

Statement for the Record

Submitted by

The Premier Inc. healthcare alliance

Markup of: H.R. 965, the “CREATES Act”; H.R. ____, the “Preserve Access to Affordable Generics and Biosimilars Act”; H.R. ____, the “Stop Significant and Time-wasting Abuse Limiting Legitimate Innovation of New Generics Act”; and H.R. ____, the “Prescription Pricing for People Act of 2019”.

House Judiciary Committee

April 30, 2019

The Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the House Judiciary Committee’s markup of several drug pricing related bills scheduled for April 30, 2019. We applaud the leadership of Chairman Nadler, Ranking Member Collins and members of the Committee for holding this markup to consider policy solutions that promote competition to lower drug costs for American patients. **Premier is committed to addressing the rising cost of pharmaceuticals and strongly supports steps to make a more competitive marketplace to lower drug prices.** A competitive marketplace allows market forces to work as intended to naturally lower drug prices for consumers, providers and the government. The key to this is enacting policies to remove barriers to competition, making it easier to develop generics, streamline the drug approval process and promote biosimilars, and accelerate the movement to value-based care.

Premier is a leading healthcare improvement company, uniting an alliance of more than 4,000 U.S. hospitals and health systems and approximately 165,000 other providers and organizations to transform healthcare. With integrated data and analytics, data-driven collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost.

Premier is saving our members millions of dollars by driving economies of scale, creating transparency around pricing and quality and applying competitive pressure to the marketplace. We put manufacturers in head-to-head competition, assess the product’s value and create market-leading contracts that may be used by healthcare providers. For our services we charge a flat percentage of the negotiated, discounted price. The fees are not varied within product categories so as to maintain a level playing field. By aggregating the buying power of U.S. hospitals, **Premier’s drug portfolio prices have grown less than half the rate of the industry average inflation rate.**

To continue to succeed in our work to reduce healthcare spending, **we need policy solutions that are attainable, practical, and sustainable.**¹ As the Committee considers policy solutions to help lower drug costs for Americans, Premier urges the Committee to focus on the following as overarching principles:

¹ Premier previously provided detailed comments in response to the “HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs” request for information. Available at: <https://www.premierinc.com/wpdm-package/premiers-response-trump-administrations-rfi-drug-pricing/>

- **Solutions that use competitive forces to lower drug prices and increase the availability of generic medications and biosimilars in the marketplace** - A wealth of research and Premier analytics show that competition in the pharmaceutical marketplace brings down prices. Competition from generic drugs has saved the U.S. healthcare system \$1.46 trillion from 2005 to 2015.² According to the Food and Drug Administration (FDA), drug prices drop to roughly 52 percent of brand-name drug prices with two manufacturers producing a generic product, 44 percent with three manufacturers and 13 percent with 15 manufacturers.³

In order to increase the competitive forces, more players are needed. **Therefore, solutions to address drug prices should focus on lowering the barriers to entry to bring additional generic and biosimilar competition to the market.**

- **Sustainable solutions to address drug shortages that decrease barriers to entry, namely the time and cost to enter the marketplace, while maintaining the quality and safety of the product** – Drug shortages continue to plague the healthcare system and have grown in both number and intensity in the past two years.⁴ Drug shortages are a major driver of skyrocketing costs contributing to over half a billion dollars in increased healthcare expenditures annually. A recent study found that prices for drugs under shortage increased more than twice as quickly as they would in the absence of a shortage adding \$230 million a year to U.S. drug costs.⁵ In addition to the increase in drug prices, drug shortages cause a multitude of downstream impacts to the healthcare system that increase healthcare expenditures such as increased labor costs⁶ and the potential for adverse events.⁷

Over the past 15 years Premier has implemented innovative strategies enabling us to reliably supply our members with 92 National Drug Codes (NDCs) that are on the drug shortage list. We have also embarked on an expanded partnership strategy with suppliers we expect will extend this progress. This work, therefore, is not done, and we will not stop until we have eliminated drug shortages. **Therefore, solutions to address drug prices should focus on eliminating drug shortages to prevent the subsequent price increases that occur during a shortage.**

Premier offers the following comments on the specific bills being considered by the Committee:

- **H.R. 965 – Creating and Restoring Equal Access to Equivalent Samples Act of 2019 (CREATES Act)**

² Generic Drug Access & Savings in the U.S. 2017. Available at: <https://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf>

³ IMS Health, Price Declines after Branded Medicines Lose Exclusivity in the U.S. January 2016. Available at:

<https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/price-declines-after-branded-medicines-lose-exclusivity-in-the-us.pdf>

⁴ FDA Public Hearing Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions. Available at:

<https://healthpolicy.duke.edu/events/drug-shortage-task-force>

⁵ Hernandez I, Sampathkumar S, Good CB, Kesselheim AS, Shrank WH. Changes in Drug Pricing After Drug Shortages in the United States. *Ann Intern Med*; 170:74–76. doi: 10.7326/M18-1137

⁶ "Impact of drug shortages on U.S. health systems" (*American Journal of Health-System Pharmacy*, October 2011).

<https://www.ncbi.nlm.nih.gov/pubmed/21930639>

⁷ FDA Public Hearing Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions. Available at:

<https://healthpolicy.duke.edu/events/drug-shortage-task-force>

Premier supports eliminating anticompetitive behaviors and closing loopholes that permit manufacturers to deny access to samples and thereby delay the introduction of generics and biosimilars to the market. Some brand and biologic manufacturers restrict access to samples for generic and biosimilar manufacturers by citing compliance with limited distribution or risk evaluation and mitigation strategy (REMS) requirements. This practice inhibits the ability of generic and biosimilar manufacturers to demonstrate bioequivalence and thereby delays the availability of generics and biosimilars in the marketplace. The Congressional Budget Office estimates that ceasing these practices will save patients and taxpayers \$3.9 billion over ten years by encouraging earlier entry of generics and biosimilars, thereby creating a competitive marketplace.

The CREATES Act uses market-based solutions to increase competition and thus lower drug prices by establishing a clear process for FDA to ensure that appropriate safety measures are in place for the sharing of samples that are subject to limited distribution or REMS requirements. In addition, the bill provides the Federal Trade Commission (FTC) with oversight to detect anticompetitive practices and a limited legal pathway for generic and biosimilar manufacturers to seek relief against brand and biologic manufacturers that unjustifiably deny access to samples. The oversight of both the FTC and the courts is important to the success of the CREATES Act.

One area that the CREATES Act does not account for is when samples are denied as a result of evergreening or patent hopping. In this scenario, a brand or biologic manufacturer makes slight improvements to their product, such as moving from a twice-a-day formulation to a once-a-day formulation, and markets the improved product under a new patent and therefore a new exclusivity period. Typically, the brand or biologic manufacturer ceases marketing of the prior product and may use this as a reason to deny samples citing a lack of supply of the prior product. ***To fully resolve the issue of brand and biologic manufacturers denying samples, Premier recommends that the Committee also consider language, either within the context of CREATES or in a separate bill, that would require manufacturers to share samples of products that have been discontinued for reasons not associated with safety or efficacy concerns.*** These products should still be eligible for generic and biosimilar manufacturers to bring to market resulting in increased competition and decreased costs for patients.

Premier supports the CREATES Act and encourages its adoption.

- **H.R. ____ - Preserve Access to Affordable Generics and Biosimilars Act**

Premier supports eliminating anticompetitive practices that permit manufacturers to enter into patent settlements to delay the introduction of generics and biosimilars to the market. Some brand and biologic manufacturers have been able to sidestep competition by offering patent settlements that pay generic and biosimilar manufacturers to not to bring lower-cost alternatives to market. These are voluntary settlements where a generic or biosimilar manufacturer agrees to refrain from marketing its product for a specified period in return for compensation from the brand or biologic manufacturer. A 2013 FTC study reported that these anticompetitive practices cost consumers and taxpayers \$3.5 billion in higher drug

costs every year.⁸ Since 2001, the FTC has filed several lawsuits against brand and generic manufacturers to stop these deals, however, even with some success by FTC, the practice continues, and additional congressional action is needed.

The Preserve Access to Affordable Generics and Biosimilars Act would prohibit brand and biologic manufacturers from compensating generic and biosimilar manufacturers to delay the entry of a lower-cost alternative into the market.

Premier supports the Preserve Access to Affordable Generics and Biosimilars Act and encourages its adoption.

- **H.R. ____ - Stop Significant and Time-wasting Abuse Limiting Legitimate Innovation of New Generics Act (Stop STALLING Act)**

Premier supports eliminating the ability of manufacturers to file citizens petitions with the primary purpose of delaying the approval of a generic or biosimilar application. Citizen petitions, when used properly, can bring important information to the FDA's attention necessary to protect the public health. However, when citizen petitions are filed with no real merit, they delay generic medication and biosimilar entry into the market, and in doing so, stymie competition and the ability to lower prices for patients.

In October 2018, the FDA issued draft guidance⁹ to 1) determine whether a citizen petition was submitted for the primary purpose of delaying the approval of a generic or biosimilar application and subsequently deny the petition; 2) refer anticompetitive citizen petitions to the Federal Trade Commission (FTC); and 3) highlight these determinations in the FDA's annual report to Congress.

The Stop STALLING Act builds upon the FDA's work in this space and would allow the FTC to take civil action to deter drug companies from filing sham citizen petitions to delay approval of competing generics or biosimilars. ***To further strengthen the bill and provide additional transparency, Premier recommends that the bill be amended to require that petitions be filed directly by the principals (e.g. manufacturers) and not by law firms or consultant groups that mask the identity of the principal.***

Premier supports the Stop STALLING Act and encourages its adoption with amendments.

In closing, the Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the House Judiciary Committee markup on drug pricing. As an established leader in using competitive forces to lower drug prices and working towards eliminating drug shortages, Premier is available as a resource and looks forward to working with Congress as it considers policy options to address this very important issue.

⁸ Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in Fiscal Year 2012: A Report by the Bureau of Competition. Available at: <https://www.ftc.gov/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement>

⁹ FDA-2009-D-0008, Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability. Available at: <https://www.fda.gov/media/117884/download>

If you have any questions regarding our comments or need more information, please contact Soumi Saha, Senior Director of Advocacy, at soumi_saha@premierinc.com or 202-879-8005.