. It did not, that is right. Using a variety of anti-competitive practices, AbbVie has suppressed alternative drug options in the U.S. market until 2023. That will allow your company to continue to exploit patients and to rake in astronomical profits. Mr. Gonzalez, will you admit the lack of competition means that government has to pay more, and patients have to make greater sacrifices? Yes or no.

Mr. GONZALEZ. Congresswoman, I would like to address the comment you made earlier.

Ms. PRESSLEY. Yes or no, Mr. Gonzalez.

Mr. GONZALEZ. Yes.

Ms. PRESSLEY. Are patients having to pay more and make greater sacrifices? AbbVie's own documents estimate that the delay will cost the U.S. healthcare system at least an additional \$19 billion, and for patients, it will cost them their physical, psychological, and financial health. We live in the richest country on the planet, yet drug prices are so high that people can't afford to live happy, healthy, longer lives. People demand deserve and require better from AbbVie and all other price gouging drug companies. Thank you, and I yield back.

Chairwoman MALONEY. The gentlelady yields back. The gentleman from California, Vice Chair Gomez, is recognized for five minutes.

Mr. GOMEZ. Thank you, Madam Chair. I wanted to focus in on a part of Mr. Gonzalez's testimony. He mentioned AbbVie's use of a Patient Assistance Program, which we examined last fall. But before I go on to Mr. Gonzalez, Dr. Kesselheim, is it correct to say manufacturers like AbbVie benefit from third-party patient assistance foundations? Yes or no.

Dr. KESSELHEIM. Yes, they do.

Mr. GOMEZ. Thank you. And one of those third-party foundations is the Patient Access Network, or PAN Foundation. Mr. Gonzalez, your company makes donations to the PAN Foundation, correct?

Mr. GONZALEZ. Correct.

Mr. GOMEZ. I would like to display a November 2017 email from Mr. Dan Klein, the president of the PAN Foundation, to AbbVie's director of the Patient Access Program. This is Exhibit 27 in your packet. In this email, Mr. Klein is seeking a donation from your company to help offset the cost of the drug, Humira. He wrote, "We also know these patients would be much more likely to start and stay on treatment if they were not stymied by high, out-of-pocket cost." Mr. Klein is essentially saying that by making a donation to his foundation, AbbVie will be able to attract and retain more Humira patients. Mr. Gonzalez, are donations to patient assistance foundations part of AbbVie's strategy to maximize sales or the use of your product?

Mr. GONZALEZ. No, they are not. We do it as a donation because we feel that it is appropriate. We do it by disease state. The foundation is not required to use our drug. They can provide—

Mr. GOMEZ. Thank you so much. Let me reclaim my time. Mr. Gonzalez, I would like to switch gears. I understand that AbbVie co-promotes your cancer drug, Imbruvica, with Janssen Pharmaceuticals, so that means your company jointly developed the sales and marketing strategy for this drug, right?

Mr. GONZALEZ. That is correct.

Mr. GOMEZ. But AbbVie's subsidiary, Pharmacyclics, leads U.S. commercialization and sales, correct?

Mr. GONZALEZ. That is correct.

Mr. GOMEZ. In 2017, AbbVie and Janssen executives met to evaluate "optimal spend to maximize Imbruvica sales growth in existing and new indications." This is Exhibit 24 in your packet. A chart on page 22 of the presentation breaks down the proposed spending for the next fiscal year. The chart includes a line item for foundations with the proposed, "collaboration spend of \$55 million in Fiscal Year 2017." This is the largest single proposed increase of any spending amount two companies would spend together, correct?

Mr. GONZALEZ. I am not familiar with this document, but I would assume so, yes.

Mr. GOMEZ. So let me ask you again. Are donations to the Patient Assistance Foundations part of AbbVie's strategy to maximize sales? Yes or no.

Mr. GOMEZ. No.

Mr. GOMEZ. Mr. Gonzalez, you also said that your patient assistance programs provide one year free drug costs, right? Correct?

Mr. GONZALEZ. That is correct.

Mr. GOMEZ. What happens to the patient after that one year?

Mr. GONZALEZ. They reapply and we refund it.

Mr. GOMEZ. And the reason why I am asking this is that, you know, we understand that a lot of the investment, everything from research to marketing, also the donations to these foundations, is all taken on into the price of the drug. It might appear that it is something that is altruistic, but you also get tax write-offs. You also get other benefits. I am one of the few members of this com-

mittee who also serves on the Ways and Means Committee, which is the tax committee. A lot of the programs that you are talking about is just a way to get people hooked on these drugs that are high cost in the long term. It subsidizes the patient, but that is not who you are going after. Really, these drug companies are going after the spin from the insurance companies, increasing the number of people that are on the drug, but also increasing the amount of money that you are receiving.

One of the things that we need to do is we understand that the system is broken, everything from the drug companies, to the insurance companies, to now the patient assistance programs, that all jack up the price of pharmaceutical drug prices in this country. With that, I yield back.

Chairwoman MALONEY. The gentleman yields back. I thank him for his statement. But before we close, I would like to offer the ranking member an opportunity for any closing remarks. Ranking Member Comer, you are now recognized.

Mr. COMER. Thank you, Madam Chair, and I just want to be very clear what the Republican position is. We strongly support a patent system that encourages innovation. However, we certainly don't want to see a patent system that is abused, and there are always going to be bad actors, and those bad actors need to be held accountable. But to be completely candid about this conversation and the Democrat proposal that has been mentioned several times today, the Biden Administration and the House Democrats have lost a lot of credibility when we talk about the patent system when the Biden Administration announced its effort to give our pharmaceutical intellectual property, with respect to the COVID vaccine, to China, a country that still has a lot of questions to answer about the origination of the COVID-19 virus. So we have got some credibility issues on the other side of the aisle with respect to the patent system.

Nobody wants to see price gouging. Nobody wants to see excessive CEO pay on the backs of hardworking Americans that have to make a decision on whether to pay for their medicine or put food on the table. We all know the horror stories, and we all know people that have had terrible experiences in trying to buy medication. I think there is a way that we can come to terms and protect our patent system because it takes investment, private sector investment, to come up with the cures for all the diseases that we want cured in America. But at the same time, we have to make sure that the patent system is not abused.

So I look forward to working with Members of Congress that feel this way and that will respect our patent system, but hold those accountable who choose to abuse the patent system. With that, Madam Chair, I yield back.

Chairwoman MALONEY. Thank you. The gentleman yields back.

Before I close, I would like to enter into the record several letters and statements for the record the committee received leading up to today's hearing. These statements include: Professor Robin Feldman at UC Hastings Law, Protect Our Care, Families USA, the American Economic Liberties Project, the Health Advocacy Summit, the Maryland Citizens Health Initiative, Treatment Action

Group, and many more. I ask unanimous consent that these materials be entered into the official hearing record.

So ordered.

Chairwoman MALONEY. At the beginning of today's hearing, we heard patient stories of how they struggled to afford AbbVie's products, including Humira and Imbruvica. AbbVie's CEO, Mr. Gonzalez, thought to cast blame on others for AbbVie's high prices, but the facts show that AbbVie raised prices on Americans for one simple reason: greed. This morning, we released a staff report based on our review of over 170,000 pages of AbbVie's own documents and data. These documents show AbbVie intentionally targeted the U.S. for higher prices as it cut prices in the rest of the world. And Mr. Gonzalez admitted today that his company charges higher drug prices in the United States because other countries are doing such a good job of negotiating lower prices for their citizens. Every American should be outraged.

AbbVie's internal data show that Medicare would have saved billions of dollars had it been able to negotiate directly with the company. The documents also show that the financial assistance for patients that AbbVie provides are not actually charity. They make AbbVie more money by keep using their products. AbbVie has also claimed that it needs to charge high prices to stimulate innovation, but the company's own internal documents show that much of its research budget is actually dedicated to suppressing competition. AbbVie also employed potentially illegal anti-competitive tactics to delay lower price biosimilars from coming to market. Those tactics led to higher prices and less innovation for Americans, but more profits for the executives at AbbVie.

Enough is enough. Congress has an opportunity, and I would say a responsibility, to ensure that Americans no longer have to choose between taking their lifesaving medication or paying their rent and putting food on their table. We must pass H.R. 3, which would finally empower Medicare to negotiate lower prices, just like the Defense Department and the VA-HUD already do, and that foreign countries, they do. And we must pass legislation to crack down on AbbVie's anti-competitive abuse so market competition can drive down prices.

I urge my colleagues on both sides of the aisle, especially those on the other side of the aisle who have acknowledged the harm caused by skyrocketing drug prices, to join me in pushing for these reforms. This should be a bipartisan issue. I hope we can all agree that no person should go without potentially lifesaving treatment in this country. Let's act together. Let's do something about it. Let's help the American people.

I thank everyone who participated, and I particularly want to thank our panelists for their remarks, and I want to commend my colleagues for their important contributions, their questions, for participating in this important conversation.

With that, and without objection, all members have five legislative days within which to submit extraneous materials and to submit additional written questions for the witnesses to the chair, which will be forwarded to the witnesses for their response. I ask our witnesses to please respond as promptly as they are able to.

Chairwoman MALONEY. I also want to thank the staff of the Oversight Committee for what I would call a labor of love and deep commitment, and you can see that in reading their report. I particularly thank the team leaders, Ali Golden and Amish Shah, for an extraordinary effort and an extraordinary hearing today.

This hearing is adjourned.

[Whereupon, at 1:44 p.m., the committee was adjourned.]

