Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA. 91320
www.amgen.com

TESTIMONY OF KAVE NIKSEFAT
VICE PRESIDENT, U.S. VALUE & ACCESS
AMGEN
BEFORE THE U.S. HOUSE COMMITTEE ON ENERGY AND COMMERCE, SUBCOMMITTEE ON HEALTH
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Full Committee Chairman Pallone and Ranking Member Walden, Health Subcommittee Chairwoman Eshoo and Ranking Member Burgess, and Members of the Subcommittee, thank you for inviting me to participate in today's hearing. I am Kave Niksefat, Vice President and Head of U.S. Value and Access at Amgen.

I commend the Committee and Subcommittee for holding a second hearing on the drug supply chain, given the important role it plays in determining what patients pay for their medicines. And I appreciate the opportunity to provide Amgen's perspective.

Amgen was founded nearly 40 years ago by a handful of biotech entrepreneurs who set up shop in a small office park in Thousand Oaks, California. Our first medicine, Epogen®, was approved by the Food and Drug Administration (FDA) in 1989 and changed the lives of many thousands of dialysis patients suffering from chronic kidney disease. Today, Amgen is still based in Thousand Oaks, but we now employ more than 21,000 staff members, who do business in roughly 100 countries globally. Our portfolio includes 20 medicines that treat many of the world's most devastating and costly illnesses, including cancer, cardiovascular disease, migraine, and osteoporosis. We are committed to the discovery and development of new medicines, having invested $3.7 billion in research and development last year and nearly $19 billion over the last five years. We also operate one of the most reliable biologics manufacturing networks in the world, including facilities in California, Massachusetts, Rhode Island, Puerto Rico and Kentucky and we just broke ground on a new, next generation biomanufacturing plant in Rhode Island.

Tremendous advances in science and technology have put us on the cusp of what we hope will come to be seen as the "biocentury." Just as physics and engineering led to extraordinary advances in the 20th century, we are now at a true inflection point in terms of our understanding of biology and, with it, our ability to take on serious illness, such as Alzheimer's disease, and help people live longer, healthier lives. The promise of the biocentury comes at a critical juncture for our country, as an estimated 10,000 Americans will turn 65 every day for the next 20 years – leading to an inexorable rise in diseases associated with the aging process.

We recognize that patients are having difficulty affording their health care, including their prescription medicines and we want to help this Committee and others advance solutions to lower out-

of-pocket costs for patients. We acknowledge that rising drug costs are a burden to patients especially as co-payments and deductibles on medicines have increased and as high deductible health plans become more prevalent. All of these factors together mean more patients experience increased out-of-pocket costs for prescription medicines and they need our collective help to ensure they can access needed therapies.

We also recognize that the healthcare supply chain is complicated, but that each participant in it plays an important and valuable role in our market-based system which I firmly believe is and continues to be the best healthcare system in the world. Simply put, the biopharmaceutical industry discovers more innovative medicines in the United States (U.S.) than anywhere else in the world and the benefit is that patients in our country get broader and faster access. Competition is driving bigger rebates on medicines every year and last year list prices for brand-name medicines increased less than the overall rate of inflation.[1]

But we can still do better – much better. And that starts by ensuring that all patients benefit directly from the market-based competition and negotiations that exist today when they pick up their drugs from the pharmacy counter.

I would like to thank the Committee for bringing to light the complexity of the U.S. drug supply chain and trying to find bipartisan solutions to improve access to medicines. The truth is that without all of us on this panel and others in the marketplace working toward solutions such as health insurers, employers, drug distributors, hospitals and physicians, we can make little progress for patients. There is too often a singular and overly simplistic focus on the list price of medicines and pharmaceutical companies' role in drug pricing. While Amgen and all innovators seek to set the list price of our medicines appropriately based in part on their value to patients, all parts of the supply chain have a role in ensuring the affordability of medicines[2].

In my testimony today, you will not hear me blame any one actor in the supply chain or call to eliminate pharmacy benefit managers (PBMs). To the contrary, we believe that PBMs play an essential role in the supply chain and as a large employer, Amgen works with a PBM each year to manage our own pharmacy benefit for our employees. What you will hear from me, however, are my impressions of the embedded complexities in the system that exist in portions of the supply chain as well as some solutions Amgen supports for remedying these important issues for patients so they can start to access needed medicines at more affordable prices.

First, I will describe some of the actions Amgen is taking to address the affordability problems that face our patients. We take seriously our duty for pricing products responsibly and have put forward

[1] IQVIA. The Global Use of Medicine in 2019 and Outlook to 2023. January 2019. Available at: https://www.iqvia.com/institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023.

[2] Amgen establishes the list prices of our medicines in the context of an established set of pricing principles. These principles guide that the prices of our medicines account for the economic value that is delivered to patients, providers, and payers, the unmet medical need, the size of the patient population, the investment and risk undertaken, and the need to fund continued scientific innovation.

several solutions to health plans, PBMs and patients that lower both the net and list price of many Amgen medicines.

Second, I will highlight areas of the drug supply chain that fail to drive the more than $150 billion dollars that the biopharmaceutical industry provides in price concessions[3] to the patient in the form of lower out-of-pocket costs at the point of sale.

Third, I will offer policy solutions that Amgen supports to improve access and affordability for our patients.

Part 1: Amgen Actions to be Part of the Solution

Amgen has taken a number of steps to proactively offer solutions to address affordability issues for our patients.

List Price Reduction for Repatha®

Amgen continues to work diligently to address affordability issues for our patients. Last year, Amgen took the unprecedented step of making our innovative therapy Repatha® available at a 60% reduced list price, with the hope of improving affordability for patients, while also supporting the growth of this product in a competitive marketplace. Repatha® is one of Amgen's growing new medicines. It is approved by the FDA to prevent heart attacks and strokes by substantially lowering critically high levels of cholesterol in a wide range of high-risk patients with established cardiovascular disease. In clinical trials, Repatha® reduced the risk of heart attack by 27%, the risk of stroke by 21%, and the risk of coronary revascularization by 22%.[4]

Cardiovascular disease is one of the nation's most significant health challenges, costing the U.S. more than $600 billion each year and expected to exceed $900 billion by 2030. It is estimated that 39 million adults could benefit from managing their cholesterol. Repatha® is part of the solution to reducing the overall cost of healthcare in the U.S.

Amgen estimates that approximately half of all potential Repatha® patients are Medicare beneficiaries. For Medicare patients in particular, the new lower list price should have immediately reduced patient out-of-pocket costs from approximately $280 - $370 per month to $25 - $150 per month.

As I will explain later in my testimony, despite this list price reduction, embedded issues in the supply chain in combination with marketplace competitive dynamics have stymied a rapid move to better affordability for our Medicare patients despite the dramatic reduction.

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[3] See https://www.drugchannels.net/2019/04/the-gross-to-net-bubble-reached-record.html. Gross to net includes rebates, off-invoice discounts, price concessions, as well as manufacturers' payments to drug channel participants such as administration fees, product returns, the 340B Drug Pricing Program, and other items.

[4] Sabatine MS, Giugliano RP, Keech AC, et al, for the FOURIER Steering Committee and Investigators. N Engl J Med. Evolocumab and Clinical Outcomes in Patients with Cardiovascular Disease. 2017; 376:1713-22.

Leveraging 21st Century CURES to Establish a Lower than Expected List Price for Aimovig™

In 2018, we launched Aimovig™, a novel treatment developed specifically for migraine prevention and the first FDA-approved treatment to block the calcitonin gene-related peptide receptor (CGRP-R). For patients with migraine, no new preventive options have been made available for many years and significant unmet need remains for these patients. Prior to approval, Amgen was able to use key new communication pathways provided by the 21st Century CURES Act and subsequent FDA guidance to have economic discussions with payers around this important innovation. This dialogue with payers was helpful in informing our decision on how to price Aimovig™ and was a key factor in us introducing Aimovig™ at a list price that was approximately 20% to 65% below initial expectations.[5] More than 200,000 patients have accessed Aimovig™ since its approval. We would like to thank the committee for their bipartisan work in enacting the 21st Century CURES Act and wanted to illustrate that your legislative actions have made a difference.

Within a few months of Aimovig™'s launch, two competitors entered the migraine market which has driven the net price of our product down. While this demonstrates that market-based competition is working to reduce costs in the system and manufacturers are offering lower net prices, most of today's migraine sufferers are not directly benefiting from negotiated discounts. As I articulate below, Amgen believes that there are policy solutions to ensure patients get access to the lower prices that are negotiated on the product they need and that they see this benefit in the form of lower out-of-pocket costs at the pharmacy.

Developing a Robust Portfolio of Biosimilars as a Means to Further Improve Patient Affordability

Another way that Amgen is paving the way on affordability is through our commitment to bringing U.S. consumers one of the largest portfolios of biosimilars. When Chairwoman Eshoo and Ranking Member Barton reached across the aisle and led development of the Biologics Price Competition and Innovation Act (BPCIA), which created the biosimilars approval pathway, we embraced the opportunity to bring more affordable biologics therapies to U.S. consumers. We recognized that biosimilars would become an important part of broadening patient and physician options for treatments and foresaw that our expertise in developing and manufacturing biologics also would apply to biosimilars. We currently have 10 biosimilars in our portfolio. As we launch our biosimilars over the coming years at the appropriate times, we continue to believe that they will bring meaningful cost savings to the healthcare system for patients, physicians, pharmacists, and payers.

As I will explain later in my testimony, we believe that the current U.S. biosimilar market is healthy and robust and that patients will benefit from fairly-based competition on a level playing field. Therefore, we are not supportive of policy changes that have been proposed which would create an unlevel playing field between innovator medicines and their biosimilar competitors that could drive up costs to patients and the government.

[5] https://www.optum.com/resources/library/new-migraine-drugs.html

A Leader in Value-Based Partnerships

Amgen remains a leader in value-based partnerships with over 120+ value-based partnerships across 35 countries in 6 therapeutic areas and at least 20 value-based partnerships in the U.S. with at least 15 different commercial payors. A value-based partnership is a collaboration that allows partners to experiment with innovative approaches designed to improve the patient experience, quality and efficiency of care, or both. Examples of value-based arrangements that Amgen has sponsored include our Repatha® Outcomes Based Rebate in which drug costs will be refunded if patients experience a heart attack or stroke while on our drug; the Imlygic® Population Cost Cap where Amgen takes risk for any additional doses of a cancer chemotherapy drug beyond a set level; and Enbrel® Effectiveness constructs where Amgen takes risk on the outcomes, and provides higher discounts if patients do not obtain expected outcomes. These value-based arrangements are offered in addition to standard discount contracts and support mutually beneficial opportunities to reduce costs, improve care and enhance patient experiences. Such partnerships reflect the company's belief that managing disease through innovative medicine is key to containing healthcare costs and improving population health.

As I will explain later in my testimony, we believe there is still more that can be done here especially in Medicare, where the opportunities to offer value-based contracts is limited.

Competing Within the Marketplace to Lower Net Prices

In addition to the steps that I just mentioned, the average net price for our medicines has not increased above the rate of inflation since 2017. Further, the net selling price of our medicines declined in 2018 and we expect a mid-single-digit decline in 2019.

Additionally, it is important to highlight that patient out-of-pocket costs have continued to increase year over year even as our discounts in competitive marketplaces continue to increase and our net prices continue to decrease.

As I will explain later in my testimony, we are supportive of policies that would pass rebates on to patients at the point of sale or that would move from back end rebates to up front discounts so patients can directly benefit from these rebates.

Part 2: Removing Barriers to Patients Realizing the Savings Generated by Our Market Based System

Much of the public debate about the cost of medicines has focused on list prices. Pharmaceutical companies set the Wholesale Acquisition Cost (known as "WAC") which is often referred to as the "list price." While the WAC or list price for each of Amgen's products is in part anchored to a medicine's value driven price – the value a medicine is likely to deliver to patients, to payers, and to society – the price is frequently established against a backdrop of a competitive environment. List price is the price we charge to wholesalers and distributors who purchase our medicines, but it does not account for the rebates and discounts we negotiate with the complex web of wholesalers, distributors, hospitals, providers, pharmacies, PBMs, health plans and other entities. Increasingly, list price has also become the basis of patient out-of-pocket costs with the growth in high deductible health plans and coinsurance constructs. The problem is not that the market-based negotiations are not effective at generating savings, it is that the savings never make their way to patients in the form of reduced out-of-

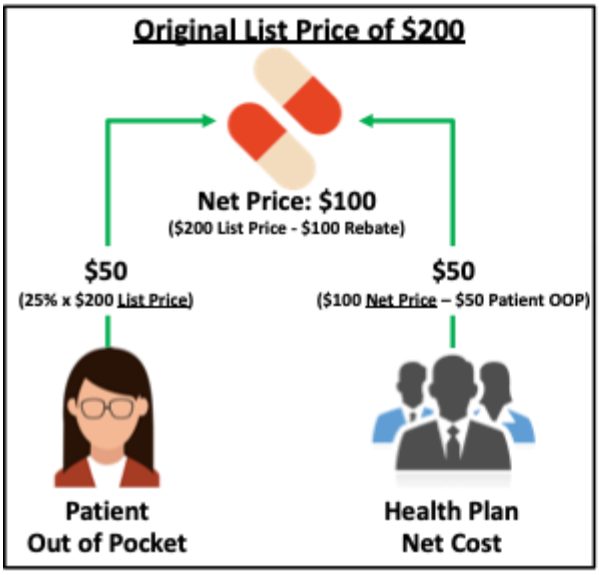
pocket cost at the pharmacy counter since patient out of pocket cost continues to be tied to list price rather than net price.

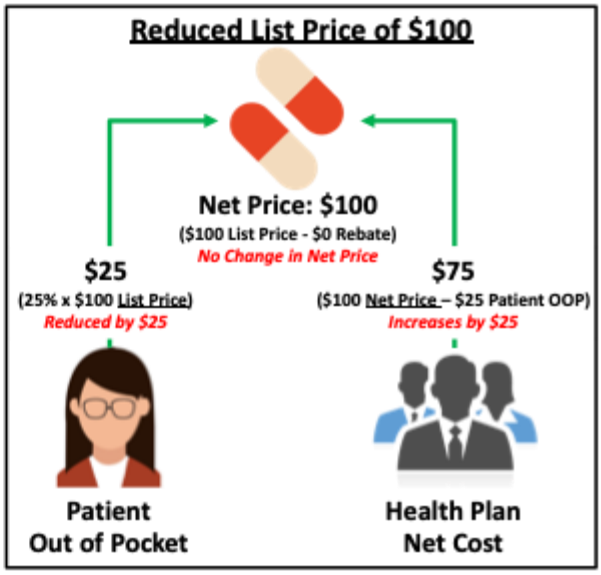
PBMs play an important role by handling the pharmacy benefit for health insurers and employer groups and facilitate access to drugs for millions of consumers who have medicines prescribed by their physicians. But due to marketplace consolidations which have occurred in recent years, three PBMs now control access to medications for over 80% of the market. PBMs exert great influence over terms for how much pharmacies are paid for dispensing the drug and use volume-buying leverage to negotiate deep discounts off the price of the drug. When competitor products are available, PBMs have the leverage to determine whether drugs are placed on formulary and which drug products are used most frequently. So, in competitive therapeutic classes if rebate concessions are not granted, PBMs often exclude a medicine from the formularies.

The pressure to increase rebates and price concessions in exchange for coverage under the health plan has grown immensely in recent years as prospective, multi-year, ever-increasing rebate guarantees have grown exponentially in the commercial market and competitive dynamics in the Medicare Part D marketplace have often driven plans to seek ever larger rebate pools. As a result, the current system sees drug manufacturers competing against each other not only on the lowest net price of a drug, but also the largest total rebate. This dual focus creates pressure on net prices and list prices, but in opposite directions: in a competitive environment, net prices are especially pressured to decrease but list prices are pressured to increase in order to provide greater rebates. The growing gap between list prices and net prices from price concessions (also known as the "gross-to-net bubble") has expanded to more than $150 billion in 2018.[6]

At the same time, the manner in which PBMs determine a health plan's "net cost" creates barriers to reducing list prices. PBMs calculate plan "net cost" by taking the net price of the drug (list price minus rebate) and reducing it further by the patient's out of pocket cost. So, the more the patient pays out of pocket, the lower the plan's "net cost". Since patient out of pocket cost is increasingly based on list price, higher list price drugs result in higher patient out of pocket costs and, therefore, lower plan "net cost". This means that PBMs can view list price reductions as <u>increasing</u> plan "net cost" for the sole reason that they <u>decrease</u> patient out of pocket cost. See below for an illustrated example in which a drug reduces its list price of $200 to its net price of $100.

[6] See https://www.drugchannels.net/2019/04/the-gross-to-net-bubble-reached-record.html. Gross to net includes rebates, off-invoice discounts, price concessions, as well as manufacturers' payments to drug channel participants such as administration fees, product returns, the 340B Drug Pricing Program, and other items.





As you can see in the illustration, without changing the net price to the healthcare system, the lower list price drug is viewed as increasing plan "net cost" because the patient pays less out of pocket at the pharmacy counter. In a better functioning system, list price reductions should be encouraged not discouraged. We believe the best way to get to this better functioning system is to pass along negotiated discounts to patients at the pharmacy counter, just like other negotiated discounts in the healthcare system are passed along to the patient at the provider's office. This system would incentivize list price reductions and reduce the pressure to lift list prices to generate ever increasing rebate demands.

We believe our experience with Repatha® is a good example to highlight these embedded complexities in the system.[7] As mentioned above, in October of 2018 we announced that Amgen made Repatha® available at a reduced list price of $450 per month, a 60% reduction from the medicine's original list price, with the hope of improving affordability for patients. Amgen made Repatha® available at a reduced list price by introducing new National Drug Codes (NDCs). The new lower list price option for Repatha® is identical to the original list price option of Repatha®. Amgen is preparing to discontinue the original list price option of Repatha® by the beginning of 2020. We chose this approach in consultation with multiple stakeholders in the supply chain, including health plans and PBMs, in an attempt to minimize the disruption to the drug supply chain during a transition period while PBMs adjust their agreements with their downstream employer and health plan clients. Absent such a transition period, we were concerned that commercial health plans and PBMs would immediately shut off access to Repatha® in favor of the other proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor option on the marketplace that offered a higher overall rebate based on a higher list price.

While we have seen some adoption of the lower list price option for Repatha®, thus far the uptake has been slower than you might imagine. This, despite the fact that Amgen has offered all PBMs and health plans contracts that ensure the net price after rebates of the lower list price option of Repatha® is always equal to or less than the contracted net price paid for the original list price option of

[7] The complexities here are exacerbated by the presence of a competitor who has admitted infringing our patents.

Repatha®. Unfortunately, even with the favorable net pricing of low list price Repatha®, some PBMs have determined that the lower list price option of Repatha® has a higher "net cost" because the patient's out of pocket cost is reduced with the lower list price.

In Medicare Part D, approximately 60% of patients have access to the lower list price option of Repatha® but the vast majority of Part D plans continue to classify Repatha® as a Specialty medication despite the fact that the list price of $450 per month is below the $670 per month Specialty threshold established by the Centers for Medicare and Medicaid Services (CMS). In fact, only 6% of Medicare beneficiaries can access Repatha® on a non-specialty, fixed co-pay of less than $50 per month commonly associated with similarly priced drugs. We understood that PBMs and plans found it challenging to change Repatha's tier when it did not make sense for them to do the same with respect to our competitor's higher priced product.

Likewise, outside of Medicare, only about half of commercially insured beneficiaries have access to Amgen's lower list price option of Repatha® and it remains excluded from coverage on a number of PBM formularies. While Amgen has offered equivalent or lower net prices on the low list price option of Repatha®, Amgen pays a lower nominal rebate to achieve that same net price. This lower rebate makes the lower list price option for Repatha® patients less attractive to PBMs, especially in a marketplace where the competition can offer a higher overall rebate when achieving the same net price. Why? One word: Rebates.

It is important that policymakers understand the nuances of the market structure and problems inherent in the complex system in order to develop appropriate remedies to help fix the rising out-of-pocket costs for prescription drugs. PBMs often argue that these factors are used to keep health insurance premiums low, however it has become harder and harder to understand what proportion of rebate dollars help keep premiums affordable versus other uses. This essentially results in sick patients who take innovative medicines subsidizing the healthy patients, which is counter to the purpose of insurance.

Recently, there have been policy proposals and market shifts that would incentivize the market to move away from back end rebates and more toward up front discounts. We support ideas like these which will ensure that patients will benefit from the discounts secured by Medicare Part D plans. Actions like these will help to better align plan incentives with the interests of patients and help address rising out-of-pocket costs for prescription drugs for Medicare beneficiaries. We also support recent announcements of steps being taken in the commercial marketplace to allow patients to benefit from the net price at the pharmacy counter. Examples of such steps include UnitedHealthcare's decision to pass through rebates at the pharmacy counter in their fully insured plans in 2019; Optum Rx's similar announcement that new PBM commercial clients that sign contracts after January 1st, 2020 will be required to pass through rebates at the pharmacy counter; and Anthem's announcement that they will pass through rebates at the pharmacy counter in their Fully Insured plans in 2020. But until more plans make these kinds of changes, the majority of Americans still will not have access to lower priced medicine and the rebate dollar will continue to be the largest economic driver in the marketplace.

Part 3: Policy Solutions to Improve Affordability for Patients

We are supportive of the following policy solutions to improve affordability for patients:

- **Require Rebates to Be Passed on to Patients at the Pharmacy Counter:** We are supportive of policy changes that would ensure savings from rebates flow directly to patients. One approach would require that a portion of the rebate be passed through to patients at the pharmacy counter. We also support the Administration's proposal to move from backend rebates to up front discounts in order to lower out-of-pocket costs for patients. Even in the face of net price declines as we experienced last year, patients are not seeing the benefits of these net price declines. At the state level in 2019, five states considered requiring health plans to pass through at least a majority of rebates to patients; and last year, Louisiana became the first state requiring health plans to disclose to its insurance commissioner the percentage of rebates made available to enrollees at the pharmacy counter. The fact remains that at both the State and Federal level, we are supportive of lawmakers' efforts to look for ways to ensure patients can access these rebate dollars to improve affordability for patients. We strongly support these efforts and hope to continue to engage with the Committee on this topic going forward.

  As stated above, there have been recent announcements that health plans have started to provide offerings that give patients access to the rebates at the pharmacy counter. These are limited positive first steps in the commercial market and unfortunately do not extend to Part D. While we are encouraged to see these types of announcements that the PBM business model is beginning to evolve, the rebate dollar will continue to be the single largest economic driver in the drug supply chain. At Amgen, we continue to try to lead on these issues. For example, as a large employer, our benefits structure with a large PBM is set up such that if our employees are faced with paying the list price of a covered prescription at the pharmacy counter, the discounts are passed through to them at the point of sale.

  In terms of specific policy solutions to address the issue with Part D patients having difficulty accessing Repatha® at more affordable cost sharing levels, we think CMS can take immediate actions to help address this issue. Specifically, CMS can issue guidance highlighting that, in instances where manufacturers lower list price for medicines that puts them below the specialty tier threshold of $670, plans should move the lower list price drug from the specialty tier to a tier with better (or no worse) cost sharing (e.g., preferred brand). We hope to work with the Committee on this specific policy solution since it is a way to quickly reduce out of pocket costs for patients taking Repatha®.

- **Embrace a Robust and Competitive Level Playing Field Between Innovators and Biosimilar Manufacturers:** When the BPCIA was enacted, creating the biosimilars approval pathway, we embraced the opportunity to extend our mission to serve patients and leverage our biotechnology expertise by deciding to invest in manufacturing high-quality biosimilars. We recognized that biosimilars would become an important part of broadening patient and physician options for biologic treatments and have committed to be a part of a biosimilars market that will ensure innovation, quality, and reliable supply of biosimilars and originator biologics, as well as bring meaningful cost savings to the healthcare system for patients,

physicians, pharmacists, and payers. However, for this market to have continued success and long-term viability depends on a level playing field for competition and scientifically accurate information that establishes the confidence of patients, physicians, pharmacists, and payers – all of which are essential to achieving meaningful cost savings and multiple public health benefits. With this in mind, Congress should not adopt policies that provide for preferential reimbursement of a biosimilar over innovator medicines – especially those that add costs to patients and the government. As a manufacturer of both innovator and biosimilar medicines, we do not believe biosimilars need special reimbursement advantages to successfully compete given that this new marketplace is already succeeding at driving savings to consumers.

There have been some concerns raised that the biosimilar market is somehow "not working" or that we, in the U.S., are lagging behind Europe in this area. I would like to take this opportunity to correct these misperceptions based on our real time experiences from the U.S. marketplace. Amgen has faced biosimilar market competition in the U.S. since 2015, and now faces competition from multiple biosimilars for three of our medicines. For example, biosimilars that compete against our originator product Neupogen® have achieved majority market share and meaningful cost reductions (e.g., Zarxio® has a 43 percent market share and the majority of market share among short acting granulocyte colony-stimulating factors (G-CSFs) in the U.S.) and represents the clearest example of how biosimilar competition is working. With respect to comparisons to Europe, the U.S. is not behind. The European Union (EU) biosimilar pathway was established in 2005. During the first eight years of the EU pathway, five biosimilars were approved. The U.S. biosimilar pathway was implemented in 2010. During the first nine years of the U.S. pathway, FDA has approved 18 biosimilars, with seven currently on the market. As of January 2019, there were 70 biosimilar candidates enrolled in FDA's biosimilar product development program. This demonstrates the level of interest and commitment by manufacturers in the growth and development of the U.S. biosimilars market.

Biosimilars have an important place in the evolving U.S. market, and the competition promoted by biosimilars will result in cost savings that create budgetary space for new innovations that will also be valued in the healthcare system. Robust and fairly-based biosimilar competition on a level playing field is the best way to achieve meaningful cost savings for the healthcare system, including patients, physicians, pharmacists, and payers, in a way that builds market stability that can be realized over the long term.

- **Address Regulatory Impediments to Value-Based Contracts:** Amgen has strong interest in entering into additional value-based contracting arrangements however regulatory barriers are preventing our ability to drive more creative agreements. For example, if we enter into a value-based contract which results in a large payment because a patient did not achieve the expected clinical outcome, it could trigger Medicaid best price implications for our medicine in all 50 states. Similarly, we would like to see safe harbors created that would give the market confidence that these types of arrangements do not run afoul of the anti-kickback statute. Therefore, we are supportive of regulatory or legislative approaches that would exempt value-based arrangements from Medicaid "best price" while at the same time creating a new anti-

kickback statute 'safe harbor.' This could be done in manner that requires such arrangements to entail at least a minimal amount of risk assumed by both parties to the agreement to qualify for such exemptions. These changes would meaningfully improve the ability of manufacturers to enter into more creative value-based agreements with payers which in turn could yield savings and better deliver downstream quality of care.

- **Create a Maximum Out-of-Pocket Cap in Medicare Part D:** As benefit designs have evolved since passage of the Medicare prescription drug benefit in 2003, more and more patients are encountering affordability challenges in the Part D program. For example, patients on biologics are often put on a 'specialty tier' where cost sharing can range between 25% and 33% of the list price of a drug. While the catastrophic phase of the current benefit reduces beneficiary cost-sharing to 5%, that amount can still be a significant burden for beneficiaries, particularly as beneficiary liability rarely is reflective of the rebates and discounts provided to Part D sponsors. One study found that in 2015, one million Medicare beneficiaries who were not receiving low-income subsidies reached the catastrophic phase and had average out-of-pocket spending of $1,215 per person above the catastrophic threshold.[8] Given that many seniors struggle with the affordability of their medicines in Part D at all phases of the benefit – deductible phase, initial coverage phase, donut hole, and catastrophic — Amgen is supportive of capping on an annual basis the level of spending a patient has in Medicare Part D.

- **Requiring 340B Hospitals to Pass Discounts onto Patients:** Consistent with what we have stated previously, we are interested in improving affordability in both the retail market and hospital market. 340B hospitals often purchase medicines at a heavily discounted price. 340B hospitals, however, are not required to make low-income patients aware of the discounts they receive and are under no obligation to pass along 340B savings to uninsured or low-income patients. Hospitals can charge uninsured patients the full list price for 340B discounted medicines. Moreover, hospitals often mark up the cost of our medicines purchased through the 340B program by hundreds of a percent. We are keenly aware of significant price mark-ups applied to drugs purchased through 340B. Last year one employee that works on our oncology team was diagnosed with cancer. This person received his/her cancer care at a premier research hospital which is also a participating 340B hospital. The hospital charged the employee multiple times the list price for the Amgen cancer product although the product was purchased by the hospital for less than half the list price. Because of this type of dynamic, where hospitals are marking up the price of our medicines at high levels, Amgen is supportive of policy changes that would require 340B hospitals to pass discounts onto a 340B patient. We would support the requirement that hospitals have a sliding fee scale, similar to grantees, that requires hospitals to share the 340B discounts with low-income patients.

[8] Juliette Cubanski et. al., No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Costs Without a Hard Cap on Spending, Kaiser Family Foundation (Nov. 7, 2017*), available at* https://www.kff.org/medicare/issue-brief/no-limit-medicare-part-d-enrollees-exposed-to-high-out-of-pocket-drug-costs-without-a-hard-cap-on-spending/.

Conclusion

In closing, we are encouraged by forums like this and appreciate the opportunity to participate. As I hope my testimony has made clear, there is no doubt that the rebate dollar will continue to be the single largest economic driver in the drug supply chain.

We know more needs to be done to improve patient access and affordability. And so, I pledge Amgen's continued commitment to working with the Committee, Subcommittee, Congress and the Administration to advance market-based reforms that will promote fair competition and improve access to new therapies without stifling innovation and crippling one of the true crown jewels of the U.S. economy.

This is not something that a single company – or even an entire industry – can make happen on its own. And, just like our work in research and development, we know that some of the efforts we undertake may not yield the results we hope for.

But, as the examples of our own medicines demonstrate, we can lower health care costs and improve population health and productivity if we create the conditions needed to drive more innovation and greater access in the health care system.

The patients in our country deserve better. We must work together to bring about needed change for them and for the future of our health care system.

Thank you.