

Senate Committee on Finance

Prescription Drug Affordability and Innovation: Addressing Challenges in Today's Market

June 26, 2018

9:30 a.m., Dirksen 215

Purpose

The purpose of this hearing is to examine the President's blueprint to address increasing the affordability of prescription drugs in the pharmaceutical drug market system.

Presiding Members

Chairman Orrin Hatch, Ranking Member Ron Wyden

Senators Stabenow, Cornyn, Thune, Menendez, Portman, Bennet, Carper, Cassidy, Cantwell, Casey, McCaskill, Brown, Whitehouse, Warner

Witnesses

The Honorable Alex Azar, Secretary, Department of Health and Human Services

Opening Statements

Chairman Hatch said the comprehensive policy options of the blueprint focuses on placing patients first. The Hatch-Waxman law regulated the price of drugs by encouraging new drugs while also encouraging generic competitors. Since Hatch-Waxman, additional steps have been taken to advocate policies that promote biosimilars as a way to foster competition in the market for drugs and reduce their costs. The pursuit of the balance of affordability and innovation has served us well in the past. The Medicare Part D prescription drug program is built on a system of private entities competing on price and service and wisely forbids Government interference from negotiating. However, drug shortages at hospitals demonstrate a weakness in our system. A market based response of forming a generic drug company is an innovative approach to meeting shortcomings. The President's blueprint contains similar market-based approaches and value-based arrangements that should be explored. The hearing today presents an opportunity to consider the blueprint's policy and how the Secretary aims to implement its innovative ideas.

Ranking Member Wyden said the party in power has not provided any legislation on the problem of prescription drug prices, despite the President's proposed blueprint. The policy idea of hiking drug prices overseas to lower prices domestically is a fantasy. The blueprint raises issues that have been raised for some time, and does not take action towards treating the underlying problem.

Testimony

Sec. Azar said drug pricing has been a top priority both in his tenure as secretary of HHS and with the Administration. We face four significant problems in the pharmaceutical market: high list prices set by manufacturers; seniors in government programs overpaying for drugs due to the lack of negotiating power; rising out-of-pocket costs; and foreign governments free-riding off of American investment. The President's blueprint addresses these problems in a number of ways. It proposes creating the right incentives for list prices

by working to require drug companies include their list prices in advertisements. It also provides for system without rebates and proposes better negotiation power under Medicare Part D and Part B, which has not kept pace with innovation in the marketplace. Looking at ways to merge Part B drugs into Part D would leverage existing private sector options within Part B. The President's blueprint also proposes a more competitive pharmaceutical marketplace by lessening the blocking ability of manufacturers keeping generic drug from entering the market. Finally, out-of-pocket costs must be brought down, which begins with the elimination of gag clauses to better inform patients on their spending options.

Question and Answer

Chairman Hatch asked about the replacement of rebates with a fixed price discount, and how this approach is better. **Sec. Azar** said the list price is taken off the table, and the fixed price becomes an actual discount. Thus, savings get directly passed onto patients, instead of misdirected savings under the current rebate format.

Chairman Hatch asked how the Medicaid drug rebate program interacts with the President's proposal. **Sec. Azar** said the current system provides for a statutory rebate, but the President's proposal allows for States to explore new approaches under innovative models.

Chairman Hatch asked what else can be done to increase the use of biosimilars in the market. **Sec. Azar** said HHS hopes to do the same for biosimilars that Hatch-Waxman did for generic drugs in bringing more competitive products to market.

Ranking Member Wyden asked what policies have actually taken effect and will hold drug prices down. **Sec. Azar** said patients have already saved 8.8 billion from added generics and \$20 million through the change to Part B Medicare reimbursement. The Secretary is disappointed by continued drug price increases and will continue to hold companies accountable.

Sen. Stabenow asked about the sustained high price of naloxone despite the availability of generics and whether this is included in the drug pricing blueprint. **Sec. Azar** said we are working with FDA to bring over-the-counter naloxone to the market and how to further increase generic competition for this drug.

Sen. Cornyn said there are other cost drivers the healthcare system that the Administration has tried to address, in addition to rising prescription drug costs. In the Department of Labor has provided access to allow people to obtain healthcare coverage through tier employer.

Sen. Thune asked what a reduction of list prices would impact the Part D plans and PBMs along the supply chain and what the beneficiary would experience. **Sec. Azar** said if list prices go down the patients will directly benefit by paying less. Additionally, the broken supply chain is broken and does not make it easy to hold price setters accountable. The

plan is to reverse the incentives to ever-increasing list prices, through eliminating rebates and getting Congress to overturn Obama-era capping rebates in the Medicaid program.

Sen. Thune asked how the drug rebate program will impact the 340B program. **Sec. Azar** said HHS is seeking to ensure the 340B program is being used as it was originally intended and is not being abused.

Sen. Menendez said Congress is working to pass the CREATES Act and whether the Administration supports the Act. **Sec. Azar** said the Administration does not take a formal position in favor or against the Act but does promote the promulgation of the Act aims to achieve.

Sen. Menendez asked about the bipartisan Reducing Drug Waste Act as a way to stop the waste of drug due to packaging. **Sec. Azar** said he did not know enough of the details but will take a look at its content.

Sen. Portman asked why information with regard to rebates and other price concessions cannot also be included on the dashboard to increase transparency surrounding drug prices. **Sec. Azar** said such a public disclosure of negotiated rebated rates creates serious anti-competitive issues that we must be careful about.

Sen. Bennet spent his questioning time asking about plans for reuniting children and families at the border.

Sen. Carper asked what stakeholders and policy experts saying about value-based contracting of prescription drugs and how this can increase affordability for patients. **Sec. Azar** said the FDA has put out guidance to create a better pathway and discussion between pharmaceutical companies and insurers so they can collaborate and build value-based arrangements as quick as possible. **Sen. Carper** asked what is needed from Congress to increase value-based reimbursement models. **Sec. Azar** said he believes HHS has the authority to create such models through anti-kickback statutes but will follow-up with the Committee if he finds this authority is limited.

Sen. Cassidy asked about generic drug prices and how the taxpayer is protected. **Sec. Azar** said PBMs and pharmaceuticals would be held more responsible for catastrophic discounts so that they have more skin in the game and a greater incentive to reduce list prices.

Sen. Cantwell asked the model of discounting drugs that are bought in bulk and why this should not be looked at as an option. **Sec. Azar** said he wants to learn more about how insurers are doing this, but is happy to consider this as an option.

Sen. Casey asked about access to healthcare coverage for individuals with preexisting conditions and what recommendations have been made to the President to ensure this access. **Sec. Azar** said existing law is being upheld, but the policy position of the Administration is to ensure provisions allows for affordable access for people with preexisting conditions.

Sen. McCaskill asked about support for CSRs and creation of reinsurance programs. **Sec. Azar** said CSRs and market reinsurance programs were supported in the Alexander-Collins legislation, but bipartisan support was not received on the Democratic side.

Sen. Brown said the incentives in the President's proposal to shift costs along the supply chain does not do enough, and asked whether the Secretary would commit to supporting his proposed legislation focused on the issue of price-gauging. **Sec. Azar** said the President's proposal does address price-gauging and that he will commit to tackling this issue.

Sen. Whitehouse asked whether monopolies exist in the drug manufacturing market. **Sec. Azar** said yes, monopolies exist both in generic market and new drug market.

Sen. Warner asked what tools have been proposed to provide the type of generic competition we need to bring drug prices down. **Sec. Azar** said streamlining any approval pathway to bring generics to market.

Sen. Wyden asked about negotiations made with manufacturers to lower the price of drugs like insulin for patients who pay cash for their drugs. **Sec. Azar** said his office has no idea about what this story was in reference to, however, HHS is having discussions with drug companies that are thinking about decreasing their list prices, such as insulin, to see whether anything can be done to facilitate this. If companies are seeking to lower their prices and are facing barriers from wholesalers or PBMs, HHS is not negotiating with drug companies, but is rather looking to see if it can clear barriers to help facilitate the reduction of drug prices.

Chairman Hatch provided clarity to what occurred on the Alexander-Collins stability package, noting that when Sen. Collins asked for unanimous consent to call up the legislation for vote, but that Sen. Murray objected. Thus, Democrats have shown an unwillingness to work in a bipartisan way to stabilize the individual market.