

Testimony Regarding:
“Improving Drug Pricing Transparency and Lowering Prices for American Consumers”

U.S. House
Committee on Energy and Commerce
Subcommittee on Health

Douglas Holtz-Eakin, President*
American Action Forum

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Chairman Pallone, Ranking Member Walden, and members of the committee, thank you for the opportunity to testify today regarding H.R. 2113, the Prescription Drug STAR Act—which includes in part or in total: H.R. 2069, the SPIKE Act; H.R. 2064, requiring manufacturers to report certain kinds of product samples provided to health care providers; H.R. 2115, the Public Disclosure of Drug Discounts Act; and H.R. 2087, the Drug Price Transparency Act—as well as H.R. 2296, the FAIR Drug Pricing Act of 2019, H.R. 2376, the Prescription Pricing for the People Act, and the CLAY Act. These pieces of legislation are, as the two main themes alluded to in this hearing’s title suggest, best viewed from the perspective of lowering the prices of prescription drugs and increasing transparency in the pharmaceutical industry. These seemingly straightforward concepts are, unfortunately, not as simple as one might hope.

1. Lowering the prices paid by Americans for drugs is, in itself, a good idea. But the objective presumes that Americans are currently paying “too much” for pharmacological treatments. In fact, the conceptual arguments and evidence are riddled with ambiguity. Prices need to be high enough to sustain innovation, but no more. And measures such as list prices, net prices, out-of-pocket prices, development costs, and total spending on drugs have displayed very different patterns over time.
2. Transparency is a healthy safeguard against abuse, especially in the case of government programs. Transparency taken to an extreme, however, can have negative effects, particularly in the private sector in the context of healthy market-driven competition.

Let me discuss each of these points further.

Identifying the Problem: Patterns in Drug Prices and Costs

The first step in identifying whether there is a drug pricing problem is to differentiate between prices, costs, and spending, which are related but not identical concepts. Concerns about increasing drug prices might refer to a narrow definition focused on the sales prices (or “list price”) set by drug manufacturers. Alternatively, the problem might not be with all drugs, but instead with the high prices of particular drugs. Or the problem may be the increasing prescription drug prices paid by patients at the pharmacy counter, which has resulted—at least in part—from an increase in high-deductible health plans and increasing use of co-insurance (as opposed to co-pays).

We could consider increasing drug costs in the context of overall prescription drug expenditures, whether in dollar figures or as a percentage of National Health Expenditures. Because spending is a function of both price and quantity, this could result from increased utilization due to rising national reliance on prescription drugs or broader access to them. History has proven the best way to reduce the price of a good for which there is growing demand is to increase its supply through competition. For drug pricing, that means bringing generics and biosimilars to market to compete with brand-name drugs.

From my perspective, there is no broad prescription-drug pricing crisis. Indeed, in most instances, things are working just fine. Rather what we face are more targeted challenges. Among them is the price of specialty drugs and biologics, which are expensive to develop and manufacture and frequently treat a limited population. In these instances, particularly with oncology drugs, it is important to make sure that the price of the treatments correlate to the value they provide patients and society as a whole. Is the policy objective ultimately low prices or is it to acquire high-value treatments? It is easy to have low-priced drugs; they, however, may not do much good. Conversely, it might make sense to spend more for a drug if its therapeutic benefits are high enough.

Transparency's Positive and Negative Implications

Many of the bills before this committee today address the issue of transparency. Transparency can bring honesty and integrity to decision-making processes. Transparent pricing information allows consumers to easily differentiate between their cost for products and services, and market competition is enhanced.

Further, when the government has clear information on what is happening within federal programs it can help the government better manage those programs. Several of the policies being considered today seek to provide the government with just such insight. In some cases, however, these policies go beyond that objective in ways that are concerning.

Transparency requirements can have unintended consequences. For example, H.R. 2264—which admirably seeks to expose potential conflicts of interest—might result in fewer medication samples being made available to providers, ultimately harming those patients with constrained ability to pay who benefit most from sample treatments. Caution and a considered examination of the potential side effects of transparency requirements is advisable.

Other proposals under consideration advocate transparency for internal proprietary information of private companies engaged in business transactions with other private entities, as in the case of H.R. 2115. This seems to me an inappropriate overreach. On the other hand, the federal government might well have reason to know some of the information sought in H.R. 2115 in the context of the Medicare Part D program. That information, however, should be held in confidence rather than shared publicly so as to preserve the competitive nature of the program. The government should not, except in exceptional circumstances, expose the details of private contracts between private parties, disclose the proprietary information of private entities, or unnecessarily disrupt the competitive advantages of private actors.

Let me now turn to the specific proposals before the committee today.

H.R. 2069, the SPIKE Act

The Stopping the Pharmaceutical Industry from Keeping drugs Expensive (SPIKE) Act (H.R. 2069) requires the Secretary of Health and Human Services (HHS), at least once a year, to

determine if the price of a drug has increased by a given minimum amount over a specified lookback period, and if so, to require the manufacturer of the drug to submit documentation justifying that price increase.

I have a number of concerns with this legislation. First, the triggers specified in legislation, particularly the last one for newly available drugs with an expected cost or spending per user of \$26,000 or more per year, are arbitrary and will place a significant burden on the manufacturers of new and innovative drugs. This burden could discourage development of new drugs, or at the very least divert important, valuable resources from productive activities.

I am also troubled by the requirement that the Secretary post online alternative percentages, dollar amounts, and lookback periods that, if applied, would increase the number of drugs for which a SPIKE increase would have been triggered, and the number of drugs that would be subject to the triggers, if those benchmarks were applied. Further, I find the information required as part of a company's justification to be overly intrusive. No other industry has such requirements.

Finally, I am not convinced that these requirements will actually do anything to bring down prices, and there are no enforcement measures being granted to make prices come down if Congress learns something it finds objectionable from these reports.

I understand an amendment has been introduced to provide exemptions for new drugs if they treat a rare disease or condition, are the first drug approved to a certain indication, or are designated by the Food and Drug Administration (FDA) as a fast-track product. Such an amendment may mitigate the deterrent effect for much-needed new treatment options. Over 95 percent of the 7,000 known rare diseases still have no treatment option, and drugs now cost more than \$3 billion on average to develop.^{1,2} The chances that a new rare disease treatment would not meet the threshold here are close to zero. Congress should carefully consider these implications.

H.R. 2296, the FAIR Drug Pricing Act of 2019

The Fair Accountability and Innovation Research (FAIR) Drug Pricing Act (H.R. 2296) requires drug manufacturers to publicly report and provide justification for any pending price increases for certain drugs provided to Medicare and Medicaid beneficiaries 30 days prior to the increase. This legislation is similar to the SPIKE Act except that it requires advance notification rather than a post-hoc explanation and is more limited in terms of the scope of the drugs to which these requirements will apply. The FAIR Act focuses on physician- and hospital-administered drugs, and excludes vaccines and drugs used to treat rare diseases or conditions.

Between the two bills, the FAIR Act seems to be more narrowly focused on the drugs which are likely to be the most expensive and may therefore result in less of a regulatory burden for the industry overall. Further, because the legislation does not have a launch-price

trigger and provides exemptions for rare disease drugs, it is less likely to deter the development of new and innovative products.

H.R. 2064, Product Sample Reporting Requirements

The next section of the STAR Act mirrors H.R. 2064, which would require manufacturers of certain drugs, devices, biologicals, and medical supplies to report on product samples provided to certain health care providers. This reporting would be in addition to existing requirements imposed by the Affordable Care Act to report financial interests to the Centers for Medicare and Medicaid Services. Manufacturers providing payments or product samples would now also be required to submit electronically to HHS a form detailing the total quantity and value of all payments or other transfers of value provided to all covered recipients and the name of the drug, device, or supply provided, as well as any other information the Secretary may request. Much of this information is already required to be provided to FDA. This information would also be required to be included in a tax return filed by the company.

This transparency can be very valuable. Taxpayers and consumer deserve to know what factors might be influencing their providers' prescribing decisions. But it is unclear what this reporting requirement will accomplish besides increased regulatory burden and the potential to discourage the provision of samples.

Product samples provide significant patient benefit, particularly when a patient is unsure which product might be best for him or her. The patient can try a product, which might be quite expensive, without worrying about potential sunk cost if it turns out to be ineffective. Free samples are also quite beneficial when an insurance plan requires prior authorization. The free product sample allows the patient to begin treatment right away, at no cost until insurance coverage kicks in. It may be worth monitoring for this possibility and reevaluating the usefulness of this requirement in the future.

There is an important difference, however, between publishing such data and using the reported data to improve understanding of the industry. The Medicare Payment Advisory Commission (MedPAC) has recommended that product sample information be made available to oversight authorities and researchers "to study their impact on prescribing patterns, overall drug spending, and patients' adherence to treatment regimens."³

MedPAC also notes findings from several studies which suggest limiting samples might be beneficial. A 2008 study found that wealthy and insured patients were more likely to receive free samples than poor and uninsured individuals.⁴ Physicians who receive free samples of a new drug are more likely to prescribe it.⁵ Patients who receive free samples have higher out-of-pocket spending on drugs than patients who do not receive samples (presumably because they are reluctant to switch off the brand-name drug for which they've received a free sample once the sample runs out).⁶ And physicians are more likely to prescribe generic medicines to uninsured patients when they no longer have access to samples.⁷

For these reasons, the Committee may want to focus on collecting the data and giving the agencies the authority to permit access to those data to study more thoroughly the potential impacts on patients, both positive and negative.

Analysis and Report on Inpatient Hospital Drug Costs

This section of the STAR Act requires the Secretary of HHS to analyze drugs furnished in inpatient settings, assessing drug costs, Medicare spending, volume, and spending per admission, as well as the trends of each of these variables by hospital size, whether the hospital is in an urban or rural area, whether it is a teaching hospital or not, and the impact of drug shortages on services furnished in an inpatient setting. The Secretary is then required to report the findings to Senate Finance and House Ways and Means Committees. In order to pay for this study, \$3 million would be transferred from the Medicare Hospital Insurance (HI) Trust Fund.

I have no doubt this will be useful information for policymakers, but shifting money from the HI Trust Fund, which is already scheduled to be depleted in just seven short years, may not be the best use of those funds. Three million dollars is enough money to pay the hospital costs of 539 Medicare beneficiaries in 2020, according to the latest Medicare Trustees Report.⁸

H.R. 2115, the Public Disclosure of Drug Discounts Act

This section of the legislation, H.R. 2115, the Public Disclosure of Drug Discounts Act, requires the Secretary to make information regarding pharmacy benefit manager (PBM) and drug manufacturer rebates, discounts, and price concessions, as well as generic dispensing rates publicly available, and requires this information to be provided separately for each PBM. The language does stipulate that the data should be displayed in a manner that prevents the disclosure of information on rebates, discounts, and price concessions, at the individual drug or plan level. In order to ensure confidentiality of proprietary information, the information would be required to be aggregated by drug class, but only if the Secretary determines the number of drugs in a class is sufficient to meet the confidentiality requirement. Further, one year's data must only be made available after two years have passed.

In thinking about this proposal, a number of issues arise. First, while I appreciate the importance of understanding the effectiveness of the Part D and other programs, I do not see a reason for a federal role in commercial market negotiations.

Second, with regard to government programs, it is important to distinguish between those data needed to understand how well programs are working, and data in general. The former could be made available to MedPAC and other researchers, but not disclosed in general.

If information is made public, it is important to not provide so much data that competition is damaged. While this may seem counterintuitive, many economists agree that there is the

potential for price transparency to backfire and lead to higher prices, rather than lower prices. For publicly available data, it is worth considering the appropriate number of drugs in a given class. A manufacturer could easily figure out the price and rebate amounts of their competitor if there are just two drugs, for example. This could violate the intent to protect proprietary information and could illustrate for a company how much it could raise its price and still be the cheaper option.

H.R. 2087, the Drug Price Transparency Act

H.R. 2087, would require drug manufacturers without a rebate agreement in effect for the Medicaid Drug Rebate Program to report ASP pricing information for the purpose of determining the appropriate Medicare Part B payment rate for such a drug. The information provided would be subject to audit by the HHS Office of the Inspector General (OIG) and subject to verifying surveys of wholesalers and manufacturers conducted by HHS. Further, the OIG will be required to submit a report to Congress on the accuracy of ASP data and any recommendations on how to improve it.

This has been recommended by MedPAC and it seems reasonable that HHS have the information needed to ensure correct payment for products and services.

H.R. 2376, the Prescription Pricing for the People Act

The Prescription Pricing for the People Act, H.R. 2376, requires the Federal Trade Commission (FTC) to study the role of intermediaries, such as PBMs, in the pharmaceutical supply chain and whether industry stakeholders engage in anti-competitive and non-consumer-friendly behaviors. If so, the FTC should make recommendations to Congress as to how to make the market more competitive and transparent. The FTC should also make recommendations that would help ensure consumers benefit from the discounts and rebates provided to the various industry stakeholders.

It seems clear that there is a role for the FTC to take action where there are obvious abuses of monopoly power and anti-competitive behavior.

The Creating Lower Cost Alternatives for Your Prescription Drugs Act

This legislation would reduce the co-payment amounts for drugs provided to low-income subsidy (LIS) Medicare Part D beneficiaries. Specifically, the co-pay amount for generic drugs would be reduced to \$0 by 2021 and a middle tier with a co-pay of \$1 would be added for single-source drugs. Multiple-source brand-name drugs would be on the third tier with a co-pay of \$3. These amounts would apply to both full and partial dual-eligible individuals, eliminating the current discrepancy in co-pay amounts between the two groups.

MedPAC has long recommended that co-pay amounts for LIS beneficiaries be reduced for generic drugs.⁹ In 2016, 71 percent of high-cost enrollees (beneficiaries reaching the catastrophic coverage threshold) were LIS beneficiaries.¹⁰ Part of the reason for this is that

LIS enrollees take more medicines and are more likely to use brand-name drugs, rather than simply needing more expensive medicines. MedPAC has noted that high-cost LIS beneficiaries took 18 more prescriptions, on average, than non-LIS high-cost enrollees in 2015,¹¹ and the generic dispensing rate has consistently been 4-5 percentage points lower for LIS enrollees than non-LIS enrollees.¹² This is likely because of the minimal price difference they face between generic and brand-name medicines. Reducing the generic co-pay amount to \$0 will provide a strong financial incentive for individuals with limited income to use generics rather than higher-cost brand-name drugs. Further, providing a middle tier for brand-name drugs which still have rights to exclusive market access (rather than placing these drugs on the higher co-pay tier with other brand-name multiple-source drugs) helps to not burden low-income individuals with a higher co-pay when there is no other option.

Notes

¹ <https://www.iqvia.com/institute/reports/orphan-drugs-in-the-united-states-growth-trends-in-rare-disease-treatments>

² <https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291>

³ http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf (page 197)

⁴ Cutrona, S.L., S. Woolhandler, K.E. Lasser, et al. 2008. Characteristics of recipients of free prescription drug samples: A nationally representative analysis. *American Journal of Public Health* 98, no. 2 (February): 284-289.

⁵ Peay, M.Y., and E.R. Peay. 1988. The role of commercial sources in the adoption of a new drug. *Social Science & Medicine* 26, no. 12: 1183-1189.

⁶ Alexander, G.C., J. Zhang, and A. Basu. 2008. Characteristics of patients receiving pharmaceutical samples and association between sample receipt and out-of-pocket prescription costs. *Medical Care* 46, no. 4 (April): 394-402.

⁷ Miller, D. P., R. J. Mansfield, J.B. Woods, et al. 2008. The impact of drug samples on prescribing to the uninsured. *Southern Medical Journal* 101, no. 9 (September): 888-893.

⁸ <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/downloads/tr2018.pdf>

⁹ <http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf>

¹⁰ http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf (page 422)

¹¹ http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf (page 425)

¹² <http://www.medpac.gov/docs/default-source/reports/chapter-13-status-report-on-part-d-march-2016-report-.pdf> (page 393)