abbvie

June 8, 2018

United States Senator Elizabeth Warren
Hart Senate Office Building
Suite SH-317
Washington, DC 20510

United States Senator Tina Smith
Hart Senate Office Building
Suite SH-309
Washington, DC 20510

Dear Senator Warren and Senator Smith:

Thank you for your letter. AbbVie is a U.S.-headquartered biopharmaceutical company with 29,000 people around the globe focused on developing advanced therapies that address some of the world's most complex and serious diseases. Our commitment to research is reflected in our annual investment of almost $5 billion in R&D, covering over 50 active clinical development programs and over 300 partnerships with biopharmaceutical companies large and small, as well as academia, nonprofits and government organizations. Today there are approximately 400 million people living with conditions that AbbVie's pipeline aims to treat, with 82 million potential patients living in the United States.

We share concerns regarding patient access to affordable prescription drugs in both commercial and government health plans. With respect to pricing of medicines, AbbVie sets the Wholesale Acquisition Cost (WAC, or "list price"), which is then subject to substantial rebates and discounts resulting from government programs and/or negotiated with health insurance companies and pharmacy benefit managers (PBMs). Insurers/PBMs in the commercial marketplace determine the out-of-pocket cost incurred by patients, while government programs (including Medicare and Medicaid) set the prices or formulas for determining out-of-pocket costs. In both cases, out-of-pocket costs most often do not reflect those rebates and discounts. Within this system, AbbVie strives to maximize patient access to our medications through co-pay assistance programs and the AbbVie Patient Assistance Foundation, which provides AbbVie medicines at no cost to people experiencing financial difficulties.

AbbVie is reviewing the administration's Blueprint and related Request for Information (RFI) and, as appropriate, will engage in the process to share ideas about how patients can access innovative medicines. We view the Blueprint/RFI as an opportunity to address many of the complicated incentives at play in the current system and to reduce out-of-pocket costs for American patients.

We appreciate your interest in our company and the need to ensure patient access to important medicines today and in the future.

Sincerely,

Greg Miley
Vice President, Government Affairs
AbbVie

AbbVie
1 North Waukegan Road
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Robert A. Bradway
Chairman and
Chief Executive Officer

AMGEN

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June 8, 2018

Dear Senator Warren and Senator Smith,

I am writing in response to your letter dated May 30, 2018 regarding the recent announcements by the Trump Administration on drug prices. As you know, Amgen is a U.S. based company that employs approximately 20,000 employees worldwide with over 500 employees based in Massachusetts who are focused on research and development. Our company is first and foremost focused on patient health and addressing unmet medical needs. We are accordingly intent upon advancing the understanding of human biology to improve people's lives dramatically. We share your concerns that affordability can serve as a barrier to patient access and consequently support policies that seek to align pricing to value to reduce costs.

We believe our pricing is consistent with the value delivered to patients, providers and society, and we continue to invest heavily in research and development of new medicines and treatments for grievous diseases. We have long recognized the healthcare delivery and payment landscape is changing and therefore have been forward-looking in developing value-based agreements with payers, providers and other healthcare organizations. By engaging in value-based programs with entities across the healthcare system, Amgen hopes to develop mutually beneficial opportunities to reduce costs, improve care and enhance patient experiences. This reflects Amgen's belief that managing disease through innovative medicine is key to containing healthcare costs and improving population health.

We are actively reviewing the President's Blueprint and Request for Information to Lower Drug Prices and Reduce Out-of-Pocket Costs and are engaged with many stakeholders on these complex and important issues. Our focus is on encouraging market-based, patient-centric solutions that improve coverage and access to help make medicines more affordable to patients. With regard to potential policy changes, we typically attempt to determine their impact upon our company and our patients, but those analyses are maintained as company confidential commercial information.

Amgen stands ready to continue to work with Congress and the Administration to foster medical advancements and promote patient access to vital treatments.

Sincerely,

Robert A. Bradway

gsk do more feel better live longer

June 7, 2018

The Honorable Elizabeth Warren
317 Hart Senate Office Building
Washington, DC 20510

The Honorable Tina Smith
309 Hart Senate Office Building
Washington, DC 20510

Re: Prescription Drug Pricing Letter

Dear Senators,

Thank you for your recent letter regarding the pricing of prescription drugs. GlaxoSmithKline (GSK) is a science-led global health care company that researches and develops a broad range of innovative medicines and vaccines to help patients do more, feel better, and live longer. We recognize that patients are increasingly concerned with issues of access and affordability. GSK is dedicated to working with policymakers to advance solutions that further enhance the private marketplace, lower costs for patients and promote continued medical innovation – and it starts with greater collaboration among stakeholders.

GSK is committed to ensuring that innovation and affordability can coexist. When establishing our prices in the US, GSK strives for a fair and appropriate balance that rewards innovation while affording appropriate access for patients. GSK's goal is to ensure that we are working in the interest of both our patients and shareholders, and the prices of our medicines reflect this approach. Significantly, we focus not just on pricing trends, but on improving patient's health outcomes and meeting unmet health needs. The key is to provide differentiated, needed medicines and price them according to the value they bring to patients, while being sensitive to the market and societal expectations.

We discipline ourselves to ensure that our medical development and commercial teams work together to answer the question 'does this new medicine have a compelling value proposition from the patient, physician, and payer perspectives'. In setting the price of our medicines, we systematically apply a value-based framework that balances access and affordability and reflects the treatment choices and clinical, humanistic and economic benefit of our innovations.

We look forward to reviewing more information surrounding the various drug pricing proposals from Congress and the Administration and working with policymakers to advance meaningful solutions that address cost challenges across the healthcare system.

Sincerely,

William Schuyler
Vice President, Government Relations

Johnson & Johnson
WORLDWIDE GOVERNMENT AFFAIRS & POLICY

DONALD BOHN
Vice President, Global Government Affairs

1350 I STREET, NW
Washington, DC 20005
Telephone: (202) 589-1000

June 8, 2018

The Honorable Elizabeth Warren
United States Senate
317 Hart Senate Building
Washington, D.C. 20510

Dear Senator Warren,

Thank you for your letter. We appreciate the opportunity to outline our commitment to transparency and our responsible approach to pricing for our medicines.

At Johnson & Johnson, we believe good health is the foundation of vibrant lives, thriving communities and forward progress. Today, as the world's largest and most broadly-based health care company, we are committed to using our reach and size for good. We strive to improve access and affordability, create healthier communities and put a healthy mind, body and environment within reach of everyone, everywhere. We are blending our heart, science and ingenuity to profoundly change the trajectory of health for humanity.

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we understand the need for greater transparency around healthcare costs. That's why we provide information about how we price our medicines and invest our resources in an annual Janssen U.S. Transparency Report. As we highlight in our second annual report released earlier this year, in 2017 the net price of our medicines in the U.S. decreased while we increased our investment in discovering and developing transformational medicines for patients facing some of the world's most challenging diseases.

Some of the key disclosures that demonstrate our commitment to responsible business practices include:

- **Our Investments**: We are passionate about our work to deliver transformational medicines that can change the trajectory of health for humanity. We focus our research and development (R&D) investments on serious unmet medical need where we can make an enduring, meaningful impact. **We invest significantly in R&D—a total of $7.9 billion in 2017, which is 88 percent more than what we spent on selling and marketing.**

- **Value**: Our Janssen Value Assessment Principles help us define and measure the value of our medicines to patients and society. In addition, we generate clinical information about how our medicines affect people in their everyday lives so we can better understand the value our medicines bring to patients and the health care system. Value assessments contribute to important conversations about health system costs and the respective value of health care interventions, including medicines.

- **Pricing & Patient Access**: We maintain a responsible approach to pricing our medicines. And we negotiate and partner with private and public payers and health care systems to support availability of our products. As in past years, we limited our annual aggregate list price increase to single-digit percentages. And last year, **we provided discounts and rebates to payers and providers that outweighed increase in list price, resulting in negative average aggregate net price**.

- **Resources for Patients**: Patients should have access to affordable medicines. We aim to help patients obtain appropriate access to medicines in a variety of ways. Through our Janssen CarePath and JANSSEN CONNECT® programs, we provide options to help patients start on, and stay on, the Janssen medicine prescribed by their health care provider. We also support charitable organizations and foundations that help patients get the medicines they need. While we recognize these programs are not a long-term solution for all patients, they are one way we strive to meet the needs of the patients we serve and the health care professionals who care for them.

Please visit http://janssen.com/2017ustransparencyreport to view more information.

In addition to the report, we can confirm that we have not taken list price action since May 11, 2018.

We are committed to ensuring all Americans have access to the benefits of innovative medicines. As such, we are currently evaluating the proposals in the "HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" to understand how they might affect access for patients today and innovation for patients tomorrow. Given that this is the beginning of a lengthy process, it's difficult to estimate the impact to the business at this time.

We are willing to explore additional options that would give patients meaningful and relevant information related to pricing in consumer-facing materials. It's important to remember that patient out-of-pocket costs can vary significantly based on an individual's health coverage. We are also supportive of exploring a broad range of policy solutions that would reduce out-of-pocket costs of medicines for patients.

As we move forward, we will continue to work with others who share our commitment to access and transparency to develop a more results-based health care system that delivers what we all want: greater access to care, at manageable cost, and most importantly, better health for all.

Thank you again for the opportunity to provide this information.

Sincerely,

Donald Bohn

Kenneth C. Frazier
Chairman, President &
Chief Executive Officer

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Kenilworth NJ 07033
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F 908 823 3644

June 8, 2018

MERCK

The Honorable Senator Elizabeth Warren
The Honorable Senator Tina Smith
United States Senate
Washington, DC 20510

Dear Senators:

Thank you for your letter. As a company, we are committed to ensuring our products are accessible and affordable for patients. We acknowledge the health care system faces a number of challenges, and we are committed to working with the Administration and Congress to develop policies that will ensure patients continue to have access to affordable, life-saving medicines. As part of this commitment, we are currently in the process of carefully reviewing and analyzing the President's Blueprint and associated Request for Information.

We are proud to be the first major pharmaceutical company to issue a report regarding our pricing practices in the United States. We previously detailed the findings from our annual transparency report in a letter to Senator Smith, dated April 11, 2018. A copy of that letter is enclosed.

Our 2017 report shows that our average discount rate across our U.S. portfolio after rebates and discounts was 45 percent. Further, the report shows that in 2017 the average annual net price across our portfolio declined by 1.9 percent. These data points for 2017, and the years before, demonstrate that Merck continues to be responsible in our approach to access and affordability.

We share your goals of improving America's health care system and we look forward to working with you to develop innovative solutions.

Thank you again for your letter.

Very truly yours,

Enclosures

MERCK & CO., INC.
Kenilworth, N.J., USA

Pricing Action Transparency Report 2017

We have a long history of making our medicines and vaccines accessible and affordable through responsible pricing practices and industry-leading patient access programs. To help people better understand our pricing practices, in 2017 we began disclosing information about our price actions in the United States. The table below shows that our average annual net price increases (after taking sales deductions such as rebates, discounts and returns into account) across our portfolio have been in the low to mid-single digits from 2010-2016. In 2017, the average annual net price across our portfolio declined by 1.9 percent, reflecting specific in-year dynamics, including the impact of loss of patent protection for three major medicines. Additionally, our weighted average annual discount rate has been steadily increasing over time, reflecting the competitive market for branded medicines and the impact of the Affordable Care Act. In 2017, our gross US sales were reduced by 45.1% as a result of rebates, discounts and returns. This information will be updated annually on our Corporate Responsibility website.

US Product Portfolio[1] % Change vs. Prior Year[2]	2010	2011	2012	2013	2014	2015	2016	2017
List Price Change (WAC)[3]	7.4	9.5	9.2	9.6	10.5	9.8	9.6	6.6
Net Price[4] Change	3.4	5.1	6.2	5.5	3.7	5.5	5.5	(1.9)

US Product Portfolio	2010	2011	2012	2013	2014	2015	2016	2017
Avg. Discount[5] (%)	27.3	28.9	29.9	32.1	37.0	38.2	40.9	45.1

[1] US Product Portfolio includes human health pharmaceutical and vaccine products marketed by the company. The product sales utilized in the analysis represent ~97% of the total US Product Portfolio in 2010, increasing each year to approach 99.8% of coverage in 2017.
[2] Annual percent change vs. prior year was calculated at a product level and weighted across the company's US Product Portfolio.
[3] Represents the year-over-year change in the average list price or wholesale acquisition cost (WAC).
[4] Represents the year-over-year change in average net price, which is WAC less rebates, discounts and returns.
[5] Weighted average annual discount is calculated by dividing annual rebates, discounts and returns by annual gross sales.

The amount of rebates, discounts and returns is estimated by the company and methodologies used may differ from methodologies used by other companies. These data are not audited and should be read in conjunction with the company's filings with the Securities and Exchange Commission.

Kenneth C. Frazier
Chairman, President &
Chief Executive Officer

Merck
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Kenilworth NJ 07033
T 908 740 1550
F 908 823 3644

April 11, 2018

The Honorable Senator Tina Smith
United States Senate
309 Hart Senate Office Building
Washington, DC 20510-5641

Dear Senator Smith:

Thank you for your recent letter. As a company, Merck is dedicated to bringing improved health and well-being to people around the globe. As part of this commitment, we share your concerns about ensuring that critical medicines are accessible to the patients who need them.

Last year, we were proud to be the first major pharmaceutical company to issue a multi-year report about our pricing practices in the United States. We believe this commitment to transparency will help policymakers, patients, and the public understand how we approach pricing and the importance of rebates and discounts.

In February, Merck released our second annual Pricing Transparency Report. The 2017 report shows that our average discount rate across our U.S. portfolio after rebates and discounts was 45 percent. Further, the report shows that in 2017 the average annual net price across our portfolio declined by 1.9 percent. These data points for 2017, and the years before, demonstrate that Merck continues to be responsible in our approach to access and affordability.

Also in 2017, Merck introduced our first biosimilar in the U.S. at a list price of 35 percent below the list price of its reference product. We support the role of generic drug manufacturers in providing low-cost products once intellectual property rights have expired, and we advocate for policy changes to speed access to generic drugs and increase generic competition. We are deeply committed to ensuring that our medicines are affordable and accessible.

As a company, we will never relent in our pursuit to invent new medicines that help patients suffering from serious unmet medical needs. We continue to focus our research on conditions that represent some of today's most significant health challenges – like

cancer, cardio-metabolic disease, antibiotic-resistant infections, and Alzheimer's disease, and we are on the front lines in the fight against emerging global pandemics, such as Ebola. In pursuit of discovery, Merck invested over $10 billion in research and development in 2017 and has invested more than $57 billion since 2010.

Specifically, regarding the recent tax reform legislation, our company announced on February 2nd that due to tax reform Merck:

- Would invest approximately $12 billion over 5 years in capital projects including approximately $8 billion here in the United States
- Made a contribution to the Merck Foundation in the fourth quarter of 2017
- Will award all eligible non-executive employees with a long-term incentive award of Restricted Stock Units in the second quarter of 2018

We acknowledge the health care system faces numerous challenges. Health care spending continues to grow as a percentage of the nation's Gross Domestic Product. In addition, the out of pocket costs paid by consumers for health care services are projected to continue to grow through 2025. We look forward to working with you to address these challenges and ensure we are able to continue to provide life-saving medicines to the patients who need them.

Thank you again for your letter.

Sincerely,

/HF

NOVARTIS

Thomas N. Kendris
President,
Novartis Corporation

Novartis Corporation
One Health Plaza, 200/732
East Hanover, NJ 07936
Tel: 862-778-3802

June 8, 2018

Senator Elizabeth Warren
317 Hart Senate Office Building
Washington, DC 20510

Senator Tina Smith
309 Hart Senate Office Building
Washington, DC 20510

RE: Your inquiry of May 30, 2018

Dear Senators Warren and Smith,

Novartis Services, Inc. is submitting this letter on behalf of Novartis Pharmaceuticals Corporation ("NPC"), Sandoz Inc. ("Sandoz"), and Alcon Laboratories, Inc. ("Alcon"). We refer to NPC, Sandoz, and Alcon collectively herein as "Novartis."

NPC researches, develops, manufactures, and markets innovative medicines aimed at improving patients' lives. NPC offers a broad range of medicines for cancer, cardiovascular disease, inflammatory disease, infectious disease, neurological disease, eye disease, organ transplantation, respiratory disease, and skin conditions.

Sandoz is a leader in generic pharmaceuticals and biosimilars, providing access to a broad portfolio of high-quality, affordable prescription drugs. Sandoz launched the first biosimilar approved under the new Biologics Price Competition and Innovation Act pathway in the United States.

Alcon is a leader in the research, development, manufacturing, and marketing of eye care products, including surgical devices and vision care products.

Novartis' mission is to discover new ways to improve and extend people's lives. We use science-based innovation to address some of society's most challenging health care issues.

NOVARTIS

We discover and develop breakthrough treatments and find new ways to deliver them to as many people as possible.

We appreciate your inquiry and share your concerns about the challenges of ensuring patient access to the medicines prescribed by their physician and their total out of pocket costs, especially for specialty products. Please see below our responses to your specific questions.

- Did you make any immediate reductions in any of your company's drug prices following the President's announcement on May 11, 2018? If so, please describe these price reductions.
    - *No, there have been no WAC price reductions across our pharmaceutical portfolio since the President's announcement on May 11, 2018. However, with continual changes in customer contracts and discounts across our business, our net prices have likely continued to drop since May 11, 2018. As noted in our attached US Price Transparency report, our aggregate gross prices increased by 6.2% and 5.4% in 2016 and 2017, respectively, but our net prices decreased by 2.0% and 2.1% in those same years. We paid total rebates and discounts of 47.7% and 49.5% in 2016 and 2017.*

    - *Additionally, with our recent product launches of Cosentyx®, Entresto®, Aimovig™, and Kymriah®, our pricing was reviewed by the Institute for Clinical Effectiveness Research (ICER) and generally deemed in the cost effective range when used as indicated and for appropriate patients.*[i]

- Have you increased any of your company's drug prices between May 11, 2018, and the present? If so, for which drugs? What was the extent of these price increases, and why did you increase prices?
    - *While we do have some planned price increases later this year, there have been no WAC price increases across our pharmaceutical portfolio since May 11, 2018*

- Secretary Azar indicated that as part of the proposal, the Administration would begin "working to examine how to require drug companies to post their list prices in direct- to-consumer advertising." But he also noted that "[d]rug

companies don't have to wait on us," asking them to immediately begin "put[ting] your list price in your ads." To the extent your company uses direct-to-consumer advertising, will you commit to including list price information?

- *We agree with Secretary Azar that price information, including patient out of pocket costs, should be transparent to patients, including in DTC advertising. Given the challenges of the fragmented US healthcare system, however, the definition of "price" is unclear as it depends on where the product is within the distribution system. The gross price charged by a pharmaceutical manufacturer for its product has no direct correlation to the net cost paid by the healthcare system nor what the patient pays for their prescription "out of pocket" at point of sale.*

- *The difference between gross and net price is largely the result of many negotiations that take place between the pharmaceutical company and other stakeholders in the supply chain – such as government payers, insurers, pharmacy benefit managers, wholesalers, retailers and hospitals – that typically result in discounts and rebates to the gross price.*
- *These discounts and rebates are not necessarily passed on to the patient, meaning net prices may differ from the final costs absorbed by payers and patients.*
- *Thus, including in a brief DTC advertisement any accurate financial information that will predict what a patient will actually pay would be quite difficult. Nevertheless, we are open to working with the Administration to explore ways of posting accurate price information in DTC advertising.*

- President Trump promised to "take on one of the biggest obstacles to affordable medicine: the tangled web of special interests," and criticized drug manufacturers "making an absolute fortune at the expense of American consumers" and their spending "nearly $280 million on lobbyists." He promised to "pu[t] American patients first." But Politico reported that "The White House official who will shape a large part of the Administration's drug price plan worked on many of the same issues as an industry lobbyist," and that this official, Joe Grogan, "has sweeping authority over drug pricing, entitlement programs, and other aspects of federal health policy at the Office of Management and Budget." Have officials from or representing your company lobbied, met with, or otherwise communicated with Mr. Grogan or any other White House or Administration official about the President's drug plan? If so, please provide a description of these actions, including a list of the individuals

involved and the issues discussed.

- *No, we have not had any communications with Mr. Grogan or other Administration officials on the President's drug plan released on May 11 or the HHS RFI published in the Federal Register on May 16. Novartis intends to provide comments to the many questions raised in the RFI through the formal government comment process.*

- Following the release of the President's drug plan, many drug manufacturers' stock prices increased, an apparent indication that the plan would have "benign" impact on drug manufacturers. But Secretary Azar said that "stock analysts ... totally missed the boat here," implying that the drug pricing plan would have an adverse impact on drug company revenues and profits. Do you agree with Secretary Azar, or do you believe that your current stock prices reflect the potential impact of the President's plan?
  - *There are many factors that affect the price of a company stock. It is difficult to identify how the release of the President's plan has specifically impacted the price.*

- Have you conducted any internal analysis of the President's proposal on your company's estimated total revenues and profits either for this year or for any of the next four years? If so, please provide this information.
  - *Our Novartis team has just begun the review and assessment process of the HHS RFI, which contains more than 135 questions. We have not conducted an internal analysis of the President's proposed drug plan given the lack of details in the plan about specific implementation framework and timing for many of the plan components. Novartis intends to provide comments to the many questions raised in the RFI through the formal government comment process.*

- What other actions will your company be taking to reduce drug prices for seniors and for other patients?

  Our approach to pharmaceutical pricing in the US:
  - *We believe in value-based pricing for our products and advocate for a healthcare system that supports this approach and ensures that patients have access to the medicines they need*

- *We will manage price adjustments responsibly for our brand medicines as well as our biosimilars and generic products*
- *We will strive to ensure patient affordability for our products*
- *Novartis is committed to taking a leading role in helping the healthcare system transform the current "pay-for-service" approach to one that ties payment to outcomes delivered.*
- *We believe medicines and healthcare services (e.g., diagnostic procedures, medical consultations and drug prescriptions) should be priced and paid for based on the outcomes they generate, namely:*
  - *Clinical outcomes, such as shrinking a tumor, reducing blood sugar levels or prolonging survival*
  - *Patient outcomes, such as improved quality of life*
  - *Health system outcomes, such as reducing the rate or duration of hospitalizations or the intensity of care*
  - *Societal outcomes, such as allowing patients or caregivers to return to work*
- *In the pharmaceutical sector, Novartis is pioneering the shift to value-based pricing. We aim to focus our pricing approach on the value our medicines deliver with respect to clinical, patient, health system and societal outcomes. We also apply US-specific cost- effectiveness modeling to inform US prices and embed patient- and payer-relevant endpoints in our clinical trial programs.*
- *When measured on the outcomes they deliver, innovative medicines can play a critical role in helping reduce waste in the system.*
  - *For example, when used appropriately, Entresto could save more than 28 000 lives per year in the US alone, and over a two-year period it could save more than $27 million from reduced heart failure hospitalizations for every 100 000 patients treated. In the largest study ever conducted in heart failure patients with reduced ejection fraction (PARADIGM HF), Entresto was shown to reduce cardiovascular deaths and heart failure hospitalizations by 20%, and all-cause mortality by 16%.*
  - *Additionally, Kymriah is the first FDA-approved CAR-T therapy and has demonstrated early, deep and durable remissions in children and young adults with relapsed or refractory B-cell ALL. It offers the potential for significant sustained remissions for children and young*

NOVARTIS

adults at high risk of death who have few remaining treatment options. More specifically, Kymriah provides 83% overall remission rate at 3 months. With median duration of response not yet reached in our clinical trials.

Novartis appreciates your consideration of these comments. We would be happy to discuss them at greater length; if you have any questions, please do not hesitate to contact me at thomas.kendris@novartis.com.

Sincerely,

Thomas N. Kendris

President, Novartis Corporation,

US Country Head

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[i] *ICER reviewed the following Novartis products indicated for:*

Cosentyx® (secukinumab), an IL-17A treatment indicated for moderate to severe plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis.

Entresto® (sacubitril/valsartan) is indicated to reduce the risk of cardiovascular death and hospitalization in patients with certain types of long-lasting (chronic) heart failure.

Aimovig™ (erenumab-aooe) is indicated for the preventive treatment of migraine in adults.

Kymriah® (tisagenlecleucel) is made from your own white blood cells and is a prescription cancer treatment used in patients up to 25 years old who have acute lymphoblastic leukemia (ALL) that is either relapsing or refractory.

Robert W. Jones
Senior Vice President
U.S. Government Relations

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Tel 202 624-7518 Robert.Jones@pfizer.com

The Honorable Elizabeth Warren
United States Senate
Washington, DC 20510

The Honorable Tina Smith
United States Senate
Washington, DC 20510

June 8, 2018

Dear Senators Warren and Smith,

Thank you for your recent letter to Pfizer Chairman and CEO Ian Read regarding medicine pricing and the Administration's recent proposals to address affordability and access to medicines. I am responding on behalf of Pfizer.

Pfizer is committed to pricing our medicines in a way that reflects the benefit they bring to patients and society; ensuring patients have reasonable access and enabling us to continue to invest in new medicines. We may consider several factors when setting a price for a product. This may include the product's likely impact on patients and their disease, the role of generic developments, affordability, investments to maintain quality, safety, reliability; and our ability to continue to innovate to bring new, life-changing medicines and vaccines to patients. We also consult physicians, payers and patient groups, as appropriate.

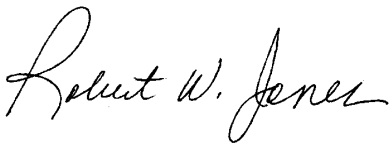
Given our concerns with affordability, we are considering the Administration's *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* very carefully. We are in the process of reviewing and assessing the wide-ranging proposals and questions included in the Request for Information (RFI) that accompanied the *Blueprint.* The RFI poses more than a hundred questions, and touches upon numerous federal and state programs which are significant to our business, and addresses critical aspects of our commercial operations. We would be pleased to share with you a copy of our response after we have submitted it to the Department of Health and Human Services.

We are particularly encouraged to see that the Blueprint furthers momentum around rebate pass-through, which we believe has the potential to meaningfully improve affordability at the pharmacy counter for the many patients for whom pharmaceutical manufacturers provide substantial rebates. More needs to be done to ensure beneficiaries directly benefit from significant price negotiations taking place in the Part D market. Seniors share the costs; they should also share the savings.

While health plans might use some portion of these rebates to lower premiums, that practice dilutes the benefits of the rebates and diverts them from the patients who need them most. Analysis by the actuarial firm Milliman finds that passing through 50% of manufacturer rebates and 100% of pharmacy discounts would reduce beneficiaries' average total out-of-pocket spending, and could save beneficiaries between $4B and $28B over 10 years. Milliman also estimates that over time, beneficiary premiums could decline once anticipated changes in plan-manufacturer contracting strategies occur. (Milliman, 2018)

Again, thank you for your letter. We look forward to working with Congress, the Administration, and other key stakeholders to help ensure that all Americans have access to affordable medicines.

Sincerely,



Robert W. Jones
Senior Vice President, US Government Relations

Genentech
A Member of the Roche Group

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Phone: (202) 296-7272
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08 June 2018

The Honorable Elizabeth Warren
United States Senate
317 Hart Senate Office Building
Washington, DC 20510

The Honorable Tina Smith
United States Senate
309 Hart Senate Office Building
Washington, DC 20510

Dear Senators Warren and Smith:

As a global leader in pharmaceutical innovation, we appreciate your interest in the important topics of health care costs and drug pricing. Genentech is committed to being part of the answer and to collaborating with the Administration, Congress, and other stakeholders to bring solutions that ensure long-term, financially sustainable access for patients, while allowing America to continue to be the global leader for the development of innovative medicines. We take decisions related to the prices of our medicines very seriously, and our commitment to patient access and investment in future breakthroughs are reflected in our actions. We also firmly believe that there are opportunities to bring positive changes to our health care system that reduce overall spending and lower out-of-pocket costs for patients, while preserving access to the life-changing medicines they need.

Genentech founded the biotechnology industry 42 years ago and has remained dedicated to the rigorous pursuit of science and the delivery of transformational medicines to the patients we serve. Now, as a member of the Roche Group, our collective mission is to deliver the right medicine to the right patient, and our integrated approach centered on biopharmaceuticals (Genentech, Inc.), genomics (Foundation Medicine, Inc.), diagnostics (Roche Diagnostics, Inc.), and real world data collection and analysis (Flatiron Health, Inc.) provides us this capability, while ensuring we bring measurable value to the health care system.

Every year, we invest approximately $10 billion in research and development, more than any other health care company in the world. This has translated into one of the most innovative portfolios in the industry, highlighted by our 21 FDA breakthrough therapy designations. We've brought 13 new medicines to patients over the last 8 years in serious, hard-to-treat diseases. In that time frame, we have also received more than 40 significant supplemental approvals, demonstrating our commitment to continued investments into our existing medicines, even those approaching patent expiration.

We believe that our launch price decisions are different from most in industry. In the last three years, we launched six new medicines, each of which was priced less than other approved medicines used to treat those diseases. Our two most recent launches, Ocrevus and Hemlibra, are illustrative of our commitment to responsible pricing:

Ocrevus - In 2016, the National Multiple Sclerosis Society reported that Multiple Sclerosis (MS) medicines cost on average almost four times more than they did 12 years prior due to aggressive launch prices and double-digit price increases year after year. In March 2017, with the FDA approval of Ocrevus — our first MS medicine and the first ever approved to treat Primary Progressive MS — we took action to disrupt this disturbing trend and priced Ocrevus at 25% less than the competitor it surpassed in the Phase III clinical trial program. Below is the statement released by the MS Society on the Ocrevus approval:

> *The approval of Ocrevus is an exciting milestone for people with primary progressive MS and an encouraging new option for people with relapsing forms of the disease. The National MS Society applauds Genentech for their leadership in setting the wholesale acquisition cost (or list price) of Ocrevus at $65,000 per year -- nearly 20 percent below the current market average for an MS treatment. The continually escalating prices of MS disease-modifying therapies are creating barriers to people with MS getting these life-changing medications. Through its action on Ocrevus, Genentech is changing industry dynamics so that more people can access the life-changing treatments they need to live their best lives. We encourage other companies to follow suit, creating a drug pricing trend that keeps patients first.*

Hemlibra – In November 2017, the FDA approved Hemlibra for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children with hemophilia A with factor VIII inhibitors. For average weight patients, the annual WAC price for Hemlibra is less than half of the currently approved prophylactic treatments for hemophilia which are over $1 million a year. In addition to the significant clinical benefit Hemlibra is bringing to patients, it will also have a meaningful impact on system-wide health care costs. In its study of Hemlibra for people with hemophilia A with inhibitors, the Institute for Clinical and Economic Review (ICER) concluded that lifetime savings per patient for Hemlibra range from $8.9M vs. no prophylaxis to $78.5M vs. prophylaxis with bypassing agents. According to David Rind, ICER's Chief Medical Officer:

> *Emicizumab appears to be a very rare win-win-win in treating a small population of patients who have hemophilia and cannot be treated with factor VIII. Not only does evidence suggest that the therapy improves patient health outcomes, which has a significant impact on patient quality of life, but it also offers substantial cost savings to the health care system, and administration is far less burdensome for patients than the previous standard of care.*

Our philosophy also extends to decisions on the price increases we take on our medicines. Over the past four years, Genentech's annual average price increase, weighted by sales, was approximately 5.5%. After discounts to private payers, the government and others, our average annual "net" price increase — meaning the portion of price increases that Genentech ultimately receives — was approximately 3%.

Genentech has engaged in dialogue with the last two administrations on the topic of drug pricing in order to provide our perspective as a manufacturer and to propose system-wide recommendations that ensure long-term financially sustainable access to health care innovation. We are a global leader in indication-based pricing and would welcome a system in the United States in which we could price a medicine based on how it performs in different indications. As the company with the most medicines reimbursed through Medicare Part B, we look forward continuing to explore market-based ideas that can meet the government's goals of

bringing down costs and preserving access, and we intend to work with other stakeholders to pursue them.

I appreciate your interest in these important issues, and we are supportive of creating a dialogue in search of solutions. If you would like to talk in more detail about Genentech, our approach to sustainable innovation in medicine, or specific pricing proposals, I would welcome the opportunity to meet and discuss. In addition, please do not hesitate to contact David Burt, Senior Director of Federal Government Affairs (burt.david@gene.com or 202-572-3077) if you have any questions about this response.

Sincerely,

Bill Anderson
Chief Executive Officer and
Region Head North America

June 8, 2018

The Honorable Elizabeth Warren
317 Hart Senate Office Building
Washington, DC 20510

The Honorable Tina Smith
309 Hart Senate Office Building
Washington, DC 20510

Dear Senator Warren and Senator Smith:

I am writing in response to your inquiry, dated May 30, 2018, addressed to Dr. Olivier Brandicourt, concerning the Administration's recent actions regarding prescription drug costs for Americans.

Thank you for the opportunity to share our perspective about prescription drug pricing and patient access and affordability to the medicines they need. As a global biopharmaceutical leader, we recognize that Sanofi has an important role to play to ensure affordable and sustainable access to the prescription medicines we discover, develop and manufacture and we have taken several steps to try to alleviate the challenges facing patients.

Sanofi's Commitment to Responsible Pricing

Last year, Sanofi announced new pricing principles. These principles express our intent to limit list price increases in the U.S. at or below an independent standard measure of health care inflation (the national health expenditures (NHE) growth projection as determined by the Department of Health and Human Services), which was estimated to be 5.4 percent in 2017 and 5.3 percent in 2018. We also pledged to provide greater transparency around how we set our prices at launch based on clinical, economic and social value, as well as affordability. This policy applies to all of our medicines.

We have also committed to greater transparency to help stakeholders better understand the interaction of list and net prices; in 2016, the average list price for all of our medicines increased by 4 percent while our total net price declined by 2.1 percent. In 2017, Sanofi increased the list price of 29 of our 85 prescription medicines, resulting in an average list price increase last year for all of our medicines of 1.6% and a net price decline of 8.4%.

While list prices often receive the most attention, they reflect the initial prices set for our medicines and are not the prices typically paid by the insurers, employers, or pharmacy benefit managers who purchase our medicines on behalf of patients and their respective health plans. We negotiate significant discounts and rebates with these payers, which leads to lower prices in exchange for greater access for patients.

It is our belief that the declining net prices for our medicines should result in improved access and lower prescription drug costs for patients. Unfortunately, it does not appear that payers consistently pass

through the growing savings from increased negotiated rebates and discounts to patients by lowering costs at the pharmacy counter.

Additionally, earlier this year, we announced the launch of the Insulins VALyou Savings Program, a new plan that aims to lower out-of-pocket costs for people who manage their diabetes with Lantus (insulin glargine 100 Units/mL) and Admelog (insulin lispro injection). The intent of the Insulins VALyou Savings Program is to help patients currently paying full retail price for Lantus and/or Admelog. This includes certain uninsured patients who don't qualify for traditional patient assistance programs as well as some commercially insured patients with a high deductible that has not been reached on their plan.
The program is available at all U.S. pharmacies and, for some people, the program could offer significant savings – up to $5,500 per year – compared to the out-of-pocket cost of other long-acting or fast-acting insulins.

Sanofi's Perspective on the Administration's Blueprint and RFI

We are currently reviewing the Administration's "blueprint" and the request for information (RFI). Though our analysis is ongoing, we believe there are a number of policies raised in the RFI which could ultimately help with patient access and affordability. For example, the Administration has indicated they support increasing competition by preventing companies from attempting to block generic entry through misuse of the Risk Evaluation and Mitigation System (REMS) process. We have a longstanding policy to provide samples to generic and biosimilar manufacturers and we support the Administration's desire to address this issue.

Additionally, Sanofi supports efforts to reduce out-of-pocket spending for patients at the point of sale. Despite increasing rebates, out-of-pocket costs for many patients have continued to grow. In some cases, the growth has been driven by changes to insurance benefit designs, including a rise in the prevalence of high-deductible health plans and coinsurance requirements. These benefit designs continue to shift costs to patients despite market competition driving costs down for both pharmacy benefit managers (PBMs) and payers in certain therapeutic areas.

There are many other issues outlined in the RFI, many of which have the potential to improve the system for patients while we believe others may have unintended consequences that could result is less access for Medicare beneficiaries. Ultimately, how each of these issues are addressed – and how some interact with each other – will determine the benefit for consumers. However, Sanofi applauds the Administration's willingness to substantively, thoroughly and openly explore a range of options to help patients instead of pursuing options, such as importation or repealing non-interference, that may be more politically expedient but repeated analysis suggests would provide little, if any, benefit for consumers.

Improving Access and Affordability

Despite the meaningful steps we have taken, we also recognize that more needs to be done to improve access and affordability for people. Given the diversity of our health care system, there is likely not a single, one size fits all, approach. Instead, all stakeholders, including policy makers, manufacturers, payers and physicians, in partnership with patients, need to work together to find a range of solutions to address high out-of-pocket burdens and to provide dependable access to needed treatments.

We look forward to continuing to work with you to ensure that people have access to affordable medicines. Should you have any additional questions or concerns, please do not hesitate to contact me.

Sincerely,

Adam Gluck
Senior Vice President, U.S. External Affairs

June 11, 2018

Honorable Tina Smith
United States Senate
Washington, DC 20510

Honorable Elizabeth Warren
United States Senate
Washington, DC 20510

Dear Senators Smith and Warren:

I write in response to your May 30, 2018 letter to Gilead's Chief Executive Officer, John Milligan, concerning President Trump's proposed plan to help reduce prescription drug prices. As you know, the President's proposal includes a number of elements that have stimulated an important debate concerning how best to ensure the affordability of prescription drugs. Gilead is in the process of reviewing the President's plan, and is not yet prepared to provide a detailed analysis, but below we offer some initial reactions to the issues raised in your letter.

Gilead and other innovative biopharmaceutical companies make enormous investments in research and development, in order to bring to patients and their physicians the means to treat life-threatening medical conditions. Many research and development efforts ultimately fail, often after years of extremely costly research and protracted clinical trials. Revenues generated by successful drugs that a company is able to commercialize after many years of research and development are essential to covering the costs of past efforts and future innovations across the company's research pipeline.

Gilead's research and development budget was approximately $3.3 billion in 2017, supporting a global research program involving hundreds of ongoing clinical trials in a wide range of therapeutic areas, including HIV/AIDS, liver diseases, cancer and inflammatory and respiratory conditions. Phase 3 trials are underway for therapies that target arthritis, Crohn's disease, ulcerative colitis, and gastric cancer, among others. These research activities build upon Gilead's prior work that led to the development of the first single-tablet regimen to treat HIV, effective cures for Hepatitis C, innovative cell therapies to treat cancer and our continuing work to develop a cure for HIV and new treatments for emerging diseases like Ebola.

In pricing its products, Gilead takes into account the clinical value of the drug to patients, the price of comparable treatments, and the need to generate revenue to support ongoing research and development, among other factors. We make very significant efforts to help ensure that patients who need our drugs have access to them. For example, in 2017, more than 40,000 patients received treatment at no cost using Gilead's patient assistance program. Half of all individuals taking Gilead's HIV medicines in the United States receive them through federal and state programs at substantially discounted prices. Gilead has also offered voluntary price freezes for the state AIDS Drug Assistance Programs (ADAP) since 2008 to ensure our HIV medicines are available to low-income individuals with limited or no prescription drug coverage.

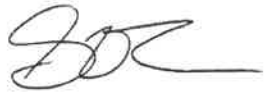
In your letter, you asked whether Gilead would support including the "list" price of its drugs in direct-to-consumer ("DTC") advertising. As you know, drugs are priced in heavily regulated markets and can be subject to a mix of government mandated and competitively

driven rebates and discounts. Therefore the publication of list price information could potentially provide consumers with incomplete information regarding the costs paid either by the patient or the insurer, employer or public program that provides their health care coverage. Gilead will continue to review any specific proposals that would mandate that pricing disclosures be included in direct to consumer advertising.

You also asked about Gilead's lobbying activities. Gilead publicly reports its federal lobbying activities, as required by law, in quarterly reports filed with the Secretary of the Senate and Clerk of the House of Representatives.

As we continue to review the President's proposals, we appreciate this opportunity to respond to your questions, in connection with your upcoming hearing.

Sincerely,



Gregg Alton
Executive Vice President
International Operations and Corporate Affairs