Testimony Submitted for the Record

U.S. House Committee on Oversight and Reform

Hearing: "Examining the Actions of Drug Companies in Raising Prescription Drug Prices"

Lauren Aronson
Executive Director
The Campaign for Sustainable Rx Pricing (CSRxP)

January 29, 2019

Chairman Cummings, Ranking Member Jordan, and members of the House Committee on Oversight and Reform, the Campaign for Sustainable Rx Pricing (CSRxP) thanks you for the opportunity to submit testimony for the record on drug company pricing practices that have resulted in out-of-control and unsustainable growth in prescription drug prices. We very much appreciate your leadership in addressing this critically important issue that American consumers face every day.

CSRxP is a nonpartisan coalition of organizations committed to fostering an informed discussion on sustainable drug pricing and to developing bipartisan, market-based solutions that promote competition, transparency, and value to improve affordability while maintaining patient access to innovative prescription drugs that can improve health outcomes and save lives. Our members represent organizations including consumers, hospitals, physicians, nurses, pharmacists, employers, pharmacy benefit managers and insurance providers.

Prescription drug prices are needlessly high and continue to grow at unsustainable rates. Twenty-three cents of every health care dollar goes toward prescription drugs.[1] One in four Americans cannot afford their medications. Excessively high prices unfairly threaten the financial security, health and wellbeing of U.S. patients and their families every day, as well as strain Federal and state health budgets and the taxpayers who fund them. Too often patients are faced with the unfortunate and unfair choice of purchasing the medications they need to get well and stay healthy and paying their bills. Patients should never be presented with such a choice.

CSRxP thus strongly believes it is imperative to rein in out-of-control drug prices and welcomes the leadership of this Committee in seeking to address this vexing problem that impacts Americans every day. In particular, we firmly believe that significant actions must be taken to address the root cause of the core problem: drug manufacturers – and drug manufacturers alone – set list prices too high and continue to raise them at unsustainably high rates.

Below we describe how the current marketplace enables the brand pharmaceutical industry to set excessively high drug prices and increase them by rates that often far exceed general inflation. We then present bipartisan, market-based solutions that improve prescription drug affordability while at the same time foster innovation and preserve access to novel therapies. CSRxP firmly believes that without major actions by this Committee and others, the pharmaceutical industry will continue to excessively profit from the anti-competitive and unsustainable pricing practices that make prescription drugs unaffordable and jeopardize access for the patients who need them. We look forward to working with

[1] AHIP. "Where Does Your Healthcare Dollar Go?" May 22, 2018.

the Committee to curbing unfair drug company pricing practices and implementing these bipartisan, market-based solutions that blunt the unsustainable growth in out-of-control prescription drug prices.

I. Growth in U.S. spending on prescription drugs is unsustainable and exceeds spending in other parts of the U.S. healthcare sector.

U.S. spending on prescription drugs is growing at an unsustainable rate – one that exceeds the rate of growth in other categories of U.S. healthcare spending. Although 2018 showed a slightly smaller growth rate in drug prices due in large part to heightened public attention over the unfair pricing practices employed by the pharmaceutical industry, historical data generally shows that spending on prescription drugs has grown at rates higher than other rates of medical spending and Medicare expenditures on Part B and Part D drugs have followed this overall historical trend.[2] To this point, the U.S. Department of Health and Human Services (HHS) Assistant Secretary for Planning and Evaluation (ASPE) found that Medicare Part B spending on prescription drugs increased at a rapid average annual rate of 7.7 percent from 2005 to 2014; during that period, specialty biologic medicines grew at a particularly fast rate, increasing from 39 percent to 62 percent of total spending, with a significant share of the growth due to price increases rather than number of patients using the medications.[3] Likewise, the HHS Office of the Inspector General (OIG) recently found that Medicare Part D spending for brand drugs grew by 77 percent from 2011 to 2015 (or 62 percent when netting out manufacturer rebates) – even though the actual number of prescriptions fell by 17 percent over the period, suggesting price increases contributed substantially to the growth in overall Part D spending.[4]

II. The brand pharmaceutical industry is driving excessive drug cost growth by setting needlessly high list prices for its products and increasing those prices by amounts that substantially exceed inflation after they enter the market.

Despite efforts from the brand drug industry to suggest otherwise, the drug industry – and the drug industry alone – is the primary driver of the needlessly high and unsustainable prescription drug prices and costs that American consumers and taxpayers face today. Brand manufacturers set high launch prices for their products and typically increase those prices at rates that far exceed inflation. As healthcare expert Avik Roy recently said: "[I]n the absence of competition, manufacturers frequently charge the highest prices they believe they can justify in the court of public opinion."[5]

To this point, one recent analysis concluded that the increasing costs of prescription drugs were due largely to price increases imposed by manufacturers of drugs already on the market. From 2008 to 2016, the analysis found costs of oral and injectable drugs increased by 9.2 percent and 15.1 percent,

---

[2] In 2014, for example, while overall growth in U.S. healthcare spending increased by 5.5 percent, prescription drugs grew by 12.6 percent, according to Keehan et al. Similarly, in 2015, while overall growth in U.S. healthcare spending increased by 5.8 percent, growth in spending on prescription drugs increased by 9 percent and outpaced spending on all other medical services, according to Martin et al.

[3] HHS Assistant Secretary for Planning and Evaluation. "Medicare Part B Drugs: Pricing and Incentives," page 6. March 8, 2016.

[4] HHS OIG. "Increases In Reimbursement for Brand-Name Drugs in Part D." June 2018.

[5] Roy Avik. "Drug Companies, 'Not Middlemen', Are Responsible for High Drug Prices." *The Apothecary*. October 22, 2018.

respectively, on an annual basis with existing drugs contributing to much of the growth.[6] [7] Costs increased for specialty oral and injectable drugs by 20.6 percent and 12.5 percent, respectively, with 71.1 percent and 52.4 percent of these increases attributable to new drugs.[8] A separate recent study from AARP found that retail prices for 87 percent of the most widely used brand name drugs by older Americans increased from 2016 to 2017, with 30 percent having price increases of 10 percent or higher.[9] Overall, prices for prescription drugs in the AARP study increased by an average of 8.4 percent from 2016 to 2017 – or four times the 2.1 percent rate of general inflation for the period.[10] These 2017 price increases followed average double-digit annual price increases every year from 2012 to 2016.[11]

High-cost specialty medications in particular are driving much of this unsustainable growth in prescription drug prices and spending. Pharmacy benefit manager Express Scripts reported, for example, that even with strategies in place to lower costs for consumers on specialty medications, growth in commercial spending on high-cost specialty products far outpaced growth in overall prescription drug spending in 2017: 11.3 percent versus 1.5 percent.[12] Similarly, a separate AARP analysis found that retail prices for 101 widely used specialty drugs increased by 9.6 percent in 2015, continuing the increasing trend of specialty product price increases seen since 2006.[13] In 2015, the average annual cost of for a single specialty medication used on a chronic basis exceeded $52,000, with the annual cost of these therapies growing by almost $35,000 from 2006 to 2015.[14]

III. Drug manufacturers suggest that research and development (R&D) justifies high drug prices – but data show that the excessive amounts charged to *U.S.* patients in aggregate exceed the industry's *global* R&D budget.

Researchers have found that the drug prices paid by *U.S.* consumers create significantly more revenue for the brand pharmaceutical industry than the amount the industry expends *globally* on research and development. Specifically, the research concluded that the 15 drug companies manufacturing the 20 best-selling drugs worldwide in 2015 made $116 billion in excess revenue from U.S. drug prices.[15] [16] Meanwhile, brand drug makers only spent $76 billion – or $40 billion less – on global research and

---

[6] Hernandez et al. "The Contribution of New Product Entry Versus Existing Product Inflation in the Rising Cost of Drugs." *Health Affairs*. Vol. 38, No. 1. January 2019.
[7] Kodjak, Alison. "Prescription Drug Costs Driven By Manufacturer Price Hikes, Not Innovation." *National Public Radio*. January 7, 2019.
[8] Hernandez et al. "The Contribution of New Product Entry Versus Existing Product Inflation in the Rising Cost of Drugs." *Health Affairs*. Vol. 38, No. 1. January 2019.
[9] AARP Public Policy Institute. "Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans: 2017 Year-End Update," page 8. September 2018.
[10] *Ibid*., page 5.
[11] *Ibid*., page 6.
[12] Express Scripts. "2017 Drug Trend Report," page 4.
[13] AARP. "Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans, 2006 to 2015," page 1. September 2017.
[14] *Ibid*.
[15] Note that this study looked at net prices – not list prices – that U.S. consumers paid for prescription drugs. Net prices reflect discounts and rebates that pharmacy benefit managers, wholesalers, pharmacies, and other members of the supply chain negotiate with drug manufacturers to lower the list price initially set.
[16] Yu, Nancy et. Al. "R&D Costs for Pharmaceutical Companies Do Not Explain Elevated US Drug Prices." *Health Affairs Blog*. March 7, 2017.

development that same year.[17] As one author of the analysis Dr. Peter Bach, Director of Memorial Sloan Kettering Cancer Center's Center for Health Policy and Outcomes, clearly said: "the math doesn't work out."[18] Indeed, when discussing the relationship between drug prices and industry research and development costs, John Hopkins University professor of health policy and management Gerard Anderson recently said: "Research and development is only about 17 percent of total spending in most large drug companies. Once a drug has been approved by the FDA, there is minimal additional research and development costs so drug companies cannot justify price increases by claiming research and development costs."[19]

Moreover, brand drugs with the highest prices sometimes are the ones that are the least costly to develop, indicating that a drug maker's R&D budget does not necessarily justify the setting of high drug launch prices or imposing price increases that vastly exceed inflation. In other words, high prices do not necessarily correlate with the innovative R&D that the pharmaceutical industry maintains it is supporting in part through high drug prices, as a separate analysis concluded.[20] This analysis found that the "costliest drugs to develop are those which require large phase III clinical trials involving tens of thousands of patients, such as drugs for diabetes, high blood pressure, and heart disease….But, in fact, new drugs in these areas have little pricing power, because doctors have the ability to prescribe effective and inexpensive generics for these conditions."[21] By contrast, the "cheapest drugs to develop are those which require small clinical trials involving dozens of patients, such as drugs for ultra-rare, or 'ultra-orphan' conditions….Phase III trials for these conditions, which only affect several thousand people in the United States, run in the tens of millions. But manufacturers have generated billions in revenues from them."[22]

IV. Out-of-control drug prices paid by U.S. consumers enable the drug industry to pay for needless advertising and marketing – and contribute to drug makers' profitability and bottom lines.

If the drug industry does not spend all of the money it receives from U.S. consumers on its products on R&D as shown above, the question arises as to where the industry actually spends those excessive revenues. It turns out that brand manufacturers are using a significant portion those funds for marketing and advertising – and to increase their bottom lines.

First, the drug industry spends a significant amount of money on direct-to-consumer (DTC) advertising – over $5.5 billion in 2017, including nearly $4.2 billion on television advertising.[23] In 2016, drug advertising represented the sixth largest category of TV advertising, accounting for eight percent of total

[17] *Ibid*.
[18] Sagonowsky, Eric. "High U.S. Drug Prices Cover Pharma's Global R&D – And a Whole Lot More, Study Finds." *Fierce Pharma*. March 10, 2017.
[19] Kodjak, Alison. "Prescription Drug Costs Driven by Manufacturer Price Hikes, Not Innovation." National Public Radio. January 7, 2019.
[20] Roy, Avik. "The Competition Prescription: A Market-Based Plan for Making Innovative Medicines Affordable," page 7.
[21] *Ibid*., page 7.
[22] *Ibid*, page 8.
[23] 83 FR 52792

TV advertising revenue and increasing six places from twelfth place in the category in 2012.[24] Of significant concern is the fact that many brand drug manufacturers spend more on advertising and marketing than R&D. One analysis found that nine of the 10 largest drug companies spent more on sales and marketing, including marketing directly to prescribers, than they did on research in 2013.[25]

Importantly, while brand drug manufacturers suggest marketing and advertising help inform patients and their providers of treatment options, these industry tactics can result in unnecessary utilization of often expensive prescription drugs, causing needless out-of-pocket spending by patients on drugs that they may or may not need based on their individual medical conditions or that may not be the most cost-effective choice according to their individual insurance plans. Indeed, research has shown that DTC advertisements can induce demand and increase unnecessary utilization.[26] [27] [28] One recent survey found, for example, that one in eight adults (12 percent) reported a doctor prescribed them a specific drug after asking about it as a result of seeing or hearing at DTC advertisement.[29] Notably, unnecessarily utilization increases costs not just for the patients who use them, but also for all consumers through higher aggregate healthcare spending – which must be paid for in part by higher consumer premiums.[30]

Second, and very importantly, brand drug manufacturers depend on these unsustainable high drug prices to help support their bottom line growth; price increases now are replacing a decline in prescription volume that the industry is facing for at least certain types of medications. To this point, a recent analysis concluded that between 2011 and 2014, *sales* from the top 10 drugs increased 44 percent even though *prescriptions* for the medications decreased by 22 percent.[31] Likewise, yet another analysis determined that drug price increases contributed $8.7 billion to net income for 28 companies analyzed, representing 100 percent of earnings growth for those companies in 2016.[32] Hence, it seems very unlikely that brand drug makers have little to any incentive to curb the unsustainable and excessive growth in prescription drug prices absent bipartisan action to change these unfair pricing practices and tactics employed by drug companies that hurt American patients and their families every day.

V. Bipartisan, market-based solutions can help rein in unfair drug company pricing practices that have caused out-of-control drug prices to increase at unsustainable rates.

CSRxP supports adoption of bipartisan, market-based solutions to help curb the excessive and unsustainable growth in prescription drug prices for U.S. consumers and taxpayers. To that end, CSRxP

---

[24] Appleby, Anne and Horovitz, Bruce. "Prescription Drug Costs Are Up; So Are TV Ads Promoting Them." *The USA Today*. March 16, 2017.
[25] Swanson, Ana. "Big Pharmaceutical Companies Are Spending Far More on Marketing than Research." *The Washington Post*. February 11, 2015.
[26] Dhaval Dave & Henry Saffer, Impact of Direct-to-Consumer Advertising on Pharmaceutical Prices and Demand, 79 *Southern Economic Journal* 97 – 126 (2012).
[27] Balaji, Datti & Mary W. Carter, The Effect of Direct-to-Consumer Advertising on Prescription Drug Use by Older Adults, 23 Drugs Aging 71-81 (2006).
[28] Barbara Mintzes et al., Influence of direct to consumer pharmaceutical advertising and patients' requests on prescribing decisions: Two site cross sectional survey, 324 *The BMJ* 278-29 (2002).
[29] Kaiser Health Tracking Poll. October 2015.
[30] 83 FR 52793
[31] Humer, Caroline. "Analysis: Drugmakers Take Big Price Increases on Popular Meds in U.S." *Scientific American*.
[32] Tirrell, Meg. "The Drug Industry Is Addicted to Price Increases, Report Shows." *CNBC*. April 20, 2017.

strongly urges the Committee to consider enactment of legislation that would implement the following policies to promote transparency, foster competition, and incentivize value in the marketplace, making prescriptions drugs more affordable and accessible for the patients who need them while at the same time preserving incentives for innovation and new drug development.

Promote Transparency

CSRxP ardently believes that improving transparency in prescription drug pricing is a critical component to making prescription drugs more affordable for consumers and taxpayers. Among other benefits, increased transparency will better enable transformation of the U.S. healthcare system toward one based on value; will better inform patients, prescribers, and dispensers of actual drug costs as they determine the most appropriate treatments to meet individual patient needs; and encourage drug makers to actually justify the high prices they set for their products. Hence, CSRxP urges the Committee to consider policies that promote pricing transparency, including:

- **Require drug manufacturers to include list prices in all forms of direct-to-consumer (DTC) advertising:** DTC advertising has come under scrutiny as prescription drug spending takes up a bigger portion of health care dollars each year both for consumers and taxpayers and has the potential to lead to over-utilization of – and unnecessary spending on – high-cost medicines. Requiring the inclusion of list prices – as well as price increases – in all forms of DTC advertising will make patients much more aware of prescription drug costs when they talk with their providers about treatment options for their individual healthcare needs.

- **Mandate that drug makers release details of a drug's unit price, cost of treatment, and projection on federal spending before FDA approval**: Given the significant impact pharmaceuticals have on overall health care spending, manufacturers should be required to disclose information on the estimated unit price for the product, the cost of a course of treatment, and a projection of federal spending on the product so that patients, providers, taxpayers and policymakers have a better understanding of actual treatment costs.

- **Require drug companies to annually report increases in their drugs' list prices:** Similar to requirements already in place for other entities like health plan issuers, hospitals and nursing facilities, pharmaceutical companies should have to report increases in drug's list price on an annual basis, as well as how many times during the year the price has increased. To this end, CSRxP urges the Committee to consider the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act, which would require manufacturers to report to HHS expensive drugs with significant price increases.

- **Compel drug manufacturers to disclose R&D costs**: Drug makers should be required to disclose how much research was funded by public entities like the National Institute of Health (NIH) or other academic entities or by other private companies, so that regulators and taxpayers can properly weigh return on investment.

- **Produce annual HHS reports on overall prescription drug spending trends and price increases for individual prescription drugs:** HHS should produce and publicly release annual reports covering (1) overall prescription drug pricing trends similar to the one produced by the HHS

ASPE in March 2016; and (2) the top 50 price increases per year by branded or generic drugs; the top 50 drugs by annual spending and how much the government pays in total for these drugs; and historical price increases for common drugs, including those in Medicare Part B.[33] These important pieces of information will better inform patients, prescribers, dispensers, policymakers, and taxpayers about the high drug prices and substantial costs of prescription drugs that U.S. consumers face today.

- **Update routinely and expand the amount of information available on the Medicare and Medicaid Drug Dashboards:** The Medicare and Medicaid Dashboards have provided valuable data and information to consumers and providers on prescription drug costs in a transparent manner. HHS should continue routinely updating information included on both dashboards, including list prices, price increases, and year-over-year pricing data, among other data points, so that consumers have a more transparent understanding of the prescription drug cost increases they face each year.

Foster Competition

CSRxP strongly believes that bringing more competition to the prescription drug market will give consumers more choices and more control – resulting in lower prices and improved access. As such, we urge the Committee to consider policies that foster competition, including:

- **Curb misuse of FDA's Risk Evaluation Mitigation and Strategy (REMS) program:** FDA uses the REMS program to allow products with potential safety issues to enter the market. Drug manufacturers often abuse REMS to block generic drugs from obtaining samples of brand drugs under the guise of addressing patient safety concerns, effectively preventing them from pursuing the research needed to bring generic drugs to market. There is concern that this practice could extend into the burgeoning biosimilars market as well. To thwart this anti-competitive practice by manufacturers, CSRxP urges quick enactment of bipartisan legislation – the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act and the Fair Access to Safe and Timely (FAST) Generics Act – that would curb misuse of REMS.

- **Give FDA additional resources to speed approval of generic drug applications – especially for lifesaving drugs and for drugs with no or limited generic competition**. The FDA faces a backlog of nearly 4,000 generic drug applications, yet approval times can be three or more years. The FDA should receive the resources necessary to clear this backlog and prioritize generic drug approval applications, especially for lifesaving drugs and drugs with no or limited generic competition.

- **Promote a robust market for more cost-effective biosimilars and interchangeable biologic products:** Biosimilars and interchangeable biologic products have the potential to expand treatment options and substantially lower prescription drug costs for consumers and taxpayers. For example, one study found that 11 biosimilars already approved for sale in Europe and elsewhere could generate approximately $250 billion in savings over 10 years if they were

[33] HHS ASPE. "Observation on Trends in Prescription Drug Spending." March 8, 2016.

available in the U.S.[34] Multiple policies could bolster the burgeoning U.S. market for biosimilar and interchangeable biologics, including:

  - **Shorten market exclusivity for brand biologics from 12 years to 7 years:** Currently, reference biologics enjoy a 12 year market exclusivity period. Analyses suggest this amount of time may be unnecessary and prevents lower-cost alternatives from entering the market.
  - **Speed the availability of interchangeable biologics:** FDA should release final guidance documents on interchangeable biologic development so that developers of these products have more regulatory certainty.
  - **Educate patients, providers, and payers about the value, safety, and effectiveness of biosimilars:** FDA and the Centers for Medicare and Medicaid Services (CMS) should engage in a robust education campaign to increase physician and patient confidence about these products and encourage their use.
  - **Improve information in FDA's Purple Book:** FDA should increase the amount of information available and make the Purple Book more user-friendly so that developers of biosimilars and interchangeable biologics better understand the regulatory landscape they face when developing these products.

- **Target exclusivity protections to the most innovative products:** Drug manufacturers can extend patent and market exclusivity protections by seeking approval for a "new" product that is essentially the same as the original product, such as extended release formulations or combination therapies that simply combine two existing drugs into one pill. These anti-competitive tactics – often referred to as "evergreening" or "product hopping" – inhibit entry of generic drugs into the market. For example, a recent analysis suggested that anti-competitive drug reformulations potentially can result in up to $2 billion in losses per anti-competitive reformulation for consumers each year.[35] Appropriate federal agencies should closely monitor these schemes and prosecute if they find any violation of anti-trust laws.

- **Target Orphan Drug incentives to those products that treat orphan diseases:** The Orphan Drug Act introduced a range of incentives to encourage the development of medications to treat rare diseases that treat a patient population of 200,000 or less individuals. A recent investigation found that about a third of orphan approvals by the FDA since the program began have been either for repurposed mass market drugs or for drugs that have received multiple orphan approvals; of the approximately 450 drugs that have garnered an orphan designation since the program's inception in 1983, more than 70 were first approved for mass market use.[36] Given the potential for abuse, steps should be taken assess such trends and ensure that the Orphan Drug Act's incentives are utilized to develop medicines to treat truly rare diseases.

---

[34] Express Scripts. "The $250 Billion Potential of Biosimilars." April 23, 2013.
[35] Shadowen, Steve et. al. "Anticompetitive Product Changes in the Pharmaceutical Industry." *Rutgers Law Journal*, Vol. 41, No. 1-2, Fall/Winter 2009. Page 78.
[36] Tribble and Lupkin. "Drugmakers Manipulate Orphan Drug Rules to Create Prized Monopolies." *Kaiser Health News*. January 17, 2017.

- **Reduce drug monopolies by incentivizing competition for additional market entrants**. Several FDA programs are intended to expedite review of new drugs that address unmet medical needs for serious or life-threatening conditions. Incentives should drive competition for expensive treatments where no competitors exist and encourage a second or third market entrant.

- **Strengthen post-market clinical trials and surveillance.** Currently, expedited drug approvals often involve small clinical trials with a narrow patient population and trials are not regularly reported publicly. Once a drug enters the market, research into the long-term efficacy and side effects should continue within specific timeframes and reporting requirements. Even if a product is not approved, manufacturers should be required to report data for all trials that summarizes non-identifiable demographics and participant characteristics, primary and secondary outcomes results, and adverse event information.

- **Thwart abuse of the patent system:** Drug companies increasingly have used "patent thickets" and "patent estates" to game the regulatory system and inappropriately extend market exclusivity for their products. A recent study of the roughly 100 best-selling drugs between 2005 and 2015 found, for example, that on average 78 percent of the drugs associated with new patents in the FDA's records were not for new drugs coming on the market, but rather for existing drugs.[37] These anti-competitive abuses of the patent system to extend brand drug market monopolies should be stopped by having appropriate Federal agencies apply increased scrutiny to biopharmaceutical patents. In addition, Congress should enact the Preserving Access to Cost-Effective Drugs (PACED) Act to prevent drug manufacturers from transferring their patents to Native American tribes with sovereign immunity.

- **Curb anti-competitive "pay-for-delay" settlements:** Brand and generic drug makers enter into patent dispute settlements – often referred to as "pay-for-delay" settlements – that result in a generic company agreeing to refrain from marketing its products for a specific period of time in return for compensation (often undisclosed) from the branded company. The Federal Trade Commission (FTC) has cited these arrangements as anti-competitive and estimates that they cost consumers and taxpayers $3.5 billion in higher drug costs every year.[38] More recently, these settlements unfortunately have extended to biologics, delaying the entry of less costly biosimilars into the market. For example, the top-selling product in the world, Humira, with global sales exceeding $18 billion in 2017 and a more than doubling of its price over the past five years, will not face biosimilar competition until 2023 due to a settlement agreed to by the brand and biosimilar manufacturer of the product.[39] [40] [41] Federal agencies should apply increased scrutiny to these "pay-for-delay" agreements so that consumers can access more affordable generic drugs and biosimilars.

---

[37] Feldman, Robin et al. "May Your Drug Price Ever Be Green." UC Hastings Research Paper No. 256. October 31, 2017, page 48.
[38] FTC. "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions." January 2010.
[39] AbbVie. "AbbVie Reports Full-Year and Fourth-Quarter 2017 Financial Results." January 26, 2018.
[40] Reuters. "AbbVie, Amgen settlement sets Humira U.S. biosimilar launch for 2023." September 28, 2017.
[41] The Center for Biosimilars. "Latest Humira Price Increase Could Add $1 Billion to US Healthcare System in 2018." January 5, 2018.

- **Improved flexibility to better manage high-cost medications in Medicare Part D:** High-cost drugs are significant drivers in the unsustainable growth in prescription drug costs. With increased flexibility and additional tools employed in the commercial sector, health plans can employ their substantial private sector experience to Medicare Part D and lower costs particularly for high-cost medications while maintaining appropriate beneficiary access to treatments needed to get well and stay healthy

Incentivize Value

CSRxP believes that patients deserve reliable information regarding whether a drug's "therapeutic outcome" – or its health benefit – is in line with its price. This information is critical to moving America's prescription drug market toward a system that empowers doctors and patients to choose medications based on the value they provide – not the "value" set by drug manufacturers. Therefore, CSRxP urges the Committee to consider policies that would incentivize greater incorporation of value into the use and purchase of prescription drugs, including:

- **Increase funding for private and public research efforts like the non-profit Institute for Clinical and Economic Review (ICER) to test the value of medical tests and treatments.** Investment in objective information is critical for physicians, patients and payers as more and more high-price drugs enter the healthcare system.

- **Require drug makers to conduct comparative effectiveness research (CER) studies of new versus existing drug products.** Through CER studies, manufacturers should have to demonstrate that their product is better than others, so that physicians and patients can make smart decisions about the value of different treatments, particularly those with very high costs. Many other countries currently require drug manufacturers to provide CER studies; they should be expanded in the U.S. to reduce spending on unnecessary or ineffective treatments.

- **Expand value-based pricing in public health programs like Medicare and Medicaid.** Currently Medicare and Medicaid purchase prescription drugs for their beneficiaries, but not generally in a manner to accommodate value-based payment models. Steps should be taken to ensure these program can best take advantage of recent developments in value-based purchasing to ensure all parts of the U.S. healthcare system benefit from market-based negotiating efforts to lower drug prices.

VI. Conclusion

In conclusion, CSRxP again thanks the Committee for the opportunity to submit testimony for the record to address the unsustainable and excessive growth in prescription drug prices in the U.S. We very much appreciate the leadership from the Committee in addressing this critically important issue that affects American patients and their families every day. Policies must be implemented to address the root of the problem: brand drug makers set list prices too high and increase them at excessively high rates. Prescription drug prices will continue to grow at unacceptably unsustainable rates unless serious actions are taken to thwart the anti-competitive pricing practices of the brand industry. CSRxP looks forward to working with the Committee to implementing bipartisan, market-based policies that promote

transparency, foster competition, and incentivize value to make prescription drugs more affordable for all consumers while at the same time maintaining access to the treatments that can improve health outcomes and save lives.