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**TESTIMONY OF ROBERT A. BRADWAY
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AMGEN INC.
BEFORE THE U.S. HOUSE COMMITTEE ON OVERSIGHT AND REFORM
October 1, 2020**

Full Committee Chairwoman Maloney, Ranking Member Comer and Members of the Committee, I am Robert A. Bradway, Chairman and Chief Executive Officer of Amgen Inc. I appreciate the opportunity to provide written testimony about how best to ensure that innovative, life-changing medicines from Amgen and others are accessible and affordable to the many patients who need them.

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.

I commend the Committee for holding this hearing to better understand how this complex drug pricing system works in the U.S. marketplace. We have been cooperating with the Committee's request for pricing information and I appreciate the opportunity to provide Amgen's perspective.

Amgen was founded 40 years ago by biotech entrepreneurs who set up shop in a small office park in Thousand Oaks, California. Today, Amgen is still based in Thousand Oaks, but we now employ approximately 23,000 people, including nearly 14,000 in the U.S. 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 are continuing to invest in the U.S. by building a new, eco-friendly manufacturing plant in Rhode Island next to our existing facility there.

Our first medicine, Epogen[®], was approved by the U.S. Food and Drug Administration in 1989 and has been prescribed to approximately 2.8 million patients on dialysis.ⁱ Our portfolio now includes 23 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 and to this end, we invested \$4 billion in research and development (R&D) just last year and nearly \$19 billion over the last five years. Today, more than 33,000 patients globally are enrolled in over 150 clinical trials for new Amgen medicines.ⁱⁱ We are also engaged in the fight to understand, treat, and prevent COVID-19, including taking the following steps:

- Entering into a manufacturing collaboration with Eli Lilly for antibody therapies for the prevention and/or treatment of COVID-19;
- Investigating use of Otezla[®] as a potential immuno-modulatory treatment in adult patients with COVID-19 through several clinical studies;
- Researching what might prove to be the second generation of neutralizing antibody therapies based on characteristics of antibodies produced by patients who had COVID-19 but who did not suffer symptoms;
- Studying the genetics and epidemiology of the disease to better understand how the virus spreads and mutates; and
- Partnering with the National Institutes of Health (NIH) through the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) – a public/private collaboration to accelerate COVID-19 treatments and vaccines.

Additionally, Amgen has invested over \$2 billion in recent years to build an industry-leading biosimilars business – with a portfolio of ten biosimilars, including four that are FDA-approved. Backed by Amgen's four decades of biologics expertise, our high-quality biosimilars can potentially offer more affordable, life-altering treatment options that contribute to the sustainability of our healthcare system and allow for greater investment in new medicines for patients.ⁱⁱⁱ

Tremendous advances in science and technology have put us on the cusp of what we believe 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 cancer and cardiovascular 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.^{iv}

Today, the biopharmaceutical industry discovers more innovative medicines in the U.S. than anywhere else in the world and our market-based system ensures that Americans get broader and faster access to these medicines than patients in other countries. Prescription medicines play a crucial role in improving health outcomes and reduce overall health care costs. Better use of medicines, such as improved adherence to needed treatments, offers the opportunity for better results for patients and an estimated \$213 billion per year in health care savings.^v

Despite these potential savings, much of the public debate about the cost of medicines has unhelpfully 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 competitive backdrop. List price is the price we charge to wholesalers and distributors who purchase our medicines, but it does not reflect the true price of the medicine after the rebates and discounts we negotiate with the complex web of wholesalers, distributors, hospitals, providers, pharmacies, pharmacy benefit managers (PBMs), health plans and other entities in the supply chain. In the current health care system, competition is driving ever-larger rebates on medicines, with net prices for brand-name medicines in the U.S. increasing less than the overall rate of inflation in 2018.^{vi}

So why are we seeing that too many patients are increasingly having difficulty affording their prescription medicines? One reason is that unlike any other category of healthcare, list price serves as a primary basis of determining patient out-of-pocket costs for prescription medicines. As a result, the negotiated savings of the market-based healthcare system do not reach patients at the pharmacy counter, especially as co-payments and deductibles on medicines have increased and as high-deductible health plans become more prevalent. 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 costs.

We want to continue working with Congress to advance solutions to lower out-of-pocket costs for patients. But there is too often a singular and overly simplistic focus on the list price of medicines and pharmaceutical companies’ role in drug pricing. The truth is that without others in the healthcare system – such as insurance companies, PBMs, employers, drug distributors, hospitals, and physicians – working together with pharmaceutical companies toward solutions, we will make little progress for patients.

In this testimony, I will first describe some of the actions Amgen is taking to address the affordability challenges that face our patients. We take seriously our duty to price products responsibly and have put forward several solutions to health plans, PBMs and patients that lower the net price of many Amgen medicines.

Second, I will share some perspective on Enbrel® and Sensipar® -- Amgen medicines that are of particular interest to the Committee.

Third, I will review some of the policy solutions that Amgen supports to improve access and affordability for our patients.

Part 1: Amgen Actions to Address Patient Affordability Challenges

In the U.S., people know intuitively that the healthcare system is cumbersome and the upward curve of cost is not sustainable. At Amgen, we are sensitive to this reality and have taken a number of steps to proactively offer solutions to address affordability issues for our patients. Since 2018, the average net price for Amgen medicines has declined, and we expect a continued mid-single digit percentage decline in the net price across our U.S. portfolio of products in 2020 due to rebates and

discounts negotiated with payers, providers and others in the drug distribution chain to ensure patients continue to have access to our medicines. The average list price increase across Amgen's entire U.S. portfolio of products is in line with inflation and key pricing indices. And to repeat, our net prices have declined.

Because of the way the U.S. healthcare system is organized, we recognize that many uninsured and vulnerable patients need extra help affording their medicines. For that reason, we established the Amgen Safety Net Foundation to provide access to our medicines at no cost to qualifying patients in the U.S. (including Puerto Rico) who have a financial need and are uninsured or have an insurance plan that excludes the prescribed Amgen medicine. Since 2008, the Amgen Safety Net Foundation has provided \$7 billion in free medicines to assist these U.S. patients. In addition, Amgen offers generous copay assistance to reduce out-of-pocket costs for commercially insured individuals regardless of income.

Beyond lowering our net prices and providing assistance to qualifying patients, Amgen has taken a number of concrete and innovative steps in recent years to ensure the affordability of our medicines in order to ensure patients ultimately receive the benefit as reflected in their out of pocket costs. I would like to highlight two Amgen medicines and other examples that illustrate our commitment to addressing affordability for our patients.

List Price Reduction for Repatha®

Repatha®, a PCSK9 inhibitor, is an Amgen medicine proven to reduce heart attacks and stroke in patients with cardiovascular disease and persistently high cholesterol levels. Barriers to Repatha®, put in place by insurance companies and PBMs, were preventing clinically appropriate patients from getting the drug. As a result, nearly 75% of Medicare patients prescribed a PCSK9 were not able to fill their prescriptions. And this was after prescribing doctors' staff spent countless hours filling out lengthy forms and fighting to gain access to Repatha®, a medicine for which many patients have no alternative therapy to mitigate their risk.

In 2018, Amgen took the unprecedented step of making Repatha® available at a 60% reduced list price to help lower patients' out-of-pocket costs. We estimate that more than half of all potential Repatha® patients are Medicare beneficiaries. For Medicare patients in particular, the lower list price should have immediately reduced patient out-of-pocket costs from approximately \$280 - \$370 per month on a specialty cost sharing tier to \$25 - \$50 per month on a preferred brand cost sharing tier. However, after our list price reduction for Repatha®, it took the Part D plans more than a year to pass these savings on to Medicare patients so that they could access Repatha®.

For this medicine, we saw a particularly vexing problem and we acted to address it. This is indicative of a market in need of reform and Amgen supports policy changes that would ensure that savings from rebates flow directly to patients. We are encouraged by the Administration's recent proposal to help reform this broken rebate system and we welcome additional reforms that put patients first and preserve incentives for companies like Amgen to innovate on their behalf.

Leveraging 21st Century CURES to Establish a Lower than Expected List Price for Aimovig[®]

In 2018, after many years of research and development, 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 had been available for many years and significant unmet need remains for these patients. Migraine is ranked among the top 10 causes of years-lived-with-disability worldwide.^{vii} The economic impact is profound, with ~\$20 billion in direct and indirect costs attributable to migraine in the U.S. alone.^{viii}

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 was a key factor in our decision to introduce Aimovig[®] at a list price that was approximately 20% to 65% below initial market expectations.^{ix} More than 440,000 patients worldwide have been prescribed Aimovig[®] since its approval, with over 1 million prescriptions filled.^x

Within a few months of Aimovig[®]'s launch, two competitors entered the migraine market, which has driven the net price of our product down further. 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 at the pharmacy counter. As I will 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 counter.

Developing a Robust Portfolio of Biosimilars

Although Amgen is known primarily as a biologics innovator, when Congress enacted the Biologics Price Competition and Innovation Act (BPCIA), which created the biosimilars approval pathway, we recognized that biosimilars would become an important part of broadening patient and physician options. We realized that our expertise in developing and manufacturing biologics also would apply to biosimilars and consequently committed billions to build an industry-leading biosimilars business. We launched our first two biosimilars in the U.S. last year to compete with two of the top-selling cancer medicines in the country. We priced both biosimilars at a 15% discount to the originator products, creating the opportunity for immediate and significant savings for patients. And we have recently launched our third biosimilar in the U.S.

As competition has grown, lower prices have followed. Medicare and commercial payers are seeing prices decline for both originator and biosimilar medicines in marketplaces where biosimilar competition has begun.

For example, as an originator product manufacturer, we've witnessed the impact of biosimilar competition on several originator biologics. Take the oncology supportive care market: filgrastim biosimilars have experienced strong adoption, and our share, as the innovator of this biologic, has dropped by roughly 70 percent.^{xi} As the oldest biosimilar class in the U.S., this progress bodes well for newer products.

The biosimilar marketplace is now flourishing in the U.S. and functioning as we hope free markets would. The remarkable 143 percent increase in launched biosimilars in the past year reinforces that perspective. Every company finds itself winning and losing some market share, hallmarks of a competitive marketplace.

It's clear that competition is robust, biosimilar market share is increasing, prices are coming down, and substantial savings are being generated. According to an IQVIA report, projected cost savings in the next 5 to 10 years of approximately \$150 billion are expected from biosimilar competition in the U.S.^{xii} In 2020, we can say with confidence that biosimilars can help deliver a brighter future for our healthcare system.

We plan to launch several additional biosimilars in the coming years and continue to believe that they will bring meaningful cost savings to patients and to the healthcare system.

A Leader in Value-Based Partnerships and Value-Based Contracts

We're helping to evolve the complex health ecosystem by actively engaging with and leveraging the strengths of governments, manufacturers, academics, payers, and practitioners to enable health systems to co-create novel solutions to transform reactive care to more proactive, predictive and preventive care.

Amgen is engaged in over 160+ value-based partnerships, spanning all of our therapeutic areas of focus.^{xiii} By engaging in value-based partnerships with entities across the healthcare system, Amgen hopes to develop mutually beneficial opportunities to reduce costs, improve care and enhance patient experiences. This reflects the company's belief that managing disease through innovative medicine is key to containing healthcare costs and improving population health.

In addition to our value-based partnerships, we are working with payers, PBMs, health plans, and other stakeholders to find new, innovative ways to work together to improve patient access to medicines while providing budget predictability that will help patients access the medicines they need. These include value-based contracts like that with Harvard Pilgrim Health Care in which we provide a rebate for the cost of Repatha[®] if a patient experiences a heart attack or stroke while on the drug. Separately, Oklahoma Health Care Authority and Amgen entered into a public-private contract for Enbrel[®] in 2020. This is the first value-based contract Amgen has in the Medicaid channel stipulating additional supplemental rebates paid contingent on real-world outcomes.

We believe outcomes-based contracts provide a valuable option to payers interested in evolving from volume-based contracts to those focused on the value medicines can bring to patients. Amgen has more than 120+ value-based contracts globally; 30 which are in the U.S.^{xiv}

Part 2: Enbrel[®] and Sensipar[®] – Addressing Patient Needs and Providing Economic Value

ENBREL[®]

Enbrel[®] is an Amgen medicine that treats several autoimmune disorders that can have a devastating impact on patients, including those suffering from moderate-to-severe rheumatoid arthritis

(RA) and moderate-to-severe plaque psoriasis. Patients with these conditions have overactive immune systems that can cause severe inflammation. This inflammation is what causes severe joint damage, swelling, pain, and fatigue in patients with rheumatoid arthritis, and itchy and often painful raised patches of dead skin cells or scales in patients with plaque psoriasis. Enbrel® helps reduce joint pain and stiffness in patients with moderate to severe rheumatoid arthritis and juvenile idiopathic arthritis. In patients with psoriatic arthritis, Enbrel® helps reduce joint pain and stiffness, and improves skin symptoms. It also helps stop further joint damage, improves physical function and daily activities in patients with moderate to severe rheumatoid arthritis and psoriatic arthritis. For patients with moderate to severe plaque psoriasis, Enbrel® has been shown to help achieve clearer skin. The evidence base for Enbrel® has evolved dramatically over the years with multiple new indications and, importantly, provides demonstrated disease modification in addition to relief of signs and symptoms of disease.

Physicians who treat patients with autoimmune disorders like moderate to severe rheumatoid arthritis remind us that their waiting rooms used to be cluttered with canes, crutches, and wheelchairs – even stretchers. That’s how debilitating untreated moderate-to-severe rheumatoid arthritis can be. That is no longer the case due to the introduction of innovative medicines like Enbrel®.

Along the way, Enbrel® has become one of the most studied biologic medicines.^{xv} Enbrel®’s strong evidence base, costing hundreds of millions of dollars, includes large clinical registries and more than 100 trials globally involving approximately 115,000 patients.^{xvi} In the U.S., over 29 million prescriptions have been dispensed across all indications since Enbrel® was approved.^{xvii} Amgen also invested more than \$1.6 billion in building and improving our manufacturing facilities so that we can produce sufficient quantities of products including Enbrel® to meet patient demand.

The list pricing of Enbrel®, often viewed as the “sticker price” of a medicine, has increased over the years as we have invested capital studying it for additional indications and introduced new, more patient-friendly formulations and administration methods. As an example, we recently introduced an easy-to-use, self-injection device specifically designed to meet the needs of moderate-to-severe rheumatoid arthritis patients and psoriatic arthritis patients.

But the primary reason the list price of Enbrel® has increased as much as it has is because the market for innovative products is structured in a way to benefit intermediaries and not in a way to get lower prices to patients. Enbrel® is in a highly competitive marketplace that includes approximately 20 other medications that are competing for formulary position with PBMs to enable patient access, including the largest pharmaceutical product in the world Humira®. In these highly competitive marketplaces, companies are forced to simultaneously compete both on lowest net price (“all in” price to the PBM) and highest total rebate. In a competitive market, we often have to pay higher and higher rebates to remain on formulary—even as list prices rise and the net price to the PBM often decreases. Because of the way PBMs structure these contracts, increases in list prices generally have limited impact on net prices but significantly increase total rebates paid to the PBMs. In light of this environment, Amgen has increased list prices over the years in response to competitor list price increases to remain available as a choice on PBM formularies. If we had not done so, we believe the PBMs would have simply removed Enbrel® from their formularies in favor of a competitor who provided a higher rebate to

the PBM. Since Enbrel® and its competitor products do not provide the same response in all patients, they are not simply interchangeable. If taken off formulary, many Enbrel® patients would not have access to the medicine that they and their doctor had determined worked best for them.

Unfortunately, the current rebate system in the U.S.—in which companies like Amgen pay billions of dollars in rebates to insurers and PBMs based on the list price of our medicines—creates a situation in which not getting kicked off formulary often requires counterintuitive pricing behavior. For example, PBMs can receive lower net prices but consumers instead see prices go up and see little relief at the pharmacy counter since these savings from the PBMs are often not passed on.

We do not like a system where we lower the net price of a drug yet our patients pay more, and we are advocating to change it. But it's the system that exists today and we must operate within it to stay competitive and ensure that patients have access to Enbrel®.

We strive to ensure that every patient who needs our medicine can get access to it. We understand that the dynamics that exist in today's supply chain, such as high coinsurance and deductible levels, can make needed therapies expensive for patients. This is why we sponsor industry leading patient support programs that provide medicine for free to those who cannot afford their medicine. As indicated above, we have provided \$7 billion in medicines since 2008 under these programs.

SENSIPAR®

Sensipar® is an advanced therapy for secondary hyperparathyroidism in patients with chronic kidney disease on dialysis.

Before Sensipar® was approved in 2004, many patients were undertreated with older vitamin D therapies, eventually leaving many in need of having parathyroidectomy, a surgical procedure associated with distinct risks leading to potentially more complex disease management and high costs. Since the introduction of Sensipar®, the proportion of patients achieving treatment guidelines has steadily improved.

The list price of Sensipar® increased over time, reflecting Amgen's approximately \$500M investment in ongoing research and development in support of this product and other medicines to support critically ill end-stage renal disease patients.^{xviii} In 2018, the last patent covering the active ingredient in Sensipar® expired, which has ultimately led to generic competition and, as publicly available pricing information shows, lower prices. In fact, generics now have an estimated 95% volume market share of the cinacalcet market.^{xix}

PATENTS

There have been increasing questions about the role of intellectual property in ensuring sustainable access to medicines. We believe that intellectual property is essential to innovators, like Amgen, that are bringing forward new medicines for patients with serious illness. Medical innovation now enables us to live longer and better lives than ever before, bringing benefits to patients, healthcare systems, and society.

This innovation is the product of large-scale, long-term, and high-risk investments since as few as one in ten drugs that even gets to the point of entering a clinical trial are successful and the average

cost of developing such a drug is estimated to be \$2.6 billion. Patents help inventors obtain return on their investments in research and development, which encourages future research and investment that makes further drug development sustainable. These incentives also allow for incremental innovation while not extending exclusivity in perpetuity.

There have also been concerns about patents being used for lifecycle management of products that are going off patent. The lifecycle management process at Amgen evaluates how we can continue to add value for patients by making improvements to our products or the patient experience. This includes developing new formulations, new uses, new processes and new devices. Amgen works on these improvements “at risk,” that is without knowing if the investment in the hoped-for results will pay off by benefitting patients. So in the cases in which Amgen does provide benefits to patients, we believe those improvements deserve patent protection.

In summary, biopharmaceutical research is an incremental process driven by the science, and ongoing innovation after product approval can lead to meaningful medical advances and improving the patient experience. We believe that protecting intellectual property is critical to fully develop a medicine’s therapeutic potential for patients.

Part 3: Policy Solutions to Improve Affordability for Patients

We are focused on developing market driven policy solutions that improve affordability for our patients. For example, the benefit design of Medicare Part D creates affordability challenges in the initial coverage phase, coverage gap and the catastrophic levels of the benefit. Patients need help with challenges presented by an outdated benefit design in Part D so we look forward to working with Congress and the Administration on policy solutions designed to lower patient out of pocket costs at the pharmacy counter. More specifically, 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 efforts to consider the Administration’s recent Executive Order to reform how rebates are handled in the marketplace by moving from backend rebates to up front discounts in order to lower out-of-pocket costs for patients at the pharmacy counter. Without these changes, even in the face of net price declines, patients will not get the benefits of these 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. 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 Administration and Congress on this topic going forward.

Rebates 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.

- **Embrace a Robust and Competitive Level Playing Field Between Innovators and Biosimilar Manufacturers:** When the BPCIA was enacted, creating the biosimilars approval pathway, we decided to invest in manufacturing high-quality, reliably supplied biosimilars. We believe the continued success and long-term viability of this market 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 actually result in the cost of the biosimilar being greater to patients and the government than the cost of the innovator product.

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. Furthermore, we believe such distortions would risk creating structural supply problems such as those experienced in the generic market.

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 experiences from the U.S. marketplace.

Our two currently marketed oncology biosimilars, which have a list price that is 15 percent lower than their originator biologic list price and a Medicare average sales price 20 percent lower than the originator biologics, are gaining adoption quickly, securing over 30 percent of their respective share in the U.S. in the last year. This is generating significant cost savings for both Medicare patients and commercial payers.

Amgen has faced biosimilar market competition in the U.S. since 2015, and now faces competition from multiple biosimilars for three of our brand medicines. For example, biosimilars that compete against our originator product Neupogen® have achieved majority market share and meaningful cost reductions (e.g., short-acting granulocyte colony stimulating factor (GCSF) competitors have achieved more than 70 percent share in five years. Long-acting GCSF biosimilars have achieved 20 percent share in 12 months).^{xx} By any metric, these examples reflect that the marketplace with biosimilar competition is an emerging success.

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 ten years of the U.S. pathway, the FDA has approved 28 biosimilars, with 18 currently on the U.S. market.^{xxi} 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.

Conclusion

In closing, 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.

There are so many more diseases to confront and patients to help. If we all stay focused on what's best for patients, I'm confident we will end up in a better place.

ⁱ Amgen data on file, 2020.

ⁱⁱ Amgen 2019 Annual Report & Shareholder Letter <https://wwwext.amgen.com/media/featured-news/2020/03/2019-letter-to-shareholders/>

ⁱⁱⁱ IQVIA Report (2018). The Impact of Biosimilar Competition in Europe.

^{iv} U.S. Census 2019. <https://www.census.gov/library/stories/2019/12/by-2030-all-baby-boomers-will-be-age-65-or-older.html>

^v IMS Institute for Healthcare Informatics. Avoidable Costs in U.S. Healthcare: The \$200 billion opportunity from using medicines more responsibly. June 2013.

^{vi} IQVIA. The Global Use of Medicine in 2019 and Outlook to 2023. January 2019.

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- ^{xiii} Amgen data on file.
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