

Statement for the Record

Submitted by

The Premier Inc. healthcare alliance

Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition

Senate Judiciary Committee

May 7, 2019

The Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the Senate Judiciary Committee's hearing titled "*Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition*" scheduled for May 7, 2019. We applaud the leadership of Chairman Graham, Ranking Member Feinstein and members of the Committee for holding this hearing to consider policy solutions that balance innovation while promoting competition to lower drug costs for American patients. Solutions to address the rising cost of pharmaceuticals must appropriately reward innovation and provide incentives for the pharmaceutical industry to continue to bring transformative and curative therapies to market, but also must address any anticompetitive behaviors and loopholes that are preventing a robust and competitive marketplace.

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. Loopholes and speedbumps in the patent system, however, can slow the introduction of competitor products. 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:

- ***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.***

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/>

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 offers the following specific recommendations as it relates to patent reform and striking the appropriate balance between innovation and competition:

- ***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 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.

Legislation such as *S. 64/H.R. 2375 – 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 eliminating anticompetitive practices that artificially extend patent protections for drugs.*** Known as “evergreening” or “patent hopping,” 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. In other examples, manufacturers have begun to file for multiple patents for their products that cover not only the active ingredient but also cover manufacturing, delivery systems and other elements. This practice extends exclusivity for the product beyond the patent for the active ingredient alone, thereby delaying introduction of alternatives to the marketplace.

A recent study⁹ quantified how pervasive these practices are and found that between 2005 to 2015, 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. Once a company starts down this road, there is a tendency to continue adding additional patent protections as 80 percent of drugs had more than one additional patent added. Furthermore, this practice is most common amongst blockbuster drugs as of the roughly 100 best-selling drugs, more than 70 percent had their patent protection extended at least once, with almost 50 percent having the protection extended more than once.

Legislation such as *S. 1209 - Reforming Evergreening and Manipulation that Extends Drug Years Act* would help address this anticompetitive behavior. In addition, Congress should work

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 Robin Feldman. “May Your Drug Price be Evergreen” *Journal of Law and the Biosciences*, Isy022. December 2018. Available at: <https://doi.org/10.1093/jlb/Isy022>

with the United States Patent and Trademark Office (USPTO) to ensure that patents are appropriately awarded for truly innovative and new discoveries.

- **Premier supports changes to the Orphan Drug Act to ensure it is meeting its original intent of fostering the development of innovative drugs for rare conditions and not unintentionally delaying competition.** Concerns have been raised about the potential abuse of the Orphan Drug Act by manufacturers that initially apply for a single indication that qualifies for orphan drug status but then apply for broader non-orphan indications once the product is approved by the FDA. Conversely, manufacturers may seek orphan drug status for a product that is already approved for a non-orphan indication prior to expiration of the original exclusivity period to further extend the product's exclusivity. These practices delay the introduction of generic and biosimilar alternatives to the marketplace, as the product is protected under extended exclusivity given its orphan drug status. Potential solutions to address the abuse of the Orphan Drug Act include:
 - Strengthening the “medically plausible” criteria where FDA can deny orphan drug status if determined that a manufacturer artificially limited the investigational and potential use of the drug to only the subset of interest;
 - Limiting orphan drug status to new molecular entities; and
 - Requiring the disclosure of additional indications for which the manufacturer intends to seek FDA approval.
- **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 guidance¹⁰ 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.

Legislation such as *H.R. 2374 – 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 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

¹⁰ 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>

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.

Legislation such as *H.R. 965/S. 340 - 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 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.

- ***Premier supports the ability of generic and biosimilar manufacturers to expeditiously enter the market upon winning a patent challenge.*** Legislation such as *H.R. 1506 - The FAIR Generics Act* would allow any generic filer who wins a patent challenge in court or is not sued for patent infringement by the brand manufacturer to share in the 180-day exclusivity period of first applicants that enter into patent settlements that delay entry. It would also hold such first applicants to the launch date that was agreed to in any patent settlement agreement.
- ***Premier supports transparency in helping generic and biosimilar manufacturers understand when certain patents and exclusivity periods expire to encourage the entry of cost-saving medications into the marketplace.*** Legislation such as *H.R. 1520 - Purple Book Continuity Act of 2019* and *H.R. 1503 - Orange Book Transparency Act of 2019* would require brand and biologic manufacturers to report patent expiration dates and exclusivity periods to the FDA for publication in the Orange and Purple Books. This information will create transparency and predictability for generic and biosimilar manufacturers regarding when they are eligible for FDA approval and could enter the marketplace as a competitor.

In closing, the Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the Senate Judiciary Committee hearing 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.

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.