



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

April 28, 2017

The Honorable Lamar Alexander
Chairman
Committee on Health, Education,
Labor & Pensions
U.S. Senate
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
Committee on Health, Education,
Labor & Pensions
U.S. Senate
Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray:

Thank you for the opportunity to provide comments on the discussion draft of the Food and Drug Administration (FDA) Reauthorization Act of 2017, which would renew the FDA's authority to collect user fees from the makers of prescription brand drugs, generic drugs, biosimilars, and devices.

The Campaign for Sustainable Rx Pricing (the "Campaign") is a project of the National Coalition on Health Care Action Fund. Our members represent organizations including consumers, hospitals, physicians, nurses, pharmacists, employers, pharmacy benefit managers and health plans. The Campaign's mission is to foster and inform the debate on sustainable drug pricing and to develop market-based policy solutions that focus on transparency, competition and value while ensuring access to necessary treatments.

We strongly support efforts to ensure timely passage of the updated user fee agreements, which we believe are critical for the FDA's work ensuring that new, innovative treatments are available to patients. We generally support the provisions in the proposed draft, including provisions that provide goal dates for all outstanding generic applications; establishment of priority review timelines for generic drugs; and efforts to continue building the biosimilars review program.

However, we are concerned that moving forward with these user fee agreements without addressing the fundamental and troubling issues of the skyrocketing costs of pharmaceuticals is a missed opportunity. The problem of high drug costs has been well documented. Relentless prescription drug price increases are not sustainable and place an increasing financial burden on our healthcare system. Of great concern, these trends are not isolated instances of "bad actors" but rather evidence of a much larger, systemic problem that directly and negatively impacts patients, employers, payers, providers, and taxpayers.

CSRxP strongly urges the committee to consider including additional provisions aimed at addressing these concerns as part of the FDA Reauthorization Act of 2017. We have long advanced proposals that we believe would bring about a more functional market through better competition, enhanced transparency, and a focus on value while ensuring that patients have timely access to the therapies they need. Additional policies that we urge the Committee to consider:

Stop Anti-Competitive Practices that Prohibit Generic Drugs from Coming to Market: CSRxP strongly urges the Committee to consider policies that would combat anticompetitive behavior that delays or blocks the availability of more affordable generic drugs. Currently, brand name drug companies can use a loophole in U.S. law to prevent generic drug companies from accessing samples of their products, effectively preventing them from pursuing the research needed to bring generic drugs to market. This

practice restricts competition in the market and often leaves patients with fewer choices for their medications. As a result, patients may be at the mercy of a single drug company for the medication they need to stay healthy, and that company is free to set the price for the medication indiscriminately. Such practices put a financial strain on patients and drive up health care expenses for everyone.

Bipartisan legislation has been introduced in both the Senate and the House – the CREATES Act and the FAST Generics Act – that would stop this anticompetitive practice. We therefore encourage the Committee to consider bipartisan legislation that addresses these abuses by prohibiting companies from restricting access to samples.

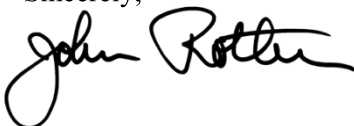
Reducing the Backlog of Generic Applications: In addition to provisions that would speed up approval timelines and provide for priority review of generic prescription drugs, we urge the Committee to ensure that the FDA is provided the resources necessary to clear the current backlog of generic applications. Also, we support prioritizing the FDA approval of applications for classes of drugs with no or limited generic competition.

Promoting a Robust Biosimilars Market: Regulatory policies should encourage market entry and uptake of biosimilars, as they have significant potential to expand treatment options and reduce costs through increased competition. For example, one study found that eleven biosimilars already approved for sale in Europe and elsewhere could generate \$250 billion savings over 10 years if they were available in the U.S.¹ We urge the Committee to consider provisions—such as reducing the market exclusivity period for brand name biologics—that would help support the development of a robust biosimilar market and help ensure that patients have access to lower cost alternatives to existing, expensive biologics.

Targeted Orphan Drug Incentives: The Orphan Drug Act introduced a range of incentives to encourage the development of medications to treat rare diseases -- diseases that affect fewer than 200,000 individuals. Since passage of the Orphan Drug Act, hundreds of orphan drugs have been approved. Many of these medications are helping patients who previously had no treatment options. However, an increasing number of orphan drugs have achieved blockbuster status, with billions of dollars in sales annually. Much of this revenue is generated by other FDA-approved, non-orphan indications or off-label use. We urge the Committee to consider provisions that would help ensure that the Orphan Drug Act's incentives are being utilized to develop medicines to treat true rare diseases.

Thank you for consideration of our comments. Our more detailed policy platform – which includes additional proposals to promote competition, transparency, and value – is available at our website, www.csrxp.org.

Sincerely,



John Rother,
Executive Director
Campaign for Sustainable Rx Pricing (CSRxP)

¹ExpressScripts 2013, [http://lab.express-scripts.com/lab/insights/industry-updates/the-\\$250-billion-potential-of-biosimilars](http://lab.express-scripts.com/lab/insights/industry-updates/the-$250-billion-potential-of-biosimilars)