Testimony Submitted for the Record

U.S. Senate Committee on Health, Education, Labor and Pensions

Full Committee Hearing on "The Cost of Prescription Drugs: How the Drug Delivery System Affects What Patients Pay"

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June 13, 2017

Chairman Alexander, Ranking Member Murray, and members of the Senate HELP Committee, the Campaign for Sustainable Rx Pricing (CSRxP) thanks you for the opportunity to submit testimony for the record on the critically important issue of unsustainable growth in prescription drug prices.

CSRxP is a project of the National Coalition on Health Care Action Fund. We are nonpartisan coalition of organizations committed to fostering an informed discussion on sustainable drug pricing and to developing bipartisan, market-based solutions that improve affordability while maintaining access to prescription drugs for American patients and their families. Our members represent organizations including consumers, hospitals, physicians, nurses, pharmacists, employers, pharmacy benefit managers and health plans.

We look forward to continuing our work with the Committee to address the unsustainable growth in prescription drug prices, which can threaten the financial security, health and wellbeing of American patients and their families. Below we describe how the current marketplace enables the brand pharmaceutical industry to engage in anti-competitive practices that drive up prescription drug prices for consumers and present market-based, bipartisan solutions that would allow U.S. patients to continue to access the medicines they need at prices more affordable than currently available to them.

I. Spending growth on prescription drugs far exceeds spending growth in the U.S. healthcare sector more broadly.

U.S. spending on prescription drugs is unsustainable and growing at a rate faster than the rest of the healthcare sector. In 2015, for example, 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.[1] Medicare has followed a similar trend in recent years, as spending growth on drugs has exceeded spending growth in other parts of the program. The Medicare Trustees stated in their 2016 report, for example, that per capita drug spending in Part D grew faster than historical rates in 2015, driven in large part by continued growth in prescription drug prices and a "surge" in spending on expensive specialty medicines, and they project such accelerated growth will continue in the future for similar reasons.[2] Likewise, Medicare Part B spending on prescription drugs increased at a rapid

[1] Centers for Medicare and Medicaid Services. "NHE Fact Sheet." See link: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.html

[2] 2016 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, page 108. See link: https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/reportstrustfunds/downloads/tr2016.pdf

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]

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 name drug industry to suggest otherwise, the pharmaceutical industry is the primary driver of the unsustainable and needless growth in prescription drug costs that American patients and their families face today. The industry sets high initial prices for its products and consistently increases those prices at rates that typically exceed inflation.

The brand pharmaceutical industry acknowledges that the list prices it sets represent the majority of the cost that U.S. patients pay out-of-pocket for their prescription drugs. "More than half of what commercially-insured patients pay out-of-pocket for brand medicines is based on the list price," the Pharmaceutical Research & Manufacturers of America states.[4] In other words, the industry alone sets the lists price that comprises a majority of the patient's out-of-pocket spending, meaning that the brand drug industry has significant control over the excessive and unsustainable costs that U.S. patients and their families bear in purchasing prescription drugs.

Indeed, the brand industry today is using its ability to set high list prices for its products – and add to the already unwarranted costs consumers pay out-of-pocket for the prescription medications they need. One recent analysis found, for example, that list prices for prescription drugs grew 9.8 percent in 2016 after a 10.8 percent increase in 2015.[5] By way of comparison, the CPI increased by 2.1 percent and 0.7 percent, respectively, in 2016 and 2015.[6]

The industry also acknowledges the important role that pharmacy benefit managers, wholesalers, pharmacies and other intermediaries play in reducing the list price by negotiating discounts and rebates off that list price, thereby lowering overall cost of medicines for U.S. consumers. However, brand drug makers find ways to keep costs unsustainably high even after these discounts and rebates are negotiated for consumers by implementing excessive price increases that typically exceed inflation after a product enters the market.

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[3] HHS Assistant Secretary for Planning and Evaluation. "Medicare Part B Drugs: Pricing and Incentives," page 6. March 8, 2016. See link: https://aspe.hhs.gov/system/files/pdf/187581/PartBDrug.pdf

[4] Pharmaceutical Research & Manufacturers of America. "More Than Half of Patients' Out-of-Pocket Spending for Brand Medicines Is Based on List Price." March 27, 2017. See link: http://www.phrma.org/graphic/more-than-half-of-patients-out-of-pocket-spending-for-brand-medicines-is-based-on-list-price

[5] Saganowsky, Eric. "Report: Price Hikes Are Still Driving Pharma's Earnings Growth. Who's Most At Risk?" *Fierce Pharma.* April 19, 2017. See link: http://www.fiercepharma.com/pharma/despite-scrutiny-price-hikes-still-driving-pharma-s-eps-growth-report

[6] Bureau of Labor Statistics. "CPI Detailed Report. Data for December 2016," page 2. See link: https://www.bls.gov/cpi/cpid1612.pdf

AARP found, for instance, that retail prices increased in 2015 for 97 percent of the widely-used brand name prescription drugs and all of these increases exceeded the rate of general inflation that year.[7] Another study showed that prices for four of the 10 top-selling drugs in the U.S. increased by more than 100 percent between 2011 and 2014 and for six of the 10 top-selling drugs in the U.S. grew by more than 50 percent during that same period.[8] The trend appears to be continuing in 2017, as another analysis determined that there were 40 drug price increases in the first quarter of 2017 – up from 33 in 2016.[9]

Manufacturers of expensive specialty medications in particular significantly contribute to this critical problem of unsustainably high list prices and price increases in excess of inflation. AARP determined, for example, that the average cost of a specialty medication in the U.S. was $53,000 in 2013.[10] In that year, that amount was more than: (1) the average annual U.S. household income - $52,250; (2) two times the median income of a Medicare beneficiary - $23,500; and (3) three times the average Social Security retirement benefit - $15,526. [11]

Within specialty medicines, one area of particularly significant concern is the treatment of patients with cancer. In the U.S., a novel anti-cancer drug routinely costs more than $100,000 per year or course of treatment and the median launch price of a new oncology drug has increased in each decade from the 1960s to today from $100 to $10,000 per month of treatment.[12] Similarly, a separate analysis demonstrated that the inflation-adjusted price of an anti-cancer medicine often increases after launch, by as much as 44 percent over the course of the decade.[13] These rapidly growing and excessive oncology drug costs represent potentially significant barriers for patients in accessing lifesaving and life-sustaining treatments who simply may not be able to afford them.

In analyzing this extreme and rapid growth in cancer drug costs, researchers emphasized how these costs both hurts patients, who in many cases may not be able to afford these expensive medications, and society at large, which simply will not be able to financially bear the unsustainable burden of excess drug cost growth over the long-term: "Not only are launch prices high and rising, but individual drug prices are often escalated during exclusivity periods. High drug prices harm patients – often directly through increased out-of-pocket expenses, which reduce levels of patient compliance and lead to

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[7] AARP Public Policy Institute. "Rx Price Watch Report: Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans, 2006 to 2015," page 10. December 2016. See link: http://www.aarp.org/content/dam/aarp/ppi/2016-12/trends-in-retail-prices-dec-2016.pdf

[8] Humer, Caroline. "Exclusive: Makers Took Big Price Increases on Widely Used U.S. Drugs." Reuters Health News. April 5, 2016. See link: http://www.reuters.com/article/us-usa-healthcare-drugpricing-idUSKCN0X10TH

[9] Tirrell, Meg. "The Drug Industry Is Addicted to Price Increases, Report Shows." *CNBC*. April 20, 2017. See link: http://www.cnbc.com/2017/04/20/the-drug-industry-is-addicted-to-price-increases-report-shows.html

[10] AARP Public Policy Institute. "Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans, 2006 to 2013," page 8. November 2015. See link: http://www.aarp.org/content/dam/aarp/ppi/2016-12/trends-in-retail-prices-dec-2016.pdf

[11] AARP Public Policy Institute. "Rx Price Watch Report: Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans, 2006 to 201," page 1. February 2016. See link: http://www.aarp.org/content/dam/aarp/ppi/2016-02/RX-Price-Watch-Trends-in-Retail-Prices-Prescription-Drugs-Widely-Used-by-Older-Americans.pdf

[12] Prasad et. Al. "The High Price of Anticancer Drugs: Origins, Implications, Barriers and Solutions." *Nature Reviews Clinical Oncology*. 2017. Advanced Online Publication, page 1.

[13] *Ibid*.

unfavorable outcomes – and harms society – by imposing cumulative price burdens that are unsustainable."[14]

III. Drug manufacturers suggest that research and development 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.

A recent analysis concluded 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 analysis found that 15 drug companies that manufactured the 20 best-selling drugs worldwide in 2015 made $116 billion in excess revenue from U.S. drug prices.[1516] Meanwhile, brand drug makers only spent $76 billion – or $40 billion less – on global research and 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]

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 prices or excessive price increases. In other words, as one recent study found, high prices do not necessarily correlate with the innovative R&D that the pharmaceutical industry maintains it is supporting in part through excessive drug cost growth.[19] Specifically, the study explains 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."[20] 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."[21]

IV. Excessive drug prices paid by American patients and families enable the drug industry to pay for needless advertising and marketing – and contribute to drug makers' bottom lines.

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[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. See link: http://healthaffairs.org/blog/2017/03/07/rd-costs-for-pharmaceutical-companies-do-not-explain-elevated-us-drug-prices/
[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. See link: http://www.fiercepharma.com/pharma/high-u-s-drug-costs-pay-for-pharma-s-global-r-d-plus-more-study-finds
[19] Roy, Avik. "The Competition Prescription: A Market-Based Plan for Making Innovative Medicines Affordable," page 7. See link: http://www.csrxp.org/wp-content/uploads/2017/05/The-Competition-Prescription1.pdf
[20] *Ibid*., page 7.
[21] *Ibid*, page 8.

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, many members of the brand drug industry spend more on advertising and marketing than R&D; one analysis determined that nine of the 10 largest drug companies spent more on marketing than they did on research in 2013.[22] A separate analysis found that drug makers specifically are increasing their spending on television advertising in the U.S., spending $6.4 billion on TV consumer advertising in 2016 – an increase of 5 percent over 2015 and of 62 percent since 2012.[23] Along those same lines, in 2016, drug advertising represented the sixth largest category of TV advertising, accounting for eight percent of total TV advertising revenue and increasing six places from twelfth place in the category in 2012.[24]

Importantly, while drug makers suggest marketing and advertising help inform patients and their providers of treatment options, these industry tactics also drive up health care costs for all consumers – not just those that take prescription drugs. Television advertisements often induce unnecessary demand, encouraging patients and their families to ask physicians for drugs they may not need.[25] Similarly, drug makers' direct marketing to physicians informs prescribers about the availability of specific treatment options – and not necessarily those that treatments that are the most effective and least costly for the patient. Both cases needlessly and unfairly increase healthcare costs for all Americans – not just those using prescription medicines – by unnecessarily increasing spending on prescription drugs overall, thereby driving up overall insurance premiums for all U.S. consumers.

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, one recent analysis found that between 2011 and 2014, *sales* from the top 10 drugs increased 44 percent even though *prescriptions* for the medications decreased by 22 percent.[26] Likewise, 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.[27] Hence, it seems very unlikely that many brand drug makers have much incentive to curb the unsustainable and excessive drug price growth absent bipartisan action to change these unfair pricing practices that hurt American patients and their families.

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[22] Swanson, Ana. "Big Pharmaceutical Companies Are Spending Far More on Marketing than Research." *The Washington Post*. February 11, 2015. See link: https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/?utm_term=.916fc28032c9

[23] Appleby, Anne and Horovitz, Bruce. "Prescription Drug Costs Are Up; So Are TV Ads Promoting Them." *The USA Today*. March 16, 2017. See link: https://www.usatoday.com/story/money/2017/03/16/prescription-drug-costs-up-tv-ads/99203878/

[24] *Ibid*.

[25] *Ibid*.

[26] Humer, Caroline. "Analysis: Drugmakers Take Big Price Increases on Popular Meds in U.S." *Scientific American*. See link: https://www.scientificamerican.com/article/analysis-drugmakers-take-big-price-increases-on-popular-meds-in-u-s/

[27] Tirrell, Meg. "The Drug Industry Is Addicted to Price Increases, Report Shows." *CNBC*. April 20, 2017.

VI. Rules embedded in the U.S. regulatory system permit the brand drug industry to engage in anti-competitive practices that block affordable generic competition and keep drug prices high, driving up prescription drug costs for patients and families and all U.S. consumers.

The brand drug industry often manipulates the current U.S. regulatory system in an anti-competitive manner to limit and restrict patient access to the affordable medications they need.

First, the Orphan Drug Act introduced a range of incentives – most importantly seven years of market exclusivity with no competition – to encourage the development of medications to treat rare diseases, or those diseases that affect fewer than 200,000 patients. Since passage of the Orphan Drug Act, hundreds of orphan drugs have been approved. Many of these medications are helping patients who previously had no treatment options.

However, an increasing number of orphan drugs have achieved blockbuster status, with billions of dollars in sales annually. Oftentimes in these cases, drug manufacturers have secured a single "orphan" indication for a drug's use and then, after FDA approval, patients use the drugs off-label far more broadly beyond that single indication use. In effect, manufacturers benefit from having the special orphan exclusivity period that restricts competition but allows their products to be used off-label for treatments of other types of disease – and oftentimes at very high prices for patients. To this point, a recent analysis found that seven of the top 10 best-selling drugs in the U.S. in 2014 came on the market with an "orphan" designation.[28]

Second, brand name drug companies are using FDA regulations to engage in anti-competitive behavior that blocks competition of certain drugs that require additional safety protections. For specific drugs with specific safety risks, FDA requires manufacturers to develop detailed Risk Evaluation and Mitigation Strategies (REMS) prior to entering the market. While this type of information creates additional safety information for patients and offers safeguards for providers, brand drug manufacturers have manipulated REMS to block generic manufacturers from obtaining samples of brand drugs under the guise of addressing patient safety concerns. This practice restricts competition in the market and often leaves patients with fewer choices for their medications. As a result, patients may be at the mercy of a single drug company for the medication they need to stay healthy, and that company is free to set the price for that medication indiscriminately. This practice stifles the introduction of generic competition, thus preventing lower-priced options from being available to patients and increasing costs for everyone. Bipartisan legislation has been introduced in both the Senate and the House – the CREATES Act and the FAST Generics Act – that would stop this anticompetitive practice. We therefore encourage the Committee to consider bipartisan legislation that addresses these abuses by prohibiting companies from restricting access to samples.

VII. Market-based solutions can help rein in excessive drug cost growth for U.S. patients and families.

CSRxP supports adoption of bipartisan, market-based solutions to help curb the excessive and unsustainable growth in prescription drug spending for U.S. patients and their families. To that end, CSRxP strongly urges the Committee to support and adopt the following policies that promote

[28] "'Orphan Drug' Loophole Needs Closing, Johns Hopkins Researchers Say." November 19, 2015. See link: http://www.hopkinsmedicine.org/news/media/releases/orphan_drug_loophole_needs_closing_johns_hopkins_researchers_say

transparency, foster competition, and incentivize value in the marketplace, making drugs more affordable and accessible for the patients who need them.

1. Promote Transparency

- **Drug manufacturers should 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.

- **Drug makers should annually report increases in a drug's list price.** Similar to requirements already in place for other entities like health plan issuers, hospitals and nursing facilities, pharmaceutical companies should report increases in drug's list price. Furthermore, HHS should provide an annual report to the public that includes 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 covered by Medicare Part B.

- **Manufacturers should disclose drug R&D costs**. Drug makers should be required to disclose how much drug 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.

We encourage the Committee to consider bipartisan legislation, the FAIR Pricing Act, sponsored by Senators Baldwin and McCain that would bring great transparency to the pharmaceutical industry.

2. Foster Competition

- **Speed FDA 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.

- **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.

- **Target exclusivity protections to the most innovative products.** Currently, pharmaceutical manufacturers can extend market exclusivity protections by seeking approval for a "new" product that is essentially the same as the original. Prohibiting such tactics will bring consumers more options and lower prices more quickly. Anti-competitive pricing schemes should be closely monitored by federal agencies and prosecuted if violations of antitrust law are found.

- **Curb misuse of REMS.** As we noted above, the FDA uses REMS to allow products with potential safety issues to enter the market. Drug manufacturers often manipulate 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. Bipartisan legislation has been introduced in both the Senate and the House – the CREATES Act and the FAST Generics Act – that would stop this anticompetitive practice. CSRxP encourages the Committee to consider this bipartisan legislation that addresses these abuses by prohibiting companies from restricting sample access.

- **Promote a robust biosimilars market**. Regulatory policies should encourage market entry and uptake of biosimilars, as they have significant potential to expand treatment options and reduce costs by increasing competition in the marketplace. 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 available in the U.S.[29] We urge the Committee to consider provisions – such as reducing the market exclusivity period for brand name biologics – that would help support the development of a robust biosimilar market and help ensure that patients have access to lower cost alternatives to existing, expensive biologics.

3. Incentivize Value

- **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.

[29] Express Scripts. "The $250 Billion Potential of Biosimilars." April 23, 2013. See link: http://lab.express-scripts.com/lab/insights/industry-updates/the-$250-billion-potential-of-biosimilars

- **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.

VIII. Conclusion

In conclusion, CSRxP appreciates the leadership from the Committee and again thanks the Committee for the opportunity to submit testimony for the record to address the unsustainable and excessive growth in prescription drug costs in the U.S. The Campaign looks forward to continued work with the Committee in the future in developing market-based policies that promote competition, transparency, and value to make prescription drugs more affordable for all American patients and their families while at the same time maintaining access to the treatments that can improve health outcomes and save lives.