sanofi

Testimony of Paul Hudson
Chief Executive Officer
Sanofi

Before the Senate Committee on Health, Education, Labor & Pensions
May 10, 2023

Chairman Sanders, Ranking Member Cassidy, and Members of the Committee, thank you for the opportunity to appear before the Senate Committee on Health, Education, Labor & Pensions to discuss issues related to pricing, affordability, and patient access to insulin in the United States. I am Paul Hudson, the Chief Executive Officer of Sanofi.

I am here today to have an open discussion about the current system for pricing and accessing insulins in the U.S., the actions we have taken to improve patient access and affordability to our insulins, and, most importantly, what more can be done to make the system work better for patients and ensure every patient has affordable access to insulin.

I. Chasing the Miracles of Science to Improve People's Lives

At Sanofi, we work passionately to prevent, treat, and cure illness and disease, understand and solve health care needs of people across the world, and transform the practice of medicine. Our focus spans therapeutic areas, including immunology, oncology, rare diseases, rare blood disorders, neurology, diabetes, and cardiovascular diseases, as well as vaccines.

We employ approximately 14,000 professionals in the U.S. in a broad range of critical roles, including research and development, manufacturing, and business operations. Our most significant U.S. presence is in Massachusetts, where we are one of the largest employers in the life sciences industry, and in New Jersey. We also have major research and development (R&D), manufacturing, and business operations in Pennsylvania and Tennessee.

Last year, Sanofi spent more than $7 billion globally on R&D, reflecting our commitment to pursuing first-in-class and best-in-class medicines and vaccines that have the greatest potential to transform the practice of medicine, improve peoples' lives, and protect public health. With a strong focus on difficult-to-treat diseases and immunization, our R&D pipeline includes 84 clinical-stage projects, 26 of which are in phase 3 or have been submitted to regulatory authorities for approval.

Today, I am very proud of the progress we've made. Earlier this year, we announced positive results from a Phase 3 study in COPD, the third leading cause of death worldwide. If approved, this medicine will be the first innovation for patients suffering from this disease in over a decade. This fall, we anticipate approval for the first immunization against RSV disease **for all infants**. With this immunization, the burden RSV placed on providers and its toll on families may never happen again. Finally, we also recently launched Tzield, the first medicine proven to **delay** the onset of type 1 diabetes.

These treatments directed to meet unmet patient needs serve as an important reminder of the importance of fostering a policy environment that makes these breakthroughs possible.

Our responsibility includes demonstrating the value of our medicines through clinical data and real-world evidence, assuming massive risk to discover, develop, and deliver the medicines and vaccines that solve meaningful health problems for patients, and to enable continued investment in the innovation cycle.

II. Evolution in Insulins

Sanofi's innovations in diabetes, and, specifically, for insulin, have been significant. Much like modern cars bear little resemblance to Ford's Model T, the variety of insulin products available for diabetes patients today reflects years of research that have led to significant improvements over early formulations.

The earliest insulin preparations were limited by their short duration of action, requiring patients to inject themselves multiple times a day and wake up at night for injections to control blood glucose levels.

We are proud at Sanofi of our innovation history in insulin and the meaningful ways in which this has transformed the standard of care for patients, from the introduction of Lantus, which provided significant improvements in basal insulin levels, to the introduction of Toujeo®, a next generation basal insulin that more closely mimics the body's endogenous insulin secretions, among others. In addition to delivering meaningful innovation in the types of insulin available to patients, we are proud of the role we have played in transforming the patient experience through the development of devices to ease the daily burden of insulin administration, allowing for fewer injections and, in some cases, fewer refills and related patient copays.

Today, our goal is to transform diabetes care by treating not just symptoms but addressing the underlying disease. We are attempting to understand and disrupt the immunological triggers for the development of diabetes through several partnerships, including the recent launch of a groundbreaking medicine TZIELD, which is approved in the U.S. as the first and only therapy to delay the onset of Stage 3 type 1 diabetes in adults and pediatric patients aged 8 years and older with Stage 2 type 1 diabetes.

III. Sanofi's Commitment to Responsible Pricing

Pharmaceutical innovation brings value to patients, our society, and our health care systems. Our responsible approach to pricing reflects our medicines' value, and our commitment to patient access and to minimizing our contribution to health care inflation.

In May 2017, Sanofi announced our commitment to sustainable pricing through our progressive and industry-leading principles. This commitment includes transparency to help stakeholders

understand our pricing decisions and to advance a more informed discussion regarding our approach to pricing our medicines.[1]

We hold ourselves to a rigorous and structured process, that includes consultation with external stakeholders, when we set the price of a new medicine. Our approach considers the following factors:

- **A holistic assessment of value,** including 1) clinical value and outcomes, or the benefit the medicine delivers to patients, and how well it works compared to standard of care treatments; 2) economic value, or how the medicine reduces the need—and therefore costs—of other health care interventions; and 3) social value, or how the medicine contributes to quality of life and productivity. Our assessments rely on a range of internal and external methodologies, including health technology assessments (HTAs) and other analyses that help define or quantify value and include patient perspectives and priorities.
- **Similar treatment options** available or anticipated at the time of launch, in order to understand the landscape within the disease areas in which the medicine may be used.
- **Affordability**, including the steps we must take to promote access for patients and contribute to a more sustainable system for payors and health care systems.
- **Unique factors** specific to the medicine at the time of launch. For example, we may need to support ongoing clinical trials to demonstrate the longer-term outcomes of our medicines, implement important regulatory commitments, or explore opportunities to improve care management/patient experience and help decrease the total cost of care.

When evaluating whether to change the list price of any of our medicines, including our insulin products, we consider four factors:

- Our ambition to chase the miracles of science to improve people's lives and ensure patients have access to the medicines they need now and in the future;
- Patient affordability;
- Government policies, including inflation penalties enacted under the Inflation Reduction Act; and
- Evolving trends in the marketplace.

In 2020, 2021, and 2022, Sanofi did not increase the list price of any of its insulin products.[2]

[1] For more information on our Responsible Pricing policies and initiatives, please see our "Sanofi 2023 Pricing Principles Report," at https://www.sanofi.us/dam/jcr:356cc1f5-92dd-47a1-9770-ba60dfdfab1e/Sanofi-2023-Pricing-Principles- Report.pdf.

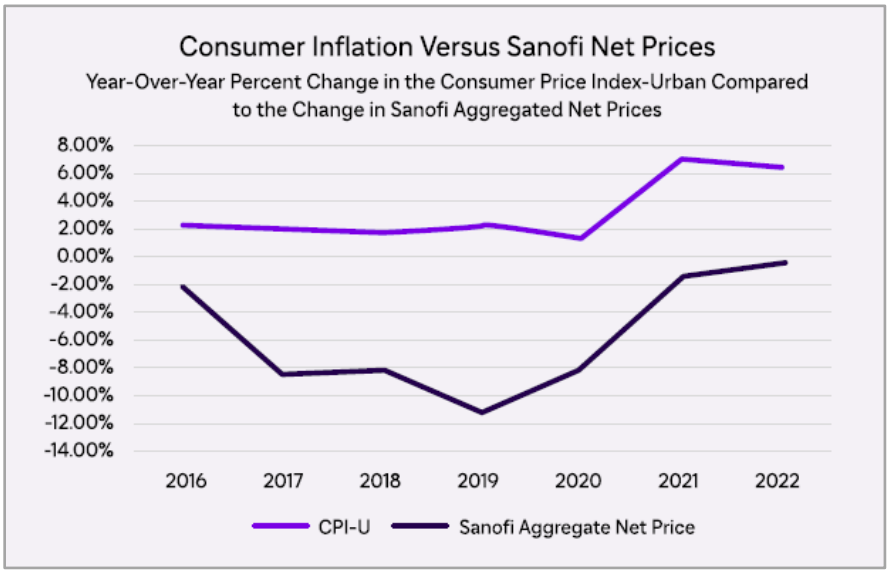
[2] Price increases on Sanofi's combination product, Soliqua®, have been within the National Health Expenditures (NHE) growth rate, a measure of medical inflation.

The table and graph below demonstrate how our responsible approach to pricing has been put into action, with limited list price increases resulting in an average aggregate net price decline every year since Sanofi started reporting data in 2017—even as consumer inflation has increased prices on other goods and services:

The net price paid to Sanofi for our products has declined for seven consecutive years:

Year	Average Aggregate List Price	Average Aggregate Net Price
2016	4.0% INCREASE	2.1% DECREASE
2017	1.6% INCREASE	8.4% DECREASE
2018	4.6% INCREASE	8.0% DECREASE
2019	2.9% INCREASE	11.1% DECREASE
2020[3]	0.2% INCREASE	7.8% DECREASE
2021	1.5% INCREASE	1.3% DECREASE
2022	2.6% INCREASE	0.4% DECREASE

U.S. Portfolio Annual Aggregate Price Change from Prior Year[4]



A. List Prices versus Net Prices

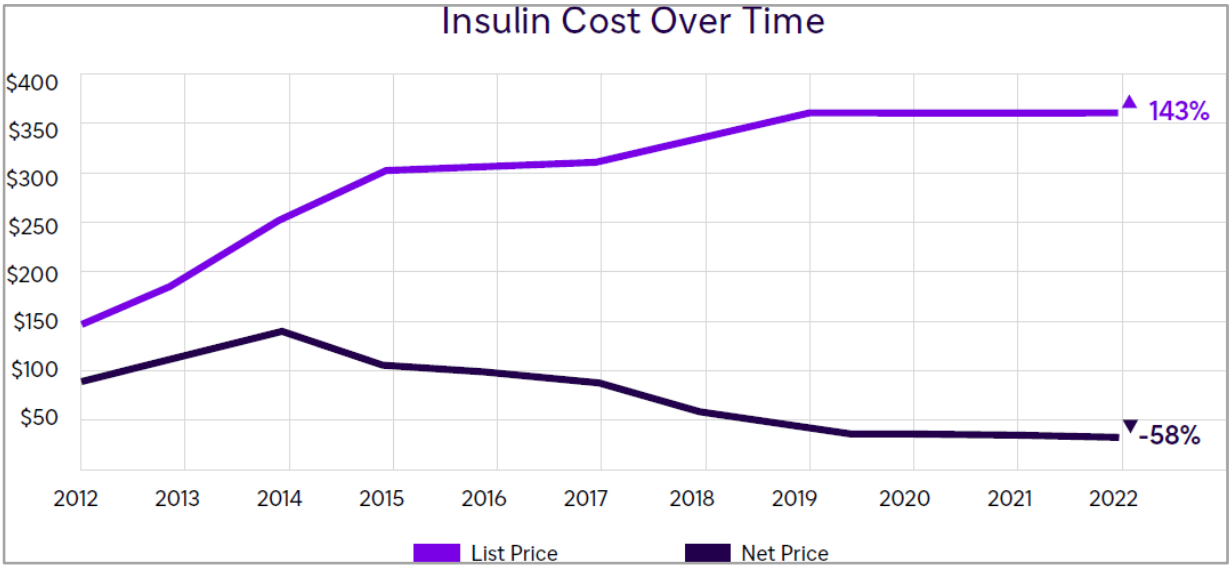
While list price often receives the most attention, it simply reflects the initial price Sanofi sets for a medicine. It is not the amount Sanofi receives, nor the price typically paid by government and

[3] Price increases or reductions that are taken mid-year may have an impact in two calendar years. In our 2019 pricing report, Sanofi announced that it took a price reduction on Admelog® (insulin lispro injection) 100 Units/mL in July 2019. The 2020 carryover impact of that change is not included in the 2020 Average Aggregate List Price above. If included, the 2020 Average Aggregated List Price change vs. 2019 would have been effectively zero percent, and the Average Aggregate Net Price would decrease by 8.0 percent.

[4] Aggregated across Sanofi's prescription portfolio.

commercial insurers, employers, pharmacy benefit managers (PBMs), or patients. Manufacturers, including Sanofi, pay significant discounts, rebates and fees—often as a percentage of a medicine's list price—to different stakeholders across the health care system with the goal of ensuring our medicines are available to patients at affordable prices. Payors, including their PBMs and government and private insurance plans, ultimately decide which medicines to make available to patients through their plans in part based on the discounts and rebates we give them for each of our medicines. **In 2022 in the U.S., across all insulin medicines, Sanofi returned 84 percent of our gross insulin sales to payors as rebates.**

Due to increased competition, including from biosimilars, the growth of rebates for insulins has been significant. Sanofi is committed to making transparent both the average aggregate list and net price changes across its portfolio to help illustrate how revenue accrues to Sanofi versus other parts of the pharmaceutical supply chain, highlighting our discrete role in the broader U.S. health care environment and enabling a better-informed discussion on solutions to improve patient access and affordability. Between 2012–2022, the net price for commercial insurance and Medicare Part D plans for our most prescribed insulin, Lantus®, has fallen by 55 percent. **In fact, the average net price of Lantus® is lower today than it was in 2004.**

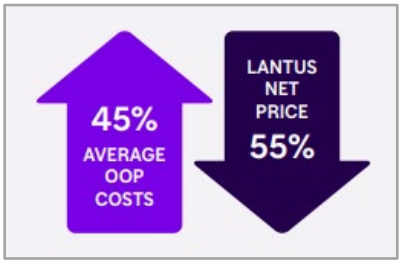


sanofi

B. The Growing Disconnect Between Net Prices and Patient Out-Of-Pocket Costs

Unfortunately, there is a growing disconnect between net prices and patient out-of-pocket costs.

Indeed, despite the significant decrease in net price, the average out-of-pocket costs for Lantus® for patients with commercial insurance and Medicare have risen approximately 45 percent since 2012. Although PBMs frequently pass rebates on to their plan clients, health plans are placing more of the cost burden on patients through benefit designs that include high deductibles, coinsurance, and multiple cost-sharing tiers—often coupled with narrower drug formularies offering fewer choices in covered medicines.



For individuals on health plans provided by employers, average patient spending on deductibles has increased by 61 percent from 2012 to 2022.[5] Such high cost-sharing, particularly for highly rebated therapies like insulin, creates a financial barrier for patients, making it difficult to obtain essential treatments without the manufacturer's financial assistance programs. Rather than lowering out-of-pocket costs for medicines, plans often use rebates to subsidize premiums or other costs. As a result, the chronically ill in this country subsidize insurance costs for the healthy.

At the same time, there has been significant consolidation across the system. As a result, PBMs, insurers, wholesalers, specialty and retail pharmacies, group purchasing organizations, and, more recently, provider groups, are now increasingly under common corporate ownership, with three consolidated entities now covering 80% of American lives.

In addition to rebates, many of these intermediaries require manufacturers to pay fees, and other payments based on a percentage of a medicine's list price which are increasing in scope and amount. Today, we pay administrative fees, data fees, and GPO fees, among others, to ensure access to our medicines. Over the past 10 years, both the scope and quantity of these fees have grown and are an increasing source of revenue for the various intermediaries in the system[6].

Can the system do more to use the value extracted from manufacturers to lower costs for all patients at the pharmacy counter? We believe the answer is yes. We support policies requiring

[5] Kaiser Family Foundation (KFF), *2022 Employer Health Benefits Survey* (Oct. 27, 2022), https://www.kff.org/report-section/ehbs-2022-summary-of-findings/.
[6] https://wendellpotter.substack.com/p/unitedhealth-cvsaetna-cigna-pulled

all fees to be calculated based on a flat payment, otherwise the incentive in the system of high list prices will continue.

C. Sanofi's Lower List Price Insulins

Sanofi's recent announcement regarding lowering the list prices of Lantus® and Apidra® is just the latest in a series of actions we have taken to introduce lower list price products. Sanofi has previously launched two insulin products at prices well below other available therapies, but as described below, our experience demonstrates that the current incentives in the system led to limited uptake of our lower list price options.

In 2018, Sanofi launched Admelog®, a follow-on biologic to Eli Lilly's Humalog®, at a list price that was 15 percent lower than the reference product. In July 2019, Sanofi reduced the list price of Admelog® by 44 percent and then again by another 25 percent in January 2022. Despite Admelog® launching at the lowest list price among mealtime insulins and subsequent list price cuts, we continue to see very limited coverage of Admelog® by PBMs and health plans.

Similarly, in June 2022, we launched the unbranded biologic Insulin Glargine Injection 100 Units/mL (U-100)—an insulin identical to Lantus®—at a list price 60 percent less than the 2022 list price of Lantus®. As with Admelog®, commercial and Medicare coverage for our unbranded Insulin Glargine Injection has been limited, with less than 25 percent of commercial and 5 percent of Medicare Part D plans choosing to cover the lower list price version in 2023, even though we offered this version at a similar net price to Lantus.

It appears that the reason these low-priced options have not had broad uptake in the system stems from the precise issues outlined above: because many intermediaries in the pharmaceutical supply chain require manufacturers to make payments based on a percentage of a medicine's list price, rather than as a flat fee, they generate more revenue from high list price medicines. These perverse incentives drive the system's preference for higher cost medications, even if some patients have to pay more out-of-pocket. Until there is a commitment by the full supply chain to make the system work better for patients or policies are enacted to remove these perverse incentives, the reality is that lower list prices will have limited benefit for patients and may lead to reduced coverage and access for lower-priced products.

IV. Sanofi's US Affordability and Access Programs and Initiatives Related to Diabetes and Insulin

A. Sanofi's Affordability Programs and Initiatives

As stated above, systemic reform is necessary so that patients can access lower costs at the pharmacy counter. But these challenges have not stopped Sanofi from doing our part: within the confines of the system, we have developed and evolved a suite of innovative and patient-informed savings programs to help people reduce their prescription medicine costs, regardless of their insurance status or income level. Each of our programs is tailored to a specific population and designed within the parameters of U.S. legal and regulatory requirements. We broadly inform patients and providers about the availability of these programs through a number of different avenues and continue to look for additional ways to educate the public about their availability so that all eligible patients have access to them.

We are proud that our actions to improve access and affordability have benefited millions of patients, but we are not satisfied stopping here—we are continually listening to patients, patient advocates, caregivers, and others to better understand additional actions we could take to address ongoing and/or emerging access or affordability challenges. As we have done several times in the past, Sanofi will continue to review and evolve these programs to better serve and improve affordability for our diabetes patients.

1. Copayment Assistance Programs

Sanofi offers copayment assistance programs for its insulins and other products covered on commercial formularies. These programs aim to lower out-of-pocket costs for commercially insured patients regardless of income level, and eligible patients can enroll online or over the phone in only a few minutes.[7] Through these programs, in 2022, the majority of participating patients paid $15 or less for their diabetes medicines. Beginning January 1, 2024, all commercially-insured patients who fill their Lantus® prescriptions at participating pharmacies will be auto-enrolled in this program and will not pay more than $35 for a monthly supply.

In 2022, across Sanofi's diabetes medicines, patients used a Sanofi copay assistance card more than 582,000 times at the pharmacy counter, saving more than $70 million.

[7] US Department of Health and Human Services' Office of the Inspector General (HHS-OIG) has issued guidance stating its view that, under the federal Anti-Kickback Statute, manufacturers cannot offer co-pay support through manufacturer-sponsored programs for prescriptions covered by federal healthcare programs, such as Medicare and Medicaid. *See* HHS-OIG, "Special Advisory Bulletin: Pharmaceutical Manufacturer Copayment Coupons (May 2014), *available at* https://www.oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf. Consistent with this guidance, Sanofi does not make its co-pay card programs available to patients covered by federal healthcare programs. Sanofi supports policy changes that would expand these financial out-of-pocket support programs to all patients who might benefit from copay assistance.

2. Insulins Val*you* Savings Program

In 2018, Sanofi launched the Insulins Val*you* Savings Program to lower out-of-pocket costs for uninsured patients who pay cash for their insulin. This program helps patients, regardless of income level, who are exposed to high out-of-pocket prices at the pharmacy counter and who do not qualify for Sanofi's free drug or other patient assistance programs. In June 2019, Sanofi expanded this program to provide eligible patients with a predictable and affordable monthly out-of-pocket cost for any combination of Sanofi insulins, regardless of the quantity they need.

Today, our Insulins Val*you* Savings Program allows uninsured patients with a valid prescription to buy any combination and amount of Sanofi insulins (Lantus®, Insulin Glargine Injection, Toujeo®, Admelog®, and Apidra®) for $35 per 30-day supply.[8] Eligible patients can enroll online or over the phone in only a few minutes.

In 2022, patients used the Insulin Val*you* Savings program more than 98,000 times, resulting in savings of almost $44 million.

3. Sanofi Patient Connection Free Drug Program

Sanofi Patient Connection is a patient assistance program (PAP) that provides free Sanofi medicines, including insulin,[9] to low- and middle-income patients earning ≤400% of the current Federal Poverty Level (in 2023, $120,000 for a family of 4), including Medicare beneficiaries, who meet eligibility criteria.

In 2022, more than 53,000 patients received free diabetes medicines through the PAP, valued at more than $185,000,000.

B. Sanofi's Efforts to Promote Awareness of its Affordability Programs

Sanofi has taken steps to increase awareness of these affordability programs so that as many eligible patients as possible may benefit from them. Sanofi includes descriptions about how to enroll in applicable affordability programs on each medication's website and on the Sanofi Patient Connection website. We also promote these assistance programs directly to patients through social media platforms and syndicated, direct-to-consumer advertisements in local newspapers and radio stations. Sanofi shares program information with patient advocacy groups which then publish that information on their websites and otherwise share program details with their members. Specifically, Sanofi meets with more than a dozen advocacy stakeholders at least quarterly to share information and updates about Sanofi's programs and other information that may benefit patients and to obtain feedback about affordability and access barriers.

[8] Additionally, through the Soliqua® co-pay card, uninsured patients can pay $99 per box of pens for up to two boxes of pens for a 30-day supply.

[9] Sanofi Patient Connection provides eligible patients with access to free supplies of Admelog®, Apidra®, Lantus®, Soliqua® 100/33, and Toujeo® SoloStar®, among other Sanofi medicines and vaccines.

Sanofi also has partnered with other organizations to disseminate information about its affordability programs. For example, Sanofi's affordability programs are included in the Pharmaceutical Research and Manufacturers of America's (PhRMA) Medication Assistance Tool (MAT), a search engine designed to help patients, caregivers, and healthcare providers locate patient assistance resources offered by biopharmaceutical manufacturers. Information about Sanofi's affordability programs is also available at GetInsulin.org, an online tool created by the patient advocacy organization Beyond Type 1 to connect diabetes patients in the US with insulin access and affordability options, as well as other resources to support diabetes care and management that match a patient's particular circumstances. Lastly, information about Sanofi's affordability programs are accessible through GoodRx's platform and Optum Store's digital pharmacy platform.

C. Participation in the Part D Senior Savings Model

Before the Inflation Reduction Act (IRA) capped insulin out-of-pocket costs in Medicare, Sanofi worked with the Centers for Medicare and Medicaid Services (CMS) Innovation Center to support the creation of the Medicare Part D Senior Savings Model. Launched in January 2021, the Senior Savings program enabled Medicare beneficiaries to access insulins at a maximum $35 copay for a month's supply. Based on CMS's estimates, beneficiaries who used insulin and enrolled in a plan that participated in the Model could see an average out-of-pocket savings of $446 or 66 percent annually, funded in part by an estimated additional $250 million in discounts from manufacturers over the five years of the model.

V. Market-Based Policy Solutions to Address Patient Access and Affordability

Sanofi is committed to working with Congress and other stakeholders to identify market-based policy solutions that will incentivize a high-value and sustainable healthcare system that improves the affordability of innovative medicines in the U.S. and in which the patient truly benefits. By establishing policies that encourage competition and align incentives so the value driven by competition accrues to patients, we can accomplish our shared goal of lowering drug prices and patient costs, while also protecting and cultivating the entrepreneurial risk-taking necessary for pharmaceutical manufacturers to continue to discover, develop, and bring to market life-saving new medicines.

Reducing out-of-pocket costs for patients should remain a top priority, but as we have experienced, limiting launch prices or reducing the list price of medicines alone is not sufficient to solve this problem. We support Congress' recent reforms to the Medicare Part D benefit that cap patient out-of-pocket costs and allow beneficiaries to spread their payments across the benefit year. There are a number of additional policy options that could effectively reduce out-of-pocket costs for patients, including:

- Requiring at least a substantial portion of the discounts and rebates paid by manufacturers to be used to reduce costs for patients at the pharmacy counter (not simply passed through to plans, which is common today), such as requiring any coinsurance amounts be based on the net price and not the list price.

- De-linking fees (e.g., wholesaler and retailer fees, and PBM and group purchasing organization (GPO) administrative fees) from list price, which would remove the perverse incentives that sometimes feed the cycle of higher list prices paired with higher rebates and fees and create impediments to patient access to lower list price medicines.

- Prohibiting commercial health insurance plans from misappropriating patient-directed savings through accumulator, maximizer, and alternative funding programs, and requiring commercial payers to designate all covered drugs as "essential health benefits" and count manufacturer copay coupons towards any plan deductible and/or out-of-pocket limit.

- Prohibit the use of spread pricing to save money and ensure everyone is getting the best deal possible.

- Let people get the medicines their doctors prescribe at a pharmacy that is most convenient for them, not one that makes the middleman more money.

Our shared goal of lowering drug costs while maintaining the innovation engine of the U.S. to bring novel, beneficial medicines to patients will not be fully realized if policies are enacted that solely target the list price of medicines. Without a holistic approach that addresses current system incentives favoring higher list prices, as well as common-sense patient protections paired with continued incentives for innovation, U.S. health system challenges, including access and affordability of medicines, will not be adequately addressed. For our part, we will continue to listen to patients, patient advocates, caregivers, and others to better understand additional actions we could take to address access and affordability.

* * *

I look forward to having a productive conversation about the complexities of the current system and policy solutions to improve affordable patient access to medicines.

Thank you for the invitation to speak with you today. I welcome the opportunity to work with you on this important issue.