House Committee on Oversight and Reform
Unsustainable Drug Prices: Testimony from the CEO's (Parts I and II)
September 30-October 1, 2020
10:00 AM Hybrid in person/remote hearing
2154 Rayburn House Office Building

Purpose
The purpose of these hearings was to examine the pricing practices for some of the costliest drugs in the United States.

Part I:

Members Present
Chairwoman Maloney, Ranking member Comer, Representatives Foxx, Hice, Roy, Welch, Palmer, Norton, Connolly, Kelly, Cloud, Raskin, Norman, Mfume, Keller, Wasserman-Shultz, Grothman, Sarbanes, Higgins, Speier, Lawrence, Gomez, Miller, Tlaib, Pressley, Ocasio-Cortez, Porter

Witnesses
Mark Alles., Former Chief Executive Officer, Celgene Corporation
Dr. Giovanni Caforio., Chief Executive Officer, Bristol Myers Squibb
Kåre Schultz., Chief Executive Officer, Teva Pharmaceuticals

Opening Statements
Chairwoman Maloney said that it is important to remember that drug innovations have resulted in millions of Americans having a better quality of life. Americans rely on the drug industry. However, this committee has completed an investigation surrounding how drug companies price their products. The results are concerning to say the least. The documents show that drug price increases are simply unsustainable. Drug companies continue to raise prices while bringing in record profits every year. The document also reveals that these massive price increases are based on generating windfall profits for the shareholders and executives. Drug companies like to claim that they need these profits to invest in research and development. Unfortunately, this committee's research has shown that that argument does not hold any water. Finally, the committee found that drug companies are targeting the United States in order to exploit the high prices paid here. The United States continues to subsidize the rest of the world's drug prices. Earlier this year, the House passed H.R. 3, an important bill to lower the cost of drugs. Sadly, President Trump and Republicans in Congress refuse to act on this landmark legislation.

Ranking member Comer said that the issue of high drug prices is a concern for all Americans. This concern is also shared by President Trump. Over the last four years, the current administration has worked to lower drug prices and approve a record number of generic drugs. Unfortunately, the

hearings this week are designed to demean and publically shame pharmaceutical CEOs. Democrats are eager to cast these witnesses as villains and place all of the blame on the private sector. However, just the opposite is true. The free market has led to developments and innovations that have improved the lives of Americans. That is especially evident now as everyone eagerly awaits an approved COVID-19 vaccine. It is time to stop the repeated attacks on the vaccine development process. It is important to find a balance between innovation, cost and patient access. More government is not the answer. Government red tape has created the current environment.

Rep. Foxx said that many Americans pay too much for prescription drugs. Luckily, the Lower Costs, More Cures Act (H.R. 19) contains many bipartisan reforms to lower out of pocket spending. Democrat's bill, H.R. 3, would eliminate 30 new drugs over the next decade. There is no way to know what drugs would be eliminated, but it is possible that they would be lifesaving treatments. H.R. 3 makes no effort to truly solve the structural problem that exist today. If Democrats truly want to reduce the price of drugs, there is a bipartisan bill ready to be passed and signed into law.

Rep. Hice said that H.R. 3 would destroy pharmaceutical innovations. The Congressional Budget Office said that H.R. 3 would result in nearly 38 fewer drugs from coming to the market. These could be drugs that would cure deadly diseases and conditions. For some reason, Democrats think that this is a good idea. We need to be working to make innovation easier as opposed to more difficult. H.R. 3 would be devastating for the American people.

Rep. Roy said that Americans depend on the pharmaceutical industry. However, it is important to solve the problem as a whole instead of vilify individual actors. Pharmaceutical manufacturers are not the only stakeholders, Bristol Myers Squibb and insurance companies are also to blame. It is a good thing that drug companies make a profit. They are producing a good needed by the public, and deserve to operate a profitable business. It is time to look at the entire supply chain from top to bottom and make structural changes.

Rep. Welch said that every single American at some point is going to need pharmaceutical assistance. Furthermore, every American needs relief from drug prices that are far beyond reach. The question in front of this committee is whether it will take an active role in preventing price gouging occurring in the pharmaceutical industry. Drug manufacturers have turned America's pain into their profits. The only way to really get fair pricing is to have negotiation. In fact, negotiation is core to a free market economy. Medicare and Medicaid are the only buyers that do not negotiate for drug prices.

<u>Testimony</u>
Mr. Alles said that one of the most clinically important therapies discovered by Celgene is the novel medicine lenalidomide, marketed as Revlimid. Revlimid's primary use is for the treatment of multiple myeloma – a rare and incurable blood cancer. Celgene invested approximately $800 million over 14 years to invent and develop Revlimid before its first FDA approved use in late 2005. Revlimid is a unique, patented molecule that required a completely independent development program and a full FDA approval process. Revlimid has become a standard of care for the treatment of myeloma based on several large clinical studies that have demonstrated significant patient benefits. Since Revlimid's initial FDA approval, the company continued to invest several hundred million dollars into the research and development of this medicine. At the time it

was acquired, Celgene had, and was sponsoring, more than 50 additional Revlimid clinical studies for patients with different types of cancer. As is common in drug development, many studies did not succeed. However, several of these studies were successful and resulted in six additional FDA approvals – including the most recent in 2019. Since 2005, more than 700,000 patients have been treated with Revlimid worldwide. At Celgene, pricing decisions for our medicines were guided by a set of long-held principles that reflected our commitment to patient access, the value of a medicine to patients and the health care system, the continuous effort to discover new medicines and new uses for existing medicines, and the need for financial flexibility. In 2018, the company publicly committed to full pricing transparency by limiting price increases to no more than once per year, and at a level not greater than the Centers for Medicare and Medicaid Services' (CMS) projected increase in National Health Care Expenditures for the year, absent exceptional circumstances. To help ensure patient access to our medicines, the company's Patient Support programs provided copay assistance to eligible, commercially insured patients, and provided free medicine to eligible patients. More than 140,000 people in the United States prescribed a Celgene cancer medicine received some form of assistance. Celgene sold and offered to sell samples of its patented medicines to generic manufacturers, so long as those companies met critically important safety standards. These requirements were established to protect the public from the risks of severe birth defects associated with the known and suspected teratogenicity of some of its products – including Revlimid. In fact, multiple generic versions of Revlimid are licensed to enter the U.S. market within the next two years.

Mr. Caforio said the COVID-19 pandemic has brought the issues of health care costs and drug pricing, patient access, and scientific innovation into even sharper focus. Bristol Myers Squibb is seeking to do our part to support efforts to combat COVID-19 and mitigate the pandemic's impact on patients and families. Over the past several decades, medical innovations have made dramatic improvements in the treatment of cancers. Bristol Myers Squibb has been a pioneer in the field of immunooncology through the development of two medicines, Yervoy and Opdivo, that have transformed survival expectations for many patients with cancer. As one example, prior to the availability of modern immuno-oncology treatments, only 25% of patients diagnosed with metastatic melanoma survived a year. Today, thanks to immuno-oncology therapies, the one-year survival rate has increased threefold to 74%. Through our continued investments in research, we are now on the cusp of a new generation of treatments that harness the power of the body's own immune system to treat cancers. Significant and sustained investment in research and development by Celgene resulted in a robust pipeline of new products. This pipeline, along with its extensive research capabilities, was the primary factor in Bristol Myers Squibb's decision to pursue an acquisition of Celgene. Celgene's substantial near-term pipeline of products will now benefit from Bristol Myers Squibb's larger scale and existing experience in oncology and immunology. We believe that drug pricing should be considered in the context of the value, or benefit, the medicine delivers to patients, healthcare systems, and society overall. As such, at Bristol Myers Squibb, we price our medicines based on a number of factors, including, among others, the value of scientific innovation for patients and society in the context of overall healthcare spending; economic factors in relation to the healthcare systems' capacity to provide appropriate, rapid, and sustainable access to patients; and the ability to sustain our research and development investment in new innovations that address serious unmet medical needs. To address rising out-of-pocket expenses, we support reforms of the rebate system to focus on the best interests of patients. We also support efforts to ensure generic drugs are made available more

quickly and more broadly when possible. Generic entry is an essential corollary to our system of promoting medical innovation through the patent system's period of exclusivity. We applaud the Administration's success with speeding the approval of generics, and supported the important improvements that Congress achieved with the passage of the CREATES Act. Finally, we support pricing innovations, such as value-based purchasing arrangements that tie payments to value. These models can reduce costs, improve access and adherence, and, most importantly, contribute to better outcomes. We support the efforts by the Department of Health and Human Services to remove regulatory barriers and facilitate greater use of these arrangements.

Mr. Schultz said Teva is a global pharmaceutical company committed to helping patients access affordable medicines and benefit from innovations to improve their health. Our mission is to be a global leader in generics and biopharmaceuticals, improving the lives of patients. We were founded in Israel 120 years ago and operate worldwide, with a significant presence in the United States, Europe, and many other markets. Teva is the world's leading provider of affordable medicines, with the industry's largest portfolio of generic medicines and a strong portfolio of specialty medicines, including COPAXONE. With over 3,500 products across almost all therapeutic areas, Teva reaches nearly 200 million people every day and is proud to provide American patients with approximately 1 out of 10 medicines they take. Teva has also been an active contributor to economic growth globally, as the largest Israeli company and as the largest Israeli foreign investor in the United States. In the United States, we employ nearly 7,000 Americans and indirectly support more than 57,300 full-time jobs. This contributes $15 billion to the country's GDP and generates $4.8 billion in labor income. We also manufacture $11 billion worth of medicines at our 10 American manufacturing sites each year. In fact, 42 percent of Teva's finished drug products are manufactured in the United States. As the world's leading provider of affordable medicines, Teva drives access and provides direct savings to patients and healthcare systems around the world. For example, in 2018, on the strength of our generics business, Teva delivered $55 billion in savings to healthcare systems in 18 global markets. In the United States, specifically, Teva saved the healthcare system $41.9 billion, including $5.9 billion in savings directly to patients, in 2018 alone. We also provided over $40 million worth of medicines to 12,800 patients in the United States through the Teva Cares Foundation in 2019. COPAXONE is one of the best examples of our dedication to innovative research and patient support. Our significant investments in researching, developing, and commercializing safe and effective treatments led us to introduce COPAXONE in the United States in 1996 to treat relapsing forms of MS, and Teva has supported MS patients in this country for almost 25 years. Since first introducing COPAXONE, we have continued our studies, and, most recently, in 2014, introduced a more efficient version of that drug that only needs be administered 3 times a week as opposed to daily. Teva acknowledges that the pharmaceutical industry as a whole needs to be mindful and responsible about the pricing of medications and understand that each company plays a role in keeping down healthcare costs. Teva renews its commitment today to continue to provide unfettered access to high-quality generic medicines, to innovate and create solutions for patients, and to strive to make health care more accessible and affordable.

Questions and Answers

Chairwoman Maloney asked if it is true that Celgene targeted selling products in the US due to high prices. **Mr. Alles** said that there are fundamental differences in drug pricing around the world, however the US is the home of medical innovation. This is due to the free market aspect of

the United States. The United States is a good market to sell drugs in. **Chairwoman Maloney** asked if Teva raises prices so often in the United States because they are allowed to do so, whereas they cannot in other countries. **Mr. Schultz** said that since he started working at Teva these actions have not occurred.

Rep. Palmer asked if extending patent protections would help to reduce the cost of drugs. **Mr. Alles** said that this question is very complicated. If patent reform extended the life of a patent and were combined with other reforms like capping out of pocket spending, this could help to reduce drug prices.

Rep. Norton asked if Bristol-Myers raised the price of Revlimid. **Mr. Caforio** said yes. **Rep. Norton** asked if Celegene raise the price of Revlimid. **Mr. Alles** said yes. **Rep. Norton** asked if Teva raised the price of Copaxone**. Mr. Schultz** said yes. **Rep. Norton** asked if the witnesses knew that ¼ Americans have trouble affording medicine. **All Witnesses** said yes.

Rep. Foxx asked what country will deliver the first credible and widely used vaccine for COVID-19. **Mr. Caforio** said that many countries are working on this. Innovation does happen primarily in the United States. **Rep. Foxx** asked what the best incentives to develop new treatments are. **Mr. Alles** said that the ability to have financial flexibility built into the innovation cycle is very important. **Rep. Foxx** asked if the US had implemented the same price controls as Europe, would it be more or less likely to develop a COVID-19 vaccine. **Mr. Schultz** said less likely because the financial incentives would be less.

Rep. Connolly asked if Celgene makes a profit off Revlimid in Europe. **Mr. Alles** said yes. **Rep. Connolly** asked if there is a difference in R&D investments between the US and Europe. **Mr. Alles** said that they can often be different.

Rep. Kelly asked if Bristol-Myers Squibb has any patient assistance programs. **Mr. Caforio** said yes. They help nearly 100,000 patients every year. **Rep. Kelly** asked what impact increasing drug prices has on communities of color. **Mr. Caforio** said that Bristol-Myers Squibb is dedicated to supporting vulnerable communities. It is clear that the current environment has made economic challenges harder.

Rep. Cloud asked how the drug pricing system works. **Mr. Caforio** said that pricing systems are very complex. One of the objectives is to resolve some of the complexity. Medicines are typically priced based on the value they offer. Patient affordability is also taken into consideration. Discounts and rebates are often provided to Bristol Myers Squibb, but these should really be passed on to the consumer. **Rep. Cloud** asked if generics generally bring prices down. **Mr. Caforio** said yes.

Rep. Raskin asked what Mr. Schultz's salary is. **Mr. Schultz** said about $12 million. **Rep. Raskin** asked if Teva has ever justified the increase in price of copaxone by saying that copaxone revenues are used to invest in research and development. **Mr. Schultz** said since he began working, the price did not increase. **Rep. Raskin** asked what proportion of revenue made from copaxone was invested into research and development. **Mr. Schultz** said he did not know.

Rep. Norman asked what effects Bristol Myers Squibb have on drug prices. **Mr. Caforio** said that Bristol Myers Squibb play an important role but at the same time, the discounts and rebates do not make their way to patients at the pharmacy counter. Patients should be getting these rebates. **Mr. Schultz** said that Bristol Myers Squibb consolidate and negotiate on behalf of managed care plans. Over the lifetime of a pharmaceutical product, rebates increase but patients do not get these savings.

Rep. Mfume asked if Teva negotiates with the VA. **Mr. Schultz** said yes. **Rep. Mfume** asked if Teva directly negotiates with Medicare. **Mr. Schultz** said no, they indirectly negotiate through Medicare private insurance plans. **Rep. Mfume** asked if negotiating with Medicare directly would force drug prices down. **Mr. Schultz** said that is a very complicated and difficult question to answer. **Rep. Mfume** asked what Congress should do to lower drug prices. **Mr. Schultz** said that it is important to try to make the system slightly less complicated. It is difficult to equally evaluate all of the different levers.

Rep. Keller asked what effects socialized medicine would have on innovation. **Mr. Caforio** said that access to new medications should be the priority. Currently, when a drug is developed it becomes immediately available in the US. If the system were to dramatically change, there could be significant delays in bringing new treatments to market. **Rep. Keller** asked if manufacturers have a role in the drug supply chain outside of manufacturing the drug. **Mr. Caforio** said no.

Rep. Wasserman-Schultz asked if the Risk Evaluation and Mitigation Strategy (REMS) is designed to protect patients. **Mr. Alles** said yes. **Rep. Wasserman-Schultz** asked if Celgene used REMS to prevent generic encroachment. **Mr. Alles** said no. **Rep. Wasserman-Schultz** asked if it is true that Celgene attempted to secure additional patents on the RMS process. **Mr. Alles** said yes.

Rep. Grothman asked when Bristol Myers Squibb acquired Celgene. **Mr. Caforio** said 2019. **Rep. Grothman** asked if the price of Revlimid increased dramatically in January 20202. **Mr. Caforio** said that it increased by 6%. **Rep. Grothman** asked if there has been a price increase since then. **Mr. Caforio** said no. **Rep. Grothman** asked if Teva entered into an agreement with Amgen as a pay for delay contract. **Mr. Schultz** said that he does not know. **Rep. Grothman** asked if there is competition for Revlimid. **Mr. Caforio** said no because it is protected by patents until 2027. **Rep. Grothman** asked why the US pays so much more for drugs than other countries. **Mr. Caforio** said it is because innovation is recognized and incentivized in the United States.

Rep. Sarbanes asked if it is fair to say that the price of Revlimid has risen faster than any rebates and discounts provided since 2009. **Mr. Alles** said that he does not have the information in front of him but he trusts Rep. Sarbanes representation of the price increase. **Rep. Sarbanes** asked if Teva provides rebates for copaxone. **Mr. Schultz** said yes.

Rep. Higgins asked if generic drugs generally lower the price of brand name drugs. **Mr. Caforio** said yes. **Rep. Higgins** asked if pharmaceutical companies extend their patent protections by slightly altering an aspect of the drug. **Mr. Caforio** said the approach is to patent meaningful innovations that are beneficial for patients. **Rep. Higgins** asked how a change is determined to be meaningful. **Mr. Caforio** said that when a new medicine is introduced, it is really at the beginning

of its development process. Over time, these products are improved and become a better drug for the patient.

Rep. Welch asked if it is true that the top Celgene executives were paid $400 million between 2006 and 2017. **Mr. Caforio** said that Celgene was acquired in 2019 so he is not sure. **Rep. Welch** asked if $400 million seems a little high. **Mr. Caforio** said that he cannot comment on this. **Rep. Welch** asked if sales of remlivid have increased as a result of the Medicare Part D program. **Mr. Caforio** said that sales have increased for a number of reasons, including more clinical indications for prescribing it. **Rep. Welch** asked if Celgene increase the price of remlivid 25 times since its introduction. **Mr. Alles** said yes. **Rep. Welch** asked if Bristol Myers Squibb increased the price of remlivid after acquiring Celgene. **Mr. Caforio** said yes. **Rep. Welch** asked what the out of pocket cost is for Remlivid for a Medicare beneficiaries. **Mr. Caforio** said that he knows it is expensive. **Rep. Welch** asked how much remlivid costs the federal government. **Mr. Caforio** said it is expensive due to volume. **Rep. Welch** asked if Bristol Myers Squibb have offered discounts to the Medicare program from remlivid. **Mr. Caforio** said yes.

Ranking member Comer asked how to balance the need for innovation with the need to bring down costs. **Mr. Caforio** said the most important part is that the system needs fundamental change. Bristol-Myers Squibb is dedicated to work with Congress to create a less complex system. Introducing a Medicare out of pocket cap would alleviate much of the burden felt by patients. **Mr. Schultz** said that the system does work well and this can be judged by the fact that most innovation happens in the United States. Furthermore, patents work very well. With that being said patents should expire after a reasonable amount of time. **Ranking member Comer** asked how long a patent should last. **Mr. Schultz** said the current initial patent duration is good.

Rep. Speier asked why Celgene has raised the price of Remlivid so much over the last 15 years. **Mr. Alles** said that a very important portfolio of cancer drugs was developed using the revenue brought in through Remlivid. **Rep. Speier** asked why taxpayers are picking up the tab to pay for CEO salaries and research and develop payment. **Mr. Alles** said that the success of Remlivid will fund the development of multiple drugs for years to come. **Rep. Speier** asked what should be done to bring down the cost of drugs. **Mr. Alles** said that out of pocket costs should be capped. In order to do this, industry has to come together and work with Congress. **Mr. Caforio** said that companies should be able to provide financial assistance to patients in Medicare. There should also be an out of pocket cap in Medicare. **Mr. Schultz** said that Teva is committed to promoting generics, and increasing transparency.

Rep. Lawrence asked if Bristol-Myers Squibb has committed to not increase the price of remlivid this year. **Mr. Caforio** said yes. **Rep. Lawrence** asked if regulations need to be set on research and development. **Mr. Caforio** said that when a medicine is first introduced it is often at the beginning of its research and development process. Remlivid is a much better product now than it was when it was introduced. It now has more indications than it did previously.

Rep. Gomez asked if it is true that Teva tried to extend the patent on copaxone despite no clinical difference in the drug from when it got its original patent. **Mr. Schultz** said that he is not sure. **Rep. Gomez** asked if the life cycle management team is on the business side of the company. **Mr. Schultz** said not necessarily. They are in charge of research and development. **Rep. Gomez** asked

if there can be meaningful innovation without scientific backing. **Mr. Caforio** said that he cannot answer that.

Rep. Miller asked how much Bristol Myers Squibb spends on research and development every year. **Mr. Caforio** said $10 billion. **Rep. Miller** asked how much Celgene spends on research and development. **Mr. Alles** said $5.7 billion. **Rep. Miller** asked how much Teva spends on research and development. **Mr. Schultz** said $1 billion. **Rep. Miller** asked how research affects the price of drugs. **Mr. Caforio** said that it affects it greatly. There is a need to get a return on investments made in research and development. **Mr. Alles** said that research and development is very expensive. **Mr. Schultz** said that it impacts it significantly for the reasons previously stated.

Rep. Tlaib asked if it is reasonable for patients to pay $70,000 a year to get copaxone. **Mr. Schultz** said no. **Rep. Tlaib** asked if Teva donates to third party independent charities that cover Medicare beneficiaries out of pocket costs. **Mr. Schultz** said yes. **Rep. Tlaib** asked if these donations should be considered financial investments. **Mr. Schultz** said no.

Rep. Pressley asked if pharmaceutical companies should prioritize people over profit. **Mr. Alles** said that people need to be prioritized. **Rep. Pressley** asked if thalidomide was a new drug when Celgene acquired it. **Mr. Alles** said no. **Rep. Pressley** asked if Mr. Alles knew that the NIH funded a thalidomide research study. **Mr. Alles** said that he was not surprised. **Rep. Pressley** asked if it is true that Celgene utilized these federally funded studies to decide to invest in thalidomide. **Mr. Alles** said there were many studies that were conducted.

Rep. Ocasio-Cortez asked why the price of copaxone is so much more expensive in the United States than in other countries. **Mr. Schultz** said there is early and broad access in the US which comes with a high list price. **Rep. Ocasio-Cortez** asked if Teva was pressured to lower the price in copaxone. **Mr. Schultz** said that he does not know. **Rep. Ocasio-Cortez** asked if it is true that most countries in Europe use reference pricing. **Mr. Schultz** said yes. **Rep. Ocasio-Cortez** asked if Teva makes a profit in Europe. **Mr. Schultz** said yes.

Rep. Porter asked what the price of Remlivid was when it hit the market in 2005. **Mr. Alles** said he was not sure. **Rep. Porter** asked what he price was in 2013. **Mr. Alles** said he was not sure. **Rep. Porter** asked what the price of Remlivid was in 2017. **Mr. Alles** said about $700. **Rep. Porter** asked if the drug has gotten more effective since its introduction. **Mr. Alles** said there are more indications for the drug. **Rep. Porter** asked what changed about remlivid to justify the price increase. **Mr. Alles** said the manufacturing of the pill is the same. **Rep. Porter** asked if there are uninsured patients who pay the list price. **Mr. Alles** said yes. **Rep. Porter** asked if Mr. Caforio would commit to bringing down the price of remlivid to reflect the rise in inflation. **Mr. Caforio** said no.

Part II:

Members Present
Chairman Maloney, Ranking member Comer, Representatives Massie, Norton, Gosar, Clay, Palmer, Rouda, Cloud, Welch, Gibbs, Sarbanes, Higgins, Wasserman-Schultz, Miller, Khanna, Steube, Speier, Keller, Connolly, Foxx, Plaskett, Grothman, Raskin, Gomez, Tlaib, Porter, Kelly

Witnesses
Robert Bradway., Chief Executive Officer, Amgen, Inc.
Mark Trudeau., Chief Executive Officer, Mallinckrodt Pharmaceuticals
Thomas Kendris., U.S. Country President, Novartis AG

Opening Statements
Chairman Maloney said that it is clear that the current drug prices in the United States are unsustainable. Not only are they unsustainable for everyday consumers but they are also unsustainable for government programs. Today the committee will continue its second day of hearings to investigate why drug prices are so high.

Ranking member Comer said that Republicans have introduced legislation (H.R. 19) that is full of bipartisan policies to lower drug costs. This bill could pass the house today and be signed into law by the end of the week. In addition, innovation is remarkably important. The cost of drugs cannot be reduced at the expense of innovation. Finally, it is important to look at all of the players in the drug supply chain when contemplating how to lower drug prices.

Rep. Massie read the patent and copyright clause in the Constitution. He continued by saying that it is important to incentivize the manufacturing of generic drugs. However, patent laws are necessary to provide financial predictability for investors. Without this financial predictability drug, innovation would be destroyed.

Testimony
Mr. Bradway said that we have entered a golden age of innovation where remarkable advances in science and technology are giving us powerful new weapons in the fight against COVID-19 and some of the most serious diseases we face as a society. We have made considerable investments researching possible treatments for COVID-19, including a recent collaboration with Eli Lilly and Company to manufacture a promising antibody therapy, and look forward to working with the government, academia and industry to bring meaningful treatments to patients. Separate from COVID-19, we continue to race to bring helpful treatments to patients with serious conditions including cancer, heart disease, and inflammatory conditions such as asthma. In recent years, however, after obtaining Food and Drug Administration (FDA) approval, we have found that the real challenge is overcoming barriers that keep medicines out of reach for those who need them. First, there are prior authorization barriers imposed by payers that restrict access by burdening physicians with various steps to obtain approval for their patients to access the medicine the physician determined is medically necessary. Then there are barriers at the pharmacy counter when people find out what they have to pay out of pocket for the medicine they need. This, in turn, is a function of a dizzying array of variables such as the design of insurance plans, current deductible status, and other factors making it hard to know in advance how much a given

prescription will cost. We believe that innovative biopharmaceuticals are part of the solution to the significant burden of serious diseases that impact patients and society. What we need is more innovation, not less. Changes are needed to encourage innovation while providing patients access to these innovative medicines. As the examples of our own medicines discussed above show, we have implemented reforms to improve affordability for our patients. Whether we are dramatically cutting the list price of our medicines, as we did with Repatha or significantly increasing the rebates we pay for our medicines to lower the net price, as we've done with Enbrel, too many patients still don't benefit. However, this is not something that a single manufacturer or even an industry can make happen. Changing this system requires help from all stakeholders and Amgen stands ready to work with members of both parties and the Administration to develop policy solutions to help improve access and affordability for our patients.

Mr. Trudeau said that this has been a year of unprecedented challenges. When COVID-19 hit, we mobilized to identify therapies to combat the disease. We consulted with the U.S. Food and Drug Administration (FDA) and National Institutes of Health (NIH) regarding potential evaluation of INOmax® – our inhaled nitric oxide therapy – for the treatment of COVID-19 related respiratory complications and supported an independent clinical trial being coordinated by Massachusetts General Hospital, the original and largest teaching hospital of Harvard Medical School. As of September 2020, nearly 250 hospitals and health systems in the United States have used INOmax as an experimental treatment for pulmonary complications in COVID-19 patients. We also secured our supply chain to avoid manufacturing interruptions for the critical medications, active pharmaceutical ingredients and treatments we make, and donated 54,000 pieces of personal protective equipment, several ventilators and more than 16,000 gallons of hand sanitizer manufactured in our Missouri plant to locations across 47 states. Our resolve to help patients has never been stronger, and we understand the American people's concerns over the availability and cost of medical treatments, particularly as the nation continues to combat the novel coronavirus pandemic and as patient out-of-pocket costs grow with increasingly higher deductibles in health insurance plans. We share those concerns and recognize that, if patients cannot obtain access to our therapies, we have failed in our mission. We are committed to ensuring that every patient with a valid prescription can obtain Mallinckrodt's innovative products. While Mallinckrodt's transformation into a science-based company developing new therapies for seriously ill patients with hard-to-treat conditions is not yet complete, and we have challenges to navigate, we are well on our way. We have built the infrastructure and cultivated the talent needed to develop and bring to market innovative treatments for complex diseases and serious conditions. We remain unwavering in our determination to find new solutions for sometimes old and often overlooked conditions that keep patients from living their best lives, while continually working to improve patient access to our innovative products and producing more affordable specialty generic medicines.

Mr. Kendris said Novartis is a global developer and manufacturer of pharmaceutical products. We use innovative science and digital technologies to develop transformative medicines that improve and extend people's lives. We also produce generic drugs and biosimilars through our Sandoz division, the third-largest generics company in the U.S. Our medicines reach close to 800 million people every year, treating diseases including cancer, heart disease, autoimmune diseases, respiratory illnesses, neurological conditions, and several rare diseases. In the U.S., we employ approximately 15,000 associates, including scientists, physicians, and business professionals, and

we support more than 100,000 additional jobs at small, medium, and large U.S. businesses. In the U.S., we operate in all 50 states, the District of Columbia, and Puerto Rico, with five headquarter campuses, six research facilities, including our global R&D headquarters, and eight operational sites. The coronavirus pandemic has demonstrated the importance of a vibrant and innovative pharmaceutical industry which is flexible enough to pivot to address a new global health crisis. It has also highlighted the value the industry delivers to society. We have quickly mobilized R&D capabilities, medicines, clinical trials expertise, and philanthropic aid to address the pandemic. We have committed to donating $40 million to support communities around the world affected by the pandemic. This includes financially supporting more than 30 organizations in the U.S. such as Americares, Feeding America, and the Cancer Support Community. And Novartis has been active in two key cross-industry research initiatives, the COVID-19 Therapeutics Accelerator, coordinated by the Bill & Melinda Gates Foundation, and Mastercard, as well as a COVID-19 directed partnership organized by the Innovative Medicines Initiative. The company is also supporting COVID-19 related clinical investigations of several Novartis medicines. To support access, Sandoz became the first company to commit to keeping stable prices for a basket of essential medicines that may help in the treatment of COVID-19 and entered into a partnership with U.S.-based Civica Rx to support a stable supply of essential generic hospital medicines. We are making 15 drugs that treat key symptoms of COVID-19 available to low- and lower-middle income countries at zero profit until a vaccine or curative treatment is found. In recent decades, trust in the pharmaceutical industry has eroded, and our industry must work to regain it. At Novartis, we understand that trust is earned not just from bringing transformative medicines to patients, but by pricing these medicines responsibly and ensuring broad access. We are passionately committed to this purpose.

Questions and Answers

Chairman Maloney asked if premium therapies is code for 'expensive' therapies. **Mr. Trudeau** said no. **Chairman Maloney** asked if Acthar is seen as a cash cow rather than an innovative therapy. **Mr. Trudeau** said no. He continued by noting that the document Chairman Maloney is referring to is simply a draft document and was never used. **Chairman Maloney** asked if the decision to increase the price of Enbrel was determined based on the fact that a competitor would raise the price on their product. **Mr. Bradway** said yes. This is a reflection of the rebate and discount system. It is necessary to stay competitive. **Chairman Maloney** asked if it was true that pharmaceutical companies increase their prices in tandem. **Mr. Bradway** said that price changes are often done to get a more favorable spot on a payer's formulary. **Chairman Maloney** asked if Novartis chose the most aggressive price model for Gleevec. **Mr. Kendris** said that the price increased for Gleevec because it became a more valuable drug overtime. This drug is essentially a cure for cancer.

Rep. Massie asked what percent of prescriptions in the US are generics. **Mr. Trudeau** said about 90%. **Rep. Massie** asked if the cost of generics in the US is higher than in other countries. **Mr. Trudeau** said that prices drop the most rapidly in the US because it is a very efficient market. **Rep. Massie** asked what challenges are faced when developing a generic drug. **Mr. Trudeau** said that it is difficult to generate bioequivalence data. **Rep. Massie** asked if there is anything Congress can do to aide generic manufacturing. **Mr. Trudeau** said that the generic environment in the US is good as it is. **Rep. Massie** asked if patents can be licensed. **Mr. Trudeau** said that could happen but it is not typical. **Rep. Massie** asked how long patents last for. **Mr. Trudeau** said that it is typically 20

years from the time of discovery. **Rep. Massie** asked what percent of the money spent on drugs goes to PBMs. **Mr. Bradway** said that 46% of the cost goes to an intermediary. **Rep. Massie** asked if drug rebates go to consumers. **Mr. Bradway** said no. They go to intermediaries. As list prices go up, intermediaries make more money. **Rep. Massie** asked if the copay that consumers pay is based on the final price the drug company receives for the drug. **Mr. Bradway** said no. It is based on the list price and the drug companies receive the net price. **Rep. Massie** asked what the intent of the PBM system was. **Mr. Bradway** said that this system was created by legislation and allows pharmaceutical companies the opportunity to secure a favorable placement on a formulary.

Rep. Norton asked if Mr. Bradway will commit to lowering the list price of Enbrel and Sensibar. **Mr. Bradway** said that Sensibar is now off patent. In addition, Amgen has committed to lowering the price of the drugs in their portfolio. **Rep. Norton** asked if Mr. Trudeau will commit to lowering the list price of Acthar. **Mr. Trudeau** said that he will commit to lowering the net price of Acthar down to the levels that it was in 2015. **Rep. Norton** asked if Mr. Kendris will commit to lowering the list price of Gleevec. **Mr. Kendris** said that they have already given discounts on the list price in recent years. Novartis also provides patient assistance programs.

Rep. Gosar said that other entities involved in the drug process like PBMs, became a main focus of Obamacare and fueled the creation of new rules by CMS under the Obama administration. And how about pharmacies and how they must deal with the 340B contracts that set strict price controls on various drugs. No market force there! And what about the drug makers who could go on all day about how the government is involved in their day to day business. Colleges want to point to the system and say that this is a free market. This is not the free market and it pushes us closer to socialized medicine. It is time to simplify the drug making process.

Rep. Clay asked why it is important to modernize Acthar. **Mr. Trudeau** said that many old drugs have been repurposed for new uses. In the case of Acthar it is important to provide patients and prescribers with the appropriate scientific information to make good clinical decisions. **Rep. Clay** asked how much Mallinckrodt spends on research and development every year. **Mr. Trudeau** said $350 million dollars. The pipeline is currently very promising. **Rep. Clay** asked what is being done in response to the COVID-19 pandemic. **Mr. Bradway** said that Amgen is dedicated to finding cures and treatments for COVID-19. **Mr. Trudeau** said that Mallinckrodt is engaged in clinical trials to develop therapies for those with COVID-19. They have also donated PPE and hand sanitizer to many different entities.

Rep. Palmer asked if extending patent protections would reduce drug prices. **Mr. Trudeau** said that anything to incentivize innovation would give the health care system an opportunity to deliver drugs more efficiently and potentially at lower prices. **Mr. Bradway** said that the current patent laws are an appropriate standard. **Mr. Kendris** said yes. Patents are essential. **Rep. Palmer** asked what would happen to drug development if companies could not recover their cost. **Mr. Trudeau** said that incentives are important. Any additional incentive that can be provided are likely to lead to more innovation.

Rep. Rouda asked how much Mallinckrodt has collected from Medicare Part D. **MR. Trudeau** said he didn't know. **Rep. Rouda** asked how much of Acthar sales came from Medicare at the time of acquisition. **Mr. Trudeau** said about 20-30%. **Rep Rouda** asked how much of Acthars sales come

from Medicare now. **Mr. Trudeau** said about 50%. **Rep. Rouda** asked how much Medicare could save if the same discounts given to private insurance were given to Medicare. **Mr. Trudeau** said a significant amount. But it is not on Medicare's formulary.

Rep. Cloud asked if manufacturers have to pay rebates to a get a higher placing on the formulary. **Mr. Bradway** said yes. **Rep. Cloud** asked if generics are available for Sensipar. **Mr. Bradway** said yes.

Rep. Welch asked if Amgen acquired the rights to sell Enbrel in 2002. **Mr. Bradway** said yes. **Rep. Welch** asked if that means that Amgen didn't invent the product instead they bought the product. **Mr. Bradway** said yes. **Rep. Welch** asked if Amgen has raised the price 400% since Enbrel was acquired. **Mr. Bradway** said yes. **Rep. Welch** asked if Enbrel is cheaper in Canada. **Mr. Bradway** said yes. **Rep. Welch** asked why Americans can't buy it for the same price as Canadians. **Mr. Bradway** said the drug landscape in the US often brings products to market quicker at the expense of a slightly higher cost. Many of the drugs available in the US are not available in Canada. **Rep. Welch** asked if Amgen would support making a law that makes it legal for Medicare to negotiate a bulk price discount. **Mr. Bradway** said that Amgen is already negotiating with intermediaries on behalf of Medicare.

Rep. Gibbs asked if Novartis has reduced the price of Gleevec. **Mr. Kendris** said no, the price has increased. **Rep. Gibbs** asked why the price went up if the volume of services also went up. **Mr. Kendris** said that the value of Gleevec went up for a variety of reasons. The price increase reflects this value. **Rep. Gibbs** asked if it is true that 60% of Gleevec is given away for free. **Mr. Kendris** said 55% of Gleevec is given away. **Rep. Gibbs** asked if anyone who needs the drug goes without it. **Mr. Kendris** said Novartis investigates every single claim of someone having trouble securing Gleevec. They work to make sure that everyone has access to it **Rep. Gibbs** asked what role pharmacists play. **Mr. Kendris** said that pharmacists at the drug counter are not responsible for rebates and intermediaries. **Rep. Gibbs** asked if we should investigate the role of intermediaries. **Mr. Kendris** said yes.

Rep. Sarbanes asked if it is true that Amgen collected nearly $7 billion in gross sales by selling Enbrel to Medicare Part D between 2013 and 2018. **Mr. Bradway** said yes. **Rep. Sarbanes** asked if Amgen offers Medicare part D discounts comparable to other government purchasers. **Mr. Bradway** said that discounts given to Medicaid and the VA are greater than given to Medicare part D. This is mainly due to statutory requirements.

Rep. Higgins asked what would happen to the development of new drugs if companies were prevented from recouping their initial investments. **Mr. Bradway** said that drug development would stop. There would be no more innovation. **Rep. Higgins** asked why drugs are so much less expensive in Canada than in the United States. **Mr. Bradway** said that in the United States, 46 cents of every dollar goes to intermediaries. This is not the case in Canada. In addition, many of the drugs available in the United States are not available in Canada.

Rep. Wasserman-Shultz asked if Novartis engaged in patent litigation with the first manufacturer to apply to make a generic version of Gleevec. **Mr. Kendris** said yes. **Rep. Wasserman-Shultz**

asked if it is good news for patients when a generic version of a drug is delayed. **Mr. Kendris** said that the lawsuit resulted in Novartis bringing a generic version of the drug to market faster.

Rep. Miller asked how COVID-19 has highlighted the need for innovation. **Mr. Kendris** said that many companies are working on therapeutics to assist those who have fallen ill with COVID-19. Manufacturers are doing all they can to support patients. **Rep. Miller** what impact the classification 'specialty medication' has on the price of a product. **Mr. Kendris** did not answer the question. **Rep. Miller** asked what a single payer system would do to drug innovation. **Mr. Bradway** said that the effect would be chilling on innovation.

Rep. Khanna asked if Enbrel was created in 1998. **Mr. Bradway** said yes. **Rep. Khanna** asked if the primary patent expired in 2010. **Mr. Bradway** said that the patent on the molecule has not expired. **Rep. Khanna** asked what patent expired in 2010. **Mr. Bradway** said it was a use patent. **Rep. Khanna** asked how many patent applications were filled for Enbrel. **Mr. Bradway** said he wasn't sure. **Rep. Khanna** asked how much Enbrel costs in Europe when compared to the US. **Mr. Bradway** said that Amgen does not own the rights to sell Enbrel in Europe. **Rep. Khanna** asked if Mr. Bradway will commit to selling Enbrel in the US at the same price as it is sold in Europe. **Mr. Bradway** said that in Europe the intellectual property for that product has expired.

Rep. Steube asked what Amgen is doing to provide Americans with lower drug prices. **Mr. Bradway** said that net prices in the US have decreased and they are on track to decrease again in 2020. Amgen also made investments in biosimilars. **Rep. Steube** asked how patient assistance programs work. **Mr. Bradway** said that for Enbrel, Amgen employ copay assistance. This brings the average copay down to less than $50 a month. **Rep. Steube** asked if Amgen utilizes rebates with PBMS. **Mr. Bradway** said yes. This secures a competitive formulary placement.

Rep. Speier asked if it is true that Novartis tried to get as much value out of Gleevec prior to loss of exclusivity by increasing the price by 20%. **Mr. Kendris** said that he was not there for this action. He cannot comment on this. **Rep. Speier** asked how much money is spent on marketing. **Mr. Kendris** said about $400 million in the US. **Mr. Bradway** said less than $200 million. **Mr. Trudeau** said $0. **Rep. Speier** asked if the witnesses will commit to not increase the price of any drug above the rate of inflation. **Mr. Bradway** said that is how his company has operated in the past few years. **Mr. Trudeau** said they will reduce the net price. **Mr. Kendris** said he can commit to not raise the net price.

Rep. Keller said that contract pharmacies are essential to the rural areas of PA. About 80% of rural hospitals are 340B. They use pharmacies to provide access to outpatient drugs for those who need them, many of whom are seniors and have chronic conditions. Mr. Kendris thank you for being here. Rep. Keller wanted to ask you about the new "integrity initiative to address duplicate discounts" requiring covered entities to register and upload 340B claims data originated from contract pharmacies onto a new web based platform. The announcement from August expresses support for a sustainable 340B program. There are concerns about this threatening hospitals in PA and their ability to offer home infusion services, telemedicine, and expand their out patients facilities, stretching scare resources to patients in need. Mr. Kendris, what kind of collaboration have you had with 340B hospitals regarding this integrity initiative. **Mr. Kendris** said that Novartis supports the intent and design of the 340B program to help lower outpatient drug prices

for the uninsured and the net profit of safety net providers. They serve underserved populations in those communities and the 340B program helps them. However, Novartis also believes that over many years abuses have grown into the system and Novartis is dedicated to solve this. Many companies have raised the problem over the years with HRSA and Novartis is committed to ensuring their medicines ae as widely available as possible, through the 340B program as well. But the current state of the program is somewhat distorted from its original intent. **Rep. Keller** said that he has a Letter dated August 17th, explaining the integrity initiative. The question was, prior to the letter, has Novartis talked to hospitals about this program and how it may be implemented. **Mr. Kendris** said that he believes his staff is communicating with hospitals. **Rep. Keller** asked when Novartis was planning on making this in effect and stopping some of the discounts to 340B hospitals. **Mr. Kendris** said that Novartis has asked to receive the data by October 1st. They are currently in the process of evaluating that data. As we move forward it will be based on what the data says. **Rep. Keller** asked if a hospital has not registered that data by October 1st, will they still be able to participate in the discounts. **Mr. Kendris** said yes. Novartis will still honor valid and legitimate 340B discounts. **Rep. Keller** asked if the web based portal is a secure platform. **Mr. Kendris** said that he thinks it is a secure platform. **Rep. Keller** asked if there will be a burden placed on hospitals to gather this data. **Mr. Kendris** said no. The data should be widely available. **Rep. Keller** asked if Novartis ever considered asking the intermediaries for the data rather than the hospitals. **Mr. Kendris** said that relationship is between the hospital and the intermediary. Novartis has to ask the hospitals. **Rep. Keller** ended by saying that 340B drug discounts are crucial to his constituents and we should be thoughtful in how any changes to the program would affect us going forward. Any changes need to be manageable and in the patients best interest.

Rep. Connolly asked if when quest core was acquired, Acthar was the main drug being produced. **Mr. Trudeau** said yes. **Rep. Connolly** asked if the price of Acthar increased from $40 to $31,000. **Mr. Trudeau** said yes. **Rep. Connolly** asked if the only difference in the drug is the fact that the legal status of the drug is now an 'orphan drug'. **Mr. Trudeau** said that isn't the only difference, but that certainly did occur. **Rep. Connolly** asked if the orphan drug status made Acthar an attractive purchase. **Mr. Trudeau** said that the original manufacturer was about to go out of business. This presented a good business opportunity. **Rep. Connolly** asked what discount is given to the Medicare program. **Mr. Trudeau** said that they offer all discounts available under statue. **Rep. Connolly** asked if the discount provided to Medicare is around 1%. **Mr. Trudeau** said yes.

Rep. Foxx asked why Gleevec is such an important drug. **Mr. Kendris** said that it was the first targeted therapy. It turned off a specific gene and resulted in great outcomes. **Rep. Foxx** asked what the current list price of Gleevec is. **Mr. Kendris** said $120,000. **Rep. Foxx** asked how much the average patient pays. **Mr. Kendris** said that the average out of pocket cost for a Part D patient is $800 every year. **Rep. Foxx** asked how Mallinckrodt prices a drug. **Mr. Trudeau** said that Mallinckrodt tries to evaluate the true value a drug may bring to the overall healthcare system. **Rep. Foxx** asked what the impact would be on patients if there were 38 fewer cures developed over the next decade. **Mr. Trudeau** said that it would be tragic.

Rep. Plaskett asked if it is correct that copays are based on the list price and not discounts applied after the list price. **Mr. Trudeau** said yes. **Rep. Plaskett** asked how to lower the prices consumers pay. **MR. Trudeau** said that rebates should be passed on directly to consumers.

Second, Medicare beneficiaries should have a cap on out of pocket costs. **Rep. Plaskett** asked if the net price for any of the drugs developed by Mallinckrodt have decreased over time. **Mr. Trudeau** said yes. **Rep. Plaskett** asked how net price can decrease while list price increases. **Mr. Trudeau** said this happens when rebates are rise faster than the list price.

Rep. Grothman said that he is also concerned about the 340B program. There are companies out there, like Eli Lilly, that have refused to continue to offer the 340B prescription drug discounts to contract pharmacies that safety net hospitals, critical access hospital and community health centers rely upon. To his knowledge Novartis has not refused to provide any discounts, however they have been requesting claim's data in order to prevent potential duplicative discounts. Is Novartis willing to give assurances today that they will be a good steward of the 340B program moving forward and will not do what Eli Lilly has done. **Mr. Kendris** said that the intent of Novartis is to be a good steward of the 340B program. As Rep. Grothman mentioned Novartis has asked for data from the hospitals that will help avoid paying multiple duplicate discounts. Novartis supports the program and allowing hospitals to use the discount to provide the patient care that was originally intended by 340B. What they don't support is allowing intermediaries to profit from this. **Rep. Grothman** asked if any of the witnesses have tried to prevent biosimilars from coming to market. **Mr. Trudeau** said no, he is focused on what is best for patients.

Rep. Raskin asked if National Drug Code blocks are fundamentally anti-competitive. **Mr. Kendris** said now. **Rep. Raskin** asked if Novartis tries to encourage consumers to purchase brand name drugs as opposed to generics. **Mr. Kendris** said no because Novartis owns a generic manufacturing company.

Ranking member Comer asked how net prices are calculated. **Mr. Trudeau** said that rebates paid to the intermediary after the list price generate the net price. **Ranking member Comer** asked how patients can be sure they are getting the best price possible for a drug. **Mr. Trudeau** said this underscores the need for more transparency. **Ranking member Comer** asked what Congress can do to make sure that consumers are benefitting from drug discounts. **Mr. Kendris** said that more transparency is needed. It is important to encourage patient access and affordability by giving priority to high value products with low cost sharing. Plans should also have to pass on the rebates they get to consumers at the pharmacy counter. **Ranking member Comer** asked how much money is spent on litigation when compared to the US. **Mr. Kendris** said that he will have to get the information to the Ranking member after the hearing.

Rep. Gomez asked if it is true that Mallinckrodt considers Acthar a cash cow. **Mr. Trudeau** said no. **Rep. Gomez** asked if Mr. Trudeau was trying to mislead the committee by claiming that Acthar is not a 'cash cow'. **Mr. Trudeau** said no.

Rep. Tlaib asked if Novartis' copay and finical assistance program should be considered and investment or a charity. **Mr. Kendris** said that it is designed to help consumers. **Rep. Tlaib** asked if Novartis expected that every dollar put into the enhanced copay program would lead to return on investment. **Mr. Kendris** said that he does not agree with this characterization.

Rep. Porter asked what Amgens total revenue was in 2017. **Mr. Bradway** said $23 billion. **Rep. Porter** asked how much of its own revenue did Amgen invest in research and development

between 2017 and 2019. **Mr. Bradway** said $10 million. **Rep. Porter** asked how much was spent on lobbying in that same time. **Mr. Bradway** said $30 million. **Rep. Porter** asked how much was paid to the top executives over this time. **Mr. Bradway** said $124 million. **Rep. Porter** asked how much was spent on stock buy backs. **Mr. Bradway** said close to $30 billion. **Rep. Porter** asked if Amgen did the research that led to the creation of Enbrel. **Mr. Bradway** said no. But they conducted research to improve it. **Rep. Porter** asked what Mr. Bradway does to earn so much money. **Mr. Bradway** said that he gets compensated based on the success of the company.

Rep. Kelly asked if Acthars list price increased more than rebates provided to intermediaries. **Mr. Trudeau** said no.