

**“Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of
Insulin”**

by

**Amy Bricker, R.Ph.
Senior Vice President, Supply Chain
Express Scripts**

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Subcommittee on Oversight and Investigations**

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Chair DeGette, Ranking Member Guthrie, 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 am a registered pharmacist and spent the beginning of my career working in the retail pharmacy setting. 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 address key disease states, including diabetes. Until recently, I had the honor of serving on the Medicare Payment Advisory Commission (MedPAC).

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 purchasers, 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 a range of conditions.

Cigna completed its combination with Express Scripts in December 2018. The combination integrates two complementary companies, each with industry-leading cost trend capabilities, which together are 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 strive 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. Innovation can yield

exciting and life-changing new therapies and treatments. But innovation often comes with a high price tag, especially in the pharmaceutical sector. At Cigna and Express Scripts, we believe we can do better by our citizens to achieve better health, with greater choice, affordability, and predictability. We are focused on accelerating solutions that support both innovation and price stability, and we challenge ourselves every day to achieve those goals.

We are already making good progress. Cigna and 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.¹ 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. Further, we delivered an unprecedented 0.3 percent decline in drug spending across Medicare plans. The average 30-day prescription cost Americans only 6 pennies more than in 2017. All of this was accomplished in an environment where manufacturers raised list prices 7.3 percent. We guide patients to effective, lower-cost therapies, and secure deep discounts from manufacturers and pharmacies.

I appreciate the opportunity to testify on affordability and access to insulin products in the United States. Cigna and Express Scripts support the Committee's efforts to make insulin more affordable, and new innovations more accessible, to all patients and payers in the United States.

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

- Our efforts to improve quality and drive value to lower health care costs;
- Increases in the list prices of insulin;
- The role of rebates in the prescription drug supply chain;
- Rebates for insulin products;
- Opportunities to improve affordability and patient care; and,
- Legislative and regulatory solutions to lower insulin costs for patients.

Our Efforts to Improve Quality and Drive Value to Lower Health Care Costs

Express Scripts' innovative pharmaceutical and pharmacy solutions position Cigna to offer even greater value to our clients, public health 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. Total direct and indirect estimated costs from diabetes topped \$327 billion in 2017, a 26 percent increase over a five year period.² Medical costs for people with diabetes are 2.3 times higher than for those

¹ <http://lab.express-scripts.com/lab/drug-trend-report/2018-drug-trend-report>

² American Diabetes Association. Economic costs of diabetes in the U.S. in 2017. *Diabetes Care* 2018 May; 41(5): 917-928.

without.³ People with diabetes in the U.S. pay between 5.7 times and 7.5 times more than those in the UK for their insulin.⁴ For some patients, the increasing price of insulin limits access and adherence. When Cigna and Express Scripts announced the merger, we clearly stated we would improve choice, affordability, and predictability. 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. This 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 just one example of private sector innovation and solutions aligning incentives in the financing and delivery of care.

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. The discounts negotiated in the supply chain for our clients ultimately benefit patients in the form of 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 **SafeGuardRxSM** programs allow us to 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 take on some of the most challenging therapy classes, including hepatitis C, high cholesterol, cancer, inflammatory conditions, pulmonary conditions, and multiple sclerosis.
- One of our SafeGaurdRx programs – The **Diabetes Care Value Program** – improves pharmacy care while controlling plan costs for people 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 pharmacist 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

³ <https://www.cdc.gov/diabetes/data/statistics-report/deaths-cost.html>

⁴ <https://www.dailymail.co.uk/health/article-3269835/The-transatlantic-drugs-divide-Patients-pay-THREE-TIMES-drugs-UK.html>

the rebate. We welcome manufacturers lowering their list prices so that patients can have greater access to medications. Eli Lilly recently announced it is reducing, by half, the price of its Humalog® insulin. We are proud more manufacturers are responding to our call to lower prices and increase affordable access to medicine. We are in discussions with Eli Lilly about a Humalog® authorized alternative, and if the net cost is lower, we will add it to our Flex Formulary.⁵

- **SmartShareRxSM** 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. For more than 10 years, we have offered the option to clients to provide rebate value at the point-of-sale. To date, only a handful of clients have opted to apply rebates at the point of sale and instead use those discounts to offset premiums and benefit designs.
- **Inside RxSM** is a prescription savings program launched in partnership with drug 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 of 2017, we've helped patients save an estimated \$400 million. Insulins are among the brand drugs for which Inside Rx offers more affordable options to those in need. The average patient savings on brand insulin products through the Inside Rx savings program is \$150 per claim. Savings on branded diabetes products averaged 47 percent in 2018, and savings on all diabetes products, brands and generics, averaged 52 percent.

Express Scripts builds products that fit a wide variety of use cases, working to uniquely partner across the health care ecosystem to uncover opportunities, take action, and deliver better outcomes. Express Scripts' **Real Time Prescription Benefit**, launched last November, helps to simplify the patient's experience with their prescriber and improve the transparency of drug costs. Real-time clinical alerts that reach physicians through electronic prescribing systems can turn data into actionable patient intelligence, helping people stay on their therapy and avoid dangerous drug-drug interactions. 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 vs. brand pricing;
- Coverage information, including electronic prior authorization requirements, step therapy requirements, or quantity limits; and,

⁵ <http://lab.express-scripts.com/lab/insights/drug-options/flexibility-to-make-insulin-more-affordable>

- 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 eliminating confusion and pain points for patients at the pharmacy counter. A 2018 annual report by Surescripts on price transparency found that provider adoption of Real-Time Prescription Benefits has grown by 1,338 percent, with monthly benefit checks growing to over 6 million by December 2018.⁶ Surescripts’ data shows that Real-Time Prescription Benefit saved patients as much as \$8,032 in out-of-pocket costs on a single prescription.⁷ These systems are delivering measurable savings to patients at the pharmacy counter, while ensuring providers and patients are communicating to make better-informed medication choices. Electronic prior authorization capabilities are improving as well, allowing prescribers to switch the drug 28 percent of the time and eliminating over 158,000 hours of potential wait time in December 2018, according to Surescripts’ report.

Increases in the List Prices of Insulin

Express Scripts welcomes lower list prices, known as a manufacturer’s wholesale acquisition cost (“WAC”), and has gone on record favoring them. List prices are exclusively controlled by manufacturers.⁸ Over the last several years, the list prices for insulin products have steadily increased. We’ve seen rates of growth in list prices of widely-used insulins increase more than 50 percent—and in some cases even higher—over the last five years. Cigna and Express Scripts share this Committee’s concerns about the affordability of insulin, and we are working every day to lower the cost of this life-saving medication for the patients we serve.

We have not observed a manufacturer *decreasing* its list price for any insulins. It is important to note that nothing in our contracts with manufacturers addresses the maintenance of list prices, and certainly nothing in our contracts prohibit a manufacturer from *decreasing* the list price of a drug.

The Role of Rebates in the Prescription Drug Supply Chain

Approximately 90 percent of all prescriptions we fill 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 health care costs for consumers. Today, employers and

⁶ <https://surescripts.com/news-center/press-releases!/content/new-data-from-surescripts-shows-that-patients-are-getting-more-affordable-prescriptions-faster-and-with-less-hassle>

⁷ <https://surescripts.com/news-center/press-releases!/content/price-transparency-at-the-point-of-care-boosts-patient-savings-and-prescriber-efficiency>

⁸ <https://www.businessinsider.com/express-scripts-responds-to-gilead-drug-pricing-comments-2017-3>

others use the value of discounts to help keep premiums affordable, lower out-of-pocket costs, and offer workplace wellness programs, just to name a few ways they put discounts to work.

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.⁹ 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.¹⁰
- 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.¹¹
- 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.¹² Rebates are not available on these drugs, but the manufacturers continue to increase list prices.

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.¹³ From 2014 to 2018, the 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 the Department of Health and Human Services' (HHS) recently proposed rule addressing rebates in Medicare Part D and Medicaid, 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.¹⁴

⁹ 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.

¹⁰ Express Scripts, Let's Talk About Rebates, May 15, 2018. <http://lab.express-scripts.com/lab/insights/industry-updates/lets-talk-about-rebates>

¹¹ 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>

¹² <http://lab.express-scripts.com/lab/insights/industry-updates/sharing-smarter>

¹³ Oliver Wyman, Premium Impact of Removing Manufacturer Rebates From the Part D Program. July 2018. <https://www.pcmnet.org/wp-content/uploads/2018/07/OW-Part-D-Manufacturer-Rebate-Premium-Impact-FINAL.pdf>

¹⁴ <https://aspe.hhs.gov/system/files/pdf/260591/OACTProposedSafeHarborRegulationImpacts.pdf>

- Data released by the Centers for Medicare and Medicaid Services (CMS) for 2019 Part D premiums, and national average plan bids, show a negative trend for the first time in more than a decade.¹⁵ 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.”¹⁶
- The actuarial firm Milliman 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.¹⁷

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 plans to show how they are using rebates to deliver Part D 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.¹⁸

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 Cigna and Express Scripts choose how rebates are used. Some use them to lower premiums and cost sharing, others choose to expand access, fund wellness programs, 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.

¹⁵ 2019 Medicare Advantage ratebook and Prescription Drug rate information. <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvntgSpecRateStats/Ratebooks-and-Supporting-Data-Items/2019Rates.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending>

¹⁶ *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>

¹⁷ Milliman, Prescription Drug Rebates and Part D Drug Costs. July 16, 2018.

¹⁸ 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>

Cigna welcomes the opportunity to work with policymakers to bring down drug prices 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 overall lower 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.

Rebates for Insulin Products

Express Scripts negotiates retrospective rebate discounts with manufacturers of all major insulin products. The amount of rebate discounts varies significantly based on utilization and a plan's benefit design. The overall value extracted from manufacturers through rebates has increased over time, as has the value shared with our clients.

Express Scripts also negotiates discounts from retail pharmacies that dispense insulin, although it generally does not negotiate rates specific to insulin products. Discounts realized by clients at pharmacies vary significantly based on the benefit design, pharmacy network, geography, and the type of pharmacy.

Express Scripts has published data regarding general trends around the net costs of drugs, and particularly the cost of medications used to treat diabetes. Our most recent Drug Trend Report showed a 4.3 percent decrease in spending for diabetes medication in 2018 for plans enrolled in our clinical solutions. For insulin, the same plans saw a 1.5 percent decline in unit cost. This net decline in insulin per unit cost occurred despite a growth in the average list price of insulin products during the same period. Express Scripts achieved this result by driving competition among manufacturers while also leveraging pharmacy discounts to drive savings.

Regarding clients' net prices for drug products, closely managed plans that adopt strong clinically-driven benefit designs generally experience slower growth in their net cost, or in some cases even a flat or negative trend in net cost, even when the list prices change. Comparatively, plans that offer broader benefits generally experience higher rates of growth in net cost. We have observed that, on average, and particularly over the last five years, the net cost to our clients for

insulins, like many other drugs, has generally increased at a lower rate than the rate manufacturers have increased list prices.

Opportunities to Improve Affordability and Patient Care

We believe that our national formularies drive clinical efficacy at lower costs. Insulins are considered highly interchangeable by our National Pharmacy & Therapeutics Committee, which is comprised of 15 independent physicians and one pharmacist. In fact, many competing insulin products contain the same active ingredient (e.g., Humulin® vs. Novolin®; Lantus® vs. Basaglar®) and we offer clients exclusions in certain categories. In August, we announced our 2019 NPF changes, of which there are 48 new formulary exclusions. Less than 0.2 percent of members will see a change in coverage for a medication. These changes will save plans an estimated \$3.2 billion; cumulative savings for plans leveraging the NPF since 2014 is estimated to reach \$10.6 billion.

As with formularies, copay tiers and other elements of benefit design are ultimately determined by Express Scripts' clients. 64 percent of high-deductible health plans used the preventive drug list offered by Express Scripts which includes first-dollar coverage of insulin. Clients may also select a narrower network of retail pharmacies where their members can fill insulin prescriptions, generally at greater savings. Further, Express Scripts offers clients various utilization management options to further reduce costs for members covered by their plans.

Value-Based Contracting for Insulin

As noted previously, Express Scripts also offers several value-based arrangements, including our Diabetes Care Value Program, and we continue to develop program offerings for insulin and other products that focus on value enhancement.¹⁹ We believe that arrangements that tie reimbursement with patient outcomes is key to improving value and health outcomes for patients with diabetes.

Regarding potential value-based contracts for insulin, Express Scripts would recommend monitoring outcomes such as hemoglobin A1c/glucose goals, escalation of therapy, and hypoglycemic episodes for patients. Given the complexity of dosing and management for insulin, these alternative factors will provide appropriate indicators of a patient's response to insulin therapy over a short term period and subsequently appropriate pricing of insulin based on outcomes. We would provide blood glucose remote monitoring devices for patients on insulin that connect to a care manager to monitor when blood sugars are too high or low. Based on overall performance of the drug in connection with the monitoring, and whether the patient had any hypo/hyper episodes or emergency room visits as a result, we would receive value back from the manufacturer for lack of performance or to cover emergency room visits.

Improving Insulin Adherence

¹⁹ See, e.g., <http://lab.express-scripts.com/lab/insights/drug-options/flattening-the-trajectory-of-the-diabetes-epidemic>

Despite industry demand for a uniform standard for measuring insulin adherence, no such standard exists due to wide variations in patients' medication administration directions and use. Typical industry methods of measuring adherence for other medications involve calculation of Medication Possession Ratio (MPR) or Proportion of Days Covered (PDC). Both of these measures are commonly used to determine whether a patient has sufficient supply of medication on hand to maintain adherence to their prescribed drugs. Due to variable dosing of insulin based upon individual blood glucose levels, the number of units a patient should be taking is very difficult to calculate for an accurate MPR or PDC.

Express Scripts saw an overall 1.9 percent improvement in *Adherence for Diabetes Medications*, the quality metrics tied to the 2017 CMS Star Ratings for clients in a Preferred Value Network. Express Scripts started measuring this variable in 2017 with the launch of our first Preferred Value Network. Due to the lack of an industry standard to measure insulin adherence, Express Scripts offers a number of solutions and attempts to identify adherence gaps through numerous methods: predictive modeling, late-to-fill logic, and proactive adherence opportunities. Our clinicians, who have therapy-specific specialized training, partner with pharmacies to identify and recommend programs to best address nonadherence.

Proprietary predictive modeling is used, in combination with personalized clinical services and interventions, to attempt to prevent or minimize nonadherence. Information is first gathered on patients' potential personal adherence obstacles, such as cost, clinical concerns, and/or personal behaviors or preferences. The predictive models are then used to assess which patients are at risk to be nonadherent in the future. Using this data, a tailored approach is made—through personal clinical services and interventions with licensed pharmacists—to attempt to prevent or minimize future nonadherence.

Late-to-fill logic takes an active approach to message patients who are late to fill a medication. Upon login to the Express Scripts' website, the individual will receive a message that prompts the individual to act to fill the medication, speak with a specialist pharmacist, arrange for a follow-up reminder, or indicate that the medication is no longer needed. Pharmacy records are automatically updated with the individual's selection. Individuals immediately react 45 percent of the time when receiving a late-to-fill message.

Express Scripts also utilizes a number of proactive adherence opportunities. Medication refill reminders are sent via mail, email, phone, the member website, and through mobile apps. Express Scripts also sends gap in care alerts and enhanced messaging to remind patients about managing their care through standard mail, email, mobile applications and electronic medical records.

Legislative and Regulatory Solutions to Lower Insulin 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.

In our 2018 Drug Trend Report, Express Scripts indicated that no new widely used generics will be available until 2023, and that utilization and costs are expected to increase for diabetes medications.²⁰ We continue to hope that the recent appropriate reclassification of insulin as a biologic product by the Food & Drug Administration (FDA) provides an opportunity for other manufacturers to bring insulin products to the market with lower prices, which will drive down the prices brand name insulin manufacturers currently charge.

Express Scripts supports and continues to advocate for legislation that can reduce prescription costs for American families by bringing generic and biosimilar products to market as soon as possible. With an expected cost of 15 percent to 40 percent less than originator products, biosimilars create a significant savings opportunity across the U.S. health care system.

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

- **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 passage would save \$3.9 billion over 10 years.²¹
 - 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.²²
 - Encouraging the FDA to finalize guidance on biosimilar naming standards, improve the efficiency of the biosimilar product development and approval

²⁰ Diabetes trend will increase as no new widely used generics are coming to market until Januvia® (sitagliptin) generics become available in 2023. Greater utilization of diabetes medications is expected due to population aging and the obesity epidemic. See Express Scripts 2018 Drug Trend Report, pg. 17. <https://my.express-scripts.com/rs/809-VGG-836/images/Express%20Scripts%202018%20Drug%20Trend%20Report.pdf>

²¹ <https://www.cbo.gov/system/files/2018-09/s974.pdf>

²² <https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay>

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 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.
- **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.
- **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.
- **Prioritizing reforms to lower costs and protect patient access in Medicare:**

- Public programs must also have the ability to leverage the commercial market’s successful utilization management tools that lower costs while protecting patient access. We also 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 negotiation. CMS’ 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 Medicare Payment Advisory Commission (MedPAC) and the Medicaid and CHIP Payment Advisory Commission (MACPAC) have access to 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’Halloran, Rep. Greg Gianforte, and Rep. Peter Welch. We applaud the Committee for its recent passage.
- **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 for true orphan designation, and not, as some observers say, as a legal cover to seek specious orphan drug designations.²³

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 insulin products. 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.

²³ <https://khn.org/news/drugmakers-manipulate-orphan-drug-rules-to-create-prized-monopolies/>