July 13, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, Southwest
Washington, D.C. 20201
RE: RIN 0991-ZA49

Dear Secretary Azar:

The Campaign for Sustainable Rx Pricing (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. Our members represent organizations including consumers, hospitals, physicians, nurses, pharmacists, employers, pharmacy benefit managers and insurance providers.

CSRxP appreciates and welcomes the Department's interest in finding ways to improve the affordability of prescription drugs and reduce the unsustainable growth in drug costs for U.S. consumers and taxpayers. 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] Thus, CSRxP welcomes HHS's "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" (RIN 0991-ZA49) as a good first step in the effort to reduce excessively high list prices and lower overall prescription drug costs for consumers and taxpayers. The Blueprint includes a number of thoughtful and creative ideas on innovative methods to reduce prescription drug spending. CSRxP is committed to working with HHS to ensure successful implementation of those policies to make drugs more affordable for consumers and taxpayers.

That said, CSRxP firmly believes that more can and should be done to bring high drug prices down. Policies must be implemented to address the root of the problem: brand drug manufacturers set list prices too high and continue to increase them at high rates. Prescription drug costs will continue to grow at 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

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

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.

In the interim, CSRxP welcomes the Blueprint as a good first step to increase the affordability of prescription drugs. Below we offer comment on policies in the Blueprint that we agree will lower drug costs; those that, while very well-intentioned, unfortunately will not lower prescription drug spending for most patients and taxpayers; and recommend a number of additional bipartisan, market-based policies that will increase affordability and promote innovation in drug development. In particular, we comment on the following issues discussed in each of the four areas of the Blueprint:

I. Increasing Competition
   A. Support for policies that thwart anti-competitive Risk Evaluation and Mitigation Strategies (REMS) abuses by brand drug makers
   B. Support for policies that foster a robust biosimilar and interchangeable biologic product market
   C. Disagreement with the notion that the pharmaceutical industry may excessively increase drug prices due to the brand drug manufacturer tax and changes to the Medicaid Drug Rebate program in the Affordable Care Act (ACA)

II. Better Negotiation
   A. Support for improved transparency in prescription drug pricing in Medicare, Medicaid, and other forms of health coverage
   B. Support for improving the accuracy of national prescription drug spending data so long as changes do not mask price increases implemented by drug manufacturers
   C. Support for value-based arrangements, including indications-based pricing and other innovative strategies
   D. Support for increased flexibility for Medicare Part D sponsors to better manage high-cost drugs
   E. Serious concern with the establishment of long-term financing models to pay for high-cost drugs
   F. Serious concern over the potential adverse impact on Medicare beneficiaries from shifting Medicare Part B drugs to Part D

III. Creating Incentives to Lower List Prices
   A. Support for requiring manufacturers to include list prices and list price increases in direct-to-consumer advertising
   B. Support for frequently updating and expanding the amount of information available on the Medicare and Medicaid Drug Dashboards
   C. Support for establishing lookback periods for Medicare Part B and Part D drugs
   D. Interest in exploring the elimination of the inflationary cap for drugs covered by Medicaid
   E. Recognition of the value of the 340B program
   F. Support for maintaining current policy prohibiting manufacturer coupons in Federal health programs
   G. Serious concern with limiting or prohibiting rebates in Medicare Part D
   H. Adoption of policies other than point-of-sale (POS) rebates to lower out-of-pocket spending for Medicare Part D enrollees

IV. Reducing Patient Out-of-Pocket Spending
    A. Support for actionable and meaningful tools to help beneficiaries make informed Medicare Part D choices without imposing significant burden on health plans
    B. Concern with significant operational challenges in requiring pharmacists to inform beneficiaries on drug prices
    C. Support for informing beneficiaries with Medicare Part B and Part D about cost-sharing and lower cost alternatives
V. Additional Policies to Reduce the Unsustainable Growth in Prescription Drug Costs
    A. Prohibit "pay-for-delay" settlements between brand biopharmaceutical companies and generic and biosimilar manufacturers
    B. Target exclusivity protections to truly innovative products
    C. Target "orphan drug" incentives to those products that treat orphan diseases
    D. Curb anti-competitive patent thickets that inappropriately extend monopolies for brand products
    E. Strengthen post-market drug surveillance
    F. Reduce drug monopolies by incentivizing competition for additional market entrants

CSRxP's comments reflect our strong desire and commitment to partner effectively with HHS to address the critical issue of unsustainable growth in prescription drug costs facing American patients and taxpayers every day. We look forward to the successful implementation of 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. Increasing Competition

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

The FDA uses the 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 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 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.

- **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.

2. 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. One study found, for example, that eleven 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.[2] Thus, CSRxP welcomes implementation of policies identified in the Blueprint that promote and incentivize the development of biosimilars and interchangeable biologic products, including:

- **Speeding the availability of interchangeable biosimilars:** CSRxP strongly supports efforts to speed the availability of interchangeable 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 as it continues working on related guidance, which means they cannot be substituted at the pharmacy counter without the intervention of a healthcare 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.[3] CSRxP urges 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 consistent pathway for

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

demonstrating interchangeability, fostering the ability of more of these lower cost products to enter the market and increase competition with high-cost specialty biologics.

- **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."[4] 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 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 for patients, prescribers, dispensers, and health insurance providers. First, the Purple Book does not include the same level of information as that available in FDA's Orange Book for small molecule drugs; for example the Purple Book does not list the patents held by reference biological products. Lack of information has the potential to hinder development of biosimilars.[5]

  Second, the limited information available in the Purple Book is not easily accessible and searchable online, which can inhibit the development and use of biosimilars.[6] Compared to the "easy-to-use reasonably sophisticated website for the Orange Book – where a user can search by active ingredient, proprietary name, patent, applicant holder, or application number – in most cases there is no similar mechanism for the Purple Book. In fact, the Purple Book's two lists are only available in PDF format and are not easily searchable," researchers Feldman et al. reported. As such, CSRxP would welcome efforts by the 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. Broadly speaking, CSRxP strongly concurs with Feldman et. al.'s conclusion: "Biosimilars have extraordinary potential to lower pharmaceutical costs and expand access for consumers. If the FDA wishes to allow companies, academics, and other stakeholders to tap into this potential, the Purple Book must be updated to increase the amount of information available and to

[4] 83 Fed. Reg. 22696
[5] Feldman, Robin et al. "May Your Drug Price Ever Be Green." UC Hastings Research Paper No. 256. October 29, 2017. Page 89.
[6] *Ibid*., page 90.

improve the accessibility of this information. At the very least the Purple Book should be of the same caliber as the Orange Book; and it should aspire to even better."[7]

Shortening the market exclusivity period for brand biologics: In addition to these policies included in the HHS Blueprint, CSRxP urges HHS to work with the Congress 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.

3. Disputing the Notion That Drug Makers May Excessively Increase Drug Prices Due to Taxes and Changes in the Medicaid Drug Rebate Program

The Blueprint asks whether the ACA's tax on brand drug manufacturers, the increase to the Medicaid Drug Rebate (MDR) amounts, and the extension of Medicaid drug rebates to Medicaid managed care organizations has impacted the list prices that manufacturers set, suggesting that these ACA requirements may have caused higher list prices. The trade association representing brand drug manufacturers supported passage of the ACA including its tax on such manufacturers and changes in rebate structures. CSRxP strongly objects to the notion that provisions in the ACA make it acceptable for brand drug companies to set needlessly high list prices and increase those prices at excessively high rates. Drug manufacturers alone are solely responsible for the prices they set and must bear full responsibility for the resultant high out-of-pocket expenses that American patients and families pay every day to receive the treatments they need to get well and stay healthy. Further, the pricing behavior that is occurring today predates the ACA.[8]

II. Better Negotiation

A. Improving Transparency in Prescription Drug Pricing in Medicare, Medicaid, and other Forms of Health Coverage

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. healthcare system toward one based on value; will foster more consumer-driven healthcare by better informing 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.

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[7] *Ibid*., page 89.

[8] AARP Public Policy Institute. "Rx Price Watch Report: Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans: 2006 to 2015."

Hence, CSRxP welcomes policies in the Blueprint that promote improved drug pricing transparency so long as they have appropriate guardrails to prohibit any violations of confidentiality protections or lead to tacit collusion among manufacturers. For example, frequently updating and increasing the amount of information on the Medicare and Medicaid Dashboards and requiring drug makers to include list prices in direct-to-consumer advertising will meaningfully improve drug pricing transparency and better inform patients of the true costs of treatment options available to them.

Furthermore, CSRxP urges HHS to build on the important transparency policy initiatives ongoing at the Department and described in the Blueprint by adopting policies that will:

- **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 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.

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

- **Produce an annual report on overall prescription drug spending trends.** The Department's Assistant Secretary for Planning and Evaluation (ASPE) previously has discussed important prescription drug spending trends through a March 8, 2016 report entitled "Observations on Trends in Prescription Drug Spending."[9] Reports such as this one from ASPE have given consumers, taxpayers, and policymakers critical information on the significant impact prescription drug spending has on consumers, federal health programs, and the U.S. healthcare system more broadly. However, since then, HHS has not released any subsequent reports. As such, CSRxP urges the Department to continue developing and publishing these reports on an annual basis to interject more transparency into prescription drug costs and pricing.

- **Releasing an annual HHS report on price increases for individual prescription drugs:** CSRxP urges HHS to release an annual report on: (1) the top 100 price increases per year by branded or generic drugs; (2) the top 100 drugs by annual spending and how much the government pays in total for these drugs; and (3) historical price increases for common drugs, including those in Medicare Part B. 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.

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

B. Improving the Accuracy of National Prescription Drug Spending Data

CSRxP supports improving the accuracy and transparency of national prescription drug data. Such data will show the high list prices that manufacturers set and increase frequently at high rates. Improved transparency and accuracy importantly will demonstrate the value that health insurance providers and other participants in the drug supply chin such as pharmacy benefit managers (PBMs) deliver for consumers, taxpayers and their clients by negotiating significant rebates and other discounts with drug manufacturers. However, CSRxP cautions that any changes in reporting of national prescription drug spending data should not mask any price increases drug manufacturers implement to make their products more costly for patients and taxpayers. Masking such data would harm – not help – in the important work to look for innovative ways to slow the unsustainable rate of growth in prescription drug costs.

C. Promoting Value-Based Arrangements in Federal Health Programs, Including Indications-Based Pricing and Supporting Value-Based Research

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. healthcare 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. Moreover, public and private institutions such as the Institute for Clinical and Economic Review (ICER) 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 result in lower drug prices. They also have been limited to a very small subset of drugs. More importantly, 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. 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 for the high cost of prescription drugs that American consumers and taxpayers face every day.

D. Better Managing 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. Part D plans typically have significant experience in applying appropriate utilization management tools for their commercial clients, which they also can apply to the Part D program. However, when permitting enhanced use of utilization management tools in Part D,

CSRxP urges the Department to ensure that all appropriate beneficiary protections remain in place. For example, beneficiaries should have sufficient notice prior to any changes in their drug benefits and ample time to appeal any benefit determinations made by the Part D plan.

CSRxP's support for increased management of high-cost Part D drugs especially those without rebates or other price concessions extends to drugs in the protected classes. Part D plans have little to no leverage in negotiating significant rebates and price concessions for these products given the regulatory safeguards from which they benefit. Beneficiaries taking medications in the protected classes could benefit from lower out-of-pocket costs if Part D plans were able to better manage their use.

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

E. Opposing the Establishment of Long-Term Financing Models for Purchase of High-Cost Drugs

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

First, long-term financing models do not address the fundamental issue of whether high-cost drugs are appropriately priced in the first place. These models simply assume that the manufacturer has assigned a correct and appropriate price for the product without actually performing an extensive analysis to demonstrate that the assigned price represents the true value of the product to the patient and her insurer. Manufacturers should have to prove in a highly transparent and verifiable fashion that the price of the product actually accords with its value based on the price they assigned to it.

Moreover, 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 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. Highly problematically, these issues would be further compounded if the patient used multiple high-cost medications that were paid for by long-term financing models, placing even more debt and long-term financial burden on Federal and State health programs.

Additionally, 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 simply are not the solution as they simply serve to prop up an unsustainable pricing market.

G. Expressing Concern over the Potential Adverse Impact on Medicare Beneficiaries with Shifting Part B Drugs to Part D

While CSRxP is supportive of policies that can make drugs more affordable for patients and taxpayers, we are concerned that shifting drugs currently covered under Part B to Part D would represent a dramatic shift in Medicare coverage policies, and requires further analysis and cost estimates, particularly on the cost-sharing implications for beneficiaries. In addition, it raises a number of safety and access concerns for beneficiaries. As such, we urge that the Department proceed very cautiously and entirely consider and address all of the operational complexities and challenges associated with such a policy before proposing it for implementation.

First, CMS carefully should review the data to demonstrate to Congress and stakeholders that drugs currently available in both Part B and Part D are less expensive in Part D after rebates, as this data will provide an important indicator of the savings potential for wholesale moving all drugs into Medicare Part D.

Second, beneficiaries face lower coinsurance obligations in Part B (20 percent) than in the standard Part D benefit (25 percent to 33 percent, in the case of specialty products). Increased coinsurance on more medications has the potential to result in significant increases in out-of-pocket spending for patients. The issue is even more concerning for beneficiaries who have purchased Medigap coverage; most of these beneficiaries currently pay no coinsurance for their Part B drugs and would be subject to new coinsurance obligations if Part B drugs were transferred to Part D. For many beneficiaries, particularly those on limited incomes, such an unplanned and costly change could have a substantial adverse financial impact and cause significant anxiety and/or nonadherence. Shifting often-expensive Part B drugs to Part D also could lead to higher Part D premiums, putting such coverage financially out-of-reach for some beneficiaries. Third, shifting all Part B drugs to Part D at once could raise access concerns for patients who need certain medications to get well and stay healthy. Lack of access leads to medication nonadherence, resulting in poor patient health outcomes.[10] Thus, CSRxP wants to ensure that beneficiaries maintain appropriate access to medically necessary therapies. Along those lines, it is imperative that HHS revisit the existing exceptions and appeals processes to ensure they are

[10] Neiman et al. "CDC Grand Rounds: Improving Medication Adherence to Chronic Disease Management – Innovations and Opportunities." November 17, 2017.

transparent, easy-to-understand, and fair. HHS should be willing to regularly revisit and make changes as appropriate to such processes.

Finally, CSRxP is concerned that shifting Part B drugs to Part D could introduce the significant potential for "brown bagging." This occurs when a patient fills a prescription through a pharmacy and brings medication to a physician to have it administered (e.g., moving drugs currently covered under Part B benefit to the Part D benefit). This practice can result in providers losing control of product distribution, thereby losing the ability to ensure product integrity. Moreover, storage and handling issues could arise if drugs are delivered through the mail or patients have to travel long distances to have their drugs infused. Additionally, certain "brown bagged" products may be wasted if the drug expires or cannot be transported when the patient is able to receive the infusion. All of the aforementioned issues represent just a few of the many complexities and operational challenges with shifting Part B drugs to Part D. Hence, CSRxP again urges that HHS proceed with significant caution before implementation of such a policy.

III. Creating Incentives to Lower List Prices

A. Requiring Drug Manufacturers to Include List Prices in 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 high-cost medicines. Presenting list prices 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 healthcare needs. Thus, CSRxP urges FDA to require drug makers to include list prices – and list price increases – in DTC advertisements for their products.

To further enhance transparency for patients and providers, CSRxP recommends that drug manufacturers include list prices and list price increases in DTC ads. We also recommend that the list price reflect the course of treatment for the average patient; if it is a maintenance drug that is taken for an extended period of time (e.g. longer than one year), the price should be for a 30-day fill period for the average patient. If it is a drug with a course of treatment less than one year, the list price should be for the course of treatment for the average patient. Disclosing list prices, list price increases, price increase frequency, and the cost for the course of treatment of an average patient will better inform patients of the treatment options available to them. This will enable patients to become more engaged in consumer-driven healthcare decisions and determine which treatments best meet their individual care needs.

B. Frequently Updating and Expanding the Amount of Information Available on 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. Enhanced transparency fosters a better understanding of the unsustainable growth in prescription drug pricing that consumers and taxpayers face every year. Hence, we appreciate HHS updating both Dashboards and urge the Department to continue updating them on a frequent basis.

As HHS continues to update the Dashboards, CSRxP urges the Department to include information on list prices, list price increases, and year-over-year pricing data. We particularly welcome and appreciate the

new data included in the Dashboards on manufacturers and manufacturer rebates; we recommend that HHS continue to update and add more comprehensive information on rebates to further enhance transparency in prescription drug pricing. Additionally, the Medicare Drug Dashboard previously included data on the number of beneficiaries using Part D drugs and the average cost-sharing they paid according to whether the beneficiary had Low-Income Subsidy (LIS) status or not; CSRxP urges HHS to reintroduce this information to the Dashboard. In sum, CSRxP recommends the continued addition of more data to the Dashboards to extend increased transparency to consumers and taxpayers on prescription drug pricing.

C. Establishing Lookback Periods for Medicare Part B and Part D Drugs

CSRxP appreciates HHS consideration of innovative ways to lower high list prices for prescription drugs. Therefore, we are interested in potential policies that would discourage manufacturers from raising prices for Part B and Part D drugs over a certain lookback period in time. For example, we are interested in a policy that would permit CMS to assign a Healthcare Common Procedure Coding System (HCPCS) code to a Part B drug immediately at launch if the manufacturer committed to a certain price over a specific lookback period. We also are interested in a policy that would prohibit an otherwise eligible drug from benefiting from Part D "protected class" status in if its manufacturer increased the price or did not provide a discount over a particular lookback period; CMS's program guidance requiring coverage of all or substantially all drugs in the "protected classes" in particular does not deter drug makers from raising prices, giving insurers little to no leverage in negotiations with manufacturers for price discounts. CSRxP cautions, however, that implementing lookback periods in Part B and/or Part D would present significant program complexities and operational challenges and thus recommend that HHS thoroughly consider these issues prior any proposals for policy implementation.

D. Eliminating the Inflationary Cap for Drugs Covered by Medicaid

CSRxP welcomes policies that will improve the affordability of prescription drugs for consumers and taxpayers and recognizes that eliminating the inflationary rebate cap for drugs covered under the Medicaid Rebate Program has the potential to discourage drug makers from implementing large price increases. Hence, this policy possibly can represent one tool as part of a broader solution to lower drug prices for Americans. That said, CSRxP recommends that HHS proceed cautiously when implementing this policy, recognizing that it could result in unanticipated changes to the Medicaid drug program. CSRxP wants to ensure that Medicaid beneficiaries continue to have access to the prescription drugs they need to get well and stay healthy and does not support policies that would hinder or negatively impact such access.

E. Recognizing the Value of the 340B Program

The 340B program provides meaningful relief from high prescription drug costs for safety-net providers that serve many of the nation's most vulnerable patients. As such, CSRxP urges the Department to ensure that safety-net providers and their patients continue to benefit from the critical drug savings afforded by the 340B program. Furthermore, the 340B program will be further served by finalizing rulemaking to penalize manufacturers that "knowingly and intentionally charge a covered entity more than the ceiling price for a covered outpatient drug" (340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation). The effective date of this rule has been delayed five times and currently will not be effective until July 1, 2019. The Health Resources and Services Administration (HRSA) will improve the integrity of the 340B program by implementing this rule.

F. Maintaining Current Policy Prohibiting Manufacturer Coupons in Federal Health Care Programs

Manufacturer coupons can induce unnecessarily utilization and correspondingly cause unnecessary spending on prescription drugs by Federal health care programs like Medicare Part D and their enrollees.[11] Indeed, manufacturer coupons appear to allow drug prices to grow more quickly than they would otherwise: branded drugs with coupons experience growth of 12 to 13 percent per year, compared with 7 to 8 percent per year for branded drugs without coupons.[12] As such, the drug industry appears increasingly to have relied on coupons to sell its products during the past five years. There were fewer than 100 brand-name drugs with coupon programs in 2009; in 2016, there are nearly 750 coupons to help patients pay for their drugs.[13] Therefore, CSRxP supports HHS maintaining current policy of banning drug manufacturer coupons in Federal healthcare programs.

First, the Anti-Kickback Statute prohibits drug coupons because they "induce the purchase of Federal health care program items or services," according to the HHS Office of the Inspector General (OIG) – that is, the drug manufacturer offering the coupon is directly benefiting from its use. [14] Second, when consumers use coupons for brand drugs over generics, this raises costs for everyone in the form of higher premiums and increases federal health care program costs for taxpayers. The HHS OIG recognized this phenomenon when prohibiting coupons in Federal health care programs: "[t]he availability of a coupon may cause physicians and beneficiaries to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available."[15] Hence, to protect against unnecessary spending, CSRxP recommends keeping the existing prohibition on manufacturer coupons in Federal health care programs. We note that even though coupons are banned in government programs, enforcement is inconsistent and thus suggest more consistent enforcement going forward. Further, if HHS ultimately determines that it will permit some coupons in Federal health care program we urge that coupons only should be available for medications without therapeutic equivalents and should not count toward a beneficiary's True Out-of-Pocket (TrOOP) costs for purposes of Medicare Part D.

G. 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 costs for consumers and taxpayers and 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 Part D enrollees, as well as employers, unions, and government plans offering prescription drug coverage.

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[11] Nuys et. al. "A Perspective on Prescription Drug Copayment Coupons." USC Leonard D. Schaeffer Center for Heath Policy & Economics. February 2018.

[12] Dafny et. al. "Kellogg Insight: Prescription Drug Coupons Actually Increase Healthcare Spending by Billions." October 3, 2017.

[131313] Johnson, Carolyn. "Secret rebates, coupons, and exclusions: how the battle over high drug prices is really being fought." The Washington Post. May 12, 2016.

[14] HHS OIG. "Special Advisory Bulletin: Pharmaceutical Manufacturer Copayment Coupons." September 2014, page 3.

[15] *Ibid*. page 2.

Indeed, a recent study found that there is no correlation between the prices drug companies set and the rebates they negotiate with PBMs and that drug companies increase prices regardless of rebate levels.[16] 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.[17] In other words, rebates negotiated by PBMs do not correlate with or necessarily lead to higher list prices; instead, brand drug makers set those excessively high prices and frequently raise them, needlessly increasing costs and placing undue burden on patients and taxpayers.

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 Part D and its beneficiaries over $20 billion in drug costs in 2017 and are projected to save the program more than $300 billion from 2017 to 2026.[18] 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.[19] 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.

H. Adoption of Policies Other than Point-of-Sale Rebates to Lower Out-of-Pocket Spending for Medicare Part D Enrollees

The Blueprint notes that HHS previously released a Request for Information (RFI) soliciting comment on potential policy approaches for applying some manufacturer rebates and all pharmacy price concessions to the price of a Medicare Part D drug at point-of-sale (POS).[20] CSRxP appreciates the intent of the policy under consideration, which could provide meaningful assistance to a limited number of Medicare Part D beneficiaries with high out-of-pocket prescription drug costs. However, as CMS acknowledges in the RFI, the policies likely would lower costs for a small number of beneficiaries at the expense of significant premium increases for *all* Part D enrollees.[21] Such an outcome in particular would negatively impact the many Medicare beneficiaries who live on fixed incomes and simply cannot afford unnecessary increases to their monthly Part D premiums. We know that HHS agrees with us that prescription drug coverage should become more – not less – affordable for all Part D enrollees.

Moreover, and of significant concern, is the fact that minimum POS rebates would substantially raise Medicare Part D program costs while perversely increasing the profitability of the brand pharmaceutical industry. The HHS actuaries estimate that the policy could cost taxpayers between roughly $27 billion to

[16] Visante. "No Correlation between Increasing Drug Prices and Manufacturer Rebates in Major Drug Categories." April 2017.
[17] *Ibid*.
[18] Milliman. "Value of Direct and Indirect Remuneration: Impact on Part D Prescription Drug Plan (PDP) Stakeholders." July 2017.
[19] 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.
[20] 82 Fed. Reg. 56336
[21] 82 Fed. Reg. 56421

$82 billion over ten years, depending on the minimum rebate amount.[22] Brand drug manufacturers, in turn, would pay out nearly $10 billion to $29 billion less in price discounts in the Part D coverage gap over ten years.[23] Such outcomes are extremely unfortunate for taxpayers as well as current and future Medicare beneficiaries given that they inappropriately place Medicare on less sound financial footing. Indeed, the Medicare Payment Advisory Commission (MedPAC) shares our concerns and, consequently, "strongly encourage[d]" CMS to find a less complex policy to lower out-of-pocket spending for Part D enrollees in its comments on the RFI.[24]

Finally, and most importantly, a policy to implement minimum rebates for Medicare Part D drugs at POS simply does not address the root cause of the unsustainable growth in prescription drug costs: brand drug manufacturers alone set list prices too high and regularly raise those prices at excessively high rates. Again, while CSRxP very much appreciates the intent of this policy under consideration, we would believe alternative market-based approaches could lower high list prices for prescription drugs and reduce the out-of-pocket prescription drug spending burden that Medicare beneficiaries and all American patients and families unfortunately face every day.

IV. Reducing Patient Out-of-Pocket Spending

A. Support for Actionable and Meaningful Tools to Increase Transparency and Help Beneficiaries Make Informed Part D Choices without Imposing Significant Burden on Health Care Entities

CSRxP very much appreciates the Department's intent to increase transparency in the Medicare Part D Explanation of Benefits (EOB) form. However, we are concerned that adding information on rate of price change could be administratively challenging to implement and could place significant burden on Part D plans. Moreover, we are concerned that too much information potentially could cause confusion and possibly upset beneficiaries, worrying them about price increases they may or may not actually experience depending on their plan benefit design. Thus, while we strongly agree with HHS that improving transparency in prescription drug pricing is critical, CSRxP believes that making this information available to beneficiaries when it is actionable is most important for Medicare beneficiaries.

The period during which new information on rates of change in drug pricing is most actionable is during Part D open enrollment season. Occurring once per year, this is the time when beneficiaries make decisions on Part D plan enrollment for the upcoming benefit year. Rates of change in drug prices would add to the information available to beneficiaries to make more informed choices on the Part D plans that best meet their individual care needs. We also encourage HHS to develop standard language for Part D sponsors to use when communicating this information to help reduce confusion for beneficiaries.

B. Concern over Significant Operational Challenges in Requiring Pharmacists to Inform Beneficiaries about Drug Price Changes

CSRxP welcomes policies that arm consumers with information to make more informed choices on the medications that best meet their individual treatment needs and budgets. Successful implementation would require pharmacists to be continuously fully informed of all price changes in all Part D plans

[22] 82 Fed. Reg. 56425
[23] 82 Fed. Reg. 56425
[24] MedPAC January 3, 2018 letter to CMS Administrator Verma on CMS-4182-P, pages 14 – 15.

available to all beneficiaries in their market. Prices increase frequently and vary by each insurance plan. Hence, it would be nearly impossible for pharmacists to remain continuously current on all price changes impacting the Medicare beneficiaries they serve. Thus, we suggest that the Department not pursue a policy to require to inform beneficiaries about drug price changes. That said, we very much appreciate the intent of the policy to better educate patients about prescription drug prices and welcome other policies that would improve drug pricing information available to patients in a less administratively complex manner.

C. Informing Beneficiaries with Medicare Part B and Part D about Cost-Sharing and Lower Cost Alternatives

CSRxP agrees it would be helpful for the prescriber and the patient to have access to cost-sharing information through real-time benefit inquiry (RTBI) software at the point of prescribing, assuming that the software is available. With this information, patients and prescribers would be better able to determine if a lower cost alternative is available and should be considered. This technology also has the potential to reduce the workloads of the prescriber and pharmacist since the technology could provide information immediately about the patient's formulary and whether additional work is required for the prescriber or pharmacist in order for the beneficiary to access a given drug, for example due to prior authorization requirements. Therefore, CSRxP believes that policies that would support increased availability of RTBI software could be beneficial to patients, prescribers, and pharmacists. **V. Additional Policies to Reduce 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 face 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 HHS to work with the Congress to adopt the bipartisan, market-based solutions described below, which inject more competition into the market 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.[25] 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

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

competition until 2023 due to a settlement agreed to by the brand and biosimilar manufacturer of the product.[26] [27] [28]

"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 – tactics often referred to as "evergreening" or "product hopping." Generic dispensing laws generally permit pharmacists to substitute a generic for a brand only when the products are exactly same. Reformulations of original products are not the same as the original product and, thus, "dispense as written" generally prohibits pharmacists from switching the reformulated product with the generic. Thus, these reformulated and combination therapies effectively can delay generic competition and keep prescription drug costs needlessly high for consumers.

A recent analysis by researchers Shadowen et al. suggests that consumers can lose up to $2 billion per year per each anti-competitive product reformulation.[29] Specifically, the study analyzed a comprehensive database of more than 400 pharmaceutical reformulations from 1995 through April 2009 and showed that 32 reformulations representing more than $28 billion in combined annual sales were temporally linked to imminent generic competition and clearly "suspect," e.g. "minor reformulations such as changes from capsule to tablet or vice versa; changes in chemical structure that yielded little or no consumer value; and multiple seriatim product reformulations."[30] Additionally, 22 reformulations with combined annual sales of $15.8 billion involved switches to extended release or "combination" products.[31] In other words, the study demonstrated that both reformulations and "combination" products raise potentially significant anti-competitive concerns and should be monitored. Notably, the analysis found that not all reformulations appeared to pose competition concerns as they were not linked temporally to generic entry.

Increasing scrutiny of anti-competitive tactics like "evergreening" and "product hopping" will bring generic options and lower costs to consumers more quickly. Therefore, CSRxP urges HHS to work with appropriate Federal agencies to enhance scrutiny of these schemes. Those that may be deemed anti-

[26] AbbVie. "AbbVie Reports Full-Year and Fourth-Quarter 2017 Financial Results." January 26, 2018.
[27] Reuters. "AbbVie, Amgen settlement sets Humira U.S. biosimilar launch for 2023." September 28, 2017.
[28] The Center for Biosimilars. "Latest Humira Price Increase Could Add $1 Billion to US Healthcare System in 2018." January 5, 2018.
[29] Shadowen, Steve et. al. "Anticompetitive Product Changes in the Pharmaceutical Industry." Rutgers Law Journal, Vol. 41, No. 1-2, Fall/Winter 2009, page 78.
"[30] *Ibid*., page 3.
[31] *Ibid*., page 3.

competitive should be closely monitored by the appropriate federal agencies and prosecuted if found to be in violation of antitrust laws.

C. 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. These incentives include waived FDA fees, tax credits, and seven years of marketing exclusivity. 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 options. However, FDA has granted a growing number of orphan drug designations in the recent past. A recent analysis by Feldman et al. showed that between 2005 and 2015, the number of drugs that added an orphan drug exclusivity tripled from 9 drugs in 2005 to 27 drugs in 2015.[32] Between 2010 and 2015, the number of drugs adding an orphan exclusivity nearly quadrupled from 7 drugs in 2010 to 27 drugs in 2015.[33]

Moreover, an increasing number of orphan drugs have achieved blockbuster status, with billions of dollars in sales annually. Orphan drug sales increased 12.2 percent to $114 billion from 2015 to 2016 while non-orphan sales increased 2.4 percent to $578 billion.[34] The fast growth in orphan drug sales is expected to continue with projected growth of 11.1 percent per year between 2017 and 2022 to $209 billion, which is more than double the expected 5.3 percent growth of over the overall prescription drug market over the same period.[35] Orphan drugs are expensive for patients. The average cost per patient for an orphan drug in 2016 was $140,443 versus $27,756 for a non-orphan drug.[36]

Biopharmaceutical companies often use multiple techniques to maintain high prices for orphan products in non-orphan patient populations. For example, in "spillover pricing" companies obtain orphan exclusivity for their product and then encourage doctors to prescribe the medication for off-label indications with broader patient populations not included in the FDA's approved label for the product. In "salami slicing," drug companies separate patient populations into subpopulations to reach the orphan limit population of 200,000 or less, thereby enabling them to market the product effectively in patient populations that exceed the orphan threshold.

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, including high-selling drugs such as Crestor, Abilify, Herceptin and Humira. More than 80 orphan drugs received approval for more than one rare disease and, in some cases, multiple rare diseases – each time qualifying for additional exclusivity.[37] For example, Gleevec has received nine separate orphan drug

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[32] Feldman, Robin et al. "May Your Drug Price Ever Be Green." UC Hastings Research Paper No. 256. October 31, 2017, pages 60 – 61.
[33] *Ibid*., pages 60 – 61.
[34] Evaluate Pharma. Orphan Drug Report 2017, page 8.
[35] *Ibid*., page 8.
[36] *Ibid*., pages 9 – 10.
[37] Tribble, Sarah Jane and Lupkin, Sydney. "Drugmakers Manipulate Orphan Drug Rules to Create Prized Monopolies." Kaiser Health News. January 17, 2017.

designations and had a reported $3.3 billion in sales in 2016.[38] 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."[39]

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. For example, the FDA could require additional information when companies seek orphan drug status, such as providing information about additional indications for which a company intends to seek approval. HHS should also analyze and report on orphan drug utilization and pricing trends, including trends by indication for orphan and non-orphan uses.

D. Curbing Anti-Competitive "Patent Thickets" 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. Rather than only securing a patent for a drug's active ingredient or a biologic's composition of complex molecules, brand biopharmaceutical manufacturers typically obtain secondary patents for manufacturing, methods of production, or other aspects of a product to help extend its market exclusivity period. These secondary patents enable brand drug makers to game the system by prolonging monopolies and claiming "newness" where none often exists.

A recent study by Feldman et al. of the roughly 100 best-selling drugs between 2005 and 2015 concluded that "[r]ather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones. 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 existing drugs. In some years, the percentage reached as high as 80 percent."[40] Specifically, the study found that the quantity of patents on the drugs in the study increased from 349 to 723 between 2005 and 2015, which the researchers attributed to two factors: (1) the growth in the number of drugs adding patents; and (2) the growth in the number of patents added per each one of those drugs.[41] The number of drugs adding a high quantity of patents in a single year has substantially increased. In particular, the number of drugs adding three or more patents in one year doubled from 37 in 2005 to 76 in 2015.[42] Similarly, the number of drugs adding five or more patents doubled from 14 in 2005 to 34 in 2015.[43] As a result, Feldman et al. assert: "The upward trend in the number of drugs adding a high quantity of patents in a single year seems to indicate

[38] National Academies of Sciences, Engineering, and Medicine. "Making Medicines More Affordable: A National Imperative." Page 115.
[39] *Ibid*., page 123.
[40] Feldman, Robin et al. "May Your Drug Price Ever Be Green." UC Hastings Research Paper No. 256. October 31, 2017, page 48.
[41] *Ibid*., page 49.
[42] *Ibid*., page 70.
[43] *Ibid*., page 70.

that drug companies are increasingly applying for as many patents as possible and seeing what they get."[44]

For example, the manufacturer of the best-selling product in the world, Humira, has obtained over 70 newer patents in recent years covering formulations of the drug, manufacturing methods, and use for specific diseases. Humira's patents potentially could extend market protection for the brand biologic as far as 2034, according to an October 2015 presentation by its manufacturer Abbvie outlining Humira's "patent estate," but a recent settlement agreed to by AbbVie and a biosimilar manufacturer will result in market competition by a biosimilar in 2023.[45] [46] [47] This is well beyond the 12 years of market exclusivity granted to Abbvie for Humira, which protected the brand biologic from competition into 2014. In another case with small molecules, Pfizer's strongest patents for the blockbuster statin Lipitor expired March 2010 and June 2011, but generic settlements delayed generic entry until 2016 due to expiration of minor patents at that time.[48]

While it is important to protect intellectual property and incentivize the development of innovative medicines, brand drug companies should not abuse the system and obtain patents that simply extend their market monopolies. This gaming of the system makes medicines even more unaffordable and needlessly raises costs for patients and taxpayers. To stop these anti-competitive practices, CSRxP urges HHS to work with appropriate Federal agencies to increase scrutiny of biopharmaceutical patents so that drug makers are appropriately rewarded only for those patents that are truly innovative and new.

E. Strengthening Post-Market Surveillance

Today, manufacturers may be required to conduct additional clinical trials post approval of a particular product. This is often the case when expedited approval pathways are used, which typically involve smaller clinical trials with a narrower patient population. In such cases a given drug may show significant promise and, because of high unmet need, the FDA wants to get the product to market despite an incomplete understanding of long-term efficacy or side effects. However, once a drug is approved, many of these studies are never conducted. A related concern is that for the clinical trials that are completed, much of this information is never reported publicly. Specific timelines must be put in place to ensure that post-market trials are conducted. If manufacturers do not follow through with their commitment to complete a required trial, they should be subject to fines or other penalties unless an exception has been granted by the FDA. In addition, manufacturers should be required to report summary data for all trials (whether a product is approved or not) that summarizes non-identifiable data on demographics and baseline characteristics of participants, primary and secondary outcome results, and information on any adverse events.

F. Reducing Drug Monopolies by Incentivizing Competition for Additional Market Entrants

Delays in the FDA approval process often prevent competitors from coming to market in a timely manner; in such situations, adjustments should be made to bring potential market competitors to the

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[44] *Ibid*., page 70.
[45] Gonzalez, Richard. "Abbvie Long-Term Strategy." October 30, 2015. Slides 13 - 16.
[46] Pollack, Andrew. "Makers of Humira and Enbrel Using New Drug Patents to Delay Generic Versions." The New York Times. July 15, 2016.
[47] Slide presentation by Michael Carrier at FTC November 8, 2017 workshop. Slide 48.
[48] Slide presentation by Michael Carrier at FTC November 8, 2017 workshop. Slide 48.

market more quickly. The tools to do so already exist. For example, several FDA programs are intended to expedite review of new drugs that address unmet medical needs for the treatment of serious or life-threatening conditions. These include: fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation. These incentivizes also should be utilized to drive competition for expensive treatments where no competitors exist and encourage a second or third market entrant. Such a strategy could not only increase competition, but also will serve as an important protection to consumers if the first market entrant has to be withdrawn due to safety concerns. We would caution, however, that manufacturers should not be able to inappropriately take advantage of any incentives for purposes of sheer profitability. For example, currently manufacturers are permitted to sell the priority review designations they obtain without any requirements to conduct new research or market the drug in the U.S.; such parameters should be put in place for any designations developed to incentivize new market competition.

VI. Conclusion

In conclusion, CSRxP again wishes to thank you for the opportunity to comment on the "HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" (RIN 0991-ZA49). CSRxP looks forward to working collaboratively with the Department to address the critical problem of unsustainable growth in prescription drug costs through adoption and implementation of bipartisan, market-based solutions that promote transparency, foster competition, and enhance value drug pricing. Our more detailed policy platform with additional proposals for your consideration is available at our website, www.csrxp.org.

Sincerely,

Lauren Aronson

Executive Director
The Campaign for Sustainable Rx Pricing