House Energy and Commerce Committee, Subcommittee on Health

Improving Drug Pricing Transparency and Lowering Prices for American Consumers

May 21, 2019

10:30 AM, 2123 Rayburn

Purpose

The purpose of this hearing was to consider seven bills: H.R. 2296, the "Fair Accountability and Innovative Research Drug Pricing Act"; H.R. 2069, the "Stopping the Pharmaceutical Industry from Keeping drugs Expensive Act"; H.R. 2087, the "Drug Price Transparency Act"; H.R. 2115, the "Public Disclosure of Drug Discounts Act"; H.R. 2064, To amend title XI of the Social Security Act to require manufacturers of certain drugs, devices, biologicals, and medical supplies to report on product samples provided to certain health care providers, and for other purposes; H.R. 2376, the "Prescription Pricing for the People Act"; and H.R. 2757, the "Creating Lower cost Alternatives for Your prescription drugs Act".

Members Present

Chairman Eshoo, Ranking Member Burgess, Representatives Butterfield, Schakowsky, Matsui, Upton, Lujan, Griffith, Schrader, Bucshon, Cardenas, Bilirakis, Welch, Mullin, Kuster, Hudson, Barragan, Carter, Sarbanes, Gianforte, and Guthrie

Witnesses

Ms. Lisa Joldersma, Senior Vice President, Insurance and State Issues, Pharmaceutical Research and Manufacturers of America (PhRMA)
Ms. Kristin Bass, Chief Policy and External Affairs Officer, Pharmaceutical Care Management Association
Ms. Madelaine Feldman, President, Coalition of State Rheumatology Organizations, Alliance of Specialty Medicine
Mr. Frederick Isasi, Executive Director, Families USA
Mr. Mark Miller, Executive Vice President of Health Care, Arnold Ventures
Mr. Douglas Holtz-Eakin, President, American Action Forum

Opening Statements

Chairman Eshoo said that there is too much secrecy in how drugs are priced. Today, the committee is examining seven bipartisan bills to shed light on this process. The first set of bills make sure seniors can afford their drugs. These bills will not only save seniors money, it will save lives. Some of the bills also shed light on the decisions drug manufacturers make. Others expose the deals between pharmacy benefit managers (PBMs) and others in the supply chain. Each bill is directed to reform the drug supply chain. Transparency is the first step.

Ranking Member Burgess said that there are a number of stakeholders in the drug supply chain, making the pricing system very convoluted. Transparency can certainly be a good thing, but it can be easier said than done given the intricacy of the system. It is important for Congress to be conscious of unintended consequences to the industry and the patients. He has some concerns about provision in some of the bills that may hamper innovation.

Rep. Butterfield said that Democrats are serious about the threat of rising drug prices. All too often, patients are unable to afford their treatments. Quality and affordable health care is a basic necessity. We understand that corporations exist to make a profit, and pharmaceutical innovation is extremely valuable. But unlike other consumer products, a prescription can mean the difference between life and death. Pharmaceutical drugs must be accessible to all Americans.

Rep. Schakowsky said that the pharmaceutical industry is holding American consumers hostage. Patients are dying because they cannot afford the medicine they need. We still do not fully understand why drug prices continue to skyrocket. Transparency is the very least that we can expect from drug manufacturers. Patients deserve notice of price increases and basic transparency, though this is only a start.

Rep. Walden said that innovative medicines don't mean much if patients can't afford them. Prices continue to rise. Where market forces weaken or fail, Congress needs to step in with common sense legislation. Lawmakers must be sure to put the patient first. The market needs to work for patients, but also be sustainable to ensure the development of the cures of the future. He is concerned that provisions of some of the bills could lead to shortages that would harm patients.

Testimony

Ms. Joldersma said that developing new pharmaceuticals is incredibly difficult and costly. The average cost of developing a new medicine is $2.6 billion and takes 10 to 15 years. While medicine's importance to health care has grown considerably, the portion of health care costs attributable to drugs has remained stable. Generic drugs have been key to keeping costs down, and biosimilars have the potential to do so as well. But patients are still struggling, and PhRMA accepts that a product's list price influences what patients pay. However, there are other entities that play a significant role in what patients pay as well. PhRMA is committed to finding solutions that help patients afford their medication while maintaining innovation. PhRMA supports transparency across the drug supply chain. When evaluating specific proposals, they have three questions in mind: is the measure likely to yield information that will be helpful to patients; does the measure give companies a reasonable opportunity to comply; and are there are appropriate protections for proprietary information. PhRMA is ready to come to the table to address these issues.

Ms. Bass said that PBMs' only mission is to increase affordability and access to drugs for consumers. They are an important link in the drug supply chain. Within that chain, PBMs are the only one whose mission is to control cost. But PBMs can only negotiate lower prices when there is competition between drug manufacturers. Too many individuals still find their drugs unaffordable. Driving more competition among drug companies is key to lowering costs for patients. Transparency across the supply chain can also be a useful tool. Her organization welcomes review of PBM practices.

Ms. Feldman said that specialty therapies have helped make tremendous progress against many diseases. But they often do not have sufficient generic competition to make prices

affordable. Samples of drugs are incredibly important to patients. Sometimes, offering a sample is the only way a doctor can get a patient started on a treatment right away. She is concerned that the samples provision of the STAR Act, which would require the total quantity and value of samples to be included in manufacturers' reporting, could have a chilling effect on manufactures providing the samples. While transparency across the supply chain is important, the policy must ensure no harm to patients.

Mr. Isasi said that patients all across America are choosing not to take the drugs they need because of cost. One in three families is affected by drug costs. As families struggle, the pharmaceutical industry continues to enjoy some of the highest profit margins of any industry. They can only get away with this because Congress lets them. Drug makers are spending less than a quarter of their total revenue on innovation. It is not true to say that innovation will dry up if government takes action to lower prices.

Mr. Miller said that his organization is dedication to reforming markets to work better. There are strong reasons for Congress to intervene in the drug market. Spending on drugs is out of control. Congress should act to curb anticompetitive behavior, lower market distortions by encouraging transparency, directly address high launch prices and price increases for drugs that do not have competitors, and reform the payment structure of Medicare Part D. There is value in transparency, but there must be enforcement action.

Mr. Holtz-Eakin said that the largest issue areas in drug pricing are specialty and sole-source drugs. Solutions should be targeted to these areas. However, it is also important to recognize that this is a world of tradeoffs. Efforts to increase transparency and lower prices may have unintended consequences for innovation and supply.

Questions and Answers

Chairman Eshoo asked Ms. Feldman if PBMs contribute to higher drug prices. **Ms. Feldman** said that she has seen lower price drugs come to market and be unable to get on formularies because their list price was too low to generate rebates. **Chairman Eshoo** asked Ms. Bass to respond. **Ms. Bass** said that her members always negotiate to the lowest net cost. In some cases, the lowest net cost of a drug can be lower than that of another drug with a lower list price. **Chairman Eshoo** asked why a reporting requirement would deter manufacturers from offering samples. **Ms. Feldman** said she is worried that manufacturers would begin to see it as a huge giveaway. **Chairman Eshoo** said that money spent advertising and marketing exceeds money spent on innovation. And yet she has never seen an ad for a generic drug. **Ms. Joldersma** said that PhRMA members spend more on innovation than they do on advertising.

Ranking Member Burgess asked if pharmacists are able to dispense generic drugs, even when a doctor writes a prescription for a brand name. **Ms. Feldman** said yes.

Rep. Butterfield asked what areas would be inappropriate for Congress to impose transparency requirements. **Ms. Joldersma** said it is important to protect proprietary information that could cause market distortions if released publically. **Rep. Butterfield** asked what circumstances would cause a drug maker to significantly raise prices. **Ms.**

Joldersma said increased costs, expanded applications, or expanded value could all lead to increased prices. **Rep. Butterfield** asked if rebate practices drive increased drug costs. **Ms. Bass** said no. **Rep. Butterfield** asked if there is room for PBMs to improve their transparency. **Ms. Bass** said that her organization supports publishing aggregate rebates and other transparency measures that protect against market distortions. **Rep. Butterfield** asked why transparency is so important for implementing effective reforms. **Mr. Miller** said that transparency may produce useful information for policymakers. But it won't be enough in itself.

Rep. Walden asked if H.R. 2064 creates a perverse incentive for manufactures to stop providing samples to physician offices. **Ms. Joldersma** said she is concerned about this issue. FDA also already requires reporting with regard to samples, so this would be a duplicate measure. **Ms. Feldman** said that samples are very important to patients. **Mr. Holt-Eakin** said that he doesn't know if the policy would eliminate samples, but there is a risk. **Rep. Walden** asked if a federal price increase disclosure law should preempt state laws. **Ms. Joldersma** said that there should be harmony among all the different reporting requirements. **Mr. Holtz-Eakin** said yes, there should be a single set of rules across the country. **Rep. Walden** asked if certain transparency measures can lead to anticompetitive behavior. **Mr. Holtz-Eakin** said yes. If one industry member knows the deal that other members are getting, that could affect their prices.

Rep. Matsui asked why prices are increasing for drugs already on the market. **Mr. Isasi** said that drug companies are raising the price of their brand name drugs to make up for generic competition. **Rep. Matsui** asked if these kinds of price increases happen in other industries. **Mr. Miller** said no. **Rep. Matsui** asked how drug rebates are preventing costs from coming down. **Mr. Miller** said that there is a role for negotiation over net cost. But some drugs are being placed on preferred formularies because of the rebate they generate, especially in Part D. That drives up the out-of-pocket costs for beneficiaries.

Rep. Upton asked if policy should focus on reporting of price increases, rather than launch prices. **Mr. Holtz-Eakin** said it is important to focus on what beneficiaries end up paying. List prices are important to that. But Congress should be concerned about the burden on manufacturers, especially small ones.

Rep. Lujan asked what tools are currently available to control the list prices of specialty and sole-source drugs. **Mr. Miller** said there are none. **Rep. Lujan** asked how Congress can ensure that drug companies are more accountable to the public. **Mr. Miller** said there are reforms to Part D that would increase their accountability.

Rep. Griffith asked if PBMs force patients to change their medication to something that might not work. **Ms. Bass** said that PBMs work with doctors to determine the best course of action if a patient has already determined a drug doesn't work for them. **Ms. Feldman** said this is an example of why samples are so important. So patients can continue taking the drug they need while they work through an appeals process.

Rep. Schrader asked for examples of higher price drugs being given preferential treatment on formularies. **Ms. Joldersma** said that one of her members testified before this committee that they had trouble getting their drug on formularies after lowering the price. **Rep. Schrader** asked if cost and rebate amount play a role in PBM decisions about formularies. **Ms. Bass** said that physician committees make recommendations to PBMs based on the efficacy of a drug, then PBMs negotiate for the lowest net cost. **Rep. Schrader** asked if reporting about samples will really do much good. **Ms. Feldman** said her only concern is making sure patients still have access to samples.

Rep. Bucshon asked if PhRMA opposes making medical devices subject to price reporting requirements. **Ms. Joldersma** said no. **Rep. Bucshon** asked if the sample reporting provision would have any impact on lowering drug prices. **Mr. Holtz-Eakin** said no. **Rep. Bucshon** asked what Ms. Bass thinks of the Administration's proposed rebate rule. **Ms. Bass** said she doesn't think it will do anything to lower list prices.

Rep. Cardenas asked how rebates directly impact consumers. **Ms. Bass** said that in Part D, rebates are used to lower the premiums for all beneficiaries. In the commercial market, plan sponsors determine how to use the rebates. **Rep. Cardenas** asked if plan sponsors are required to disclose how they use the rebates. **Ms. Bass** said no.

Rep. Bilirakis said that he believes H.R. 2757 is an important first step towards modernizing Part D. He asked what else should be done. **Mr. Holtz-Eakin** said that the greatest harm to beneficiaries comes from the catastrophic phase. So an important change would be for plans and manufacturers to have more liability at that stage.

Rep. Welch asked if PhRMA would provide the committee with how much its members spend on research and development, advertising, stock buy-backs, and top five salaries. **Ms. Joldersma** said she would have to consult with counsel. **Rep. Welch** asked if Mr. Holt-Eakin supports the negotiation transparency that's being discussed. **Mr. Holtz-Eakin** said he doesn't believe that will lower prices. **Rep. Welch** asked what top three things Congress could do to reign in drug prices. **Mr. Miller** said Congress could reform Part D and implement reference pricing or something similar for drugs that have no competition.

Rep. Mullin asked if PhRMA is opposed to reporting price increases. **Ms. Joldersma** said no. **Rep. Mullin** asked what problems there are with the FAIR Act. **Ms. Joldersma** said the leading concern is that it could apply retroactively.

Rep. Kuster asked if requiring justification for price increases will deter drug companies from raising prices. **Mr. Miller** said to a small degree, probably. But it's not enough. **Rep. Kuster** asked how Part D negotiation might help. **Mr. Miller** said a reference price tied to the clinical value is one option. **Rep. Kuster** asked if the government is taking full advantage of its drug purchasing power. **Mr. Miller** said the government could be doing more.

Rep. Hudson said that the FAIR Act includes high penalties for noncompliance. He asked where that revenue should go. **The witnesses** said it should go to benefit patients. **Mr. Hudson** asked how the PBM industry can support cost transparency for patients. **Ms. Bass** said there are tools already in use for patients to see what their cost sharing for a drug will be. But those should be expanded and improved.

Rep. Barragan asked if patients should have access to lower price drugs. **Ms. Bass** said that PBMs negotiate to the lowest net cost. **Ms. Barragan** asked what impact Part D negotiation would have on drug prices. **Mr. Isasi** said it is difficult to project the savings given the current lack of transparency around price setting. But a strong negotiation policy with enforcement mechanisms would undoubtedly save patients money.

Rep. Carter asked if patient cost-sharing is based on the list price or net price of a drug. **Ms. Bass** said typically the list price. **Rep. Carter** asked how spread pricing impacts drug prices. **Mr. Miller** said he has concerns about prior notice of price increases.

Rep. Sarbanes asked how the pricing information that is currently released differs from the information that would be required by these bills. **Mr. Isasi** said that currently available information is not sufficient. **Rep. Sarbanes** asked what concerns the witnesses have with the transparency proposals. **Ms. Bass** said that CBO has estimated that making prices public would deter manufacturers from discounting as deeply. **Mr. Isasi** said there has to be transparency with teeth.

Rep. Gianforte asked what kind of burden the reporting requirements of these bills would have on companies. **Mr. Holtz-Eakin** said that the reporting requirements are very extensive. And if they apply retroactively, some companies might not have the records to comply. **Rep. Gianforte** asked if there are areas of health care besides drugs that should report price increases as well. **The witnesses** said there should be more transparency across all of health care.

Rep. Guthrie asked if information regarding samples should be shared with select entities or publically posted. **Ms. Feldman** said that public posting risks having unintended consequences. **Rep. Guthrie** asked how Congress can ensure that its transparency requirements don't drive anticompetitive behavior. **Mr. Holtz-Eakin** said that details of negotiations shouldn't be made public.