**House Committee on Energy and Commerce**

*Making Prescription Drugs More Affordable: Legislation to Negotiate a Better Deal for Americans*

10:30 am, 2322 Rayburn House Office Building

Purpose

*The purpose of the hearing was to consider four bills: H.R. 3, the "Lower Drug Costs Now Act of 2019", H.R. 275, the "Medicare Prescription Drug Price Negotiation Act of 2019", H.R. 488, the "Medicare Drug Price Negotiation Act", and H.R. 1046, the "Medicare Negotiation and Competitive Licensing Act of 2019'*

Members Present

Chairman Eshoo, Ranking Member Burgess, Representative Pallone, Walden, Matsui, Upton, Welch, Lujan, Butterfield, Shimkus, Castor, Griffith, Sarbanes, Long, Kennedy, Bucshon, Schrader, Carter, Brooks, Ruiz, Hudson, Blunt- Rochester, Gianforte, Cardenas, Bilirakis, Guthrie, Flores, Engel, Walberg, Latta,

Witnesses

**Robert Fowler, Ph.D.,** Professor Emeritus, Baldwin Wallace University
**Gerard Anderson, Ph.D.,** Johns Hopkins Bloomberg School of Public Health
**Benedic Ippolito, Ph. D.,** Research Fellow in Economic Policy Studies, American Enterprise Institute

Opening Statements

**Chairman Eshoo** said millions of Americans are fighting not only their illness but also the cost of their medications. Many Americans are rationing insulin and delaying or foregoing necessary treatment. There is a law in the United States that prevents Medicare from negotiating drug prices. Some of the bills being considered today deal with this issue directly. The rest of the world negotiates drug prices and it is time for the United States to catch up. H.R. 3 also caps out of pocket costs for seniors and prevents predatory price hikes on prescription drugs. H.R. 3 includes many policies that President Trump and many Republicans have publically supported. These bills are not representative of socialism and there are many areas of agreement among Democrats and Republicans.

**Rep. Matsui** said that seniors spend a significant amount of money for prescription drugs, especially for individuals with a fixed income. It is this committee's duty to lower drug costs for the average American and increase accessibility.

**Ranking member Burgess** said that every representative has heard horror stories from constituents about the price of prescription drugs. This committee has continued to push forward with bipartisan hearings and discussions. However, this bill seems to be a partisan exercise and left little time to evaluate the legislation. This committee has a history of achieving results by working together instead of working in a partisan manner. Going forward we should be able to continue a bipartisan dialogue as opposed to being shut out of the negotiating room. H.R. 3 is a proposal that was drafted behind closed doors and is being forced through this committee by the chairman. We need a 21st century payment

system for 21st century cures, this is not what the bill does. Furthermore, the government should not be limiting consumer choice.

**Rep. Pallone** Today is the beginning of an important process to allow the secretary to negotiate drug prices. For too long the United States has been subsidizing drug prices around the world. These negotiations would not just affect Medicare beneficiaries, but every American that is concerned with high drug prices. While members feel that this process has been partisan, it should be noted that there is bipartisan hearing happening today. Additionally, the president has explicitly stated his support for proposals within H.R. 3.

**Rep. Welch** said this committee has a decision to make. The decision is whether or not to be consumer advocates. H.R. 3 does four really good things. First it sets a limit on the price of drugs. Second it spreads the benefits out across the population. Third, it will save billions of dollars. Fourth it will pass the savings onto the Medicare program.

**Rep. Lujan** said that it is time to come together to get this done. After Speaker Pelosi released the bill, even the President expressed his support.

**Rep. Walden** said there is no debate that Democrats and Republicans want to work together to lower drug costs. He said he wanted to express great frustration that this bill was crafted behind closed doors after the committee had already been working in a bipartisan manner to create legislation. This committee has worked in a bipartisan manner up until now. Congress needs to work together along with President Trump. Unfortunately that is not what this committee is doing. This is partisan politics at its worst. This plan puts politics over progress and there is concern that there is no room for negotiation to be had. There is a way to make the free market works for consumers and Republicans remain committed to do that.

<u>Testimony</u>
**Dr. Fowler** said that he was diagnosed in 2006 with an incurable blood cancer. The list price for his medication is $200,000. He has learned as a cancer patient that innovation is crucial to survival but so is price accessibility. As a Medicare beneficiary he will pay about $12,500 annually out of pocket for his medication. Under current law, Medicare is prohibited from negotiating prices with a manufacturer. Thus as a result, drugs purchased through Medicare are more expensive than almost anywhere else in the world. Furthermore nine out of the ten largest drug companies in the US spend more in marketing than R&D. Tax payers must have a mechanism to push back against high drug prices. Medicare should be allowed to negotiate directly with drug prices. Americans should have access to lower priced drugs. Finally, seniors should have a cap on out of pocket costs for prescription drugs.

**Dr. Ippolito** said that prescription drugs can offer a tremendous hope for patients but also present immense burdens. Medicare Part D does not reduce financial risk in the way that insurance is intended to. There are a number of problems with H.R. 3. First, the penalty

applied on manufacturers for walking away from negotiations is far too step. Second, the secretary has almost all leverage in the negotiation. Finally the economic literature states that the economic returns of expensive drugs has increased research and development. Under H.R. 3, drugs with no competition would be subject to intense rate settings. However, drugs with only one viable competitor would not be subject to such rate settings. There is concern that this would make it more profitable to be the second player on the market and discourage manufactures from creating ground breaking innovations.

**Dr. Anderson** said that economics teaches that competition brings reasonable prices to the market. When products do not have appropriate competition, economists consider it to be a market failure. This committee should try to focus on where market failure is the greatest. Some control over prices is absolutely necessary. When drugs do not have a therapeutic alternative, the secretary has no negotiating ability. H.R. 3 attempts to address this problem. There also should be no fear that international price setting will increase drug prices in other countries. The evidence does not support this idea. While many are concerned that H.R. 3 will limit innovation, this is not be the case. Without research, drug companies will have no product to sell. Drug companies may have to reduce their advertising budget but it does not mean they cannot invest in research and development.

Questions and Answer

**Chairman Eshoo** asked Dr. Fowler what drug he takes. **Dr. Fowler** said Revlimid. **Chairman Eshoo** asked if this drug has any competition. **Dr. Fowler** said no. **Chairman Eshoo** asked how much this drug costs. **Dr. Fowler** said that over ten years his private insurance company paid about $1.4 million for his prescription. **Chairman Eshoo** asked if drug companies in the US resemble monopolies. **Dr. Ippolito** said yes and that is by legislative design.

**Rep. Burgess** asked if it is true that allowing the Secretary to negotiate drug prices would not translate to significant budgetary savings. **Dr. Ippolito** said yes because the Secretary cannot exclude a drug from a formulary so there is no leverage. **Rep. Burgess** asked if H.R. 3 could stifle innovation. **Dr. Ippolito** said it could, but there is no certainty. **Rep. Burgess** asked if the excise tax in H.R. 3 would get returned to the consumer. **Dr. Ippolito** said no.

**Rep. Pallone** asked how much more on average American consumers spend on single source brand name drugs when compared to consumers in other countries. **Dr. Anderson** said on Average Americans pay three to four times more. **Rep. Pallone** asked for an example. **Dr. Anderson** said Harvoni is $11,000 in the US but only $400 in Japan. **Rep. Pallone** asked why it is cheaper in Japan. **Dr. Anderson** said the government in Japan asks pharmacies how much they paid for the drug and then sets rates based on that every single year. This means that every year prices in Japan go down as most pharmacy's buy their drugs below the price set by the government.

**Rep. Walden** asked if any of the countries referenced in H.R. 3 use cost effective standards to determine pricing. **Dr. Ippolito** said yes. **Rep. Walden** asked if it is true that newer medicines are not as readily available in these countries as in the United States. **Dr.**

**Ippolito** said yes, the United States tends to get new drugs faster. **Dr. Walden** asked what effects this has on patients. **Dr. Ippolito** said sometimes this results in not having a necessary drug available at the time it is needed.

**Rep. Matsui** asked what steps congress should take to pass the savings of drug spending onto LIS beneficiaries. **Dr. Anderson** said that increasing the number of people who are eligible for LIS is very important. Furthermore, overall prices need to come down so the government can afford to do that. **Rep. Matsui** asked why out of pocket costs have increased for Dr. Fowler since he became a Medicare beneficiary. **Dr. Fowler** said that his private insurance paid a tremendous amount of his costs and his co-pay was very low, but it is also true that his colleague's premiums went up as a result of his costs. Dr. Fowler said that his out of pocket costs are considerably higher now.

**Rep. Upton** asked if there are considerations in H.R. 3 that would evaluate patient need when determining drug availability. **Dr. Ippolito** said no.

**Rep. Butterfield** asked how capping out of pocket expenses would help individuals like Dr. Fowler. **Dr. Fowler** said it would help everyone to sleep easier at night. It would provide financial predictability and stability. **Rep. Butterfield** asked why drugs like insulin cost so much in the United States. **Dr. Anderson** said that the first thing to recognize is the fact there are only three manufacturers of Insulin in the United States. Furthermore, the competition that exists is insufficient. Manufacturers continue to tweak the product or distribution to inflate the price. **Rep. Butterfield** asked if insulin contributes to high drug costs in the Medicare Part D. **Dr. Anderson** said yes.

**Rep. Shimkus** asked if it is feasible for HHS to correctly come up with a reference price for countries listed in H.R. 3. **Dr. Ippolito** said it would be challenging because drug companies will make it as complicated as possible. **Rep. Shimkus** asked what the market value of Dr. Fowlers drugs are. **Dr. Fowler** said $200,000 a year. **Rep. Shimkus** asked if drug companies would stop innovating if H.R. 3 was passed. **Dr. Ippolito** said that venture capital firms would likely stop investing as much in drug companies and that may reduce innovation.

**Rep. Castor** asked what the non-interference clause is. **Dr. Anderson** the non-interference clause states that there can be no interference of negotiations between a PDP and drug manufacturer. **Rep. Castor** asked if the government should be allowed to negotiate prices. **Dr. Anderson** said yes. **Rep. Castor** asked if negotiation is a market based tool. **Dr. Anderson** said yes.

**Rep. Griffith** asked if the bills before the committee would undermine intellectual property. **Dr. Ippolito** said that the penalty for not agreeing to a price negotiation with the secretary is the forfeiture of intellectual property. **Rep. Griffith** asked if these restrictions would change the way people invested in drugs. **Dr. Ippolito** said yes. Mainly venture capitalists can invest anywhere they want and would probably be dissuaded from investing in pharmaceuticals.

**Rep. Sarbanes** asked why the cap for out of pocket costs for seniors in H.R. 3 was set at $2,000. **Dr. Anderson** said there is broad agreement that there should be an out of pocket cap. The disagreement is on the specific number that the cap is set at. About 4 ½ percent of Medicare beneficiaries are affected by the $2,000 cap. Furthermore, it does not cost significantly more to impose this cap.

**Rep. Long** asked why it is a bad idea to try to set prices in the United States based on an international reference price. **Dr. Ippolito** said it is important to remember that other countries are solving different prices than the United States is. Since the United States spends so much, it remains the most important payer in the pharmaceutical realm. **Rep. Long** asked what uncertainty H.R. 3 creates between transitioning administrations. **Dr. Ippolito** said any given administration could use the power given to them under H.R. 3 in different ways. The sheer existence of uncertainty is bad for the market.

**Rep. Kennedy** asked if Dr. Fowler received any benefit when the manufacturer of his life saving drug spent 5.7 billion dollars in stock buy-back. **Dr. Fowler** said no.

**Rep. Bucshon** asked if it is ethical to place a dollar amount on a human life. **Dr. Ippolito** said he is not the person to answer that ethical question.

**Rep. Schrader** asked why Medicare should not just apply the VA's price index. **Dr. Anderson** said that Medicare could adopt that policy. However, it is uncertain whether it would be possible to do that for all Americans. **Rep. Schrader** asked for Dr. Ippolito's thoughts on the Senate drug pricing bill. **Dr. Ippolito** said that there are some of the same challenges as in H.R. 3. There still remains a significant amount of uncertainty which is the biggest concern moving forward.

**Rep. Carter** asked if H.R. 3 could reduce innovation and ultimately reduce access to life saving drugs. **Dr. Ippolito** said yes. It is important to think about access today, but it is also important to think about access for tomorrow. The United States has seen a decrease in HIV mortality and that is because of innovation.

**Rep. Welch** asked how stifling innovation can be controlled if price setting is established. **Dr. Anderson** said that innovation is starting at the NIH and academic medical centers. It is not starting at big drug companies. As long as the NIH continues to be funded, there is going to be innovation. **Dr. Welch** asked if it is a good thing to pass savings of reduced drug spending onto the NIH. **Dr. Ippolito** said yes.

**Rep. Brooks** asked if it is possible that the economic incentives put in place by H.R. 3 would encourage manufacturers not to provide lifesaving drugs to certain individuals. **Dr. Ippolito** said it is unlikely. But it may reduce innovation related to new drugs. **Rep. Brooks** asked how H.R. 3 will impact US jobs and workers. **Dr. Ippolito** said individuals who are funded by venture capital firms would be harmed by this legislation.

**Rep. Ruiz** asked how the cost of Medication has impacted Dr. Fowler's life. **Dr. Fowler** said that he has a lot of anxiety about his medical condition. Furthermore the financial uncertainty contributes to this anxiety. **Rep. Ruiz** asked if there are any things in life that he has had to limit due to the costs associated with his medication. **Dr. Fowler** said no. He was lucky enough to have tremendous private insurance.

**Rep. Hudson** asked if the UK is one of the countries referenced under H.R. 3. **Dr. Ippolito** said yes. **Rep. Hudson** asked if there should be a cap on out of pocket costs for Medicare Part D. **Dr. Ippolito** said yes, because insurance is supposed to be about financial risk protection. **Rep. Hudson** asked if we could afford to lose the innovation brought about by drug manufacturers. **Dr. Ippolito** said no, but it is also true that the NIH does important work.

**Rep. Blunt-Rochester** asked what beneficiaries typically reach the catastrophic phase of their drug coverage. **Dr. Anderson** said that it is individuals who have to buy single source brand name drugs. **Rep. Blunt- Rochester** asked why the costs have gone up. **Dr. Anderson** said it is because we have a number of brand new drugs which have no completion, and Medicare cannot negotiate these prices. **Rep. Blunt- Rochester** asked if the $2,000 cap on out of pocket costs for part D beneficiaries is appropriate. **Dr. Anderson** said yes.

**Rep. Gianforte** asked what economic signal H.R. 3 sends the rest of the country. **Dr. Ippolito** said people who invest in drug manufacturing will try to make predictions about the future and realize there is a lot of uncertainty. This will prioritize short term gains over long term costs. **Rep. Gianforte** asked if price controls would limit innovation. **Dr. Ippolito** said yes.

**Rep. Cardenas** asked for a positive or negative experience when transitioning to Medicare. **Dr. Fowler** said his private insurance plan was so easy to navigate but transitioning to Medicare was extremely complicated. He also said that his costs have increased significantly more since moving to Medicare.

**Rep. Bilirakis** asked how prescription drug prices should best be lowered. **Dr. Ippolito** said the focus should be on incentives. So many incentives encourage manufacturers to inflate their list price. **Rep. Bilirakis** asked if the economic incentives in H.R. 3 encourage manufacturers to invest in rare diseases and innovative medicine. **Dr. Ippolito** said that under this proposal, all drugs would be treated differently. These regulations would impact only single source drugs and thus may reduce investment in rare diseases. **Rep. Bilirakis** asked if the United States would remain the leader in pharmaceutical research and development under H.R. 3. **Dr. Ippolito** said he was unsure. But it is possible that the US gets passed by another country.

**Rep. Guthrie** asked if the NIH is a good substitute for private research and development. **Dr. Ippolito** said the NIH does a lot of important work, especially surrounding public

goods. However, the private sector plays a crucial role that would be hard to replace with the NIH.

**Rep. Flores** asked if a 65 percent excise tax would drive businesses to another market. **Dr. Ippolito** said yes. **Rep. Flores** asked if the seizure of intellectual property would drive development to other countries. **Dr. Ippolito** said he is unsure, but it is a possibility.

**Rep. Engel** asked how the "Lower Drug Costs Now Act" would lower seniors out of pocket prescription drug costs. **Dr. Anderson** said that putting a cap on out of pocket costs would not only reduce the overall costs but it would increase predictability.

**Rep. Walberg** asked how to use competition to lower drug prices rather than bureaucracy. **Dr. Ippolito** said there is already a regulatory framework for drugs. Congress can work to make sure that patent thickets and other ever greening style maneuvers are limited. **Rep. Walberg** asked what impact H.R. 3 would have on University funded research centers. **Dr. Ippolito** said that there is not a hard wall between the pharmaceutical industry and academia. They both benefit from each other, so there may be a negative benefit.

**Rep. Latta** asked why some medications are not available in other countries. **Dr. Ippolito** said some countries use forms of negotiation or cost effectiveness analysis that simply takes time. Some countries also may determine that a drug is not worthwhile to cover. **Rep. Latta** asked what options a person has if they are in a country where a medication is not available. **Dr. Ippolito** said the person would be denied coverage and the country may potentially reenter into negotiations.