CSRxP Response to HHS Prescription Drug Pricing Blueprint Executive Summary

Consumers currently spend 23 cents of every health care dollar on prescription drugs – an amount that can and must come down, as needlessly high drug prices and out-of-pocket spending threaten the financial security, health and well-being of American patients and their families, as well as strain Federal and State budgets.[1] As such, CSRxP welcomes HHS's Prescription Drug Pricing Blueprint as a good first step in finding ways to improve prescription drug affordability for consumers while also promoting innovation in drug development.

Below summarizes key policies in the Blueprint that CSRxP believes will help slow the growth in prescription drug costs and those that – while well-intentioned – unfortunately will have the opposite effect and make drugs more unaffordable for patients and taxpayers. Ultimately, CSRxP believes more can and should be done to address the root cause of the critical problem in the unsustainable growth of prescription drug costs: drug manufacturers set list prices too high and increase them at excessively high rates. CSRxP looks forward to the successful implementation of policies that will help address the goal we share with HHS: 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. Increasing Competition

Thwarting REMS abuses: CSRxP welcomes further actions by the Food and Drug Administration (FDA) to thwart anti-competitive abuses of the Risk Evaluation and Mitigation Strategies (REMS) including: (1) evaluating current REMS programs for existing drug to determine whether existing limited distribution programs are appropriate; and (2) applying the same scrutiny to reference biologic manufacturers as applied to brand drug companies when assessing potential REMS abuses. Additionally, we urge HHS to work with the Congress to enact the CREATES Act and FAST Generics Act to further curb REMS abuses.

Fostering a robust biosimilars and interchangeable biologics market: Biosimilars and interchangeable biologics have the potential to expand treatment options and significantly lower costs for consumers and taxpayers. Hence, CSRxP urges FDA to speed the availability if interchangeable biologics by releasing final guidance as soon as possible on development of these products. We also strongly support expanded outreach and education by FDA and the Centers for Medicare and Medicaid Services (CMS) to generate improved comfort, acceptance and increased utilization of biosimilars and

[1] America's Health Insurance Plans. "Where Does Your Health Care Dollar Go?" May 22, 2018.

interchangeable biologics. Additionally, CSRxP urges HHS to work with the Congress on shortening the market exclusivity period for brand biologics to further incentivize the development of biosimilars and interchangeable biologics.

II. Better Negotiation

Fostering value-based arrangements: CSRxP agrees with HHS that steps should be taken to ensure that Medicare and Medicaid can take advantage of recent developments in value-based purchasing. However, CSRxP cautions that value-based arrangements remain in their infancy and any savings that accrue from such arrangements are not expected to occur in the immediate near-term, severely limiting their ability to provide meaningful price relief.

Better managing high-cost medications: CSRxP supports efforts by HHS to extend increased flexibility to health insurance providers so they can better manage expensive medications and lower costs for consumers. When doing so, it is imperative that HHS revisit and make changes as appropriate to its existing exceptions and appeals processes to ensure that they are transparent, easy-to-understand, and fair for patients.

Opposing long-term financing models: CSRxP is very concerned that implementing long-term financing models will make prescription drugs more – rather than less – affordable for patients and taxpayers. Very problematically, these models 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 have bear the burden of such costs over a prolonged period of time. The models also simply assume that the manufacturer has appropriately priced the product without actually being required to justify that high price in a fair and highly transparent manner to patients and health programs. Additionally, long-term financing models would be very challenging to implement and operate. Thus, CSRxP urges HHS to not pursue long-term financing models for purchase of prescription drugs.

Concern over shifting drug coverage from Medicare Part B to Part D: CSRxP is concerned that shifting drugs currently covered under Medicare Part B to Part D would raise a number of serious safety and access issues for beneficiaries such as “brown bagging” and potentially higher cost-sharing. As such, we urge HHS to proceed very cautiously and entirely address all operational complexities and challenges before proposing such a policy for implementation.

III. Creating Incentives to Lower List Prices

Including list prices and price increases in DTC advertising: CSRxP strongly supports efforts to improve transparency in prescription drug pricing. Hence, CSRxP welcomes FDA action requiring drug manufacturers to include list prices in direct-to-consumer (DTC) advertisements for their products. CSRxP further recommends that FDA mandate drug companies to disclose of list price increases, price increase frequency, and the cost for the course of treatment of an average patient in their DTC ads. Such information will better inform patients of the treatment options available, thereby enabling them to be more engaged in consumer-driven healthcare decisions.

Improving the Medicare and Medicaid Drug Dashboards: The Medicare and Medicaid Dashboards present valuable data and information to consumers, providers, taxpayers, and policymakers on

prescription drug costs in those programs in a transparent manner that helps better inform healthcare decision-making. Hence, CSRxP urges HHS to continue to frequently update and add new information on prescription drug pricing to the Dashboards.

Maintaining current policy prohibiting manufacturer coupons in Federal health programs: Manufacturer coupons can induce unnecessarily utilization and correspondingly cause unnecessary spending on prescription drugs. Such adverse outcomes led the HHS Office of the Inspector General (OIG) to ban their use in Federal health care programs. CSRxP urges the Department to continue this prohibition.

Serious concern with limiting or prohibiting rebates in Medicare Part D: The Blueprint asks whether limiting or prohibiting pharmacy benefit managers (PBMs) from negotiating rebates for Part D drugs could lower list prices and reduce costs for consumers and taxpayers. CSRxP firmly disagrees that PBMs and the rebates they negotiate are responsible for high list prices; rather, brand drug companies alone are responsible for the high list prices they set. Indeed, a recent study found that: (1) there is no correlation between prices and rebates; and (2) drug companies increase prices regardless of rebate levels.[2] Rather than increasing prices, rebates help lower costs for consumers; for example, 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.[3]

Adopting policies other than point-of-sale (POS) rebates to lower out-of-pocket spending for Medicare Part D enrollees: The Blueprint references a prior HHS comment solicitation on applying some manufacturer rebates to Medicare Part D drugs at POS. While CSRxP appreciates that such a policy would lower costs for a limited number of beneficiaries with high-out-of-pocket spending, it unfortunately would do so at the expense of a significant premium increase for *all* Part D enrollees. It also would place Medicare on less sound financial footing, potentially increasing program costs by up to more than $80 billion over ten years. CSRxP firmly believes that policies to address high drug prices should improve affordability for all beneficiaries and should not increase burdens for taxpayers.

IV. Reducing Patient Out-of-Pocket Spending

Improving cost-sharing information for patients and prescribers: CSRxP agrees that it would be helpful for patients and prescribers to have access to cost-sharing information through real-time benefit inquiry (RTBI) software at the point of prescribing. With this information, patients and prescribers would be better able to determine if a lower cost alternative is available and should be considered.

V. Additional Policies to Reduce the Unsustainable Growth in Prescription Drug Costs

Enhancing oversight of "pay-for-delay" settlements: "Pay-for-delay" settlements between brand and generic companies increase drug costs for consumers by delaying entry of generic competition into the market. These settlements now are extending beyond traditional chemical drugs to costly biologics; for example, Humira, with global sales exceeding $18 billion in 2017, will not face biosimilar competition

[2] Visante. "No Correlation between Increasing Drug Prices and Manufacturer Rebates in Major Drug Categories." April 2017.

[3] 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.

until 2023 due to a "pay-for-delay" settlement between the brand and biosimilar manufacturer. CSRxP urges robust oversight by appropriate federal agencies of these settlements and opposition to settlements that are deemed anticompetitive.

Targeting market exclusivity to truly innovative products: Currently, pharmaceutical manufacturers can extend patent and market exclusivity protections by seeking FDA approval for a reformulated "new" product that is essentially the same as the original product – tactics often referred to as "evergreening" or "product hopping." A recent analysis concluded that consumers lose up to $2 billion per year per each anti-competitive product reformulation.[4] CSRxP urges HHS to work with the appropriate Federal agencies to enhance scrutiny of these schemes and protect consumers.

Targeting "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. Many of these medications are helping patients who previously had no options. In some cases, however, patients use orphan drugs for non-orphan diseases and, very problematically, drug companies have found ways to maintain high prices for these drugs in non-orphan patient populations. Concerns about possible abuses of orphan drug exclusivity led the National Academies of Sciences, Engineering, and Medicine to declare in a 2017 report: "Programs promulgated under the Orphan Drug Act – which were originally designed to foster the development of innovative drugs for rare conditions – have expanded well beyond their original intent and are counteracting efforts to make medicines more affordable."[5] Given the potential for abuse, CSRxP urges HHS to take steps to assess such trends and ensure that the Orphan Drug Act's incentives are utilized to develop medicines to treat truly rare diseases.

Curbing patent "thickets" and "estates" that inappropriately extend monopolies for brand products: Brand biopharmaceutical manufacturers have significantly increased the number of patents for their products in recent years, in many cases as a means to game the system and extend the market exclusivity for their products. A recent of the roughly 100 best-selling drugs between 2005 and 2015 found that, on average, 78 percent of the drugs associated with new patents in the FDA's records were not new drugs coming on the market, but rather existing drugs.[6] For example, the manufacturer of the best-selling product in the world, Humira, created a "patent estate" for the product covering over 75 patents that would extend its monopoly as far as 2034. While it is important to protect intellectual property, brand drug companies should not abuse the patent system to extend their market monopolies. CSRxP urges HHS to work with appropriate Federal agencies to increase scrutiny of patent scrutiny and reward only those patents that are truly innovative.

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[4] Shadowen, Steve et. al. "Anticompetitive Product Changes in the Pharmaceutical Industry." Rutgers Law Journal, Vol. 41, No. 1-2, Fall/Winter 2009, page 78.

[5] *Ibid*., page 123.

[6] Feldman, Robin et al. "May Your Drug Price Ever Be Green." UC Hastings Research Paper No. 256. October 31, 2017, page 48.