the campaign for
SUSTAINABLE Rx PRICING
Transparency. Competition. Value.

June 5, 2019

The Honorable Lamar Alexander
Chairman
Senate Health, Education, Labor, and Pensions Committee
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
Senate Health, Education, Labor, and Pensions Committee
Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray,

The Campaign for Sustainable Rx Pricing (CSRxP) thanks you for the opportunity to comment on the Lower Health Care Costs Act of 2019. We appreciate your leadership in looking for ways to reduce health care costs and particularly the unsustainable growth in prescription drug prices that American consumers and taxpayers face every day.

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

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

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

In this context, CSRxP thanks the Committee for its leadership in developing and drafting the Lower Health Care Costs Act of 2019. We very much appreciate the Committee's clear commitment to

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

lowering health care costs for all Americans and especially its interest in improving prescription drug affordability. Below we offer our support for a number of provisions included in this bipartisan legislation that we agree represent helpful initial steps in reducing prescription drug costs for consumers and taxpayers.

CSRxP also firmly believes, however, that the Committee has missed an opportunity to include additional provisions in the legislation that will more directly target the root cause of the drug pricing problem: the brand drug manufacturers that are responsible for setting high list prices and engaging in anti-competitive tactics to extend product monopolies well beyond their original periods of periods of market exclusivity. As the Committee continues to refine the Lower Health Care Costs Act, CSRxP urges that the bill include the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act, the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act, and the Reforming Evergreening and Manipulation that Extends Drug Years (REMEDY) Act.

Each of these important bills with broad bipartisan support takes aim at the unfair practices brand name manufacturers undertake to make prescription drugs more costly for patients and taxpayers. The CREATES Act will help curb Risk Evaluation and Mitigation Strategy (REMS) abuses and better enable consumers to access more affordable generic drugs more quickly. The FAIR Drug Pricing Act will require drug makers to justify the needlessly high prices they make U.S. consumers pay. Finally, the REMEDY Act will help combat the pharmaceutical industry's anti-competitive gaming of the patent system to extend product monopolies far beyond their original exclusivity dates.

CSRxP simply does not want the Committee to miss this important opportunity to include concrete, bipartisan provisions that will have a meaningful impact on prescription drug pricing. We urge consideration of these additional pieces of legislation for inclusion in the bill. That said, we also very much appreciate the Committee's intent to improve prescription drug affordability and thus express our support for provisions in the Lower Health Care Costs Act that further this critically important goal.

Support for Section 201, Biological Product Patent Transparency: The Food and Drug Administration's (FDA's) Purple Book includes certain limited information about reference biologics, but not the same level of information as is available for small molecule drugs in FDA's Orange Book. For example, the Purple Book does not include any information related to the patents of brand biological products.[2] Moreover, the limited information available in the Purple Book is not easily accessible and searchable online. Researchers have suggested that lack of sufficient and easily accessible information in the Purple Book has the potential to hinder development and consumer accessibility of more affordable biosimilar and interchangeable biological products.[3]

CSRxP therefore supports this provision because it will increase the amount and accessibility of information available in the Purple Book about biological, biosimilar, and interchangeable biologic patents. Having improved information available in a more accessible manner will better protect against anti-competitive tactics by brand biologic manufacturers to delay or prevent competition through listing of invalid or inappropriate patents, thereby fostering increased development of biosimilar and interchangeable biologics and enhancing overall competition in the marketplace. Notably, as the Committee continues to further refine this provision, CSRxP respectfully suggests that it look to the

[2] Feldman, Robin and Wang, Connie. "May Your Drug Price Ever Be Green." UC Hastings Research Paper No. 256. October 31, 2017.
[3] *Ibid*.

Purple Book Continuity Act of 2019 (H.R.1590) for additional ways to tighten the biological patent process and prevent gaming of the system by brand manufacturers to inappropriately and unfairly extend product monopolies.

Support for Section 202, Orange Book Modernization: Drug makers list patent information in FDA's Orange Book to help generic manufacturers make drug development decisions. Recent research has shown that patent information included in the Orange Book by brand drug makers in certain cases may be of questionable validity or applied inappropriately as a way to delay generic competition.[4] "FDA does not scrutinize the company's representations, however, but merely records whatever the company submits in what is known as the 'Orange Book.' Thereafter, a competitor seeking approval of a generic drug must battle every patent listed in the Orange Book in relation to the drug. Thus, simply listing a patent in the Orange Book can operate to block or delay competition, even if the patent does not cover the drug," researchers explained.[5]

CSRxP supports this provision because it will assist generic drug manufacturers in product development and help remove barriers to generic competition in the marketplace. The provision will better ensure that information in the Orange Book is accurate and up-to-date so that generic drug makers can make more informed drug development decisions. Moreover, having the FDA work with the U.S. Patent and Trademark Office (USPTO) to increase scrutiny of patents also will better ensure that the Orange Book only lists patents that are valid and applied appropriately. Together, these policies importantly will guard against anti-competitive listing of inappropriate or invalid patents to prevent or delay generic competition.

Support for Section 203, Ensuring Access to Timely Generics: Although Congress intended FDA's citizen petition process to raise valid scientific issues with generic drug applications, in actuality brand drug makers have filed most citizen petition requests with the primary purpose of delaying FDA approval of generic competitors to their brand drugs. To unfairly game the system, brand drug makers oftentimes request that FDA mandate additional testing or other requirements; in most cases, FDA denies such requests – but through a relatively lengthy process that still delays generic drug market entry. One recent study found, for example, that FDA denied 92 percent of citizen petitions filed between 2011 and 2015, indicating that the vast majority of these requests simply did not have merit. That same study further concluded that FDA denied 98 percent of citizen petitions filed within 6 months of the expiration of a patent or FDA exclusivity date, suggesting that brand drug manufacturers filing those citizen petition requests did so strictly to inappropriately delay generic competition.[6] [7]

CSRxP supports this provision because it will help combat these abuses of the citizen petition process that needlessly prohibit and delay consumer access to generic drugs. Ensuring that FDA both has clear authority to deny sham citizen petition requests in a timely manner and to refer cases of sham requests to the Federal Trade Commission will better protect against this anti-competitive tactic employed by brand drug makers to extend their product monopolies and restrict patient access to less costly generic drugs.

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[4] *Ibid*.
[5] *Ibid*.
[6] Carrier, Michael. "Five Actions to Stop Citizen Petition Abuse." 118 Columbia Law Review Online (2018, Forthcoming). September 28, 2017. Page 2.
[7] Slide presentation by Michael Carrier at FTC November 2017 workshop. Slide 51.

Support for Section 204, Protecting Access to Biological Products: FDA is transitioning certain biologics – including, critically, many forms of insulin – currently approved under the 505(b)(2) pathway to the biologics approval pathway. This provision protects unexpired market exclusivity for these transitioning biologics and importantly ensures that they cannot receive new extended market exclusivities as a result of the transition.

CSRxP supports this provision because it will prohibit manufacturers from gaming the system to unfairly extend product monopolies and impose even higher prices on consumers. This is especially critical in the case of insulin where patients have had to bear substantial price increases to take the often life-sustaining medication they need to remain healthy and have a good quality of life. Simply put, insulin should be much more affordable for patients than it currently is; patients should not have to choose between daily living expenses like food and taking insulin. This provision importantly helps incentivize the development of biosimilar and interchangeable biologic products such as insulin that can bring more competition to the market and lower costs for patients.

Support for the intent of Section 205, Preventing Blocking of Generics: Generic drugs substantially improve prescription drug affordability for consumers and taxpayers. As such, CSRxP would welcome the opportunity to work with the Committee to develop bipartisan, market-based policies that will expedite the availability of generic drugs to consumers. As the Committee considers policies to achieve these goals it is imperative that we increase competition in the prescription drug market and maintain important incentives for manufacturers to develop generic drugs.

Support for Section 206, Education on Biological Products: High-priced specialty biologics are driving unsustainable rates of spending growth on prescription drugs both in the commercial market and in government health programs like Medicare and Medicaid. Increased competition for these expensive products will help slow this spending growth over time.[8] [9] As such, CSRxP strongly advocates for policies that foster increased development and utilization of less costly biosimilars and interchangeable biologics and therefore supports this provision of the Lower Health Care Costs Act. This provision gives the Secretary of the U.S. Department of Health and Human Services (HHS) authority to establish a website to provide educational materials to providers, patients and caregivers on biologics, biosimilars, and interchangeable biologics and requires the Secretary to advance education and awareness about biosimilars to healthcare providers through continuing medical education (CME) programs. As the Committee further refines the legislation, we respectfully suggest requiring, rather than simply permitting, the establishment of a website to provide education on biologics, biosimilars, and interchangeable biologics.

Support for Section 208, Clarifying the Meaning of New Chemical Entity: CSRxP advocates for policies that prohibit anti-competitive gaming of the system by the drug industry to lengthen product monopolies and keep list prices high. Therefore, we support this provision to tighten and clarify the definition of a new chemical entity (NCE) to guard against unfairly conferring market exclusivity to products that are not truly innovative.

Support for Section 209, Streamlining the Transition of Biological Products: This provision ensures that, as FDA transitions certain biologics from the current 505(b)(2) pathway to the biologics pathway,

[8] U.S. Department of Health and Human Services Assistant Secretary for Planning and Evaluation. ASPE Issue Brief: Medicare Part B Drugs: Pricing and Incentives. March 8, 2016.
[9] Express Scripts. 2018 Drug Trend Report.

applications submitted six months prior to the transition date will not have to be resubmitted and therefore receive a delayed review. CSRxP supports this provision because consumers should not have to experience delays in accessing affordable medications as soon as they can become available. This is especially the case for those insulin products transitioning to the biologics pathway where increased competition has the potential to result in meaningfully lower costs for consumers and taxpayers.

Concern with Section 306, Health Plan Oversight of Pharmacy Benefit Management Services: CSRxP has concerns with this provision because we are unclear how it will result in lower prices and reduced costs for consumers. There are numerous pieces to the overall provision that, when taken together, could create unintended consequences that will increase red tape and could actually raise – not lower – drug prices and costs for consumers. Clearly, such an outcome is not an intention of the Committee. Moreover, and most critically, the provision does not get to the root cause of the drug pricing problem – the manufacturers that set high list prices and generate outsized price increases. Instead of including a provision that could unintentionally increase costs for consumers like this one, CSRxP strongly encourages the Committee to instead include provisions that directly impact drug companies and the abusive and anti-competitive pricing tactics they employ.

Conclusion

In conclusion, CSRxP again wishes to thank the Committee for the opportunity to comment on the Lower Health Care Costs Act of 2019. We appreciate your leadership in seeking lower health care costs for all Americans and particularly to improve the affordability of prescription drugs for consumers and taxpayers. We again wish to urge the Committee to not miss a significant opportunity to also include in the bill pieces of legislation with broad bipartisan support – the CREATES Act, FAIR Drug Pricing Act, and REMEDY Act – that will reduce costs and directly impact the pharmaceutical industry – the root cause of the critical drug pricing problem. CSRxP looks forward to our continued work with the Committee to implementing bipartisan, market-based policies that promote transparency, foster competition, and incentivize value to make prescription drugs more affordable for all consumers while at the same time maintaining access to the treatments that can improve health outcomes and save lives.

Sincerely,

Lauren Aronson
Executive Director
The Campaign for Sustainable Rx Pricing