PREMIER TRANSFORMING HEALTHCARE TOGETHER®

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Katherine K. Vidal
Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office
Madison East Building, Concourse Level
600 Dulany Street
Alexandria, VA 22314

Robert M. Califf M.D.
Commissioner of the Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Submitted electronically via www.regulations.gov

Re: Joint USPTO-FDA Collaboration Initiatives; Notice of Public Listening Session and Request for Comments [Docket No. PTO-P-2022-0037]

Dear Under Secretary Vidal and Commissioner Califf,

Premier Inc. appreciates the opportunity to submit comments to the United States Patent and Trademark Office (USPTO) and Food and Drug Administration (FDA) on the request for comments titled "Joint USPTO-FDA Collaboration Initiatives; Notice of Public Listening Session and Request for Comments [Docket No. PTO-P-2022-0037]" which was published in the November 7, 2022 Federal Register. In the request for comments, the USPTO and FDA seek input to promote greater access to medicines for American families and increase competition in the marketplace.

Premier appreciates your joint commitment to address the rising cost of pharmaceuticals and help ensure that the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law. In our comments, Premier reflects on the legislative barriers to innovating within our current healthcare system and opportunities for action to foster innovation, competition and affordability. Specifically, Premier's comments focus on three areas:

- Deterring anticompetitive behaviors in the pharmaceutical marketplace to lower drug prices;
- Revising Stark and anti-kickback laws to include drugs and support the movement to value-based care; and
- Collaborating across Congress and Federal agencies including the Federal Trade Commission (FTC), Department of Justice (DOJ), Centers for Medicare and Medicaid Services (CMS) and others to ensure a holistic approach to fostering innovation while holding bad actors in the space accountable.

13034 Ballantyne Corporate Place
Charlotte, NC 28277
T 704.357.0022
F 704.357.6611

444 North Capitol Street, N.W.
Suite 625, Washington, DC 20001
T 202.393.0860
F 202.393.6499

PREMIERINC.COM

I. Background on Premier Inc.

Premier is a leading healthcare improvement company, uniting an alliance of more than 4,400 U.S. hospitals and approximately 250,000 continuum of care providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. A 2006 Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. A key component of our alliance is our Integrated Pharmacy Program, which combines essential clinical data with purchasing power to deliver reduced costs, improved quality and safety, and increased knowledge-sharing with other healthcare professionals. Headquartered in Charlotte, North Carolina, Premier is passionate about transforming American healthcare.

II. Deterring Anticompetitive Behaviors in the Pharmaceutical Marketplace to Lower Drug Prices

As discussions on drug pricing continue in Washington, it is critical to focus on encouraging the adoption of generic and biosimilar medications which offer patients a more affordable treatment alternative. To support market competition, which incentivizes innovation while reducing overall costs, Premier believes it is necessary to reduce the gaming of USPTO and FDA requirements or other attempts to unfairly delay competition. Premier offers several specific recommendations to help improve market competition and encourages USPTO and FDA to work with Congress and other federal agencies to move these policies forward. Premier believes these are low-hanging fruit in many ways as they have been addressed in a bipartisan and bicameral manner in prior Congressional sessions, but unfortunately never made it to the finish line. Now is the time to address these anticompetitive behaviors and help reduce the cost of drugs in the United States.

First, 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. This practice delays the introduction of generic and biosimilar alternatives to the marketplace, as the product is protected under extended exclusivity given its orphan drug status. To combat this practice, ***Premier urges 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*****.** For example, additional information can be requested of manufacturers seeking orphan drug status, such as disclosing additional indications the manufacturer intends to seek FDA approval for. Furthermore, changes could be made such that additional non-orphan indications of a product are not granted any additional exclusivity. Changing the transparency requirements and incentives for the program may deter some manufacturers from abusing the Orphan Drug Act.

Second, in recent years, 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 extends exclusivity for the product beyond the patent for the active ingredient alone, thereby delaying introduction of alternatives to the marketplace. Often referred to as “evergreening,” this practice permits manufacturers to extend monopolies by tacking on additional patents or making minor changes to drugs. ***Premier urges the prohibition of the practice of evergreening.*** Instead, Premier supports exclusivity for a pharmaceutical being tied to the patent associated with the molecule itself.

Third, manufacturers will sometimes make minor changes to their product, such as an extended-release formulation or once a day vs. twice a day dosing, and seek additional patent protection to extend exclusivity for their product. To help combat these practices that delay the introduction of alternatives to the marketplace, ***Premier urges the***

USPTO to ensure that patents are appropriately awarded for truly innovative and new discoveries and to revisit the Graham test for obviousness as it relates to pharmaceutical patents. For example, it is well known in pharmacology that most pharmaceuticals have a S-isomer and a R-isomer. It is further known that the R-isomer can typically be isolated and results in less side effects than the S-isomer. Oftentimes, we see manufacturers come to market with a product that contains both the S-isomer and R-isomer and then subsequently release a product close to patent expiration that contains the R-isomer only thereby receiving a new patent and restarting the exclusivity clock. In these types of situations, it is critical for the USPTO to ask if it was obvious that a manufacturer would eventually isolate the R-isomer and seek a new patent, and why the manufacturer did not pursue that route from the beginning other than to game the system.

Fourth, manufacturers often enter into patent settlements to delay the introduction of generics and biosimilars to the market at the expense of consumers. Referred to as "pay-for-delay" arrangements, these contractual agreements maintain monopolies and artificially extend market exclusivity thereby denying patients access to less expensive alternatives. ***Premier urges the prohibition of pay-for-delay arrangements***. For example, a manufacturer will pay generic companies to not pursue research and development of a competing generic to their product. In another scenario, a manufacturer will pay a generic company who receives an abbreviated new drug application from the FDA to purposely not market their product. In a third example, a manufacturer will pay a generic company to limit the amount of product they sell such that the manufacturer maintains a majority of the market share. In all of these examples, both the brand and generic manufacturer are equally at fault for colluding to limit market competition.

Fifth, the FDA and FTC announced a partnership in February 2020 where they will be working closer together on anticompetitive behavior, such as the filing of sham citizen petitions for the sole purpose of delaying competition. However, FTC does not have the authority to take civil action against a manufacturer that is a bad actor. Therefore, ***Premier urges Congress to pass legislation that allows the FTC to take civil action to deter drug companies from filing sham citizen petitions to delay approval of competing generics or biosimilars.***

Finally, one tactic that has been used by manufacturers to incentivize payors and pharmacy benefit managers (PBMs) to prefer a brand or biologic product over a cost-saving generic or biosimilar product is the use of rebates. In the case of biologics, manufacturers have been offering steep rebates upon market entry of a competitor biosimilar to maintain the biologic as the preferred product on a payor or PBMs formulary. This discourages adoption of the biosimilar and often prohibits patients from accessing the lower cost biosimilar. In some cases, rebates are thought to help the biologic product maintain upwards of 97 percent of market share years after a biosimilar is available.

CMS had proposed a rule that would have prohibited the use of all rebates; but it was later withdrawn in July 2019. While the rebate rule was withdrawn, there is still some interest to act in this space on a smaller scale by CMS and Congress to prevent anti-competitive behavior. ***Premier urges USPTO and FDA to work with CMS to prohibit rebates on biologics for a period of three years upon the market entry of a competitor biosimilar***. ***Premier believes this proposal would create a level playing field for biosimilars to compete with biologics based upon their scientific integrity, cost effectiveness, and patient outcomes***. The three-year timeframe is suggested to align with the three-year timeframe for pass-thru status for biosimilars, but additional timeframes can be considered.

III. Revising Stark and Anti-Kickback Laws to Include Drugs and Support the Movement to Value-Based Care

Premier strongly supports the holistic movement from volume to value, including value-based arrangements and payment models, as well as value-based contracts for drugs, amongst other innovative strategies to transform healthcare. However, several challenges exist to truly moving towards value as many laws and regulations were written to provide protections within a volume-based system, specifically the anti-kickback statute (AKS) and Stark self-referral laws.

The federal AKS and Physician Self-Referral Law were enacted to address issues for a different healthcare delivery system where providers of services and other stakeholders could encourage overutilization of services. However, new models of healthcare delivery encourage value and emphasize care coordination and integration to increase both the quality and efficiency in the delivery of services to patients. Providers of services, suppliers, and related stakeholders are concerned about inadvertent or potential violations of the AKS and Physician Self-Referral law because of the substantial breadth of the statutes, the lack of clear guidance for exceptions and the potential for civil monetary penalties. Existing safe harbors and exceptions are not designed to accommodate innovative arrangements used in new models of care delivery and those that do apply do not address specific issues raised under these arrangements or do not afford adequate protection from liability.

On November 20, 2020, the Trump Administration finalized two rules as part of the Department of Health and Human Services (HHS) Regulatory Sprint to Coordinated Care. The HHS Office of Inspector General (OIG) issued the final rule "Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements," and CMS issued the final rule "Modernizing and Clarifying the Physician Self-Referral Regulations." In the rules, HHS removed some regulatory barriers to encourage increased participation in value-based care, which can lead to improved care coordination, improved outcomes and lower costs. However, the rules are still constrained within the confines of a statutory framework that was designed to address vulnerabilities in a fee-for-service system and specifically exclude drugs. Additionally, CMS and OIG excluded certain entities from their proposals, such as drug manufacturers.

To more effectively support the movement to value-based care, Premier urges the revision of Stark and AKS policies using a new statutory framework focused on value-based care that includes drugs. These new safe harbors and exceptions should be entity agnostic and provide equal protection to all entities willing to bear risk for value-based arrangements. As part of a transition to value-based care, it is necessary to pay for medications based on outcomes.

Plans, providers, and manufacturers are seeking to develop innovative ways to align dollars spent with healthcare value gained. Failure to align the fraud-and-abuse regulatory system with these changes will result in dollars spent inefficiently and avoidable increases in healthcare costs, which ultimately harm patients. Furthermore, employers have long been calling for these types of changes to increase their competitiveness through reduced healthcare expenses and improved care coordination and health outcomes for their employees.

Stark and Anti-Kickback modernization will provide a valuable tool to constrain healthcare cost escalation. Below are some examples of how modernization of Stark and AKS to be inclusive of drugs can help further the movement to value-based care and lower healthcare costs.

- A manufacturer and payor wish to enter into a value-based contract where the manufacturer will discount the cost of therapy by 40 percent if a patient relapses within a five-year time frame. Under current law, the discount safe harbor requires that the payor claim the benefit within a two-year time frame and therefore

the five-year timeframe would not be permissible. It is also unclear if the discount safe harbor can be extended to payors as a "buyer" of the product or service.

- A manufacturer and payor wish to enter into a value-based contract where the manufacturer will provide patients with a cell phone so they can follow-up with patients and also have patients use a drug-specific app to monitor for adherence. Under current law, the OIG would likely see this as beneficiary inducement to use a certain drug to get the benefit of a free cell phone. While the OIG recently issued an advisory opinion on this and considers it permissible, an OIG opinion is only applicable to the specific parties named in the request and any additional manufacturers or payors wishing to provide cell phones would have to seek their own OIG advisory opinion.
- A manufacturer and payor wish to enter into a value-based contract where the manufacturer will reimburse all costs associated with re-hospitalization if the drug fails. Under current law, the warranty safe harbor under AKS only covers the cost of replacing the drug. The payment of costs associated with re-hospitalization would be considered remuneration under the AKS.

IV. Collaborating across Congress and Federal agencies including the FTC, DOJ, CMS and others to ensure a holistic approach to fostering innovation while holding bad actors in the space accountable

As the drug pricing debate has progressed over the years, one thing has been clear – there is no silver bullet to solving this issue and no single act of Congress or regulatory proposal is enough. ***To truly move the needle and holistically lower drug prices for Americans while continuing to incentivize innovation, collaboration amongst Congress and federal agencies is essential to tackle the issue from multiple angles and ensure that proposed solutions do not have unintended consequences on patients***. Premier encourages the development of a public-private task force, that includes federal partners as well as entities such as healthcare providers, patient representatives, manufacturers, payors and others, to collectively work together to develop consensus recommendations to meet the shared goal of lowering drug prices. Open and honest discussion and collaboration is essential as continuing to tackle this issue in a fragmented and siloed manner will not yield the intended outcomes.

V. Conclusion

In closing, Premier appreciates the opportunity to submit comments on PTO-P-2022-0037. Premier looks forward to working with USPTO, FDA and other stakeholders to encourage a robust and healthy pharmaceutical marketplace by striking the appropriate balance between innovation, access and competition.

If you have any questions regarding our comments or need more information, please feel free to contact me at soumi_saha@premierinc.com or 732-266-5472.

Sincerely,

Soumi Saha, PharmD, JD
Senior Vice President of Government Affairs
Premier Inc.