House Energy and Commerce Committee, Subcommittee on Health
Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain, Part I
May 9, 2019
10:00 AM, 2322 Rayburn

Purpose
The purpose of this hearing was to hear from stakeholders in the drug supply chain about each of their roles in the rising cost of drugs.

Members Present
Chairman Eshoo, Ranking Member Burgess, Representatives Pallone, Walden, Matsui, Shimkus, Butterfield, Griffith, Guthrie, Castor, Long, Sarbanes, Bucshon, Lujan, Brooks, Schrader, Mullin, Welch, Carter, Ruiz, Gianforte, Kennedy, Bilirakis, Dingell, Blunt Rochester, Kuster, Engel, Schakowsky, and Soto

Panel I Witnesses
Mr. Justin McCarthy, Senior Vice President, Patient & Health Impact Group, Pfizer
Mr. Kave Niksefat, Vice President, Value and Access, Amgen
Mr. Jeffrey Hessekiel, Executive Vice President & General Counsel, Exelixis
Ms. Amy Bricker, Senior Vice President, Supply Chain, Express Scripts
Mr. Brent Eberle, Chief Pharmacy Officer, Navitus Health Solutions

Opening Statements
Chairman Eshoo said that the soaring cost of prescription drugs is an American health crisis. She is ready to hear from industry stakeholders about each of their roles in the drug supply chain and the rising cost of prescriptions. She wants to know how manufactures set their prices and what value pharmacy benefit managers (PBMs) add.

Ranking Member Burgess said that perspectives from industry members are important. He is ready to hear from members of each link of the supply chain. He hopes the discussion will remain focused on the patients, because they are the ones bearing the brunt of high drug costs. Improving access to lifesaving medicines is a bipartisan priority. Industry members are the ones with the knowledge and expertise to solve this problem. But if they don't, Congress will.

Rep. Pallone said that Congress continues to be focused on reducing the cost of prescription drugs. Drug prices continue to dramatically increase. One in four Americans who take prescription drugs say it is difficult to afford their medications. Thankfully, this committee has already taken bipartisan steps to make drugs more affordable by making it easier for generic drugs to get to market. He is proud of this work, but the effort cannot stop there. It is necessary to examine the misaligned incentives in the drug supply chain that also lead to gaming and increased costs.

Rep. Walden said that it is important for Congress to hear from the players involved in the drug supply chain to understand how each step impacts consumers. The committee has done a lot to increase access to lifesaving treatments. However, the impact of cutting-edge

cures cannot be realized if patients cannot afford them. Congress has already taken steps to get more generic drugs on the market, but they must do more to address the high cost of drugs.

Panel I:

Testimony

Mr. McCarthy said that Pfizer is committed to providing breakthroughs that change people's lives. Unfortunately, these medicines cannot change lives unless people can afford them. Three trends have emerged since the Medicare Part D benefit was enacted that are contributing to the affordability challenge. Frist, patient out of pocket costs are rising due to increased co-insurance and high deductibles. Second, the growth of rebates is denying patients the benefits of discounts. Third, the advances in biomedical innovation we have seen were not envisioned when the Part D benefit was enacted. Everyone shares responsibility for addressing these problems. First, there should be a cap on out of pocket costs, and negotiated discounts should be passed through to patients. Seniors are responsible for too much of their drug costs, and the rebate incentives are misaligned. Pfizer is committed to converting all its rebates to point-of-sale discounts. Second, generic drugs are a built-in price control for many medicines. But the system is not working as well for biologics. Biosimilars have the potential to save millions in health care costs, and we need to incentivize their use.

Mr. Niksefat said that Amgen provides innovative biologic medicines for patients suffering from some of the world's worst diseases. Amgen understands its role in the drug supply chain and responsibility for increasing access to lifesaving treatments. The overall net selling price of Amgen medicines in the U.S. declined in 2018 and is expected to decline further in 2019. But many Americans are still struggling to afford their medicine. One of the reasons is the misaligned incentives of the drug rebate system. Lower rebates make lower list price drugs less attractive to certain parts of the supply chain. PBMS play an essential role in the supply chain. However, his company is supportive of policy changes to ensure that rebates actually make their way to patients in the form of lower out-of-pocket costs.

Mr. Hessekiel said that he hopes to speak for small and medium-sized biomedical companies. These companies often lead the development and commercialization of breakthrough drugs, but face tremendous risks and costs in doing so. Congress must be careful not to disrupt or undermine the bio-pharma innovation cycle that drives the development of lifesaving drugs. Some countries have implemented prices controls or weakened intellectual property protections. But American patients have benefit from the country's commitment to innovation. Congress' focus should be on patients' access to critical medicines.

Ms. Bricker said that prescription drug affordability directly impacts patients' health. Innovation can deliver therapies that change people's lives. Express Scripts is doing everything it can to ensure that these therapies are available to patients. But more must be done to lower costs. This starts with competition, consumer choice, and lower pricing.

However, those with higher deductibles, higher cost-sharing, and those with no insurance are too often unable to afford their medications because they are paying based on the list price of the drug. Too many drugs are coming to market with little to no regard for affordability. The problem starts with list prices, not rebates. Solutions include allowing more preventative services to be covered in the deductible phase and ensuring biosimilars have a clear pathway to the market.

Mr. Eberle said that his company passes along all the rebates and discounts they receive to patients. This approach ensures there is no conflict of interest. PBMs perform several critical functions. They act as consolidators of market power to balance against the market power of drug manufacturers. They also manage operational activities that help bring down costs. His company is committed to furthering transparency to help consumers understand their options. Any effort to reform the PBM industry should start with improving transparency.

Questions and Answers

Chairman Eshoo asked the manufacturer witnesses how they price a drug. **Mr. McCarthy** said that the starting point is the burden of the disease. Then they look at the benefit their medicine brings. Then they look at the population, affordability, and the cost of innovation. That determines the value of the drug. Then they talk to providers, patients, and plans and refine their pricing assumptions. Then they negotiate with plans and PBMs for coverage. **Mr. Niksefat** said he agrees with that description. Prices are not set in a vacuum. They look at the benefit of the drug, the patient population, and their company's ability to sustain investment in innovation. **Mr. Hessekiel** said his company conducts extensive market research, evaluates the benefit of the drug for the patient population, and the costs of research and development. **Chairman Eshoo** asked if manufacturers pay PBMs anything. **Mr. McCarthy** said they provide rebates to PBMs and pay additional administrative fees. **Chairman Eshoo** asked the PBM witnesses if their clients pay them for the negotiations. **Ms. Bricker** said yes. The payment arrangements vary by client. **Mr. Eberle** said his company does everything on a fee-for-service (FFS) basis, so clients pay a flat monthly fee per claim.

Ranking Member Burgess said that untreated diseases are often much more expensive than treating a disease, such as diabetes. He asked if Ms. Bricker has seen that in her business. **Ms. Bricker** said absolutely. That is why her company does everything it can to make sure patients can afford their treatment. **Ranking Member Burgess** asked if there is cost assistance available to patients with private insurance but not to those with public insurance. **Mr. Hessekiel** said yes. Legally, his company cannot provide cost-sharing assistance to patients with public insurance.

Rep. Matsui said there is need for more transparency across the supply chain. She asked if greater transparency would help improve the understanding of what is driving up the cost of prescription drugs. **All the witnesses** said yes. **Rep. Matsui** asked what kind of transparency reform Congress should pursue. **Mr. McCarthy** said that a federal transparency bill should look across the entire health care industry. **Mr. Niksefat** said that patients should always receive the negotiated discounts at point-of-sale. **Rep. Matsui** asked

how increasing price transparency at the point of prescribing could help lower costs. **Mr. Bricker** said that she supports tools for prescribers that help them understand the cost of drugs. She also supports tools to help patients make informed decisions. **Rep. Matsui** asked what factors PBMs consider when building formularies, specifically with regard to behavioral health treatments. **Ms. Bricker** said that it starts with an independent panel of physicians to determine the benefit of the product. Then the PBM negotiates with the manufactures.

Rep. Shimkus asked what government can do to accelerate value-based contracting in Medicare and Medicare Advantage. **Mr. McCarthy** said that there should be exemptions for value-based agreements in the anti-kickback statute. **Mr. Niksefat** agreed. **Mr. Hessekiel** said the best thing Congress can do is allow cost-sharing assistance for Medicare beneficiaries. **Ms. Bricker** said she also supports reforms to encourage value-based agreements. **Mr. Eberle** agreed.

Rep. Butterfield asked how the witnesses reconcile the corporate desire for profit with the fact that they provide lifesaving products. **Mr. McCarthy** said that the key is innovation. Developing an innovative product allows the company to do well and patients to do well. **Rep. Butterfield** asked if affordability is part of the price setting consideration. **Mr. McCarthy** said yes. **Rep. Butterfield** asked what reforms would need to go along with establishing an out-of-pocket cap in Part D. **Mr. McCarthy** said it would be possible to close the coverage gap and then shift the various responsibilities in the catastrophic phase.

Rep. Griffith asked how PBMs balance against the market power of pharmacy chains. **Mr. Eberle** said one of the things they negotiate is making sure there is always a pharmacy within range for beneficiaries. **Rep. Griffith** asked who a PBM's clients are. **Mr. Eberle** said that his company represents anyone who provides a pharmacy benefit, including health plans, state and local municipalities, and large employers. **Rep. Griffith** asked if it is the insurance plans that decide whether to pass rebates along to consumers. **Mr. Eberle** said yes, it is part of the plan design whether to offer point of sale rebates.

Rep. Pallone asked how PBMs can control the cost of sole-source drugs. **Mr. Eberle** said PBMs are very limited if the drug has no competition. They have no control over list price. **Rep. Pallone** asked if the administration's proposal to eliminate rebates in Part D would have any impact on the cost of sole-source drugs. **Ms. Bricker and Mr. Eberle** said no. **Rep. Pallone** asked what additional considerations manufacturers take into account when pricing drugs without competition. **Mr. McCarthy** said that companies need to assess the value that a novel therapy brings to the market. Prices are also a product of negotiation with PBMs.

Rep. Guthrie asked how PBMs decide whether to include a brand name drug or a generic on their formulary. **Ms. Bricker** said that they look at net price – the list price minus any discounts. **Mr. Eberle** agreed. They also consider clinical efficacy. **Rep. Guthrie** asked if manufactures have problems getting lower price drugs on formularies. **Mr. McCarthy** said

yes, and he believes this is in part because of the rebate incentives. **Ms. Bricker** said that she disagrees. PBMs consider net price.

Rep. Castor asked if patent settlement agreements have resulted in prolonged periods of higher prices for at least some drugs. **All the witnesses** said yes. **Rep. Castor** said that these agreements harm consumers, and she hopes to see Rep. Rush's bill become law.

Rep. Long asked how much flexibility plan sponsors have to use rebates negotiated by PBMs. **Ms. Bricker** said that Express Scripts supports rebates at the point of sale. It is an option that is available to all their clients, but few have taken it. She is concerned that the HHS proposal to require rebates at the point of sale doesn't address the core issue of the cost of drugs. **Rep. Long** noted that Express Scripts caps co-pays for insulin at $25. He asked if that program could be implemented for other drugs. **Ms. Bricker** said the best candidates for a program like that are drugs with high list prices that still offer rebates. They cannot currently provide this service for Medicare beneficiaries due to the anti-kickback statute. **Rep. Long** asked what Congress can do to promote value-based agreements. **Mr. Niksefat** said that part of the problem is the current anti-kickback statute. **Rep. Long** asked if there are any steps Congress could take in the next few months to lower drug prices for consumers. **Ms. Bricker** said that Congress could allow the tools that are working well in Part D to apply to Part B and modernize the catastrophic phase of the Part D benefit.

Rep. Sarbanes asked if lobbying has an undue influence on drug pricing policy. **Mr. McCarthy** said that government affairs is not his responsibility, but he feels that his company generally has a responsibility to be involved in the regulatory process. **Mr. Hessekiel** said that companies like his do not have much of a voice in Washington, and that's why he's here. **Ms. Bricker** said that she doesn't believe their lobbying efforts result in a competitive advantage. Rather, they engage with lawmakers to educate them and help solve problems.

Rep. Bucshon asked if direct to consumer marketing increases the demand for a drug. **Mr. McCarthy** said he's not sure if it increases demand, but advertising does create awareness of diseases and available treatments. **Mr. Niksefat** agreed. **Rep. Bucshon** asked if PBMs ever ask manufacturers to increase list prices. **Mr. McCarthy** said no. **Rep. Bucshon** asked if there is formulary pressure to increase list prices. **Mr. McCarthy** said there is certainly competitive pressure to raise rebates, though not list prices specifically.

Rep. Lujan asked what the difference is between a value-based payment and an outcome-based payment. **Mr. McCarthy** said that they are very similar. **Rep. Lujan** asked how much money Amgen has saved patients through value-based agreements. **Mr. McCarthy** said that he does not have a dollar amount in front of him, but they can look into it. **Rep. Lujan** asked what baseline Express Scripts uses to measure patient savings from value-based arrangements. **Ms. Bricker** said they compare value-based arrangements against those that are not value-based. **Rep. Lujan** asked if the list price is the highest price at which a drug can be sold. **All the witnesses** said yes. **Rep. Lujan** asked if the manufacturers would

be willing to disclose the rebates that are negotiated with PBMs. **Mr. Niksefat** said that all rebates should be available at the pharmacy counter. **Mr. McCarthy** said he believes Pfizer has disclosed the total rebates it pays.

Rep. Brooks asked how PBMs determine net price. **Ms. Bricker** said it is the list price minus any discounts offered by the manufacturer. **Rep. Brooks** asked if there are differences in how various PBMs define lowest net-cost. **Mr. McCarthy** said that every negotiation with each PBM is different.

Rep. Schrader asked if publishing aggregate price data by class of drug would help lower costs. **Mr. Eberle** said he supports the concept of that proposal. **Rep. Schrader** asked how responsibility should be shared in the catastrophic phase of Part D. **Mr. McCarthy** said Congress should close the coverage gap, cap patient out-of-pocket costs in the catastrophic phase, and then manufactures, plans, and the government should share responsibility. **Rep. Schrader** asked if PMBs take into account patient cost-sharing when determining net cost. **Mr. Bricker** said no. **Mr. Eberle** said his company looks at cost-sharing when determining formulary placement.

Rep. Mullin asked if PBMs are adding value or cost for the consumers. **Mr. Niksefat** said that PBMs add value. He believes all rebates should be passed through to consumers at the point of sale. **Rep. Mullin** asked why manufactures don't just set list prices lower. **Mr. McCarthy** said he fears it would jeopardize their ability to get formulary access. **Rep. Mullin** asked if eliminating PBMs would help lower costs for consumers. **Mr. McCarthy** said PBMs play an important role. If they were eliminated, something would have to fill the void.

Rep. Welch asked if any of the witnesses are opposed to making research and development and rebate totals more transparent. **All the witnesses** said no. **Rep. Welch** asked if bundling on formularies benefits consumers. **Ms. Bricker** said that Express Scripts does not negotiate by bundle.

Rep. Carter asked the manufacturer witnesses if they have faced any pressure to keep list prices high in order to get on formularies. **Mr. McCarthy** said that they have had trouble getting their biosimilars on formularies. **Rep. Carter** asked if PBMs require manufacturers to give them advanced notice of lowering their list prices. **Mr. McCarthy** said his company has received one letter to that effect. **Rep. Carter** asked the PBM witnesses if their companies ever ask for advanced notice of a manufacturer decreasing their list price. **Mr. Eberle** said no. **Ms. Bricker** said no. **Rep. Carter** asked if requiring rebates at the point of sale would benefit consumers. **Mr. McCarthy, Mr. Niksefat, and Mr. Hessekiel** said yes. **Ms. Bricker and Mr. Eberle** said that would only benefit a subset of patients. All would see premium increases.

Rep. Ruiz asked what role PBMs play in designing step therapy. **Ms. Bricker** said that their step therapies are determined by a team of clinical therapists and physicians with an appeals process. **Mr. Eberle** agreed. **Rep. Ruiz** asked what safeguards they have in place to protect patients from

having to repeat harmful or ineffective treatments. **Mr. Eberle** said that step therapy is designed for patients that have not already tried a certain drug. **Rep. Ruiz** said he is working on legislation to provide the necessary exemptions to step therapy requirements. **Mr. Eberle** said he would support that.

Rep. Gianforte asked what manufacturers are doing to decrease drug waste. **Mr. McCarthy** said that there is a tremendous amount of waste in the health care system. He would like to review with his colleagues and get back to the committee with the specifics. **Rep. Gianforte** asked what PBMs are doing to reduce drug waste. **Ms. Bricker** said they are focused on adherence, making sure patients are taking the drug in the right dose at the right time. **Rep. Gianforte** asked if she is aware of any practices that encourage waste that Congress could address. **Ms. Bricker** said no.

Rep. Kennedy asked if the value of a drug to a patient is the same in the U.S. as it is in other countries. **Mr. Niksefat** said that when determining value, his company looks at both the needs to the patient population and the economic conditions of the country. **Rep. Kennedy** asked if it is appropriate to keep charging patients for research and development costs of an old product. **Mr. Niksefat** said that the biosimilar and generic market is working to bring prices down.

Rep. Bilirakis asked if providers have access to price information when prescribing, and how Congress could encourage wider use of such information. **Ms. Bricker** said that pricing information is available to all providers, but not all of them are using it. One of the issues is interoperability with electronic health records. **Rep. Bilirakis** asked how long it takes, on average, for the Express Scripts network to fill a prescription. **Ms. Bricker** said she does not have those statistics in front of her.

Rep. Dingell asked how PBMs contribute to higher prices and if industry reforms are needed. **Ms. Bricker** said that PBMs exist to keep prices down. **Mr. Eberle** agreed. They do everything they can to bring costs down. **Rep. Dingell** asked if the biosimilar market is working. **Mr. Niksefat** said that his company's products face robust biosimilar competition. **Rep. Dingell** asked if changing a drug's formula so it can be taken as one pill instead of two is worth 20 years of higher prices. **Mr. McCarthy** said that Congress got it right with the Hatch-Waxman Act. There should be a period of exclusivity, and after that, generics should be permitted.

Rep. Blunt Rochester asked what Congress can do to encourage companies to enter into value-based arrangements under Medicare. **Mr. McCarthy** said the best things to do would be to change the anti-kickback statute and best price provisions. **Rep. Blunt Rochester** asked if there should be more transparency about negotiated rebates. **Mr. McCarthy** said yes. If there are discounts available, patients should know about them. **Rep. Blunt Rochester** asked how value-based arrangements would affect the PBM sector. **Mr. Eberle** said that he supports value-based agreements that work for both parties.

Rep. Kuster asked if PBM revenue is impacted by lower list prices. **Ms. Bricker** said yes, to an extent. **Mr. Eberle** said the only revenue his company receives is from administrative fees, so it is not impacted by list prices. **Rep. Kuster** asked if patients are the only ones every actually paying the list price. **All the witnesses** said yes.

Rep. Engel asked what steps PBMs take to ensure their formularies do not restrict access to medication. **Ms. Bricker** said that they use an independent panel of physicians and pharmacists to develop their formularies. **Rep. Engel** asked if manufacturers take any steps to ensure that uninsured Americans can afford their drugs. **Rep. McCarthy** said that they take affordability into to consideration when setting the list price, and they do everything they can to make sure low-income, uninsured Americans can get their medication at little or no cost.

Rep. Schakowsky asked if Mr. Niksefat would be willing to submit a transparency report to HHS that includes manufacturing and research and development costs for a drug, the net profits attributable to the drug, and the advertising spend on the drug if the company wants to increase the price. **Mr. Niksefat** said he does not make those decisions for Amgen, so he cannot comment.

Rep. Soto asked if plan design impacts the costs consumers pay. **Ms. Bricker** said yes. **Rep. Soto** asked how much of a negotiated discount is passed on to plans, and how much is guaranteed to go directly to patients. **Mr. Eberle** said 100 percent of the discount is passed on to plans, but it's up to them to decide if they want to pass it on directly to patients.