RESPONSES OF ABBVIE INC.[1] TO QUESTIONS FOR THE RECORD

MAY 18, 2021 HEARING BEFORE
THE HOUSE COMMITTEE ON OVERSIGHT AND REFORM
UNSUSTAINABLE DRUG PRICES (PART III): TESTIMONY FROM ABBVIE CEO RICHARD GONZALEZ

July **7**, 2021

The Honorable Mark DeSaulnier

In response to a question asked to you by Rep. Cori Bush, you identified "socialized medicine" as a large driver of the difference in drug prices between Europe and the U.S.

Question 1. Does AbbVie make a profit on selling to countries that have centralized government control of drug pricing? What is AbbVie's annual profit or loss from selling products to these countries?

Response:

Yes, AbbVie makes a profit in every market in which it sells products. The profits earned outside the United States, however, are not sufficient to support AbbVie's massive investment in research and development to bring new treatments to patients. Since its inception as an independent company in January 2013, AbbVie has invested approximately $50 billion in research and development. AbbVie's mission is to develop advanced therapies that address some of the world's most complex and serious diseases. That mission—which benefits patients and ultimately the entire healthcare system by reducing the cost-burden associated with ongoing disease—cannot be achieved based on AbbVie's profits from outside the United States.

Question 2. Would AbbVie turn a profit if it sold drugs in the U.S. at the prices it charges in other countries with "socialized medicine?" What would be the company's total annual profit or loss in this scenario?

Response:

Imposing "socialized medicine" prices from other countries on the United States market would devastate the research and development model upon which the United States pharmaceutical industry is built. An April 2021 report from the non-partisan Congressional Budget Office determined that legislative proposals to restrict drug prices would have the effect of reducing the number of new treatments for patients that are developed.[2] AbbVie has invested approximately $50 billion in research and development since 2013, producing cures for diseases like HCV and therapies that are changing and prolonging the lives of patients suffering with cancer, rheumatoid

[1] Please note that these responses were prepared by, and are from, AbbVie Inc.

[2] Congressional Budget Office, *Research And Development In The Pharmaceutical Industry* (April 2021) ("CBO April 2021 Report"), at 12.

arthritis, and other serious diseases. AbbVie would not have been able to develop these life-changing cures and therapies based on the prices imposed by countries outside the United States.

Records show that Humira's high-concentration formulation received approval from U.S. and European regulators in 2015. However, AbbVie waited until 2018 to release Humira's high-concentration formulation in the U.S. In response to my questioning on this matter, you responded that the company had to build up manufacturing capacity.

Question 3. Given that AbbVie brought Humira's high-concentration formulation to market in Europe in 2016, and that the market for Humira in the U.S. and Europe is of a similar product volume, how do you explain AbbVie's decision to wait three years after Food and Drug Administration approval to bring Humira's high-concentration formulation to market in the U.S. while only waiting one year to bring the product to market in Europe? Did AbbVie prioritize European patients over American patients?

Question 4. If the delay in bringing Humira's high-concentration formulation to market in the U.S. was caused by factors outside of AbbVie's control, such as regulatory issues, please demonstrate this, as well as AbbVie's efforts to move the high-concentration formulation to market in the U.S. as fast as possible.

Response to previous two questions:

The primary challenge with launching the new high-concentration/citrate-free formulation of Humira ("Humira Citrate-Free") was ensuring a reliable supply for the millions of patients around the world who depend on Humira. AbbVie's manufacturing facilities and supply and distribution chains were set up to provide the tens of millions of annual doses of Humira's original formulations that patients worldwide required. It was simply not possible to create an entirely duplicative, parallel manufacturing and supply chain to simultaneously also manufacture tens of millions of doses of Humira Citrate-Free to instantaneously offer both formulations to the entire worldwide market at the same time and toggle between those two manufacturing and supply chains as uptake and demand for each formulation ebbed and flowed. Accordingly, a phased launch of Humira Citrate-Free was necessary. Even though Humira Citrate-Free had been approved from a regulatory perspective, addressing the logistical challenges to ensure continuity of supply for patients who depend on Humira for their quality-of-life and to stop their progressive diseases was critical before Humira Citrate-Free could be launched.

It was possible to launch Humira Citrate-Free in Europe earlier because, unlike in the United States, Humira Citrate-Free was considered to be the same as original-formulation Humira from a regulatory perspective. Thus, as a regulatory matter, Humira Citrate-Free simply replaced original-formulation Humira, and patients did not need new prescriptions from their physicians. That allowed AbbVie to reliably plan for and provide a predictable supply of Humira Citrate-Free for Europe.

In the United States, by contrast, the Food and Drug Administration determined that Humira Citrate-Free needed a distinct NDC number and, as a result, Humira patients needed new prescriptions to obtain Humira Citrate-Free. That meant that, unlike in Europe, the uptake of Humira Citrate-Free in the United States was not predictable, and so AbbVie could not reliably plan for the Humira Citrate-Free supply in the United States. This uncertainty delayed AbbVie's ability to launch Humira Citrate-Free in the United States as compared to Europe. AbbVie's manufacturing and supply capabilities ultimately have finite constraints, and AbbVie did not want U.S. Humira patients to be without their preferred formulation of Humira based on AbbVie's inability to accurately gauge the ratio of demand between original-formulation Humira and Humira Citrate-Free. AbbVie began its phased roll-out of Humira Citrate-Free in the United States with pediatric indications, where the market was smaller and the injection-pain issues Humira Citrate-Free was designed to address were most acute. This allowed AbbVie to observe the uptake of Humira Citrate-Free in a limited United States market segment to better inform its overall U.S. demand planning and eventually make Humira Citrate-Free available for all U.S. patients while ensuring an adequate supply of both Humira formulations to satisfy all patient and physician preferences.

In response to my question about whether "product hopping" would be an unfair characterization of AbbVie's marketing strategy for Humira, you disputed this characterization in part by noting that when Humira's high-concentration formulation launched in Europe, the majority of biosimilars had citrate-free formulations, so AbbVie's actions did not inhibit the ability of competitors to develop high-concentration formulation biosimilars. You also noted that AbbVie has licensed all of the patents related to Humira's high-concentration formulation to biosimilar manufacturers through settlement agreements.

Question 5. Given that Humira biosimilars did not enter the European market until 2018, and no high-concentration biosimilars have entered the European market to date, please clarify how biosimilar products that have not yet been brought to market can serve as justification for disputing the characterization of AbbVie's marketing practices for Humira's high-concentration formulation as "product hopping."

Response:

AbbVie's launch of Humira Citrate-Free in the United States was not "product hopping." As the Federal Trade Commission has explained, product hopping occurs when (a) a brand manufacturer makes minor non-therapeutic changes to the brand product, and then (b) on the eve of generic competition with the original version of the brand product, withdraws it so it is no longer available.[3] This means the new generic entrants cannot be automatically substituted for the now

[3] *See* Federal Trade Commission Brief as *Amicus Curiae* in *Mylan Pharmaceuticals, Inc. et al., v. Warner Chilcott Public Ltd Co., et al.*, No. 12-3824 (E.D. Pa.), filed Nov. 21, 2012 ("FTC Brief"), at 8.

non-existent original formulation.[4] And because the new formulation has patent exclusivity, or because of technical or other barriers, no generic competition for it exists. Thus, the brand manufacturer avoids competition because it has "hopped" the market from the original formulation of the product to the new one.[5] Humira Citrate-Free's launch in the United States has none of these attributes of product hopping.

First, the improvement from original-formulation Humira to Humira Citrate-Free was not a non-therapeutic change. The FDA-approved label for original-formulation Humira states that "[t]he most common adverse reaction with HUMIRA was injection site reaction," including "pain." Clinical trial data demonstrates that patients report less pain immediately following injection with Humira Citrate-Free than with original-formulation Humira.[6]

Second, AbbVie did not withdraw original-formulation Humira from the market. It remains available for physicians to prescribe and patients to take. AbbVie has no current plans to discontinue original-formulation Humira in the United States. Withdrawing the original formulation is a necessary and defining element of "product hopping," because that is what forces patients to switch to the new formulation " – not because [they] prefer it, but simply because the original product is no longer . . . available . . . ."[7] Because original-formulation Humira remains on the market, by definition there cannot be product hopping here.

Third, in product hopping, the new formulation of the brand product does not face generic competition.[8] This is another necessary and defining element of product hopping. Without this, there can be no adverse effect on generic manufacturers' ability to compete with the new formulation. Here, however, AbbVie has fully licensed all of its intellectual property for Humira

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[4] FTC Brief at 8–9.

[5] FTC Brief at 8–9.

[6] Nash P, Vanhoof J, Hall S, et al. Randomized crossover comparison of injection site pain with 40 mg/0.4 or 0.8 mL formulations of adalimumab in patients with rheumatoid arthritis. *Rheumatol Ther.* 2016;3(2):257–270.

[7] FTC Brief at 8.

[8] The entire concept of "product hopping," moreover, originated in the small-molecule generic drug context and may be ill-suited to apply to biologic products like Humira because the competitive dynamics of these types of drugs are fundamentally different. As emphasized by the FTC, the harmful consequence of product hopping occurs when a generic drug "cannot be substituted at the pharmacy counter" for the brand product and is based "on the premise that generic products will not be promoted like brand drugs." (FTC Brief at 9.) With biologic drugs, however, a biosimilar is not automatically substitutable for the brand product at the pharmacy counter. Thus, biosimilar manufacturers must necessarily promote their products like brand products. Only a biosimilar product that satisfies the higher standard of being "interchangeable" can be substituted for the innovative biologic in ways comparable for these purposes to a small molecule generic product. To date, no Humira biosimilar has sought, much less obtained, interchangeability status.

Citrate-Free to biosimilar competitors, so there is no patent barrier to biosimilar competition with Humira Citrate-Free. As referenced in Mr. Gonzalez's testimony at the hearing, the fact that multiple biosimilar competitors to Humira have formulated and are launching high-concentration and/or citrate-free biosimilars of Humira proves that there are neither patent nor technical or other barriers to competition with Humira Citrate-Free.

For all these reasons, AbbVie's launch of Humira Citrate-Free in the United States is not product hopping.

Question 6. Are AbbVie's patents the only barrier that biosimilar manufacturers need to overcome in order to bring biosimilars of Humira's high-concentration formulation to market in 2023?

Response:

There are no barriers—patent or otherwise—that biosimilar manufacturers need to overcome in order to bring biosimilars of Humira's high-concentration formulation to market in 2023. AbbVie has fully licensed its intellectual property associated with Humira Citrate-Free to biosimilar manufacturers, so there is no patent barrier. And several biosimilar manufacturers have in fact developed and are launching high-concentration and/or citrate-free formulations of a Humira biosimilar, so there are no technical or other barriers for any biosimilar manufactures who chose to pursue biosimilar versions of Humira Citrate-Free.

The Honorable Jamie Raskin

Question 1. Will AbbVie commit to ending the practice of entering into agreements that contain conditional volume-based rebates? Humira biosimilars are scheduled to enter the market in 2023; however, AbbVie uses conditional volume-based rebates to provide AbbVie's drugs with preferential formulary placement while limiting the access of rival drugs to payors' formularies. For example, AbbVie has deployed this strategy to guarantee Humira the preferred position on drug formularies and to help launch Skyrizi and Rinvoq while successfully limiting the availability of rival drugs. According to public health experts, this rebating practice raises the list prices of prescription drugs and reduces patient choice. This practice could be used in the future to create an additional obstacle for Humira's biosimilars. If you will not commit to ending this rebate practice, please provide an explanation in your response.

Response:

AbbVie does not currently have conditional volume-based rebate agreements for Humira formulary placement as it understands that phrase (meaning a customer's rebate percentage increases incrementally based on incremental additional purchase volume), and it currently has no plans to offer any.

AbbVie does offer a broad menu of rebates (which are not conditional volume-based rebates) to payors and formulary managers. The parameters of these rebate offers are generally driven and dictated by the payors, and they choose among them based on their own preferences. None of AbbVie's current Humira rebate offers provide for exclusive or even narrowly limited access to Humira. Across large national accounts, Humira's rebate agreements typically provide for Humira to be one of approximately 10 preferred competing products in its category. And those agreements provide that an unlimited number of Humira biosimilars may also be included in the same formulary category without affecting the Humira rebate. Thus, AbbVie's Humira rebate offers do not pose the concerns postulated in the question, and AbbVie has no current plans to change that.

The Honorable James Comer

Question 1. Part D patients face significant cost burdens for medications like Humira, what is AbbVie doing to decrease that cost burden and what solutions can be adopted by Congress to relieve this burden?

Response:

Overall, most American patients have access to affordable medicines. Pharmaceutical companies, including AbbVie, provide many forms of assistance through co-pay support or free product to help defray drug costs for those who cannot afford their medicines.

At AbbVie, we believe that any patient who needs our medicines should be able to access them. We have created a broad "safety net" of programs that are designed to ensure this.

For commercially insured patients, we are able to provide co-pay assistance (regardless of income eligibility), with the majority of commercially insured patients paying only $5-$10 per month out-of-pocket. More than 90% of commercial patients are utilizing that assistance.

Since we are prohibited from directly assisting Medicare patients with their out-of-pocket expenses, we support those patients through our Patient Assistance Program (PAP) (called myAbbVie Assist), and donations to charitable co-pay foundations that provide co-pay assistance to Medicare beneficiaries in need regardless of what drug or other treatment they are prescribed. Our generous PAP provides free product to any patient, at no cost to them or the government, based on satisfying income eligibility of 600% of the Federal Poverty Level (FPL) (less than $105,000 for a household of 2) for Immunology. A patient with income exceeding this threshold may still be eligible based on their drug and other medical expenses as a percentage of their income. On average, we provide assistance to almost 90% of all Medicare Part D applicants who apply to our myAbbVie Assist PAP. In 2020 alone, we provided no-cost medicine to approximately 60,000 US Medicare Part D patients through myAbbVie Assist.

Despite these significant efforts to ensure drug accessibility across all patient channels, the single largest patient group that lacks access to affordable medicines are standard Medicare Part D patients, where the program design puts a significant cost burden on them. For these patients, reducing drug prices alone will not alleviate the challenges with access.

In general, Part D is a cost-effective program. Since 2006, the cost per enrollee has grown at 1.8%, which is below inflation, and since 2015 has been flat.

One of the debates we hear is that the government does not negotiate Medicare drug prices directly. But sophisticated Part D plan sponsors do negotiate very aggressively on behalf of the government, and they obtain very steep discounts for the government. For Humira, the average government discount across all channels is about 64%. Medicare Part D actually receives a greater discount on Humira than commercial payors do, even though Part D is only one-sixth the volume of the commercial market. When the free Humira AbbVie provides to Medicare patients at no cost to

them or the government through our myAbbVie Assist PAP, the effective Humira discount in Part D is about 60%.

We want to make sure patients can afford their medicine. But it is critical to recognize that, because of the Part D benefit design, reducing the price of the drug alone will not solve the affordability problem. When it comes to Medicare Part D the cost burden on patients must be significantly reduced, and AbbVie is willing to absorb more of those costs. Already several congressional proposals include capping the amount that seniors pay out of pocket in Part D for their medicines and allowing seniors to smooth those costs over a calendar year. AbbVie supports these congressional ideas and believes we need to do even more. To address government spending in the catastrophic phase of the Part D benefit that is increasing more rapidly than overall spending, the pharmaceutical industry, government, and health care plans should come together to re-apportion cost in the catastrophic phase so that spending will be well controlled.

Question 2. Intellectual property was a key theme during the hearing and to the development of new medicines and therapies. How do intellectual property rights benefit patients and spur the development of new medicines and therapies? Without patent protections, would AbbVie be able to continue to develop life-saving medicines and treatments? If not, why?

Response:

Intellectual property rights are integral to the development of new medicines. Intellectual property protections incentivize pharmaceutical companies to invest in new cures and therapies. AbbVie has invested approximately $50 billion to research and develop life-saving medicines and treatments since 2013. Without intellectually property to protect these critical innovations, we would not be able to continue that investment.

Revenues from today's on-market medicines with patent protections are significantly reinvested to identify and develop tomorrow's next-generation treatments. The non-partisan Congressional Budget Office recognizes that "[p]harmaceutical research is inherently risky and cancelled or failed projects are a normal part of any drug development program."[9] "Some drugs developed in the preclinical phase never enter clinical trials, and of those that do, only about 12 percent reach the market . . . ."[10] The rare successful on-market products enable innovative pharmaceutical companies to recover the cost of those failed efforts and to fund the next round of attempts to innovate new cures. Intellectual property protection is the vehicle that allows this; it is the engine that drives life-saving innovation. Without it, innovative pharmaceutical research and development would necessarily collapse, and fewer treatments and cures would be available to Americans in need.

[9] CBO April 2021 Report, at 13.

[10] CBO April 2021 Report, at 13-14.

Question 3. Humira has received FDA approval to treat many different diseases. How did AbbVie discover it could be used to treat those diseases? What was the investment costs to research Humira and fund clinical trials for Humira as a treatment for these diseases?

Response:

Since the FDA approved Humira for its first indication in Rheumatoid Arthritis in 2002, AbbVie continued to invest in researching and developing new safe, and effective uses for Humira. In total, AbbVie has invested over $16 billion in Humira-specific research, development, and facilities—the majority of that investment coming after Humira received its initial FDA approval. More than 160 clinical trials have resulted in the FDA approving Humira as safe and effective to treat 10 additional indications. For some of these conditions, Humira was the first ever FDA-approved treatment. For example, in 2015, the FDA approved Humira for the treatment of moderate to severe Hidradenitis Suppurativa (HS), a debilitating chronic skin disease characterized by inflamed nodules and abscesses that may form fistulas, leak pus, and cause scarring. Humira remains the only FDA-approved treatment for the disease to this day. Without AbbVie's continued investment in researching additional uses for Humira after its initial approval, HS patients would have no treatment option.

Question 4. How do rebates affect the price of AbbVie medicines and the price paid by patients?

Response:

The drug pricing system in the United States is very complex. There is intense scrutiny of list prices, but it is important to remember that list price is not what is paid by patients, health plans or the government. List prices do not reflect significant rebates paid by manufacturers like AbbVie in all channels of the healthcare system.

We operate in a highly competitive environment where managed care plans and PBMs negotiate aggressively to increase rebates from pharmaceutical companies to obtain formulary positions. The managed care plans and PBMs use rebate pools to defray costs of premiums, which is the basis upon which they compete for enrollees. Rebates are based upon list prices, and so the pressure to generate larger rebates creates pressure to increase list prices. Nevertheless, rebates are generally growing faster than list prices. Since AbbVie was created as an independent company in 2013, U.S. Humira rebate growth of 28.1% has significantly outpaced list price growth of 13.6%.

AbbVie responsibly balances the constant competitive pressure to increase rebates with achieving some limited amount of net fall-through on price to help offset inflation and cost increases such as employee wages as well as increased funding in research and development. Since 2013, AbbVie's overall net fall-through on price is only 0.3%. The average annual increase in AbbVie's research and development spending is ten times greater than the average annual increase in AbbVie's overall net price.

Rebates generally do not impact patient out-of-pocket costs. As noted above, payors use them to lower patient premium costs. More than 90% of commercially insured patients receive co-pay assistance that reduces their out-of-pocket drug costs substantially. The notable exceptions are Medicare Part D patients, where the benefit design imposes patient out-of-pocket costs based on a medicine's list price. This benefit design is not logical, since the government does not pay for medicine in Part D based on its list price; the government receives substantial discounts (in the case of Humira, discounts greater than the commercial channel receives). This is another example of how the Part D benefit design should be improved, with pharmaceutical companies, insurance companies, and the government coming together to help defray additional costs to reduce the out-of-pocket burden on Part D beneficiaries.

Question 5. What is AbbVie's commitment to R&D, the breadth of the pipeline and how does spending for R&D compare to other expenses that AbbVie has?

Response:

Investing in research and development is one of AbbVie's largest expenses. At the Committee's hearing, the extent of AbbVie's commitment to research and development investment was unfortunately misrepresented because a Committee member compared AbbVie's research and development investment for *just a single product* to AbbVie's *company-wide expenses* in other categories to create the misleading impression that AbbVie's research and development spending was comparatively small.

The truth is that, since its inception as an independent company in 2013, AbbVie has invested approximately $50 billion in research and development. In 2020 alone, AbbVie's investment was $7.75 billion. Currently, AbbVie is developing 60 potential new drugs across 91 indications. AbbVie is also conducting 342 studies of its existing drugs to potentially treat new indications.