“Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain”

by

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Chairwoman Eshoo, Ranking Member Burgess, and members of the Subcommittee, thank you for inviting me to testify at this hearing. I am Amy Bricker, R.Ph., Senior Vice President, Supply Chain for Express Scripts.

I have had the privilege of working in the healthcare industry for most of my career. As a registered pharmacist working in the retail pharmacy setting, I have seen first-hand the opportunities we have to improve pharmacy care. Prior to joining Express Scripts, I served as Regional Vice President of Account Management for Walgreens Health Services. During my ten years at Express Scripts, I have held leadership roles in pharmacy network management, supply chain economics, and retail contracting and strategy. As Senior Vice President, Supply Chain, I am responsible for key relationships and strategic initiatives across the pharmaceutical supply chain, including working with drug manufacturers and retail pharmacies to create value for Express Scripts' clients and keep medicine within reach for patients. My team also has responsibility for developing value-based contracts to improve affordability, access, and care for the complex and costly conditions many people face. Until recently, I had the honor of serving on the Medicare Payment Advisory Commission (MedPAC).

I appreciate the opportunity to testify on the role Express Scripts plays in the supply chain and on improving affordability and access to prescription drugs. Express Scripts helps more than 80 million Americans achieve better care at a lower cost, including those in health plans, union-sponsored plans, state employee health plans, and public programs, including Medicare Part D and Medicaid. We are proud to serve TRICARE, the health program for 9.4 million uniformed service members, retirees, and their families, for more than 10 years. Express Scripts' tools include an innovative specialty pharmacy care model for costly and complex drugs; clinically-based drug utilization reviews; clinically-based formulary management; medical and drug data analysis; and specialized Therapeutic Resource Centers, with pharmacists specially trained to serve patients with a range of conditions.

In December 2018, Cigna completed its combination with Express Scripts. Together, our companies have industry-leading cost trend capabilities that are uniquely positioned to deliver better care, expanded choice, and greater affordability. Our combined company's 74,000 employees come to work every day to enhance the health, well-being, and peace of mind of the more than 160 million customer relationships we serve globally.

Cigna is a global health services company; our subsidiaries are major providers of medical, pharmacy, dental, disability, and related products and services in more than 30 countries and jurisdictions around the world, including South Korea, China, India, the Middle East, and Europe. Cigna is also the largest provider of expatriate benefits in the world. In the United States, Cigna is one of the largest health services providers. We emphasize whole-person health and clinical quality to deliver choice, affordability, and enhanced quality of life for our customers and clients. Key enablers of our success are collaborative relationships with providers, an emphasis on outcomes- and value-based reimbursement, robust patient support services, and transparency tools for customers and clients to make informed decisions that address their specific needs.

We appreciate the opportunity to be a constructive participant in public policy discussions and to contribute workable solutions to societal challenges in all of the countries, markets, and jurisdictions in which we operate. The United States drives the most innovation in health services. While innovation can yield life-changing new therapies and treatments, it often comes with a high price tag, especially in the pharmaceutical sector.

At Cigna and Express Scripts, we strive to achieve better health, with greater choice, affordability, and predictability. We do this by supporting our customers in maintaining their health and partnering with physicians and other providers to provide coordinated, connected care that is focused on delivering value aligned to clinical quality and evidence-based guidelines. We challenge ourselves every day to accelerate solutions that enable access to new innovations and price stability. We are already making good progress.

Pharmacy is the most frequently consumed aspect of health care for Americans. On average, people use their pharmacy benefit 11 times a year, making it the most widely used benefit employers and health plans offer. For some illnesses that once required surgery, prescription drugs have emerged as an effective front-line option. However, prescription drug spending is forecast to grow at 5.5 percent per year, on average, between 2018 and 2027.[1] Over the past 10 years, the Consumer Price Index (CPI) has increased 15 percent.[2] During that same period, the prices for generic drugs have dropped by an average of 60 percent; conversely, these savings have been subsumed by an astonishing 208 percent increase in the cost of branded drugs.[3]

Express Scripts' solutions for driving lower drug spending and fostering the use of lower net cost treatments are making medications more accessible for Americans. In 2018, Express Scripts' clinical first approach returned $45 billion in savings to our clients – employers, health plans, government programs, unions, and others.[4] Because of our innovative solutions and approach to pharmacy care, our clients achieved the lowest drug trend in 25 years, just 0.4 percent across employer-sponsored plans. The average 30-day prescription cost our patients only 6 pennies more than in 2017. Further, we delivered an unprecedented 0.3 percent decline in drug spending across Medicare plans. All of this was accomplished in an environment where manufacturers raised list prices by an average of 7.3 percent for traditional brand drugs and 7.1 percent for specialty brand drugs. We secure discounts from manufacturers and pharmacies and guide patients to effective, lower-cost therapies to achieve these results.

We deliver these results because we take a holistic approach to pharmacy care. We know there is a lot that happens from the moment a person goes to their physician with a health issue, to when a diagnosis is made, to when a prescription is written, and then ultimately filled. We are there, every step of the way, to make sure patients get the care they need at a cost they, and their employers and health plans, can afford. Our focus is clear: better care, greater choice, and lower costs.

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[1] https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/downloads/forecastsummary.pdf
[2] https://www.statbureau.org/en/united-states/inflation
[3] http://lab.express-scripts.com/lab/drug-trend-report/~/media/29f13dee4e7842d6881b7e034fc0916a.ashx
[4] http://lab.express-scripts.com/lab/drug-trend-report/2018-drug-trend-report

With that context as background, our statement today focuses on the following topics:

- Our efforts to drive improved affordability, predictability, and accelerate value-based care for patients;
- The role of rebates in the prescription drug supply chain; and,
- Legislative and regulatory solutions to lower drug costs for patients.

Our Efforts to Drive Improved Affordability, Predictability, and Accelerate Value-Based Care for Patients

We are at our best when there is competition in the marketplace. When there are multiple therapies for a disease with similar clinical efficacy, we are able to leverage competition to drive discounts for our clients and customers. Our approach begins by having independent panels of healthcare professionals evaluate medicines (Pharmacy and Therapeutics Committee, or P&T Committee), and once they have determined which are necessary for our members, we can then negotiate with drug manufacturers to achieve lower net costs.

Express Scripts uses clinical expertise and scale to negotiate lower drug costs with drug manufacturers, leveraging competition to help drive savings for clients, which include employers, labor unions, health plans, the federal government, and states. These negotiations serve to create competition in the market for prescription drugs, and the savings ultimately benefit patients through lower premiums and reduced out-of-pocket costs. Additional savings are realized when clients take advantage of Express Scripts' clinical support services, which enable individuals to lead healthier and more productive lives.

When it comes to prescription drugs, our goal is to achieve improved clinical outcomes at lower costs. Express Scripts offers several innovative programs to help us achieve that goal:

- Our **SafeGuardRx℠** programs help our clients closely manage high-cost drug classes through a holistic approach that combines clinical care with advanced analytics, and patient engagement supported by technology. Through SafeGuardRx Solutions, we have leveraged value-based arrangements to expand access and lower costs in some of the most challenging therapy classes, including hepatitis C, high cholesterol, cancer, inflammatory conditions, pulmonary conditions, and multiple sclerosis.
- One of our SafeGuardRx programs – The **Diabetes Care Value Program** – improves pharmacy care while controlling plan costs for individuals with diabetes. Developed with drug makers and launched in 2017, the program has reduced diabetes drug spending by 19 percent – a total savings of $42.6 million. The program combines specialized diabetes pharmacy care with benefit strategies, such as utilization management and quality pharmacy networks, and improved compliance with recommended treatment guidelines.
- Our **National Preferred Flex Formulary** is a unique approach that provides employers and health plans with the flexibility to take advantage of the possibility of a drug manufacturer choosing to lower the price of a drug by offering an authorized generic

alternative. Should the manufacturer offer an authorized generic, that product can be added to the formulary. In the end, we care most about the lowest net cost of a drug, not the rebate. We welcome manufacturers lowering their list prices so that patients can have greater access to medications.

- **SmartShareRx℠** offers employers and plan sponsors more flexibility in how they use rebate savings. The program was established to share estimated rebate savings on eligible medications to combat patients' primary pain point: cost-sharing in the deductible phase. However, the program has evolved to apply estimated rebate value to eligible medications filled in all phases of the pharmacy benefit to reduce patients' out-of-pocket costs at the pharmacy counter. Despite the availability of point-of-sale rebate benefit designs in the commercial market for years, we have had few employers and plan sponsors take up this option. For more than 10 years, we have offered the option to clients to provide rebate value at the point-of-sale.

- **Inside Rx℠** is a prescription savings program launched in partnership with manufacturers and retail pharmacies to expand affordable access to brand and generic medications for patients with no insurance, high deductibles, or high out-of-pocket costs, by offering discounts to these patients at the point-of-sale. Since the launch of the program in May 2017, we have helped patients save an estimated $400 million.

Express Scripts builds solutions that are as unique as the clients and patients we serve, working to partner across the health care ecosystem to uncover opportunities, take action, and deliver better outcomes. Real-time clinical alerts that reach physicians through electronic prescribing systems can turn data into actionable patient intelligence, helping people stay on their therapy regimen and avoid dangerous drug-drug interactions. Express Scripts' Real Time Prescription Benefit, launched last November, helps to simplify the patient's experience with his or her prescriber and improve transparency of drug costs. We provide patient-specific information and pricing information directly into the physician's Electronic Health Record (EHR) within seconds. Physicians using electronic prescribing can see the following information to inform prescribing decisions:

- Alternative drugs and associated details, such as generic versus brand pricing;

- Coverage information, including electronic prior authorization requirements, step therapy requirements, or quantity limits; and,

- The patient's cost through each pharmacy dispensing channel: retail, home delivery or specialty pharmacy.

By providing drug cost information and reconciling coverage issues at the point of prescribing, we are mitigating confusion and pain points for patients at the pharmacy counter. These systems are delivering measurable savings to patients at the pharmacy counter, while encouraging providers and patients to communicate to make better-informed medication choices. Electronic prior authorization capabilities are improving as well, eliminating hours of potential wait time for prescribers and patients.

Cigna and Express Scripts also directly provide patients real-time pricing information, customized to their individual plans, via our websites and mobile apps, so patients can choose the pharmacy that provides the most affordable dispensing option. Our innovations help better inform patients of their cost sharing and treatment options, improving affordability and predictability for patients.

As we look ahead to gene therapies, a growing category of high cost drugs, we are actively developing new value-based payment models. For example, we have periodic payment agreements with manufacturers that are structured as value-based contracts to reward efficacy. Simply put, if a drug is working, the company gets a payment. If not, the payment stops. Similarly, we have worked to develop "discontinuation" payment arrangements that require payment to be returned if a patient does not see a benefit from the drug.

Express Scripts' innovative pharmaceutical and pharmacy solutions position Cigna to offer even greater value to our clients, public program partners, and patients. The combined company integrates Express Scripts' pharmacy benefit management with Cigna's health care products and services.

For example, over seven million Americans diagnosed with diabetes use insulin. For some patients, the increasing price of insulin limits access and adherence. When Cigna and Express Scripts announced the combination, we clearly stated we would improve choice, affordability, and predictability. As discussed at the April 10th Oversight and Investigations Subcommittee hearing on insulin, within the first 100 days of our combination we were able to launch a new **Patient Assurance Program** which will bring additional affordability and predictability to customers who rely on insulin to manage their diabetes. Furthering Cigna and Express Scripts' respective historical efforts in diabetes disease management, the Patient Assurance Program establishes a lower, fixed out-of-pocket cost for covered insulins, ensuring customers will pay no more than $25 out-of-pocket when filling a 30-day insulin prescription at a retail pharmacy or through home delivery. This is an early example of the accelerated change and innovation our new company is positioned to drive in the financing and delivery of care.

The Role of Rebates in the Prescription Drug Supply Chain

As drug pricing strategies have evolved over time, drug makers have elected to offer discounts, or rebates, rather than lower the price of their medicines in an effort to improve affordability. Part of our job is to negotiate discounts, and then pass along the value so plans can offer lower premiums and provide robust benefits.

Not all drugs are discounted. In fact, drug makers offer rebates on a relatively small number of medicines. Approximately 90 percent of all prescriptions filled are generics. The remaining 10 percent are branded drugs, which represent 70 percent of the spending on prescription drugs. We believe there are targeted solutions to address this 70 percent. We work to do this through sophisticated, evidence-based negotiations for clinically equivalent therapies.

Solutions for driving lower drug spending and fostering the use of lower net cost treatments often include negotiating discounts or rebates. The role of rebates in prescription drug pricing

has been mischaracterized. Rebates are not the cause of increasing drug prices. Rebates are discounts paid by drug manufacturers after a patient receives a manufacturer's drug. In the system today, rebates are used to reduce overall health care costs for consumers. Today, employers and others use the value of discounts to help keep premiums affordable and lower out-of-pocket costs.

Most drugs do not involve a rebate structure. For example, rebates are not typically offered for generic medications, for drugs without market competition (*i.e.*, sole-source brand drugs), or for drugs administered by a physician. According to a study of drugs covered under Medicare Part D by the actuarial firm Milliman, 81 percent of all drugs analyzed do not offer rebates and 64 percent of brand drugs analyzed do not offer rebates.[5] Many sole-source, highly expensive specialty drugs, like drugs to treat cancer, do not offer rebates and continue to be priced higher and higher:

- In 2017, non-rebated drugs treating depression, high-cholesterol, infertility, and other conditions all registered price increases of more than 15 percent.[6] This means beneficiaries who take these drugs will not benefit under the Department of Health and Human Services' (HHS) recently proposed rule reforming rebates in Medicare Part D and Medicaid.

- List prices for oral oncology medications, which are not rebated or discounted to any significant extent, doubled between 2011 and 2016, from $20 per unit to $40 per unit.[7].

- The Milliman study found that on average, the highest cost drugs have the lowest manufacturer rebates (as a percentage of gross drug cost), for brand drugs with rebates.

- Looking at the 39 oral oncology medications on the market in 2010, six experienced 100-200 percent inflation between 2010 and 2016; one was greater than 300 percent and another one was greater than 800 percent.[8] Rebates are not available on these drugs, but the manufacturers continue to increase list prices. Under HHS's proposed rebate rule, beneficiaries using non-preferred and specialty drugs would therefore see premiums increase, and will not see a reduction in cost at the pharmacy counter.

Restricting or eliminating rebates does not assure improved affordability for patients or taxpayers:

- A study by the actuarial firm Oliver Wyman found that rebates reduced overall costs in Medicare Part D by $34.9 billion from 2014 to 2018, and eliminating rebates would have driven Part D premiums higher by 52 percent in 2018 alone.[9] From 2014 to 2018, the

[5] Milliman, Prescription Drug Rebates and Part D Drug Costs. July 16, 2018. The Milliman analysis focused on approximately 1,300 drug and therapeutic class combinations, reflecting 97 percent of 2016 Part D gross drug spending.
[6] Express Scripts, Let's Talk About Rebates, May 15, 2018. http://lab.express-scripts.com/lab/insights/industry-updates/lets-talk-about-rebates
[7] Express Scripts, The Cost of Hope: 5 Things to Know about the Cost of Cancer Drugs. May 30, 2017. http://lab.express-scripts.com/lab/insights/industry-updates/the-cost-of-hope-5-things-to-know-about-the-cost-of-cancer-drugs
[8] http://lab.express-scripts.com/lab/insights/industry-updates/sharing-smarter
[9] Oliver Wyman, Premium Impact of Removing Manufacturer Rebates From the Part D Program. July 2018. https://www.pcmanet.org/wp-content/uploads/2018/07/OW-Part-D-Manufacturer-Rebate-Premium-Impact-FINAL.pdf

national average Part D premium increased less than two percent per year. Manufacturer rebates are one of the major contributors to holding premiums relatively flat over the last five years.

- The Centers for Medicare and Medicaid Services' (CMS) Office of the Actuary (OACT), in reviewing HHS's' proposed rule addressing rebates estimates that Part D premiums will increase by as much as 25 percent and that federal spending will increase by $196 billion over ten years.[10]

- The Congressional Budget Office (CBO) analysis of the proposed rule confirms these estimates. The analysis finds that implementing the proposed rule will increase federal spending by about $177 billion over ten years while increasing premiums for seniors. The CBO also does not expect manufacturers to reduce list prices following implementation of the rule.[11]

- Data released by CMS for 2019 Part D premiums, and national average plan bids, show a negative trend for the first time in more than a decade.[12] CMS cites drug manufacturer and pharmacy price concessions as a factor driving lower costs.

- A *Health Affairs* analysis of the most recent National Health Expenditures prescription drug forecast for 2017-2026 concluded that increased rebates "contributed to lower net prices for many prescription drugs in recent years and are expected to have dampened prescription drug spending growth in 2017."[13]

In the Medicare Part D program, rebate savings are passed to Part D plan sponsors and are responsible for saving enrollees and taxpayers billions of dollars each year since the Part D program began. CMS requires Part D plan sponsors to show how they are using rebates to deliver coverage to their members. All Part D plan sponsors must submit to CMS detailed annual reporting of rebate amounts by drug and Part D plan. In addition to reporting individual drug rebates, plan sponsors must also report to CMS how much of the rebate amounts were retained by the pharmacy benefit manager (PBM) rather than being shared with the sponsor, rebate guarantee amounts, rebate amounts reflected at the point-of-sale, third-party payer claim rebate amounts, and any other rebate amounts not already reported. Not only are plan sponsors required to report these rebate amounts to CMS, but they must also report what the rebates are for, such as formulary or tier placement, market share targets, volume targets, inflation rebates, or rebate guarantees. Finally, plan sponsors must report any administrative fees charged to manufacturers.[14]

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[10] https://aspe.hhs.gov/system/files/pdf/260591/OACTProposedSafeHarborRegulationImpacts.pdf

[11] https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf

[12] 2019 Medicare Advantage ratebook and Prescription Drug rate information. https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Ratebooks-and-Supporting-Data-Items/2019Rates.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending

[13] *Health Affairs*, National Health Expenditure Projections, 2017–26: Despite Uncertainty, Fundamentals Primarily Drive Spending Growth. February 14, 2018. https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.1655

[14] Final Medicare Part D DIR Reporting Requirements for 2017. Accessed 3/4/19 at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Weekly-Items/SysHPMS-Memo-2018-May-30th.html

In the commercial market, rebates are an effective tool that employers and health plans use to generate more savings for prescription drugs. Employers and other plan sponsors that work with Express Scripts choose how rebates are used. Some plan sponsors use them to lower premiums and cost sharing, others choose to expand access, or provide discounts to consumers at the point-of-sale. Nearly half of Express Scripts' clients have opted for 100 percent pass-through of rebates. Express Scripts passes approximately 95 percent of rebates, discounts, and price reductions back to its core PBM commercial and health plan clients and their customers.

Express Scripts welcomes the opportunity to work with policymakers to bring down drug costs for patients at the pharmacy counter. There are a number of opportunities to address high list prices and patient exposure at the pharmacy counter that address competition, access to generics, and benefit designs. However, legislative or regulatory efforts to eliminate or restrict the ability of plan sponsors or PBMs to negotiate lower overall costs will lead to higher drug prices not only for Medicare beneficiaries and taxpayers, but also for millions of individuals who access health benefits through their employers.

We believe there are more direct and effective ways to deliver relief to patients most in need without disrupting coverage for millions. For example, in addition to the policy opportunities discussed later, we believe a better way to address patient out-of-pocket costs is to allow payers and their PBMs to use the power of benefit designs to limit beneficiary exposure while ensuring payers continue to have all of the tools at their disposal to negotiate lower costs. For individuals in high-deductible health plans, this could include changes to the tax code to allow coverage of chronic care treatments and other services pre-deductible, for example. Additionally, many have discussed possible changes to the Medicare Part D benefit design to achieve lower patient out-of-pocket costs, and Cigna and Express Scripts welcome the opportunity to be a constructive participant in those efforts for both Medicare Part D beneficiaries and patients in the commercial market.

Legislative and Regulatory Solutions to Lower Drug Costs for Patients

We support efforts by Congress and the Administration to use market-based solutions that put downward pressure on prescription drug prices through competition, consumer choice, and open and responsible drug pricing. For example, last year we endorsed legislation championed by Rep. Buddy Carter and others to ensure patients are told the lowest cost option available to them at the pharmacy counter. We were pleased the legislation became law, and included a provision authored by Rep. John Sarbanes and Rep. Bill Johnson to provide more transparency into so-called "pay-for-delay" agreements that prevent biosimilar drugs from entering the marketplace.

Looking to the future, we believe efforts to address out-of-control drug pricing through legislative and regulatory actions should include:

- **Prioritizing reforms to lower costs and protect patient access in Medicare:**
    - Public programs must have the ability to leverage the commercial market's successful utilization management tools that lower costs while protecting patient access. We support efforts to modify the six protected "classes of clinical

concern" in Part D, where all or substantially all drugs in a class must be covered, allowing drug manufacturers to name their price with little opportunity to negotiate. CMS's plan to only moderate the effect of protected classes—not eliminate them—would save $2 billion over 10 years.

- There are also clear opportunities to achieve savings in the Medicare Part B program, including introducing Part D utilization management tools into Part B and potentially shifting some Part B drugs to Part D. Because of the complexity involved with identifying the "candidate" drugs for moving into Part D, along with assessing the consequences and impacts of doing so for both programs, we strongly recommend CMS engage stakeholders through a work group-type process where sample, de-identified data could be shared for mutual evaluation.
- We support efforts to ensure the MedPAC and the Medicaid and CHIP Payment Advisory Commission (MACPAC) have access to aggregate, de-identified information submitted currently by PBMs, Part D sponsors, and Medicare Advantage plans to CMS. Legislation to address this issue was recently introduced by several members of this Committee, including Rep. Buddy Carter, Rep. Tom O'Halleran, Rep. Greg Gianforte, and Rep. Peter Welch. We applaud the Committee for its recent passage.

- **Advancing value-based arrangements in public programs:**
  - It is essential to bring the benefit of value-based payment to spending in public programs. Such arrangements may involve outcomes-based payments that cannot be determined until well after the plan year concludes. Changes to existing laws and/or regulations would allow for such arrangements in all settings and help improve the overall value of national spending for pharmaceuticals. The specific changes Cigna and Express Scripts believe are needed include:
    - Modifying Medicaid Best Price (MBP) rules to exclude outcomes-based pharmaceutical contracts from inclusion in MBP calculations in certain situations where failure to achieve a desired outcome leads a manufacturer to refund the full (or majority) cost of the drug, or where payment is contingent on the health outcomes of individual patients;
    - Creating additional flexibility under the Anti-Kickback Statute (AKS) to support value-based contracts and other innovative programs; and,
    - Revising Part D regulations to explicitly permit and provide guidance for how outcomes-based contracting should be accounted for in plan bids or between plan sponsors when the outcome measurement period spans plan years, or when outcomes can only be measured at the end of a plan year.

- **Advancing price transparency for patients and providers in public programs:**
    - We strongly support the concept of providing information about the price of drugs, therapies, and the cost of care to beneficiaries and their providers as a means of improving price transparency, educating consumers, and incentivizing the efficient use of care throughout the health care system. We support efforts by CMS to move toward a system in which Part D enrollees and their providers have access to real-time benefit check and electronic prior authorization tools, while ensuring an appropriate standardization and timeframes for implementation.
- **Speeding generics and biosimilars to market**:
    - Enacting the Creating and Restoring Access to Equivalent Samples (CREATES) Act, introduced by Rep. Peter Welch and Rep. David McKinley, among others, which aims to lower drug prices by ending restricted access to samples by manufacturers of brand-name drugs, and help to speed generics to market. We applaud the Committee for its recent passage. According to the Congressional Budget Office, its enactment would save $3.9 billion over 10 years. [15]
    - Prohibiting patent settlements that include so-called "pay-for-delay" arrangements, which delay the availability of lower-cost generics and biosimilars. Legislation to address these arrangements was recently introduced by Rep. Bobby Rush, and we applaud the Committee for its recent passage. We hope Congress will enact authority to block these anti-competitive agreements, removing barriers to competition and expanding the availability of lower-cost generics and biosimilars. According to a Federal Trade Commission (FTC) study, these anticompetitive deals cost consumers and taxpayers $3.5 billion in higher drug costs every year.[16]
    - Encouraging the FDA to finalize guidance on biosimilar naming standards, improve the efficiency of the biosimilar product development and approval process, and develop effective communications tools to educate providers and patients about the safety and efficacy of biosimilars.
    - Preserving the ability of the Inter Partes Review (IPR) process at the U.S. Patent and Trademark Office to invalidate patents that do not represent true innovation. Legislative and regulatory efforts to weaken this process will extend patent monopolies for pharmaceutical and biological products, resulting in higher prices for patients.
    - Considering changes to provisions included in the United States-Mexico-Canada Agreement (USMCA) that would extend exclusivity for biological products in

[15] https://www.cbo.gov/publication/55181
[16] https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay

Mexico and Canada for ten years. These provisions will limit the ability of Congress to address the 12-year exclusivity period for brand-name biologics.

- **Stopping Orphan Drug Act abuses**:
    - Pharmaceutical manufacturers have been accused of abusing the Orphan Drug Act, which was introduced to incentivize drug manufacturers to prioritize the development of "orphan drugs," drugs used to treat an illness or disease that affects fewer than 200,000 people. We support efforts to ensure that this pathway is used only for true orphan designation, and not, as some observers say, as a legal cover to seek specious orphan drug designations.[17]

Thank you for the opportunity to be here today, and for the consideration of our views. We look forward to working with you and others to improve the affordability and accessibility of prescription drugs for all Americans. Many of the proposals highlighted in my testimony are achievable if we work collaboratively, throughout the system, to overcome the challenges facing public and private stakeholders, and the health of our nation.

I welcome the opportunity to discuss these issues with you and look forward to your questions.

[17] https://khn.org/news/drugmakers-manipulate-orphan-drug-rules-to-create-prized-monopolies/