

## House Ways and Means Committee

Markup of H.R. 2113

April 9, 2019

10:30 AM, 1100 Longworth

### Purpose

*The purpose of this markup was to consider the H.R. 2113, the Prescription Drug Sunshine, Transparency, Accountability and Reporting (STAR) Act of 2019*

### Members Present

Chairman Neal, Ranking Member Brady, Representatives Doggett, Nunes, Higgins, Rep. Walorski, Reed, Wenstrup, Chu, Buchanan, Reed, Boyle, Smith, Horsford, Wenstrup, Pascrell, Pascrell, Lewis, Davis, Murphy, Suozzi, Panetta, Arrington, Kildee, Sewell, Evans, Moore, Schweikert, and Schneider

### Opening Statements

**Chairman Neal** said that the STAR Act is an important piece of legislation that will seek to control health care costs. Despite world-renowned innovation in the United States, quality health care has come at a high cost. Bringing costs under control for consumers will require multiple changes to our laws. The STAR Act reforms the lack of transparency with consumers regarding the high cost of drug prices. Improved transparency to the end user will ultimately result in lower drug prices. The STAR Act makes several important critical reforms. First, the STAR Act requires that drug manufacturers publicly justify large price increases for existing drugs and high launch prices for new drugs. Second, the bill requires that applicable manufacturers report to the Health and Human Services (HHS) Secretary the total aggregate monetary value and quantity of samples provided to covered entities. The Secretary must also conduct a study on inpatient (Medicare Part A) drug costs, including trends in the use of inpatient drugs by hospital type. Another requirement is that the Secretary of HHS must publicly disclose the aggregate rebates, discounts, and other price concessions achieved by pharmaceutical benefits managers (PBMs) on a public website, so consumers, employers, and other payers can understand and compare the discounts PBMs receive. Finally, all drug manufacturers must submit information to the Secretary on the average sales price (ASP) for physician-administered drugs covered under Medicare Part B. He offered an amendment in the nature of a substitute to make minor technical changes to the draft.

**Ranking Member Brady** said that healthcare remains the number one concern among Americans due to rising out of pocket drug costs. Republicans are proud to have authorized many pieces of legislation that have reformed our nation's healthcare system. We need everyone in the medical community to identify what should be done to lower healthcare cost for consumers. Every actor in the drug supply chain needs to be held accountable for unacceptable out of pocket costs. Congress needs to continue working together to lower out of pocket costs for consumers. First, Congress needs to crack down on overpriced drugs. Second, empower patients to choose the most affordable medicines. Third, eliminate incentives in Medicare that reward bad actors and lead to higher prices. To protect the prospect of future medical breakthroughs, Republicans oppose efforts to

impose price controls, which will limit consumers' access to life saving medicine. The STAR Act is not perfect, but is a first step to improve our nation's healthcare system by providing consumers with price transparency. For that reason, this piece of proposed legislation should receive the committee's full support. More, however, needs to be done and this discussion must continue.

### Discussion

**Rep. Doggett** said that this bill wrongly allows drug companies to use their own discretion to justify price increases. For example, last fall the president of Nostrom Pharmaceutical asserted that it was a moral requirement for manufacturers to sell drugs for the highest price possible. Unlike competing proposals, this bill only requires drug companies to provide a summary at their own discretion regarding the causes of price increases.

**Rep. Nunes** said he was pleased that H.R. 2064, the Sunshine for Samples Act, was included in this package, which requires manufacturers to report the aggregate monetary value and quantities of samples given to providers each year. This does not prevent drug companies from giving out samples or creates new regulatory burdens for healthcare providers. Healthy markets need transparency, which will give us data to better understand what changes are needed to reduce drug prices for the American people. He thanked Rep. Chu and looks forward to working more on this issue with his colleagues.

**Rep. Higgins** said he applauds the work of the committee and believes this is an important step in providing greater transparency in the drug development process. He pointed out that drug companies are moving toward focusing predominantly on profitable research. On the opposite end, the federal government is a massive purchaser of drugs. For example, the Veterans Administration receives nearly a 40% discount on drugs through negotiated pricing. With this in mind, it is clear that the committee has much more work that needs to be done.

**Rep. Walorski** said that patient education is critical for consumers to learn how to use a medical device. Ultimately, a patient's success with any device is dependent on knowing how to use it. She asked if such demonstration devices would be excluded from the new reporting requirements in the STAR Act. Professional staff member **Ms. Hall**, responded that demonstration devices would be exempt under the Sunshine Act. However, **Rep. Warlorski** asserted that there is a new obligation to meet some of the exclusions in the Sunshine Act. She would thus like continued feedback with the stakeholders involved in this issue.

**Rep. Wenstrup** said he would like to know the desired outcome for tracking drug sample reporting requirements. **Ms. Hall** responded that the main purpose of the reporting requirements is to use the data to better understand spending patterns and use of drugs from patients who receive samples. For example, data could have been helpful in understanding the opioid crisis.

**Rep. Chu** asked how this bill improves the current reporting that is already given by pharmaceutical companies, such as data produced by MedPAC. **Ms. Hall**, responded that while there is some reporting, there is no uniform reporting to make different conclusion about the effects of drug samples on the market.

**Rep. Doggett** said during the past eight years, drug prices have risen on average by 57%, and 142% for drugs with no generic counterpart. It is a mistake to assume that big Pharma will collaborate with us to lower drug prices. Transparency is one of many important tools for lower healthcare costs. While this bill may help explain why pharmaceutical companies are raising prices, it will not stop them from doing it. This bill allows drug companies who have engaged in price gouging to hide information they do not want to disclose. None of the provisions in this bill reduces costs, but rather, signals a need for more reform.

**Rep. Buchanan** said this bill will provide important data to identify ways to reduce costs. He looks forward to helping lower drug prices through market-based solutions in a bipartisan manner.

**Rep. Chu** thanked the Chairman for including the HR 2064, the Sunshine for Samples Act, which closes a loophole in the Sunshine Act by requiring drug and device companies to disclose the total aggregate monetary value and quantity of drug samples given to healthcare providers. For example, the offering of 30-day free samples contributed to users becoming addicted to OxyContin. Knowing more data about drug samples will allow researchers to understand prescribing patterns and the pricing landscape. In light of these reforms, she strongly encouraged her colleagues to support this bill.

**Rep. Reed** said that he appreciates efforts of the committee and encouraged his colleagues to support the SPIKE Act.

**Rep. Boyle** said that this bill is a first step to implement rational policies that bring transparency to the market. Such transparency will inform policy makers to craft solutions that lower drug costs for Americans. He was proud to have introduced the PBM Accountability Act, which requires HHS to publish data on aggregate rebate data and generic dispensing rates.

**Rep. Smith** said he trusts that these reforms are not just for show, but will actually produce meaningful reforms without litigating past actions.

**Rep. Horsford** was pleased to see the inclusion of the SPIKE Act, which requires drug companies to explain large cost increases. The surging drug prices are simply untenable for those in need of certain drugs. Creating price transparency is thus a vital reform needed to understand and reduce drug costs.

**Rep. Wenstrup** encouraged the committee to expand its scope on implementing transparency. For example, hospitals often cost less than surgery centers. He hopes this committee will continue its vital work on producing greater transparency.

**Rep. Pascrell** said he believes that greater transparency can hold bad actors accountable. Sunlight is always the best form of disinfectant. In addition, this bill does nothing to stop American healthcare innovation. As more specialty drugs come to the market, pricing transparency will become increasingly vital to review.

**Rep. Davis** said that healthcare should be a right and not focus on extreme profits at the expense of patients. This legislation is a first step in seeking to combat the problem of rising drug costs. Patients are often forced to use older medications or stop treatment all together. Pharmaceutical companies also block competition, which result in higher prices. He supports this bill and encourages his colleagues to as well.

**Rep. Lewis** said that light needs to be shed on the high cost of drug prices. This bill is first step to bring down drug prices for Americans.

**Rep. Murphy** said she supports the STAR Act because it increases the transparency of drug prices. Drug companies will have to justify such increases, which will enable American to scrutinize such actions. Although this is a step in the right direction, more needs to be done by the committee.

**Rep. Suozzi** thanked the committee for its bipartisan work regarding the STAR Act. He criticized the large amount of money that pharmaceutical companies spend on advertising to doctors and directly to consumers. It is his hope that this legislation will begin the process of lowering prescription drug costs.

**Rep. Arrington** said that every stakeholder in the supply chain needs to be held accountable. More transparency will empower the patient and he believes the STAR Act is a step in the right direction. However, more work needs to be done to produce a cost saving market approach. He looks forward to supporting this measure and continuing to work more with the committee on the issue of rising drug costs.

**Rep. Panetta** thanked the Chairman for the committee's work on this important piece of legislation. He asked the Chairman to enter into the record a letter from Anthony Barrueta, Senior Vice President of Government Relations at Kaiser Permanente. In the letter, Barrueta stated that the prices of prescription drugs are growing at an unsustainable rate and supports the provisions in this bill but also suggests that more work needs to be done.

**Rep. Kildee** said that he is pleased the committee is working in a bipartisan manner to solve the issue of rising drug prices. Although the steps in the STAR Act are basic and important, he was disappointed to see opposition from those who benefit from the status quo. Because of this, he will view those actors negatively when seeking to enact legislation that is more aggressive.

**Rep. Sewell** said although this is an important first step, more work needs to be done, especially by tackling the root causes.

**Rep. Evans** said that he appreciates the opportunity to support this measure, which increases transparency and potentially lowers costs for everyday Americans.

**Rep. Moore** emphasized that this bill is a first step and there are many more issues to be dealt with. Other issues include rightsizing executive pay and examining the negotiations of drug prices. She personally takes medication that costs \$18,000 per month. No one can afford this, and Congress should be able to provide solutions on a bipartisan basis.

**Rep. Schweikert** said that Congress needs to have a conversation on how to finance revolutionary medicines since these are extremely costly and only service a small population.

**Rep. Holding** withdrew his proposed amendment but said that he still has serious concerns about the STAR Act. The bill should focus on unjustified price increases of bad actors instead of burdening those who seek to offer revolutionary treatment. His withdrawal was conditioned on having the Chairman address his concerns in the future. **Rep. Schneider** said he opposes the amendment because this bill adequately exposes bad actors. It is his hope that the bipartisan process continues and the legislation will eventually get signed into law.

*Chairman Neal's amendment in the nature of a substitute was adopted by a vote of 40 to 0.*

*The fill was reported favorably to the House by a unanimous voice vote.*