Attachments—Additional Questions for the Record

Subcommittee on Health
Hearing on
"Making Prescription Drugs More Affordable: Legislation to Negotiate a Better Deal for Americans"
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Gerard Anderson, Ph.D.

The Honorable Frank Pallone (D-NJ)

Protecting the Medicare Program from Excessive Price Hikes

AARP recently found that retail prices for a combined set of 754 widely used brand name, generic, and specialty prescription drugs increased by an average of 4.2 percent in 2017, well above the inflation rate of 2.1 for the same period of time. And for widely used brand name drug products, these drugs increased in price on average by 8.4 percent from 2016 to 2017. They note that this increase marked the 12th year in a row that retail drug prices have increased faster than inflation.

The AARP's report also found that the average annual cost for a drug used on a chronic basis would have been more than $12,500 lower in 2017 if prescription drug prices had been limited to the rate of general inflation from 2006 to 2017. These price hikes are unsustainable, unwarranted, and demonstrate that the prescription drug market is completely broken.

1. From your perspective, is there an economically sound reason for why annual price increases for widely used prescription drugs are outpacing inflation?

   From an economics perspective, there is no justification for the pharmaceutical industry to have price increases above inflation for an extended period of time.

   The only valid exception is for a short-term prices increase because one component in the drug manufacturing process had an extraordinary increase in the cost. This would most likely not last for more than one year and is very unlikely to actually occur since production costs are typically only a small proportion of total spending by drug companies.

   Once a drug has entered the market, the main justification for cost increases would be the cost of producing the drug. In most cases, this would increase at the inflation rate since the cost of the ingredients to produce the drug would increase at the overall inflation rate.

Research and development expenses used to develop the drug are what economists call "fixed" or "sunk" costs. These are costs that have already been incurred and cannot be used to justify future price increases since the drug company has already built the cost of research and development into the launch price.

Other costs the drug company incurs are marketing and profit. While the drug companies may want to increase their profits or marketing budget these are not valid justifications to increase drug prices.

2. Do you agree that inflationary rebates to the Medicare program for drug price hikes are an important component of an overall strategy to lower drug prices?

   Yes, they are an important component of a larger strategy to control drug prices.

   Drug prices have increased faster than inflation for many years as the AARP data shows. This is especially a burden for the patient since much of the cost sharing is based on the drug's list price. Every time the drug's list price increases it is likely that the patient will have to pay more out of pocket.

   The patient has no ability to negotiate the list price with the drug company. The patient's only recourse is for the patient to not take the drug and this could harm the patient's health.

   PBMs and PDPs have perverse incentive to allow the list price to increase. When the list price increase, the rebates the PBM/PDPs earn form the drug companies can increase and the PBM/PDPs earn larger profits. Drug companies are willing to raise the list price in order to get favorable placement on the PBM/PDPs formularies

   Having an inflationary rebate creates an economic incentive for the drug company to consider when it decides to increase the list price to try to get favorable placement on the formulary.

3. Can you discuss the value of applying these inflation penalties to all drugs in the Medicare Part D program if they cost more than $100 – regardless if they are branded sole-source drugs, or expensive generics that also could be increasing their prices?

   Branded drugs have government given monopolies – patents and market exclusivity periods. One of the first things you learn in basic economics is that monopolies will price their products to maximize their profits and that the consumer has little bargaining power.

   As a result, it is important to place a constraint on the price increases that branded drug companies are permitted to charge. The existence of the monopoly power given by the government makes this inflation penalty necessary.

Generic drugs costing more than $100 are most likely the result of a lack of a competitive market for that drug. We all remember Martin Skhreli and his drug Deraprim. He was able to raise the price of the drug by 5000% because there were no competitors to Deraprim. Deraprim is sold to only a few thousand patients a year and no other generic company finds it profitable to enter the market. Deraprim effectively had a monopoly and Martin Skhreli took advantage of the situation.

It is necessary to control the rate of increase in drugs that cost more than $100.

Enforcement Mechanism to Bring Manufacturers to the Table

Dr. Anderson, you stated in your testimony that bringing drug companies to the table to negotiate in good faith is a critical aspect to successful negotiation legislation.

You note that an enforcement mechanism needs to be big enough to incentivize drug manufacturers to participate while also effective enough to ensure the federal government will utilize the penalty as needed.

4. Why is an enforcement provision necessary to ensure good faith negotiations occur between the Secretary and a drug manufacturer?

   When there is a negotiation both sides need to have to have an incentive to negotiate in good faith. Drug companies have a government granted monopoly – patents and market exclusivity periods- which means they do not have an incentive to negotiate in good faith. They could, for example, offer to lower the price by one dollar for a drug that cost $10,000 or more. This would not be a good faith negotiation.

   An enforcement mechanism is needed to bring them to the table.

   Likewise the Secretary needs to have an incentive to negotiate in good faith and attempt to get lower prices for the Medicare program, individuals. Insurers and self insured companies.

5. Without an enforcement provision, is it unlikely that a negotiation bill would result in savings to the Medicare program or to consumers?

   The CBO has repeatedly argued that without an enforcement mechanism, the government could not negotiate effectively with the drug companies since the drug companies have the monopoly and monopolists do not have to bargain.

   The Congressional Budget Office has recently announced savings from HR3. https://www.cbo.gov/system/files/2019-10/hr3ltr.pdf

   As noted in my response to question 4 there needs to be a mechanism to bring both sides to the table and have an incentive to bargain in good faith. The CBO has deemed what is HR3 to be sufficient to allow a calculation of savings.

6. Does the use of an excise tax – instead of for example, restricting the drug from a formulary – ensure that consumers still can access the drugs they need while still providing leverage in a negotiation?

   Many countries use formulary design to limit access to certain drugs. This will restrict access. All the PBM/PDPs use formulary design to limit access to certain drugs. In both cases, the government in other countries or the PBM/PDP is restricting access or "rationing" the use of certain drugs.

   Formularies can provide value to the patient if they are used to keep patients away from drugs with less clinical value. They can also have value if they keep patients away form more expensive drugs with the same clinical value as other less expansive drugs. A concern occurs when the government or PBM/PDP has different incentives and may be choosing the drug because it gets a bigger rebate. This has been shown for PBM/PDPs which have drugs on the formularies that are more expensive because they can earn rebates .

   Having an excise tax does not create these same incentives. It would raise money only if the drug company raised the price above the rate of inflation. It would not distort the market because it applies equally to all drugs.

   Consumers would still have the same access to drugs with or without the excise tax.

   The benefit for the consumer is that the excise tax would provide an incentive for the drug companies to be less likely to raise the prices and therefore patients would pay less out of pocket.

7. Does the enforcement mechanism in H.R. 3 strike the appropriate balance that you discussed in your testimony?

   There are many different ways to have an enforcement mechanism. The approach in HR 3 is reasonable.

   The key thing is that the enforcement mechanism must be sufficiently large to bring the drug company to the table and be not so onerous that the government is unwilling to actually use the enforcement mechanism.

   I cannot tell you if the 65% tax is the correct amount. I understand the Joint Tax Committee provided guidance on the precise level and I would defer to them.

   The Congress might consider having the GAO evaluate the enforcement mechanism after a year or two following enactment to see if it is calibrated correctly.

   Having a monetary penalty that can be adjusted if needed is a good idea.

Effectively Negotiating for Certain Selected Drugs

H.R. 3 provides the authority to the Secretary to negotiate on a certain subset of sole-source drugs that lack competition in order to target the drugs that are costing our health care system the most and represent the highest proportion of spending.

8. Do you believe that targeting a certain subset of drugs for negotiation is a better use of resources by the Secretary?

   Yes it is important to focus negotiations on drugs where there are high levels of spending and where the differential between what the US and other industrialized countries pay is the greatest.

   We published a study in the journal Health Affairs showing the differential in pricing for 79 brand name drugs that do not have generic alternatives (Kang, S. Y., DiStefano, M. J., Socal, M. P., & Anderson, G. F. (2019). Using External Reference Pricing In Medicare Part D To Reduce Drug Price Differentials With Other Countries. Health Affairs, 38(5), 804-811.) We chose to focus our attention on these drugs because they represent half of all drug spending in the Medicare program.

   The Ways and Means Committee staff replicated our research and expanded the list of comparator countries and found a similar differential between what the US is paying for drugs and the other countries are paying. The differential averages 300 to 400% what the other countries are paying but the variation is quite substantial across the drugs. Some drugs are only 30% more expensive while others are 6000% more expensive.

   It makes sense to focus the attention on the drugs with the highest Medicare spending and the drugs with the greatest price differential.

9. From your perspective, is it necessary that the Secretary negotiate on all drugs covered under Part D? In many cases aren't market forces through generic competition effectively controlling prices?

   It is not necessary for the Secretary to negotiate all drugs. In fact, negotiation would be a waste of effort for many drugs.

   Most of the drugs used by Medicare beneficiaries are generic drugs where there is robust competition. When there is robust competition there is no need for negotiation. This represents almost 90% of all drugs sold to Medicare beneficiaries.

   When there are generic competitors to branded drugs the level of competition is generally sufficient to obtain reasonable prices. There are however exceptions and probably the most serious exception is when there is pay for delay and the generic drug is not being actively sold on the market.

10. Would it be logistically feasible for the Secretary to negotiate on all drugs in the Medicare Part D program?

    It would be feasible to negotiate for all drugs but it is not practical.

    There are over 60,000 different NDCs or unique drugs. Each NDC is a drug with a certain dose, means of administration, etc. The price of each NDC would have to be negotiated separately. This would be impractical. It makes sense to focus on the drugs with the highest prices: those with the greatest differential between what the US pays and other industrialized countries pay; and those drugs responsible for the most spending in the Medicare program.

11. On what drugs can the Secretary get the most "bang for our buck" and do you believe that H.R. 3 creates the right framework to achieve this?

    The drugs that would provide the most "bang for our buck" are drugs with the highest level of spending in the Medicare program and drugs with the greatest differential between the prices charged in the US and other industrialized countries.

    HR3 defines these drugs as drugs that are branded drugs without generic substitutes. These are the drugs that tend to have the highest Medicare spending and the greatest differential between the US and other industrialized countries.

NIH Research Key to Drug Development

H.R. 3 would reinvest billions of dollars in the search for new breakthrough treatments and cures at the National Institutes of Health (NIH). Based on data from a survey of PhRMA's own member companies, one out of every three dollars spent on drug research comes from American taxpayers.

12. Of the top selling drugs, how many NIH-funded research projects were associated with the development of each drug?

    We investigated the drugs that had the largest sales over the past 5 years, the drugs that had the largest sales in 2018 and the drugs projected to have the largest sales in 2022. We found that 14 out of 15 of these top-selling drugs were developed with funding from the NIH.

    Most of these drugs had received 20 or more NIH grants and some had over 300 NIH grants. Two of the drugs had over $250 million dollars of NIH funds invested in their development.

13. For the companies that owned intellectual property on the top selling drugs, what is the total amount of NIH funding that benefited each company?

We are having difficulties answering this question because drug companies buy and sell drugs to each other.

Instead we investigated NIH's role in the 15 top selling drugs. These include 5 drugs with the highest US sales in 2017, 5 drugs with the highest US sales in 2017 that were launched since 2014, and 5 drugs launched in 2017 that are expected to have highest sales in 2022.

To evaluate NIH's role, we identified all associated projects in the NIH RePORTER system using a search of all project abstracts containing the underlying drug molecule. This resulted in 619 unique core projects. These core projects were associated with $3.7 billion in NIH funding (see Table 1). The funding for all associated sub projects was $970 million.

Table 1: NIH Core Project Funding Fro 15 Top Selling Drugs

DRUG	TOTAL NIH INVESTMENT
DUPIXENT	$35,100,000
ELIQUIS	$15,000,000
ENBREL	$1,120,000,000
GENVOYA	$28,500,000
HARVONI	$14,000,000
HUMIRA	$196,000,000
IMFINZI	$31,900,000
JANUVIA	$276,000,000
OCREVUS	$288,182
OPDIVO	$790,000,000
REMICADE	$838,000,000
TECFIDERA	$94,200,000
XARELTO	$211,000,000
ZEJULA	$51,600,000
TOTAL	$3,701,588,182

The Honorable Diana DeGette (D-CO)

As co-chair of the Congressional Diabetes Caucus, particularly combatting the skyrocketing cost of insulin has been at the forefront of my work. The price of insulin has doubled since 2012, which follows a nearly 300 percent increase between 2002 and 2013. I am particularly supportive that H.R. 3 includes insulin as one of the drugs that would be considered for negotiation by the Secretary.

1. How would this negotiation process bring down the list price of life-saving drugs, like insulin, for patients who need them to survive?

   Insulin is a drug used by many patients and unfortunately the prices of the insulin

drugs keep increasing. The market is not operating effectively for patients with diabetes.

HR3 would bring down prices for insulin in several ways

1) *There would be strong incentives for the drug companies not to increase the prices of insulin above the rate of inflation or they would need to pay a significant penalty*
2) *There would be a limit of 20% above the prices paid in other countries for insulin. International data shows that insulin prices are much higher in the US than in other countries.*
3) *The federal government would negotiate prices for insulin*
4) *If a new drug to treat insulin the company was developed the company would be able to charge what ever they wanted BUT if the price was more than double what the company received in other countries it would have to pay back the difference.*

In combination, these four approaches will dramatically lower the prices for insulin and other similar drugs.

The bills being discussed today heavily focus on giving the Secretary of Health and Human Services the ability negotiate drug prices directly and introducing an out-of-pocket cap on Medicare Part D drugs.

2. What more could be done to ensure all patients, regardless of what health insurance plan they have, have affordable access to life-saving drugs?

Access is critical for patients

HR 3 is a very important step in bringing down drug prices and improving access. In my opinion, we should allow this approach to operate for a few years and then see what other adjustments are needed.

The House has already taken very important steps to address the problems of pay for delay and passed CREATES that keeps drug companies from preventing getting access to their drugs so that they can copy them and create generics.

At some time, Congress will need to address the fact that the orphan drug legislation needs revision. Many of the top selling drugs has orphan status and this granting of orphan status allows them to earn huge profits. Six of the top 10 drugs sold in the US have orphan status.

Congress will need to look at possible revisions to the Orphan Drug Act. One possibility is to limit the total number of people to 200,000 instead of the current provision which limits each disease to 200,000 but allows the drug company to have many different orphan diseases that add up to more than 200,000 lives and also allow orphan status for blockbuster drug.

Creating pathways for a robust, innovative, and competitive drug market has long been one of my priorities.

3. How would the bills being considered effect (1) the innovation of new and generic drugs, and (2) patient access to drugs, both brand name and generic?

   Generic drugs are copies of branded drugs so they are not innovative.

   I share your concern about the effect of HR 3 on innovation for branded drug companies. As someone who has spent the last 37 years as a professor at Johns Hopkins, I totally support innovation.

   Drug companies will continue to support research because without new drugs the brand name drug companies will have nothing to sell. They must invest in research to have a product.

   Hopefully the NIH will continue to conduct research that leads to drug development

   Currently, the largest drug companies allocate more resources to marketing than to research. Large drug companies spend less than 20% of the total revenues on research. This may need to change. There may be fewer drug commercials on TV.

   It is unlikely that US researchers would suffer if the US paid lower prices for drugs. While the drug companies might reward countries that pay higher drug prices on the margin, drug innovation occurs where the best scientists are located. The US has many of the best universities in the world and this is where most of the drug discoveries will occur.

   Increasingly drug research is initially being done in academic medical centers and then the drug companies purchase this research at a later stage of development.

   A recent example of this pattern of drug development was the first effective Hepatitis C drug. The initial research was conducted at Emory University, funded by the NIH, and then Gilead purchased the rights to the drug for almost $11 billion dollars.

4. As laid out in H.R. 3, if the Secretary were to directly negotiate prices on certain single source drugs, what would be the impact, if any, on PBM's negotiated prices on other drugs? Would PBMs and prescription drug plans offset the lost costs on the remaining negotiated drugs on their formularies as a result of direct negotiation?

   This is a good question and there is no real data to answer this question since this event has not happened.

   However, economic theory would suggest that here would be no impact because each negotiation for the drugs is unique. The PBM is trying to get the lowest price with the

highest rebate while the drug company is trying to get the highest prices with the lowest rebate and still have the drug remain on the formulary.

It is very doubtful that the drug companies would allow them to get lower prices or higher rebates simply because they cannot get the same amount of profit now that the government is engaged in negotiation

5. Additionally, how would negotiated drug prices for Medicare patients impact savings on drugs for patients on other insurance plans such as private insurance plans?

   The House Education and Labor Committee had a hearing on this topic the day after the Energy and Commerce Committee hearing.

   There is no data to examine to see how the program would affect other insurers so I must rely on economic theory to answer your question.

   My expectation is that the self-insured companies are negotiating as hard as they can either directly or through their PBMs to get the lowest prices possible. I expect that they would continue to aggressively negotiate prices. As a result, the prices that they pay would remain unchanged.

   More importantly the insurers and self-insured companies would also benefit from the government negotiation since the prices would apply to them if they chose to have them apply. They could also opt out if they choose.

The Honorable Robin Kelly (D-IL)

It is critical that we work together in Congress to ensure all individuals have access to the medication they need at an affordable price. H.R 3 not only allows for the Secretary to negotiate the price for certain prescription drugs in the Medicare program, the bill also requires that this price be made available to insurers in the commercial market, as well as the group and individual markets, should they choose to accept it.

While the maximum fair price agreed to by the Secretary and a manufacturer will be the price applied across Medicare Part D and Medicare Advantage, it will be up to the individual health insurer to determine whether to accept the maximum fair price for their commercial market book of business.

1. What does it mean that the prices negotiated by the Secretary can apply outside of the Medicare program to the commercial market as well?

   Self-insured companies and insurers would have the option of using the negotiated prices.

   Given that currently the self-insured companies seem to be paying similar prices to what the Medicare program pays, it would make sense for them to adopt Medicare

prices. The reason that they pay similar prices is that the same PBMs negotiate from Medicare and private sector prices and we have seen no evidence that they negotiate different prices for the public and private sectors. However, this data is confidential and there could be differences. However, when we look at the prices paid by Medicare beneficiaries and privately insured patients the prices seem to be similar.

2. Does this protect against the likelihood that drug manufacturers would attempt to increase their prices elsewhere to offset the reduction in price in the Medicare program?

   For drugs where the government negotiates prices, the self-insured companies and health insurers would be protected assuming they chose to use the government negotiated prices.

   There is the possibility that the prices could increase in the private sector because the inflationary excise tax does not apply to the private sector. However, I do not see this as a major concern because the drug companies will not want to pay the excise tax if they raise the price to the Medicare program and this will protect the private sector from price increases.

3. What impact does the publication of the maximum fair price have on increasing transparency and negotiating leverage for other payers?

   *PBMs, self insured companies and insurers will have information on what other countries are paying for dr*ugs *and what the government is paying for drugs. This will help in their negotiations*

The Honorable Greg Walden (R-OR)

1. Isn't it true, even with higher costs, spending on retail prescription medicines is only 10% of health care spending – the same as it was in 1960? In contrast, isn't it true that hospital care spending is about 32% and physician and clinical services spending is about 20%? Why is there an almost no focus on any other aspect of healthcare spending? Don't we risk losing cures that could lead to savings for the rest of the healthcare industry if we adopt prescription drug policies that take away incentives to invest in new and previously untreated disease areas? Dr. Anderson, given that other areas of the healthcare sector have higher spending than prescription medicine would you support a 120 percent cap based off of European reimbursement for hospital services?

   I agree with you that we should also tackle the prices in other parts of the health care industry

   I have written many papers about the high prices of hospital, physician, drug and other services. Two of the papers I would recommend reading are (Anderson, G. F.,

Reinhardt, U. E., Hussey, P. S., & Petrosyan, V. (2003). It's the prices, stupid: why the United States is so different from other countries. Health Affairs, 22(3), 89-105 and Anderson, G. F., Hussey, P., & Petrosyan, V. (2019). It's still the prices, stupid: Why the US spends so much on health care, and a tribute to Uwe Reinhardt. Health Affairs, 38(1), 87-95.

These papers argue that prices for hospital, physician and drugs services in the US are too high. The problem with US health spending is not that we get too many services, but the prices for the services that we receive are too expensive. This applies to hospital services, physician services and drugs.

In 1983 when I worked in the Reagan Administration, I helped design the Medicare Prospective Payment System. It moved the hospital system away from a cost based system to prospective system that encourages hospitals to control spending.

Have we done enough to control hospital spending? Absolutely not! The private sector is now paying twice what Medicare is paying for the same services. The private sector cannot negotiate effectively with hospitals that control the market in most communities. Everyone insurer needs the dominant hospitals in their network to sell insurance. The market is not working.

If you look at the hospital prices in the US compared to the other countries you will see that the US prices are much higher than other countries. The idea of 120% of external reference prices for hospitals services is an interesting idea but I would not support it for one main reason.

Drugs are the same in all countries. You can easily compare prices when it is exactly the same product. However, hospitals services are not the same product. It is not possible to compare a hospital visit in Japan to a hospital visit in the US because they are different.

I participated in a study attempting to compare the prices and inputs in several countries and got virtually nowhere. We made minimal progress in Japan after much work (Inokuchi, T., Ikegami, N., Gupta, V., Rao, S., & Anderson, G. F. (2013). Comparison of price, volume and composition of services provided to inpatients for two procedures between a US and a Japanese academic hospital. Health, 5(4), 703-11). This is because the hospital product is so different in Japan and the US. However, both use the same drug.

You are correct that the percentage of drug spending has remained around 10% for many years. However, this figure does NOT include drug spending that occurs in doctors office or in the hospital. When those expenditures are included the percentage increases to 17 or 18% in most years.

It would be like counting only Part D spending and ignoring Part B drug spending and ignoring all the expansive drugs that hospitals administer in the Medicare Part A

program.