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House Committee on Oversight and Reform

What We Know and Don't Know about Drug Pricing

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Chairman Cummings, Ranking Member Jordan, and members of the House Committee on Oversight and Reform, I am pleased to testify today. It is good to be back testifying in front of this committee. This is my sixth time testifying before the House Oversight and Reform Committee- twice on hospital pricing and now four times on drug pricing. I am also pleased to note that three times the Republicans and three times the Democrats have asked me to testify.

I am a professor at Johns Hopkins University testifying in my role as a professor and not on behalf of Johns Hopkins University.

I lead a team of 20 faculty members from the medical school, public health school, business school, and pharmacy department at Johns Hopkins studying a wide variety of drug pricing issues. The topics we research include: the drug supply chain, the cost of conducting research and development by drug companies, the operations of pharmacy benefit managers, orphan drugs, and a wide range of other topics. Our research has been published in New England Journal of Medicine, JAMA, Health Affairs and many other peer reviewed journals.

The main reason why I am so excited to testify today is that research on certain policy topics requires access to confidential data. In my testimony today, I will explain what we have learned from existing data and then highlight gaps where the investigations by the Oversight Committee are vitally important.

This morning I will focus on seven topics where the investigations by the Oversight Committee are critical.

- 1. How do branded drug companies justify their recent price increases?**
- 2. Why does it cost so much to develop a new drug?**
- 3. Why do PBM/PDPs place more expensive drugs in preferred positions on formularies?**
- 4. Why do some blockbuster drugs also have an orphan drug status?**

5. **How do PBM/PDP's manipulate direct and indirect remuneration to increase costs to Medicare and Medicare beneficiaries?**
6. **Do drug companies attempt to influence the patient assistance programs they support financially?**
7. **Do drug companies attempt to influence the patient advocacy groups they support financially?**

For each topic, I discuss is what we can learn from existing data and what the Oversight Committee should investigate because independent researchers do not have access to this data.

1. **How do branded drug companies justify their recent price increases?**

In the US, branded drug companies are much more likely to increase prices than to lower prices. According to a recent Associated Press story there were 96 price increases for every price decline in 2018¹. In other countries, the prices of branded drugs typically go down over time.

According to economic theory, research and development are fixed or sunk costs and cannot be used to justify price increases. Once the drug company has spent the money on research, there are no additional research costs that can be used to justify subsequent price increases.

The production costs of most drugs are relatively small – often pennies per pill. Inflation is still low so most drug price increases cannot be justified by higher production costs.

One possibility is that drug companies are raising prices because the PBM/PDPs are taking a larger and larger share of the revenue. Some of the drug companies have suggested this is happening.² However, there is no systematic evidence concerning why the drug companies are raising prices. All the information concerning their rationale for the price increases is proprietary and confidential.

¹ <https://www.ajmc.com/newsroom/ap-for-each-drug-price-cut-there-were-96-price-hikes-this-year-so-far>

² <https://www.jnj.com/latest-news/2017-janssen-us-transparency-report-top-5-things-you-need-to-know>

We did a survey of medical and public health students at Johns Hopkins and then a survey of 1000 eminent economists in the US³. One of the things that students and economists agreed upon was that it is not fair for drug companies to raise their prices without justification.

The House Oversight Committee should ask branded drug companies to explain why they increased prices for specific drugs.

2. Why does it cost so much to develop a new drug and what is included in research costs?

In the economics literature, there are a wide range of estimates of the cost of conducting research and development by drug companies. The most widely quoted cost of developing a new drug is \$2.6 billion.⁴

However this estimate: 1) uses proprietary data on a self selected group of drugs, 2) assumes the cost of capital is 10.5% per year (I would like to get that rate of return on my investments), and 3) was funded by the drug industry. In addition, this same team has developed cost estimates in the past. These studies show dramatic increases in the cost of conducting research by the drug companies over the years. It is unclear why the cost of research has increased so much faster than inflation.

While these number may be correct, we have no way of independently validating these number. However the cost of conducting research is one of the main reasons drug companies use to justify their high prices. We need to know why research is becoming so expensive.

We calculated the cost of developing a new drug using publicly available data instead of proprietary data. Our study used published data from the company's financial reports and we used a lower estimate (and hopefully more realistic) of the cost of capital. Our estimate of the cost of

³ Trujillo, A. J., Karmarkar, T., Alexander, C., Padula, W., Greene, J., & Anderson, G. (2018). Fairness in drug prices: do economists think differently from the public?. *Health Economics, Policy and Law*, 1-12.

⁴ DiMasi, Joseph A., Henry G. Grabowski, and Ronald W. Hansen. "Innovation in the pharmaceutical industry: new estimates of R&D costs." *Journal of health economics* 47 (2016): 20-33.

developing a new drug was \$1.7 billion or 1/3rd lower than the \$2.6 billion number.⁵

However, our study used financial from the drug companies that we do not fully understand or can verify. We cannot look behind the numbers that the drug companies report is the cost of doing research. We have no understanding of how the drug companies allocate costs to research.

We published a study in JAMA internal Medicine showing that the average cost of conducting a clinical trial is \$19 million. This suggests that less than 1% of the cost of doing the research is conducting the clinical trial.⁶ Therefore, we do not think it is the cost of doing the clinical trials to get FDA approval that is responsible for the ever-higher research costs.

What we do not know is what is included in the costs of conducting research. A drug company tells us that they spent \$X billion on research, but we have no idea how they spent this money. We all have a sense of what are research expenses – the salaries of people doing the experiments that lead to drug development and the associated equipment. We have no idea if this constitutes the bulk of what drug company call research expenses.

It is important to look behind the numbers to see how much of the research cost is used to pay the salaries of clinical researchers and purchasing equipment to conduct the research. We also need to know how much of the research cost is involved in determining the packaging and the price of the drug. But we simply do not know. This is all proprietary information.

Perhaps more important is that we do not know very much about the different ways that drug company research is being financed. I think the model that most of us have in our heads is that there is a team of researchers in the labs in the drug company busily developing new compounds and conducting experiments.

⁵ Ballreich, J., Hsu, M., Thayer, A., Bai, G., & Anderson, G. (2017, May). TWO TRANSPARENT METHODS FOR ESTIMATING DRUG RESEARCH AND DEVELOPMENT COSTS. In *VALUE IN HEALTH* (Vol. 20, No. 5, pp. A16).

⁶ Moore, T. J., Zhang, H., Anderson, G., & Alexander, G. C. (2018). Estimated costs of pivotal trials for novel therapeutic agents approved by the US Food and Drug Administration, 2015-2016. *JAMA internal medicine*, 178(11), 1451-1457.

While this is true for some companies, it is becoming increasingly common that the initial research is being conducted in academic medical centers – places like Johns Hopkins or the Mayo Clinic with funding from the National Institutes of Health. The initial research is not being done at the drug company. If the initial research is promising, then the academic medical center reaches out to venture capitalists to fund additional research. If the results are still promising then the entire research portfolio is purchased by one of the big drug companies. In this case, the initial research was not being done at large drug company.

Drugs to treat Hepatitis C are one of the major breakthroughs in the last few years. It is an example of this new financing model. Researchers at Emory University started working on a drug to treat Hepatitis C with considerable funding from the National Institutes of Health. Once they had promising results, the academic researchers formed a company (Pharmasset) that received additional funds from venture capitalists. We believe that Pharmasset received approximately \$200 million in NIH funds and \$200 million in venture capital to conduct the research.

Drug companies have teams that look for promising research and make offers to purchase these small companies with promising research. In this case, Gilead purchased Pharmasset for \$10.5 billion. The question is whether the research involved is \$400 million (of which the NIH funded half) or the cost of the research was \$10.5 billion? Once Gilead purchased the company, Gilead doubled the price of the drug from what Pharmasset was intending to price the drug.

The only reason why we know these facts is that the Senate Finance Committee conducted an investigation of the development of the Gilead's hepatitis C drug.⁷

The House Oversight Committee should use its investigative authority to understand how drug companies allocate costs to research. My suspicion is that many of the items that they include in the calculation of research costs are really not research, as many of us would define research. The

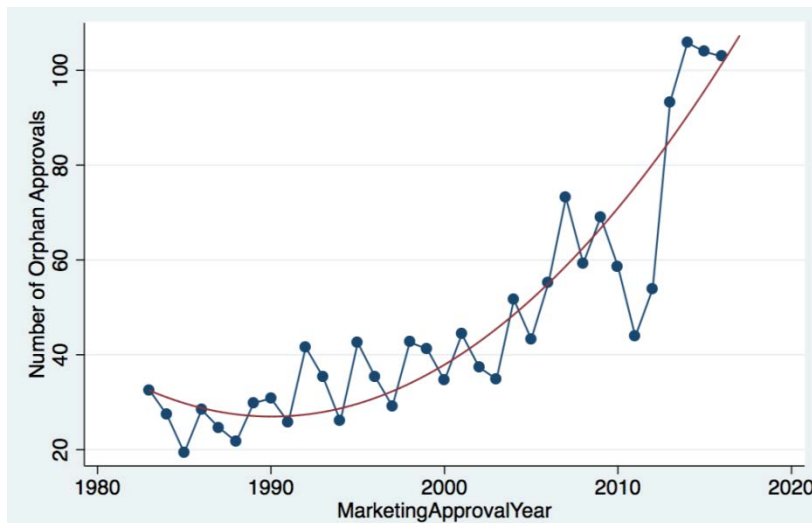
⁷ <https://www.finance.senate.gov/ranking-members-news/wyden-grassley-request-comment-on-sovaldi-report>

Oversight Committee should also examine how the research breakthroughs are being financed.

3. How do branded drug companies use orphan drug status to keep the drug from becoming generic?

When the Congress passed the Orphan Drug Act in 1983, it led to the rapid development of orphan drugs. Exhibit 1 shows that the number of orphan drugs on the market has increased dramatically as the result of the passage of the Orphan Drug Act. However, there is much more work to be done since most orphan diseases still do not have a drug to treat that disease.

Exhibit 1



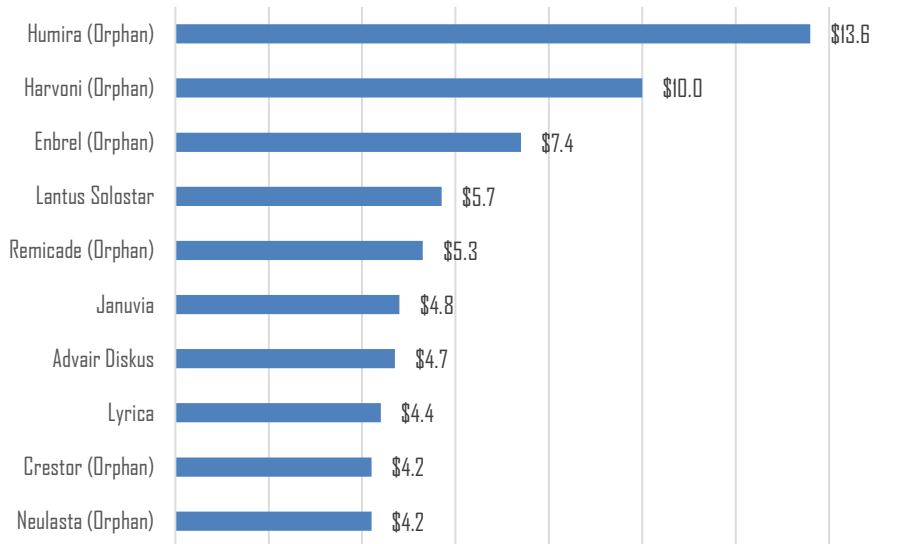
More research on orphan drugs is clearly needed so that all orphan diseases have a drug that can treat that disease.

The problem is that there are potential abuses to the Orphan Drug Act that the Oversight Committee should investigate. The Oversight Committee should examine how drug companies use the orphan drug designation to earn substantial profits on blockbuster drugs.

Exhibit 2 shows the 10 best selling drugs in the US in 2016 and the associated revenues. Surprisingly 6 of the 10 best selling drugs also have an orphan designation. Why would these six of the

ten blockbuster drugs also have orphan status including the three drugs with the most sales?

Exhibit 2 - Total Sales in 2016



We examined when the drugs applied for orphan status and how they have been able to maintain their orphan status for many years. Exhibit 3 shows some of the drugs that maintained orphan status for more than 10 years. Many of the drugs with many years of orphan status are blockbusters.

The key thing to notice is that many of these drugs receive orphan status at periodic intervals. Applying at periodic intervals maximizes their time with orphan status. It appears that the drug companies apply for a new orphan designation when the current orphan designation is about to run out. This timing of the orphan applications by drug companies needs to be studied by the Oversight Committee.

Exhibit 3

Drug	Year																				
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	>20
Adalimumab (AbbVie, Inc.)	A,B	C		1						D, 2,3	E,4,-1	5					-2,-3	-4	-5		
Bevacizumab (Genentech, Inc.)	A			B,C,D			1,2	E,F,G,H				3	4,5			6,7,8,-1,-2				-3,-4,-5	-6,-7,-8
Bortezomib (Millenium Pharmaceuticals, Inc.)	A,B,C,I	2	3		4			-1		D,E,-2	-3	5	-4							-5	
Botulinum Toxin Type A (Allergan, Inc.)	A	B	C			1,2							-1,-2				3				-3
Canakinumab (Novartis Pharmaceuticals Corporations)	A	B	I			C	D,E,2			3,4,5,-1				-2			-3,-4,-5				
Coagulation Factor VIIA (Novo Nordisk, Inc.)	A											1					B,C,D,E,F,G	2,3,4	5,6,-1		7,-2,-3,-4,-5,-6,-7
Everolimus (Novartis Pharmaceuticals Corporations)	A,B	C,D	1	2	3				4	-1	-2	-3									-4
Filgrastim (Amgen, Inc.)	A,B				1,2	C,3	D		4		-1,-2	-3									E,5,-5
Ibrutinib (Pharmacylics, Inc.)	A,B,C,D	E,F,I	2,3	G,H,4	1,5,6	7,8,9			-1	-2,-3	-4	-5,-6	-7,-8,-9								
Imatinib Mesylate (Novartis Pharmaceuticals Corporations)	A,B,C,I	2			D,E,F,G,H,I	3,4,5,6,7		8,-1	-2				9,-3,-4,-5,-6,-7				-8				-9
Lenalidomide (Celgene Corporation)	A,B,C			D	1	2			E			-1	3,-2		4		5			-3	-4,-5
Mitoxantrone (Serano, Inc.)	A,I				2,3			-1				-2,-3									
Ofatumumab (Novartis Pharmaceuticals Corporations)	A,B,C,D,I					2		3,4,-1					-2		-3,-4						

Legend: Letters (e.g. A, B, C) indicate new designations; Bold positive numbers (e.g. 1, 2, 3) indicate approvals; Negative numbers (e.g. -1, -2, -3) indicate the end of exclusivity for the corresponding approval. Gray shaded cells represent the period when a drug was on the market with at least one exclusive indication.

There are two reasons for this stacking behavior. First, the Orphan Drug Act allows a drug to receive orphan status if it treats a patient population of less than 200,000 people. The drug company needs to find a new use for a blockbuster drug that has fewer than 200,000 people with that disease. The Orphan Drug Act does not prevent the drug company from combining different groups of less than 200,000 to form a much larger group. Some drugs with orphan status have combined many patient populations over time and when all these populations are combined the drug has many more than 200,000 people.

The Orphan Drug Act does not prevent the drug company from obtaining orphan status for a blockbuster drug when the drug company can show that some subset of the population is smaller than 200,000. As a result, a blockbuster drug that also treats groups of people that are less than 200,000 can apply and receive orphan status from the FDA. As noted in exhibit 2, 6 out of 10 largest blockbuster drugs also have orphan status. Blockbuster drugs with orphan status are a common occurrence.

The important policy question is why would drug companies want to receive orphan status for a blockbuster drug? How does it benefit the company and how does it harm health insurers and patients?

First, orphan status prevents a generic drug from coming into the market. While the FDA grants this protection for the orphan indication, it makes it much less likely that a generic drug company will enter the market. In theory, a generic could be developed for the other indications that do not have orphan status. In practice, however, orphan status for one indication essentially prevents generic competition.

The two main reasons why generic companies do not enter the market are: 1) how pharmacies stock drugs and 2) how pharmacy benefit managers (PBMs) operate. A pharmacy will not want to stock both a generic version and a branded version of the same drug for liability and other reasons. If the generic version of the drug is prescribed for a patient who had a condition on orphan status and the

patient gets the generic version, then the pharmacy is at risk for not being reimbursed or could face serious liability issues. Second, the PBM will provide a better rate to the pharmacy if the pharmacy only stocks one drug and the pharmacy must stock the drug with the orphan status.

As shown in exhibit 3, the drug company often applies to the FDA to receive orphan status at periodic intervals in order to maintain orphan status. They often make a new application right before the existing approval for orphan status ends. By submitting applications at periodic intervals, the drug company is able to maximize the orphan status for the drug.

We do not know whether drug companies are purposefully stacking the FDA applications to obtain the longest possible time of orphan status or if they are periodically discovering new uses of the existing drug and applying for orphan status based on new clinical research. Our suspicion is that the drug companies knew that the drug could be used on other patient populations when the first application was sent to the FDA and the drug companies stacked the orphan applications to maximize the number of years under orphan status, but we do not know this for sure.

Why is this important? The average cost of conducting a clinical trial is only \$19 million⁸. However, for some drugs an additional year of orphan status can mean an additional \$ 2 billion in revenues for that company. That is a 100:1 return on the clinical trial investment. By stacking orphan designations and dividing the patient population into sub-populations of less than 200,000 people, the manufacturers' behavior increases costs to the public as much as \$2 billion for each additional year of orphan status that each drug is granted.

The House Oversight Committee should examine the timing of orphan drug applications to see if the drug companies are gaming the system.

⁸ Moore, T. J., Zhang, H., Anderson, G., & Alexander, G. C. (2018). Estimated costs of pivotal trials for novel therapeutic agents approved by the US Food and Drug Administration, 2015-2016. *JAMA internal medicine*, 178(11), 1451-1457.

4. How Do PBM/PDP's manipulate Direct and Indirect Remuneration (DIR) to increase costs to Medicare and Medicare beneficiaries?

This is a PBM/PDP related issue with serious implications for the Medicare program and for Medicare beneficiaries. We have a forthcoming blog post coming out in Health Affairs on this topic very soon and the testimony is partially based on the blog post. We are also working with the Senate on the issue of direct and Indirect remuneration.

Medicare Part D beneficiary's cost sharing is often based on the list price of the drug. It is well documented that Medicare cost sharing is increasing. One reason for the increase in beneficiary cost sharing is the rapidly growing direct and indirect remuneration (DIR).

Direct and indirect remuneration is based on the difference between the list price and the transaction price. It reflects various payments made by drug companies and pharmacies to PBM/PDPs after the sale. These payments include drug company rebates, pharmacy fees, and other forms of price concessions. These rebates, pharmacy fees, and other forms of price concessions are important ways that PBM/PDPs earn substantial profits⁹.

In 2012, DIR was \$10.5 billion or 12% of Part D total drug costs. In 2015, DIR more than doubled to \$23.6 billion or 17% of Part D total drug costs.¹⁰ Medicare has not disclosed direct and indirect remuneration amounts after 2015, but I expect the upward trend has continued.

Medicare may not be receiving all DIR that it is entitled to receive. In addition, the current DIR system is distorting market incentives and increasing the level of cost sharing paid by Medicare beneficiaries.

The three main problems with the current DIR system are:

A. Medicare is not receiving all DIR that it is entitled to receive.

⁹ Bai, Ge, Aditi P. Sen, and Gerard F. Anderson. "Pharmaceutical Benefit Managers, Brand-Name Drug Prices, and Patient Cost Sharing." *Annals of internal medicine* (2018).

¹⁰ Medicare Part D – Direct and Indirect Remuneration (DIR). 2017. <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir>

This is because Medicare must specify in advance what should be included in DIR, and the PBM/PDP can then use this information to exclude certain items from DIR. If Medicare says that X should be included in DIR and Y is not mentioned then the PBM/PDPs will do everything possible to classify the expense as Y in order to keep the money themselves.

The Oversight Committee should investigate what money the PBM/PDPs are collecting. It should then determine what is being passed through to the Medicare program and what is not. Any fees that are related to the list price, difference between the list and transaction price, sales volume, or meeting sales targets should be considered as DIR.

B. The current system encourages PBM/PDPs to put high priced drugs with large rebates on the formulary, which adds to the amounts that the Medicare program and Medicare beneficiaries pay.

When drug companies set the list price, a key factor they consider is that they receive favorable formulary placement by the PBM/PDP. The PBM/PDP is more likely to give them favorable formulary placement if the PBM/PDP receives a larger rebate, which is related to a high list price. In most cases, the higher the list prices the higher the rebate.

We examined the formularies of all the 750 PDPs that operate in the Medicare program. To our surprise, we found that many of the PDPs were giving branded drugs more favorable formulary placement over the less expensive generic drugs for the same exact product. This means that Medicare beneficiaries are paying higher out of pocket costs when the more expensive branded drug is dispensed instead of the less expensive generic drug. Medicare is also paying for the more expensive drug.

PBM/PDPs are also giving favorable placement to fixed-dose combination drugs, which are also called “combo” drugs. “Combo” drugs are branded drugs that contain two or more

generic products in the same pill. The cost of these combo drugs can be 100 times the cost of the when the generic drugs purchased separately.

The Oversight Committee should ask the PBM/PDPs why they are giving favorable placement to branded drugs and combo drugs instead of the less expensive generic drugs.

C. The DIR system provides incentives for PBM/PDPs to continually get larger and larger rebates, which adds to beneficiary and program costs.

The Medicare program receives DIR payments based on what the PBM/PDP estimates it will receive in DIR in the coming year. This is typically based on what they received last year. The way the current system operates, if the PBM/PDP receives more DIR in the coming year than it anticipates then the PBM/PDP gets to retain the difference. This is one reason why the DIR increases every year – they are searching for greater and greater DIR that they get to keep for that one year.

The Oversight Committee should ask the PBM/PDPs how they estimate the amounts of DIR that they expect to receive and why they continually underestimate these amounts. The Oversight Committee should ask the Medicare program if they believe the system is being gamed.

5. Why Do PBM/PDPs Place More Expensive Drugs on the Formularies?

The Medicare program requires prescription drug plans (PDPs) to provide coverage of at least two drugs in each therapeutic class (this is different from the protected classes where all drugs must be covered).

The problem is that Medicare lets each PDP define the therapeutic classes. Medicare is supposed to review the formularies every year and make sure that the coverage that PDPs offer does not discourage any group of patients from enrolling in that plan. If a drug is not covered by the

formulary and the drug is critical for beneficiaries with a certain disease, then the beneficiary with that disease will not enroll in that PDP. Certain diseases are treated by only one drug.

In our research, we have found that, there are drugs that treat certain diseases where the drugs are not covered in all the PDPs. If you are a Medicare beneficiary with one of those diseases your PDP might not have that drug on the formulary. For example, there are about one million people diagnosed with shingles in the US every year. One in every five of them may develop post-herpetic neuralgia- a serious complication. Yet, not all PDP plans offer drugs to treat shingles. There are many other examples of where the drug used to treat a specific disease is not on a formulary.

In addition, PDP formularies may change their formularies during the year and it is unclear whether the Medicare program is conducting a thorough evaluation of these changes in order to prevent adherence problems and treatment discontinuation, with potentially negative clinical outcomes. Imagine you are a beneficiary and signed up for a specific PDP because they covered a specific drug only to find out that they changed the formulary during the year and now your drug is no longer covered or has a very bad formulary placement which adds substantially to your out of pocket costs.

The Oversight Committee should ask the Medicare program to disclose the criteria it uses to evaluate the different PDP formularies. It should ask each PDP the therapeutic classification it has elected to follow and the dates and outcomes of the evaluations of each proposed change to PDP formularies in the last 2 years. It should ask PBM/PDPs how they develop the formularies and why certain branded drugs were chosen instead of generic drugs.

6. Do drug companies attempt to influence the patient assistance programs they support financially?

Drug companies provide free coupons for many drugs and provide financial assistance through patient assistance programs for people including Medicare beneficiaries to help them pay their cost

sharing. Many patients benefit from these programs.

Federal law does not permit drug coupons for federal health insurance programs including Medicare because they violate the Federal anti-kickback provisions. Drug companies are permitted to sponsor patient assistance programs through charities, so they are not subject to the anti-kickback provisions. In fact, two of the patient assistance programs are promoted on the Medicare website.

The independence of some of these independent charity patient assistance programs has been questioned by federal authorities, and five pharmaceutical companies have paid multi-million settlements, ranging from \$29 million to \$360 million, for allegedly influencing the operations of the charities.¹¹ The drug companies were accused of requiring the independent charity patient assistance programs to design patient eligibility criteria that restricted benefits to only those drugs manufactured by that company and using information gathered from the patient assistance programs to perform certain types of financial analysis.

Economists believe that coupons and patient assistance programs distort the market by reducing or even eliminating the level of cost sharing.¹² When cost sharing is eliminated, patients do not care how much a drug costs since they are not paying the higher cost. They are more likely to use the more expensive drug even if it has the same therapeutic qualities as the less expensive drug.

We examined the drugs that are mentioned on the Medicare website by the two biggest independent charity patient assistance programs. These two charities operate 123 disease-specific programs. Eligibility for these programs is based on the following criteria: annual household income,

¹¹ Jazz Pharmaceuticals PLC ("Jazz"), Form 10Q Filing, U.S. Sec. & Exch. Comm'n (May 8, 2018), available at <https://www.sec.gov/Archives/edgar/data/1232524/000123252418000094/jazz2018q1doc.htm> (disclosing that Jazz reached a preliminary settlement with DOJ for \$57 million to resolve claims relating to Jazz's support of 501(c)(3) organizations that provide financial assistance to Medicare patients); Settlement Agreement Among DOJ, OIG, & United Therapeutics Corp. (Dec. 15, 2017), available at <https://www.justice.gov/usao-ma/press-release/file/1019336/download>; Settlement Agreement Among DOJ, OIG, Def. Health Agency, & Aegerion Pharm., Inc. (Sept. 22, 2017), available at <https://www.justice.gov/usao-ma/press-release/file/998381/download>; Settlement Agreement Among DOJ, OIG, & Actelion Pharmaceuticals US, Inc. (Dec. 6, 2018)

¹² Dafny, Leemore, Christopher Ody, and Matt Schmitt. "When discounts raise costs: the effect of copay coupons on generic utilization." *American Economic Journal: Economic Policy* 9.2 (2017): 91-123.

insurance status, physician endorsement, prescription information, and the proof of receiving treatment in the US.

Contrary to the assumption that these independent charities will assist everyone in need, all 123 programs required health insurance as the first eligibility criteria. This raises questions about their charity orientation. Why would a charity exclude the uninsured?

The most common income limit employed by the two foundations was 500 percent of the federal poverty level. This is \$125,500 for a family of four in 2018.¹³ Given the current income distribution, about 80 percent of all Americans are eligible for patient assistance. But if you are uninsured, you do not qualify.

The two programs employed varying levels of financial need for the different diseases in spite of DHHS OIG guidelines requiring them to have the consistent dollar thresholds for all disease programs. It is unclear why different income thresholds are being used and if the drug companies are insisting on different thresholds for different diseases.

The charity programs favored the more expensive drugs. In fact, they covered the majority of the most expensive specialty drugs in the US. The covered drugs were 3.4 times more expensive on average than the uncovered drugs. Also, they showed a tendency to cover branded drugs favorably than equivalent generics. This increases the spending by the Medicare program and Medicare beneficiaries.

Although these programs can offset the out-of-pocket cost for Medicare beneficiaries, it left the Medicare program paying more of the cost. Based on the assumption that the beneficiary had the full out of pocket cost covered by the independent charity patient assistance program, then 97% of the total spending for specialty drugs covered by these programs becomes the responsibility of Medicare, other health plans, and subsidy programs. This suggests strategic choices by charities concerning which drugs they will sponsor. This is one reason why spending in the catastrophic portion of the Medicare Part D

¹³ \$60,700 for an individual, \$125,500 for a family of four in 2018. Available at: <https://www.healthwellfoundation.org/wp-content/uploads/2017/12/FPL-Guidelines-2018.pdf>

program is increasing three times faster than overall drug spending. The important policy question is who is making these decisions about the operations of the independent charity patient assistance programs?

It has been suggested that the drug companies receive a 4:1 to 7:1 return on these investments because they allow the patient to get the drug without any cost considerations and therefore the patient may choose the more expensive drug.¹⁴ It is unclear if this is the reason that drug companies contribute to these charity programs.

Another concern is that the charities provide initial funding for the drug and then discontinue funding of the drug after some time period. It is unclear if the reason is to get the person started on the drug and for the patient to see the potential benefits. This makes it more likely that they will stay on the expensive drug. It would be in the drug company's financial interest for this to occur.

The Oversight Committee should review internal drug company records to determine their reasons for the support of coupons and patient assistance programs and their influence on designing these independent charity patient assistance programs.

7. Do drug companies attempt to influence the patient advocacy groups they support financially?

On January 23, 2019, the Washington Post ran an article discussing how drug companies may be using other organizations to argue against the Trump Administration proposal to use external reference pricing in Medicare Part B. There are other examples of organizations receiving funding from the drug industry advocating for certain laws and regulations that might seem contrary to the positions of the patients with that disease.

We examined the funding to patient-advocacy organizations by the ten largest pharmaceutical companies in 2016. We compared the funding given to patient advocacy organizations across eight large

¹⁴ Leemore Daffny, Christopher Ody, and Matt Schmitt, "When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization," NBER Working Paper No. 22745, 2016, at <http://www.nber.org/papers/w22745>.

industrialized countries and the pharmaceutical companies' disclosure practices in each country. We found that only six of the ten largest pharmaceutical companies disclosed their financial transactions to patient organizations in the US, whereas all ten companies disclosed them in France, Germany, and the UK. This suggests that some companies will not choose to disclose the information in the US unless they are compelled.

To our surprise, the six companies that disclosed transactions in the US concentrated 78% of their funding to patient organizations in the US. While European countries have comprehensive voluntary disclosure guidelines at the trade-association level or federally mandated legal disclosure requirements, the US does not have any comparable guidelines or regulations in place despite the much larger funding to US-based organizations.⁸

The Sunshine Act requires drug companies to report payments to physicians. However, there is no similar requirement for drug companies to report contributions to patient advocacy organizations.

The Oversight Committee should investigate the contributions drug companies are making to patient advocacy organizations. The Committee should review the drug company's internal documents to examine how they allocate their funds to and interact with specific patient advocacy organizations, particularly on important drug pricing and drug coverage policy issues.

I am happy to answer any questions the Oversight Committee may have.