

## Statement for the Record

Submitted by

The Premier Inc. healthcare alliance

### ***Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition***

House Energy and Commerce Subcommittee on Health

March 13, 2019

The Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the House Energy and Commerce Subcommittee on Health hearing titled “*Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition*” scheduled for March 13, 2019. We applaud the leadership of Chairman Eshoo, Ranking Member Burgess and members of the Subcommittee for holding this hearing to examine prescription drug pricing and consider policy solutions that promote competition to lower costs for American patients. ***Premier is committed to addressing the rising cost of pharmaceuticals and strongly supports the creation of a 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 aggregates and works with healthcare providers to drive maximum market competition. 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. We see every day the power of competition. 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.*** 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.

Premier constantly scans the market and works closely with high-quality manufacturers to encourage them to bring products to the market where only one or two suppliers exist. This alleviates price spikes and drug shortages. These efforts have met with great success in lowering prices for consumers, providers and the government. For example, in 2015, isoproterenol HCl injection and sodium

nitroprusside – two very old, established off-patent cardiovascular drugs - were sold to another manufacturer. Being the only manufacturer in the market with a de facto monopoly, this company dramatically increased the prices for these products by nearly 500 percent. Premier immediately reached out to alternative suppliers to encourage them to file Abbreviated New Drug Applications (ANDAs) and supported these companies through the FDA approval process by advocating for and encouraging accelerated review of these applications. Once the new drug makers were approved and entered the market, the costs dramatically dropped, taking the prices back to their historic levels. Specifically, nitroprusside went from a high of \$650 back down to about \$20 and isoproterenol went from a high of more than \$14,000 back down to less than \$2000.

***Premier is a solution to the rising cost of drugs. We need, however, policy changes for us to continue to succeed in our work to reduce healthcare spending. We have developed policy solutions that are attainable, practical, and sustainable.***<sup>1</sup> As the Subcommittee begins to examine the rising cost of drugs and develop policy solutions to help lower costs for Americans, Premier urges the Subcommittee 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.<sup>2</sup> 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.<sup>3</sup> This dynamic is reflected in the fact that 88 percent of dispensed prescriptions are for generic drugs, yet they account for only 28 percent of total drug spending.<sup>4</sup>

The reverse is also true. When manufacturers of drugs leave the market, drugs can experience significant price spikes due to the lack of competition. Extreme price jumps can put life-saving drugs out of reach for patients. The following Drug Efficacy Study Implementation (DESI) drugs are prime examples of how market exit of manufacturers leads to significant price spikes:

- Neostigmine, a medication used to reverse the effects of neuromuscular blocking agents after surgery, was priced at \$33 (for 10 vials of 10mg/mL) in 2009. The new “brand” Bloxiverz, approved by FDA in the same package size, jumped to \$150 in 2013 and continued to experience price increases up to \$938 by 2015 when other manufacturers of these older unapproved drugs exited the market. While not anywhere near where it was prior to the removal of other manufacturers in the market, the price dropped to \$580 in 2015 with two other manufacturers entering the market.

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<sup>1</sup> 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/>

<sup>2</sup> 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>

<sup>3</sup> 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>

<sup>4</sup> *Id.*

- Epinephrine, a medication used to treat life-threatening allergic reactions and acute asthmatic attacks, was \$69 for a vial in 2015 and jumped 352 percent to \$312 in 2016 when other manufacturers were required to leave the market by FDA. The price continued to rise another 20 percent in 2017 on a drug that has long been on the market with no “new” indications or therapy improvement.
- Potassium chloride, a medication used to treat hypokalemia, in 2014 sold for \$40 for 20MEQ/15ML and when other manufacturers were required to leave the market, the price jumped to \$236 in 2016. This price increase sent a shock wave through the health community for a drug that has long been deemed safe and effective with no research and development cost attached to the product.

But 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.<sup>5</sup> 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.<sup>6</sup> Another recent study found that the price of fluphenazine tablets in 2016 increased by over 2000% during a shortage.<sup>7</sup>

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 costs associated with managing drug shortages, estimated to be \$216 million annually.<sup>8</sup>
- Increased potential for adverse events, and consequently increased costs to the healthcare system such as increased hospital days, due to the unavailability of a critical medication. For example, a shortage of norepinephrine was significantly associated with increased mortality amongst patients with septic shock.<sup>9</sup> The FDA

<sup>5</sup> 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>

<sup>6</sup> 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

<sup>7</sup> Fox E. R., Tyler L. S. (2017). Potential association between drug shortages and high-cost medications. *Pharmacotherapy* 37, 36–42. 10.1002/phar.1861

<sup>8</sup> “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>

<sup>9</sup> Vail, Emily, Gershengorn, Hayley, Hua, May, Walkey, Allan, Rubinfeld, Gordon & Wunsch, Hannah. (2017). Association Between US Norepinephrine Shortage and Mortality Among Patients With Septic Shock. *JAMA*. 317.DOI: 10.1001/jama.2017.2841.

estimates that the norepinephrine shortage resulted in \$13.7 billion of projected losses to the U.S. healthcare system.<sup>10</sup>

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 Subcommittee:

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

***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 Subcommittee also consider language, either***

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<sup>10</sup> 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>

***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. 985 – The Fair Access for Safe and Timely Generics Act of 2019 (FAST Generics)**

Similar to the CREATES Act, the FAST Generics Act would also use market-based solutions to increase competition by eliminating loopholes used by brand and biologic manufacturers to restrict access to samples thereby delaying the entry of generics and biosimilars into the marketplace.

***Premier supports the FAST Generics Act and encourages its adoption.***

- **H.R. 1499 - The Protecting Consumer Access to Generic Drugs Act of 2019**

***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.<sup>11</sup> 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 Protecting Consumer Access to Generic Drugs 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. The bill broadly defines compensation as anything of value including an exclusive license and agreements to limit or forgo research, development, manufacturing, marketing or sales of the product for any period.

***Premier supports the Protecting Consumer Access to Generic Drugs Act and encourages its adoption.***

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<sup>11</sup> 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>

- **H.R. 1506 - The Fair and Immediate Release of Generic Drugs Act (FAIR Generics)**

***Premier supports the ability of generic and biosimilar manufacturers to expeditiously enter the market upon winning a patent challenge.*** 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 the FAIR Generics Act and encourages its adoption.***

- **H.R. 938 – The Bringing Low-cost Options and Competition while Keeping Incentives for New Generics Act of 2019 (BLOCKING Act)**

***Premier supports also holding generic and biosimilar manufacturers accountable for engaging in anticompetitive behaviors that thwart market competition and thereby increase drug prices.*** Some generic and biosimilar manufacturers have chosen to purposely not market their product within the 180-day exclusivity period granted to the first generic or biosimilar manufacturer to gain FDA approval. This practice, often referred to as “parking,” prevents other generic or biosimilar products from coming to market within the 180-day exclusivity period. This in turn extends the life of the brand or biologic product’s patent until the 180-day exclusivity period expires and a subsequent generic or biosimilar manufacturer can enter the marketplace.

The BLOCKING Act would discourage parking of 180-day exclusivity by a first generic applicant by allowing FDA to approve a subsequent generic application prior to the first applicant’s first date of commercial marketing when certain conditions have been met.

Premier supports the concept of the BLOCKING Act to prevent parking, but in lieu of creating new criteria to determine abuses to the 180-day exclusivity period, ***Premier recommends the Subcommittee adopt the criteria and forfeiture clauses required under the Competitive Generics Therapy (CGT) pathway.*** Under the CGT, a manufacturer is granted a 180-day exclusivity period that is contingent upon a forfeiture clause that requires the manufacturer to market the product within 75 days of FDA approval or otherwise lose their exclusivity period. Congress passed the CGT in 2017 as part of the bipartisan Food and Drug Administration Reauthorization Act (FDARA) and specifically included the forfeiture clause to overcome concerns with parking. Therefore, there is recent bipartisan Congressional precedent to proceed with a 75-day forfeiture clause to identify abuses to the 180-day exclusivity period and prevent parking. Applying a consistent standard across the pharmaceutical industry will also create predictability for manufacturers, patients, and the government.

Furthermore, the bills scope is limited to generics only. Since this practice can also be utilized by biosimilar manufacturers, ***Premier urges the Subcommittee to expand the scope of the bill to include both generics and biosimilars.***

***Premier supports the BLOCKING Act with amendments and encourages its adoption.***

- **H.R. 1503 – The Orange Book Transparency Act of 2019**

***Premier supports transparency in helping generic manufacturers understand when certain patents and exclusivity periods expire to encourage the entry of generics into the marketplace.*** The Orange Book Transparency Act would help to ensure that the Orange Book is accurate and up-to-date, by requiring manufacturers to share complete and timely information with FDA, as well as ensuring that patents listed in the Orange Book are relevant to the approved drug product. Patents found to be invalid through a court decision or a decision by the Patent Trial and Appeal Board would be required to be removed promptly.

***Premier supports the Orange Book Transparency Act and encourages its adoption.***

- **H.R. 1520 – The Purple Book Continuity Act of 2019**

***Premier supports transparency in helping biosimilar manufacturers understand when certain patents and exclusivity periods expire to encourage the entry of biosimilars into the marketplace.*** The Purple Book Continuity Act would codify publication of approved biological products in the Purple Book in a similar format and with similar requirements to the Orange Book, specify that the Purple Book should be published electronically on FDA's website and updated routinely, and direct FDA to consider the types of patents that should be listed in the Purple Book.

Premier is concerned that as drafted, the bill would only require the listing of patent information for biologics if it is provided to the FDA by the biologic manufacturer. This creates an opportunity for biologic manufacturers to game the system and not report patent information to the FDA as it would not be required, and therefore not create transparency for biosimilar manufacturers who are looking to enter the market. To overcome this challenge and encourage a competitive biosimilars marketplace, ***Premier encourages the Subcommittee to strengthen the language to require biologic manufacturers to report patent information to the FDA for the purposes of reporting in the Purple Book.***

***Premier supports the Purple Book Continuity Act with amendments and encourages its adoption.***

In closing, the Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the House Energy and Commerce Subcommittee on Health's 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](mailto:soumi_saha@premierinc.com) or 202-879-8005.