Senate Aging Committee

The Complex Web of Prescription Drug Prices, Part II: Untangling the Web and Paths Forward

March 7, 2019

10:00 AM, 138 Dirksen

Purpose

The purpose of this hearing was to discuss potential policy solutions to lowering the high prescription drug costs faced by consumers.

Members Present

Chairman Collins, Ranking Member Casey, Senators McSally, Warren, Blumenthal, and Braun

Witnesses

Ms. Lisa Gill, Deputy Editor, Special Projects, Consumer Reports
Ms. Pooja Babbrah, Practice Lead, Point-of-Care Partners
Ms. Stacie Dusetzina, PhD, Associate Professor, Health Policy, Vanderbilt University Medical Center
Ms. Jane Horvath, Principal, Horvath Health Policy

Opening Statements

Chairman Collins said that struggling to afford prescription drugs should not be a problem in this nation. Combating high prescription drugs has long been a priority for this committee. Four years ago, a report was released on the egregious pricing of prescription drugs, which lead to laws regulating the pricing of generic drugs. Last fall, she worked with Sen. McCaskill on a bill which prohibits gag clauses, which is now law. This committee has also held a hearing on soaring insulin prices and a series of inquiries into pharmacy benefit managers (PBMs), insurance companies and drug manufacturers. She said she has found that the rebates paid to PBMs and insurers play a significant role in driving up costs to the consumer. The system seems to be powered by perverse incentives and conflicts of interests. She is working with both sides of the aisle to see what Congress can do to ensure that discounts actually translate to reduced costs for consumers at the pharmacy counter. The committee has also held a hearing to uncover the use of evergreening strategies and patent thickets that extend monopolies on blockbuster drugs, which is the opposite of what Congress intended when giving patent protection. For example, Humira is protected by more than 130 patents, with some extending to 2034. This blocks generic competition that could bring down prices. This week, the bipartisan Biologic Patent Transparency Act was introduced to shine a light on disturbing patent strategies. The time to act is now. Today Congress will examine how to fundamentally change the prescription drug landscape.

Ranking Member Casey said there are policies to implement into law so patients can focus on getting well instead of on their pocketbooks. Individuals and families are demanding and deserving of action by Congress. He said he will introduce a bill to ensure that the highest price of drugs are posted publicly on drug dashboards, and a second bill to help seniors and people with disabilities to afford their prescription drugs. It would help more people qualify for assistance and build on the Affordable Care Act and it is modeled

after the PACE program in Pennsylvania. By helping more people afford the cost of their drugs, it is hoped that there will be fewer stories about seniors splitting their pills. However, Congress must also pass additional legislation allowing the safe importation of prescription drugs. Finally, Congress must also allow Medicare to directly negotiate the price of drugs. All proposals by the Trump administration to lower drug costs must be closely examined.

Testimony

Ms. Gill said that Consumer Reports investigated Medicare Part D prescription drug affordability using secret shoppers. Five common generic drugs were studied: the generics of Lipitor, Cymbalta, Actos, Plavix and Celebrex; six midsize cities were studied: Dallas, Pittsburgh, Raleigh, Des Moines, Seattle and Denver. Consumer Reports used the Plan Finder Tool to select the three least expensive plans to compare what a consumer would pay with each pharmacy. It was found that the prices consumers could pay would vary by hundreds of dollars, and a simple mistake while signing up could cost thousands of dollars. For example, if one drug was neglected from the list, the annual drug cost could jump from $407 to $2,948. Generic Celebrex could be $6 at Kroger while Medicare charged hundreds. There was also wide discrepancy within zip codes: the same drug could increase in cost three-fold within a four-mile radius. Preferred pharmacy agreements between a store and a plan generates the discrepancies in these prices. Having a preferred pharmacy could lead to the preferred pharmacy charging wildly varying rates across different plans. It is essential that consumers have clear and comparative information that is easy to understand.

Ms. Babbrah said that she has been working on real-time pharmacy benefits check transactions since 2014. The real-time pharmacy benefit check transaction was a response to the benefit information provided in EHRs, but it has a long way to go. The transaction can provide crucial information to facilitate conversation between the physician and the patient, such as alternative medications, where to fill the prescription and out-of-pocket costs. The goal is to provide more accurate information and the cost of their medication within the physician's office. Studies have shown that cost is the number one reason patients do not adhere to treatment, whether it is through not filling the prescription or by taking a partial dose. This will lead to greater healthcare cost down the road, with potential hospitalizations and increased office visits. Real-time pharmacy benefits checks will enable providers to ensure patients take medications as prescribed. There are a few shortfalls with the check, including the lack of information about financial support programs. It should be noted that transaction only provides information on a patient's pharmacy benefit, not the medical benefit, with many specialty medications covered under the medical benefit. To date, the conversation has been focused on PBMs and providers. Widespread use of the transaction will enable patients to receive their medication at the lowest cost while increasing public health.

Dr. Dusetzina said that her research focuses on prescription drug policy that impedes the patient use of medications. Her research includes findings related to the role of drug rebates for increasing patient and taxpayer spending in the Medicare Part D program and how prescription drug list prices and increases have made many drugs unaffordable for

Americans. The Medicare Part D benefit, requires patients to pay a percentage of the drug's high list price for virtually all cancer drugs. Patients will spend thousands of dollars out-of-pocket when they fill the prescription. For Revlimid, it costs the Medicare program $21,000 for a 28-day supply, which would cost a patient over $15,000 out-of-pocket per year. This high level of spending has been shown across other disease areas. Commercially insured patients are also exposed to high out-of-pocket spending. Deductibles and coinsurance have become much more common in both commercial and Medicare Part D plans. Patients are being asked to pay based on a drug's list price, which is much higher than the price paid by the PBM or the health plan itself. For example, a consumer would have their Part D out-of-pocket cost for a Hepatitis C medication calculated based on the list price of $93,000, whereas the price for PBMs and health plans would be closer to $35,000. The best case scenario where the patient pays based on the $35,000 price would still have the patient paying an unreasonable out-of-pocket amount. Part D patients are exposed to unlimited out-of-pocket spending on the program. Stakeholders within the supply chain will all point to one another as the key problem, but they are all part of the problem and need to be part of the solution. Solutions will be complex. She recommends that the committee focuses on three goals. First, patients should have access to high-value drugs at a reasonable out-of-pocket cost. Second, incentives for high list prices should be removed. Third, reward true innovation by paying pharmaceutical companies for value.

Ms. Horvath said that states and the federal government have taken important first steps in lowering drug costs. CMS has a dashboard for rebates and Medicare and Medicaid, as well as the National Acquisition Cost Database. For states, they are doing transparency on drug price increasing, transparency on insurers' drug spending and the PBM business model's impact on the financing chain. States do not need to spend a lot of money reinventing resources to publicly release complex data, as states like Vermont and Maine already have good systems in place. The federal government can also help. OPM could produce similar data to what the states can track insurers and PBMs. It is important to understand which drugs in Medicare are rebating at the federal minimum to identify which drugs are deeply discounted. This can shed light on consumer behavior without releasing proprietary data. In Medicaid, there is a cap on a manufacturer's rebate liability at 100 percent of the market price and they get to that cap after a bunch of price increases. It would be interesting to know how many drugs and which drugs have reached the 100 percent cap of liability. Beyond transparency, federal case law hamstrings states in their ability to affect consumer cost in prescription drugs. The federal government can help open up state financing innovation in serval ways. First, expand the list of countries from which state programs can import drugs. This would certainly help Florida. Second, clarify that patent law does not limit state ability to regulate patent drugs. Third, uncap the Medicaid rebate liability.

Questions and Answers

Chairman Collins said that it is interesting that the choice of plan and pharmacy are important for drug prices, as most consumers do not think that differences in price could occur at the pharmacy level. It was shocking that a group of Maine pharmacists said that prescription drugs could be less expensive if a consumer did not use insurance. She asked how often that occurs.

Ms. Gill said that out of the 18 plans she looked at, about 18 percent of the time, it would have been less expensive to go outside of the plan. However, that is not recommended because consumers should try to reach the deductible. **Chairman Collins** said that part of the problem is how PBMs are compensated. If they are compensated through the rebate and as a percentage of the list price, and the pharmaceutical company knows that the PBM will make the decision on whether their drug is included in the formulary, it is an incentive for the list price to be kept high. **Dr. Dusetzina** agreed. As the list price increases, it benefits the PBMs and pharmaceutical companies and sometimes the insurer. It does not benefit the consumer or the taxpayer. Much of the spending once people hit the catastrophic phase of Part D is supported by the taxpayer. **Chairman Collins** asked if it would help for the compensation for PBMs to be fee-based. **Dr. Dusetzina** said that every party in the supply chain should move away from percentage-based payments, not just PBMs. A flat fee would absolutely be a step in the right direction. **Dr. Babbrah** said that it is important to look at outcomes in addition to the fee-based pricing.

Ranking Member Casey said that the cost of prescription medication should be available to the public, which is one of the few things agreed upon by the Trump and Obama administrations. The drug pricing dashboard must be updated every year regardless of who is in the White House. He asked whether drug pricing transparency can impact the cost of prescription medication. **Ms. Horvath** said no. Transparency informs conversations and policymaking on constraining the cost of prescription drugs. Manufacturers are not constraining price increases because of price publication. **Ms. Horvath** said there are only a few ways to ensure that the benefits of rebates get to the consumer. A controlled importation plan or setting upper payer limits would allow to move towards fee-based payment. To the extent that the PBMs pass through the rebates to the health plan, that basically goes to offset the cost of the premium. To just shut that off means that premiums will rise because it's uncertain that drug prices will go down. **Dr. Dusetzina** found that for people who were taking certain cancer treatments, those who were in the Extra Help Program actually did worse than those with no help or with Medicaid. The Extra Help benefit asked people to pay 15 percent coinsurance for their drug, which cost upwards of $10,000 per month. They could be completely priced out of those important drugs.

Sen. McSally said that one of her constituents, a senior resident, is currently taking seven prescription drugs and lives on $899 a month from Social Security with no additional income. She has to cut back on food, cannot make repairs to her home and runs up large debts on her credit cards. Increasingly more seniors need to choose between prescription drugs and payments for surviving. Many people in Arizona are going to Mexico to get medications they need. A hundred medical practices have been implicated in providing counterfeit medications. There should be an Expedia for prescription drugs to allow consumers to shop around. **Ms. Babbrah** responded that the real-time pharmacy benefit check is currently available between the PBM, physician and the patient's EHR. But it's only giving the cost under insurance. The CARIN Alliance is a bipartisan organization that is looking to bring this real-time benefit check to the patient. The cash price could be better than what is covered under insurance. If cash is paid at the pharmacy, the insurance may not know that. She said she is looking to close that loop. **Ms. Gill** said that it is a terrible game for consumers. Consumers should check apps and call pharmacies. The administrative burden of finding the lowest price is excessive. **Dr. Dusetzina** said that it is indicative that even Consumer Reports struggled with finding the lowest price. There must be

policies in place that make it straightforward to people. Make the drug that is cheapest and preferred for the plan have an affordable and low cost.

Sen. Warren said that one in four Americans have difficulty paying the cost of prescription drugs and 30 percent have skipped medication due to cost. Whereas the insurance companies and pharmaceutical companies are raking in the profits. Out-of-pocket costs are also a problem for patients with private insurance. **Sen. Warren** asked if it is easy for a consumer to get accurate information to shop around for a plan that will provide the lowest prescription costs. **Ms. Gill** said that if a consumer has an employer, they cannot shop. **Sen. Warren** asked if an insurance company is prohibited from changing a drug's copay after a consumer has enrolled in the plan. **Ms. Gill** replied that in 46 states, insurers can do whatever they want. A consumer is at the mercy of those plans. **Sen. Warren** asked if an insurance company has to keep covering the drug. **Ms. Gill** said that although Texas does, it varies by state, and the answer is typically no. Consumers are at the mercy of PBMs. **Sen. Warren** asked how it impacts patients if a drug price rises midyear or it gets dropped. **Dr. Dusetzina** said that patients will take less than they should or they will walk away without the drug. With the former Medicare Part D donut hole, patients would hit the high out-of-pocket spending and then quit taking their drug until the next calendar year. **Sen. Warren** said she will reintroduce a consumer protection act to crack down on shady insurance company practices to avoid covering prescription drugs, such as capping out-of-pocket drug costs at $250 a month and banning insurance companies from dropping a drug in the middle of the year.

Sen. Blumenthal said this is an issue of paramount importance to seniors in Connecticut. He reintroduced the CURE High Drug Prices Act to hold pharmaceutical companies accountable for unjustified price increases. It would provide a mechanism to oversee those prices. The Department of Health and Human Services could limit them to 10 percent a year unless there were fact-based justification. A price-restraint mechanism sounds draconian in a free market, but that kind of message must be sent. **Sen. Blumenthal** asked whether this bill will lower drug prices. **Ms. Horvath** said yes. Launch prices are just as important. Companies may frontload with a higher launch price if they know cost increases over a patient life are limited. **Ms. Dusetzina** agreed. She applauds the idea of using transparency efforts to understand real price increases and emphasized the importance of clamping down on launch prices as well. **Ms. Gill** said that Consumer Reports supports the CURE Act. **Ms. Horvath** said that there must be a distinction made between affordability and value. There are many things that are invaluable yet affordable. **Sen. Bluementhal** is concerned about the abuse of the patent process, where companies obtain new patents to keep generics off the market.

Sen. Braun said that within his own company, it took a radical system change to reach insurance transparency. He asked how a paternalistic system can get people to embrace transparency when there are copays. **Ms. Babbrah** said that the first step is helping patients and caregivers understand what they will pay out-of-pocket. **Sen. Braun** asked if patients would shop around if copays were lower than $20. **Ms. Babbrah** said that with the new high deductible plans, low copays are rarer now. **Dr. Dusetzina** said that employers can use reference pricing, which helps align what patients are doing with the highest value overall. It has been shown to work in some employer-sponsored benefits. **Ms. Gill** said that shopping around is indicative of a deep problem in the system and should not be a goal. Her advice to employers is to not put the burden on

employees to figure out the best deals of each insurance plan but to work with the PBMs and insurers.

Chairman Collins asked how the problem of insurers being unwilling to pay for essential treatments but then paying more for the hospitalization that results can be solved. **Ms. Horvath** said that the jury is still out on value-based contracting. Most of the contracting is proprietary between the state Medicaid agency and the manufacturer. 15 years ago, there were no drug deductibles. Insurers are trying to manage prices. Manufacturers built their model on price instead of units sold, which leaves consumers in the middle. **Chairman Collins** said that the Hatch-Waxman Act provided an approval for generic small molecule products, and generics account for 90 percent of the drugs in that area. But the uptake of biosimilars has been much slower with patent litigation and settlement agreements blocking market entry for many FDA-approved biosimilars. The Biologic Patent Transparency Act would require the makers of biologics to publicly disclose all the patents that protect their product. This would give the prospective biosimilar manufacturer the ability to challenge invalid patents earlier in the process. A more important provision would deter brand name companies from filing patents late in the process with the sole intent of delaying market entry. She asked if changes to patent law would help get the products to market sooner without discouraging wanted innovation. **Dr. Dusetzina** said that biosimilars are more expensive to develop than small molecule drugs. The approval pathway is more complex, which means they have not quite as large of a price reduction compared to traditional generics. This is why there is slower uptake and less formulary coverage for biosimilars than hoped. Any steps taken to make the path to developing those products less risky and clearer will help make that pathway smoother for those companies and potentially lower prices.

Ranking Member Casey asked what recommendations the Committee could make to CMS on the Medicare Pathfinder Tool. **Ms. Gill** said that it would be very helpful for consumers to be able to compare more than two pharmacies at a time and view different zip codes. Additionally, showing how well a drug is covered beyond their tier and whether it is a preferred generic would help consumers. **Ms. Babbrah** said that one problem for real-time benefit check is that patient out-of-pocket cost information isn't standardized. Specialty medication information must also be available if it is covered under the medical benefit.

Chairman Collins said that the misaligned incentives are encouraging high pharmaceutical prices. There should be a cap in the Medicare Part D program. Even when the catastrophic level is reached, there is no real dollar cap. But even if a cap helps consumers, it does not address price, it only shifts who's paying. This is an example of just how difficult untangling the web is. There is bipartisan consensus that this issue must be tackled. There can be some initial steps that will make a difference. It is a good sign that the Biologic Patent Transparency Act introduced this week has bipartisan support from Sens. Kaine, Portman, Braun, Stabenow and Shaheen. Consumer Reports has been doing vital work in bringing clearer information to consumers.

Ranking Member Casey said that this hearing affirms the value of in-person counseling programs, like the Medicare State Health Insurance Assistance Programs (SHIP) and APPRISE in Pennsylvania. Actual solutions must follow the hearings. This is of bipartisan concern.