Testimony Submitted for the Record

U.S. Senate Finance Committee

Hearing: "Prescription Drug Affordability and Innovation: Addressing Challenges in Today's Market"

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Chairman Hatch, Ranking Member Wyden, and members of the Senate Finance 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 increasing prescription drug affordability for consumers and taxpayers while at the same time fostering a marketplace for the development of innovative medicines.

CSRxP is a nonpartisan coalition of organizations committed to promoting an informed discussion on sustainable drug pricing and to developing bipartisan, market-based solutions that improve affordability while maintaining access to innovative prescription drugs for American patients and their families. Our members represent organizations including consumers, hospitals, physicians, nurses, pharmacists, employers, pharmacy benefit managers and health insurance providers.

We very much appreciate the leadership of this Committee and Department of Health and Human Services (HHS) Secretary Azar in finding ways to address the unsustainable growth in prescription drug costs. Consumers currently spend 23 cents of every healthcare dollar on prescription drugs – an amount that can and must come down, as needlessly high drug prices and out-of-pocket spending can threaten the financial security, health and well-being of American patients and their families, as well as strain Federal and State budgets.[1]

CSRxP welcomes HHS's "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" as a good first step in the effort to reduce needlessly high list prices and lower overall prescription drug costs for consumers and taxpayers.[2] The Blueprint includes a number of thoughtful and creative ideas on innovative methods to reduce prescription drug spending and we would like to work with the Committee and HHS to ensure that those policy ideas are successfully implemented. However, we believe that more can and should be done to bring prices down. 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 costs will continue to grow at unacceptably unsustainable rates unless serious actions are taken to thwart the pricing practices of the brand industry. Without addressing the root cause of the problem, many American patients, particularly those on limited incomes, will continue facing choices they should never have to make between buying groceries for their families or purchasing the medications they need to get well and stay healthy.

Below, CSRxP expresses support for policies in the Blueprint that will improve the affordability of prescription drugs while at the same time fostering a competitive market, which drives innovation in drug development. We then discuss our concern with certain policy ideas that, while very well-

[1] America's Health Insurance Plans. "Where Does Your Health Care Dollar Go?" May 22, 2018.
[2] 83 Fed. Reg. 22692 – 22700

intentioned, unfortunately will not lower prescription drug costs for most consumers and taxpayers. Finally, we recommend a limited number of additional bipartisan, market-based policies for adoption that will increase affordability and promote innovation in drug development.

CSRxP looks forward to working with the Committee and HHS to successfully implement policies that will help address the goal we all mutually share: to make prescription drugs more affordable and accessible for U.S. consumers and taxpayers without imperiling the discovery of innovative breakthrough therapies that can improve the health and well-being of patients.

I. Policies That Improve Market Competition and Lower Out-of-Pocket Costs for Consumers

A. Increasing Transparency in Prescription Drug Pricing

CSRxP strongly agrees with HHS 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 support and better enable transformation of the U.S. health care 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 justify the high prices they set for their products. Hence, CSRxP welcomes policies in the Blueprint that promote drug pricing transparency, including:

- **Requiring drug manufacturers to include list prices in direct-to-consumer (DTC) advertisements:** 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. DTC advertising has the potential to lead to over-utilization of high-cost medicines. Presenting list prices – as well as price increases – in DTC advertising will make patients much more aware of prescription drug costs when they talk with their providers about treatment options for their individual health care needs. Thus, CSRxP urges the Committee to work with HHS and the Food and Drug Administration (FDA) to require drug makers to include list prices and list price increases in DTC advertisements for their products.

- **Updating routinely, and expanding, 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. Hence, CSRxP urges the Committee to encourage HHS to routinely update information 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.

Furthermore, CSRxP urges the Committee and HHS to build on the important policy initiatives ongoing at the Department and described in the Blueprint that will increase transparency in prescription drug pricing, including:

- **Mandating 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.

- **Requiring drug companies to annually report increases in their drugs' list prices:** Similar to requirements already in place for other entities like health insurance providers, hospitals and nursing facilities, pharmaceutical companies should be required to report increases in a drug's list price on an annual basis, as well as how many times during the year the price has increased.

- **Compelling 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), other academic entities, or other private companies, so that regulators and taxpayers can properly weigh return on investment.

- **Producing 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 Assistant Secretary for Planning and Evaluation (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.[3] These important pieces of information will better inform patients, prescribers, dispensers, policymakers, and taxpayers of the significant costs of prescription drugs that consumers face today.

B. Thwarting Anti-Competitive REMS Abuses by Brand Drug Makers

The FDA uses the Risk Evaluation and Mitigation Strategy (REMS) program to allow products with potential safety issues to enter the market. When employed effectively and appropriately, REMS improves patient safety and makes accessible medicines that otherwise might not be available due to safety concerns. However, as described in the HHS Blueprint, drug manufacturers often engage in abusive, anti-competitive behaviors that manipulate REMS to block generic drug companies from obtaining samples of brand drugs under the guise of addressing patient safety concerns, effectively preventing them from pursuing the research needed to bring less expensive generic drugs to market. CSRxP appreciates the leadership of FDA Administrator Gottlieb in using administrative action to help curb these abuses. However, we believe more can be done and therefore urge the Committee to encourage and welcome further actions by the FDA to thwart anti-competitive abuses of REMS by brand drug makers identified in the Blueprint, including:

- **Evaluating current REMS programs to determine whether existing limited distribution programs are appropriate:** CSRxP urges FDA to assess whether existing REMS programs inappropriately restrict access to samples necessary for testing by generic drug makers. Lifting any inappropriate and anti-competitive restrictions in sample access will better enable generic drug makers to develop products that can inject competition into the marketplace and bring drug prices down for consumers and taxpayers.

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

- **Applying the same scrutiny to reference biologic manufacturers as applied to brand drug companies when assessing potential anti-competitive REMS abuses by reference biologic manufacturers:** CSRxP welcomes HHS's recognition in the Blueprint that reference biologic manufacturers have the potential to engage in the same shenanigans that certain brand drug manufacturers do with respect to REMS; namely, developers of biosimilars and interchangeable biologic products may face challenges in obtaining samples of reference biologics for testing due to anti-competitive REMS abuses by reference biologic manufacturers. As such, CSRxP urges FDA to apply the same scrutiny to reference biologic manufacturers as it does to brand drug companies when evaluating REMS programs for reference biologics.

Support for the CREATES Act and FAST Generics Act: In addition to the actions described in the Blueprint to curb REMS abuses, bipartisan legislation has been introduced in the Senate and the House – the CREATES Act and the FAST Generics Act – that would inhibit anti-competitive REMS practices by brand drug makers. CSRxP urges enactment of these bipartisan pieces of legislation, which will build on the important and ongoing work at FDA to curb REMS abuses and better enable generic drugs to enter the market.

C. Fostering a Robust Market for Biosimilar 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 available in the U.S.[4] Thus, CSRxP welcomes implementation of policies identified in the Blueprint that promote and incentivize the development of biosimilars and interchangeable biologic products to compete against high-priced specialty brands and lower costs for consumers and taxpayers, including:

- **Improving the interchangeability of biosimilars:** CSRxP strongly supports efforts to improve the interchangeability of biosimilars, which will provide enhanced competition in the marketplace particularly for high-cost specialty drugs. FDA has approved eleven biosimilar products since enactment of the Biologics Price Competition and Incentive Act (BPCIA) over eight years ago. However, the agency has not deemed any as interchangeable, which means they cannot be substituted without the intervention of a health care provider. CSRxP is concerned that this continued dynamic will discourage further investment from biosimilar developers and ultimately reduce the number of interchangeable biologics that reach the market.

  FDA has not finalized its draft guidance entitled "Considerations in Demonstrating Interchangeability With a Reference Product," which outlines the process a biosimilar manufacturer must follow to obtain an interchangeable designation from FDA.[5] CSRxP urges the Committee to encourage FDA to finalize this guidance as soon as possible. Developers of interchangeable products need the final guidance for certainty so that they have a clear and

[4] Express Scripts. "The $250 Billion Potential of Biosimilars." April 23, 2013.
[5] FDA. "Considerations in Demonstrating Interchangeability With a Reference Product." Guidance for Industry. Draft Guidance. January 2017.

consistent pathway for demonstrating interchangeability, fostering the ability of more of these products to enter the market.

- **Educating providers and patients on the value, safety, and efficacy of biosimilars:** CSRxP strongly agrees with HHS that, "[p]hysician and patient confidence in biosimilar and interchangeable products is critical to the increased market acceptance of these products."[6] Hence, we firmly support efforts by the FDA to educate patients, prescribers and dispensers about the value, safety, and efficacy of biosimilar and interchangeable biologic products. Along similar lines, we further recommend that the Centers for Medicare and Medicaid Services (CMS) engage with patients, prescribers, dispensers and health plans to develop and implement tools that offer education on the value, safety, and efficacy of biosimilars and interchangeable products specifically for Medicare beneficiaries enrolled in Part B and Part D. Enhanced education efforts from FDA and CMS on biosimilars and interchangeable biologics will help to generate improved comfort, acceptance and increased utilization of these more affordable products over time.

- **Improving FDA's Purple Book:** CSRxP supports improvements to FDA's Purple Book that make it a more useful tool for developers of biosimilars and interchangeable biologics, as well as patients and prescribers. Researchers have documented how the Purple Book does not include the same level of information as that available in FDA's Orange Book for small molecule drugs and have suggested that the lack of sufficient information has the potential to hinder development of biosimilars.[7] Moreover, these same researchers described how the limited information available in the Purple Book is not easily accessible and searchable online, particularly compared to the Orange Book, which can create additional challenges for biosimilar developers, patients, prescribers, dispensers, and health plans.[8] As such, CSRxP would welcome efforts by the Committee to encourage FDA to make modifications to the Purple Book so that the Purple Book for biologics maintains similar levels to – or improves upon – the information and online accessibility of the Orange Book for small molecule drugs.

Shortening the market exclusivity period for brand biologics: In addition to these policies included in the HHS Blueprint, CSRxP urges the Committee to work with the Administration on shortening the market exclusivity period for brand biologics to foster a more robust marketplace for biosimilars and interchangeable biologic products. 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. Although providing for intellectual property protections is important to encourage innovation and the introduction of medical advancements in the U.S. market, consideration should be given to shortening the periods of exclusivity. It is important to find the right balance of incentives for pharmaceutical companies while alleviating cost pressures for consumers and payers. CSRxP believes that action in this area is particularly important, as a growing proportion of the drug development pipeline is comprised of high cost biologics.

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[6] 83 Fed. Reg. 22696

[7] Feldman, Robin et al. "May Your Drug Price Ever Be Green." UC Hastings Research Paper No. 256. October 29, 2017. Page 89.

[8] *Ibid*., page 90.

D. Promoting Value-Based Arrangements in Federal Health Programs

Currently Medicare and Medicaid purchase prescription drugs for their beneficiaries, but not generally in a manner to accommodate value-based payment models. CSRxP agrees with HHS that steps should be taken to ensure these programs can best take advantage of recent developments in value-based purchasing so that all parts of the U.S. health care system benefit from market-based negotiating efforts to lower drug prices. In particular, certain value-based arrangements such as indications-based pricing have the potential to lower drug costs and would benefit from more comparative effectiveness research on the value of various treatment options. Public and private institutions such as the Institute for Clinical and Economic Review have introduced important information into the public domain on the value of particularly high-cost efforts and should receive additional funding for this critical work.

However, CSRxP cautions that value-based arrangements remain in their infancy and oftentimes do not directly lower costs for U.S. patients and their families. More importantly, any savings that accrue from such arrangements are not expected to occur in the near-term, severely limiting their ability to provide meaningful price relief. While representing innovative and important steps in helping to lower drug costs, value-based arrangements do not address the root of the problem, namely that drug prices are too high and brand pharmaceutical companies alone are responsible the high cost of prescription drugs that American consumers and taxpayers face every day.

E. Better Management of High-Cost Medications

High-cost drugs are significant drivers in the unsustainable growth in prescription drug costs. CSRxP supports efforts to lower this unsustainable growth in spending through the extension of increased flexibility to health insurance providers in managing prescription drug costs. With increased flexibility, health plans can employ their substantial private sector experience to Medicare and lower costs particularly for high-cost medications while maintaining appropriate beneficiary access to treatments needed to get well and stay healthy.

As part of these changes, CSRxP strongly urges HHS to revisit its existing exceptions and appeals processes to ensure that they are transparent, easy-to-understand, and fair. HHS also should be willing to regularly revisit and make changes to such processes as necessary.

II. Policies That Ultimately Will Not Lower Prescription Drug Costs for Consumers and Taxpayers

HHS requests information in the Blueprint on a number of policies that it believes has potential to slow the unsustainable growth in prescription drug costs and increase the affordability of medications for consumers. While CSRxP supports many of the policies under consideration, we are concerned that certain policies identified in the Blueprint unfortunately will have the unintended consequence of increasing – not decreasing – the costs of prescription drugs for most consumers and taxpayers. While we very much share the Department's goal of lowering out-of-pocket costs for patients and reducing government spending on prescription drugs, we are very concerned that certain policies will harm consumers and further strain Federal and State health budgets. In particular, policies that would limit or prohibit rebates in Medicare Part D or establish long-term financing models for purchase of prescription drugs in Federal health care programs, will harm consumers and further strain Federal and State health budgets.

A. Limiting or Prohibiting Rebates in Medicare Part D

HHS asks in the Blueprint whether limiting or prohibiting pharmacy benefit managers (PBMs) from negotiating rebates for Part D drugs could lower costs for consumers and taxpayers would lower drug list prices. While CSRxP very much shares HHS's concern that list prices for drugs are too high and welcomes actions that will actually bring down list prices, we disagree that PBMs are responsible for high list prices. In fact, brand drug companies alone set excessively high list prices and continuously implement significant price increases. By contrast, PBMs, negotiate with drug manufacturers to lower costs for Medicare beneficiaries enrolled in Part D plans, as well as employers, unions, and government plans offering prescription drug coverage.

Indeed, a recent study found that there is no correlation between the prices set by drug companies set and the rebates they negotiate with PBMs and that drug companies increase prices regardless of rebate levels.[9] In certain instances, the study pointed to prominent cases of higher-than-average price increases in drug categories where manufacturers negotiated relatively low rebates and, conversely, prominent cases of lower-than-average price increases in drug categories where manufacturers negotiate relatively high rebates.[10]

In fact, rebates and other discounts negotiated by PBMs and Medicare Part D plans produce significant savings for the program and its beneficiaries. One recent analysis estimated that PBMs and Part D plans saved the Part D program and its beneficiaries over $20 billion in drug costs in 2017.[11] Similarly, in their most recent report, the Medicare Trustees projected significantly slower growth in Part D spending in part due to higher manufacturer rebates negotiated by PBMs.[12] Again, while CSRxP appreciates the intent of the question in looking to solve this critical problem, we disagree that PBMs are the cause. Instead, the root cause of the problem belongs to drug makers and drug makers alone, which set high list prices and routinely raise them.

B. Establishing Long-Term Financing Models for Purchase of Prescription Drugs

HHS asks in the Blueprint about the feasibility of establishing long-term financing models for the purchase of prescription drugs. Once more, while CSRxP welcomes the goal of looking for innovative methods to lower drug costs, we are concerned that implementing long-term financing models for the purchase of prescription drugs actually will make prescription drugs less – not more – affordable for consumers and taxpayers.

Indeed, long-term financing mechanisms could encourage drug makers to continue increasing their prices at excessively high rates for years, knowing that the multi-year financing would blunt the total upfront cost of the drug – all at the expense and burden of patients and Federal and State health programs that unfairly would bear such costs. Any lower drug prices generated from market

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[9] Visante. "No Correlation between Increasing Drug Prices and Manufacturer Rebates in Major Drug Categories." April 2017.
[10] *Ibid*.
[11] Milliman. "Value of Direct and Indirect Remuneration: Impact on Part D Prescription Drug Plan (PDP) Stakeholders." July 2017.
[12] The Board of Trustees, Federal Hospital Insurance and Federal Supplementary Insurance Trust Funds. "2018 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Insurance Trust Funds," page 112.

competition incented in traditional insurance benefit designs would be eliminated under long-term financing models, enabling drug makers to increase prices throughout the term of the long-term financing model. Such financing mechanisms merely would function as perpetual debt payments and cost shifts, unfairly transferring the burden of prescription drug affordability from manufacturers to consumers and taxpayers; patients would have to make onerous debt payments for years while Federal and State health programs already faced with significant budgetary challenges would have to absorb even more long-term costs that they simply cannot afford in the current fiscal environment.

Moreover, long-term financing models would be very challenging to implement and operate. Drug makers likely would insist that State and Federal health programs develop the infrastructure and continuously operate a highly complex financing mechanism, increasing government administrative spending for years. Administrators of these financing programs would have to determine how to handle situations where a patient takes a drug for a meaningful period time, burdened with significant continuous costs, only to find out during the course of treatment that the drug has not been effective. These patients should not have to bear those costs, although it is unclear how a long-term financing model would handle such unfortunate situations. These represent just a few of the many complexities and operational difficulties long-term financing models present.

Insurers currently manage many costly diseases and conditions such as cancer, traumatic brain injury, and organ transplant, belying the notion that traditional insurance cannot handle the management of expensive treatments today. As such, CSRxP firmly believes that using traditional insurance rather than long-term financing models will better address prescription drug pricing problems for consumers and taxpayers. While we appreciate thoughtful and creative approaches to tackling the challenging problem of prescription drug pricing, long-term financing models are not the solution as they simply serve to prop up an unsustainable pricing market.

III. Additional Policies to Slow the Unsustainable Growth in Prescription Drug Costs

Brand biopharmaceutical companies employ a variety of anti-competitive tactics to delay competition and keep lower cost generic drugs and biosimilars from entering the market. These inappropriate and unfair abuses effectively extend the period of market exclusivity for brand products and, consequently, cause consumers to continue experiencing needlessly high out-of-pocket expenses and Federal and State governments to engage in unnecessary spending on prescription drugs. To help combat these anti-competitive tactics by brand drug makers, CSRxP urges the Committee and the Administration to work together to adopt the bipartisan, market-based solutions described below, which inject more competition into the market particularly after brand products already have benefitted from market exclusivity post FDA approval.

A. Enhancing Oversight of "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.[13] More recently,

[13] FTC. "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions." January 2010.

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.[14][15][16]

"Pay-for-delay" settlements hurt consumers who need to have lower out-of-pocket costs, especially when taking high-cost specialty medications like Humira, as well as taxpayers who effectively have to foot the bill of delayed competition. As such, CSRxP urges robust oversight and opposition to settlements that are deemed anticompetitive and prevent generics and biosimilars from entering the market in a timely manner.

B. Targeting Exclusivity Protections to Truly Innovative Products

Currently, pharmaceutical 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.[17] Prohibiting these anti-competitive "evergreening" and "product hopping" tactics by brand drug makers will foster increased availability of generic drugs, resulting in lower costs for consumers and taxpayers. Therefore, CSRxP urges the appropriate federal agencies to closely monitor and increase scrutiny of these schemes and prosecute if they are found to be in violation of antitrust laws.

IV. Conclusion

In conclusion, CSRxP appreciates the leadership from the Committee on the critically important issue of prescription drug pricing and thanks the Committee for the opportunity to submit testimony for the record on this issue that impacts consumers and taxpayers every day. CSRxP looks forward to continued work with the Committee on developing and implementing 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 innovative treatments that can improve health outcomes and save lives.

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[14] AbbVie. "AbbVie Reports Full-Year and Fourth-Quarter 2017 Financial Results." January 26, 2018.
[15] Reuters. "AbbVie, Amgen settlement sets Humira U.S. biosimilar launch for 2023." September 28, 2017.
[16] The Center for Biosimilars. "Latest Humira Price Increase Could Add $1 Billion to US Healthcare System in 2018." January 5, 2018.
[17] Shadowen, Steve et. al. "Anticompetitive Product Changes in the Pharmaceutical Industry." Rutgers Law Journal, Vol. 41, No. 1-2, Fall/Winter 2009. Page 78.