December 18, 2022

Robert M. Califf M.D.
Commissioner
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Submitted electronically via www.regulations.gov

Re: Select Updates for the Breakthrough Devices Program Guidance: Reducing Disparities in Health and Healthcare; Draft Guidance for Industry and Food and Drug Administration Staff [Docket Number: FDA-2022-D-1061]

Dear Dr. Califf:

Premier Inc. appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) in response to the draft guidance titled *Select Updates for the Breakthrough Devices Program Guidance: Reducing Disparities in Health and Healthcare; Draft Guidance for Industry and Food and Drug Administration Staff [Docket Number FDA-2022-D-1061].* The draft guidance describes how FDA intends to update the Breakthrough Devices Program to include certain devices that benefit populations impacted by health and/or healthcare disparities.

Premier strongly supports the goal of achieving health equity across the healthcare continuum. Health disparities exist across multiple dimensions including race and socioeconomic status and addressing them is important for improving health outcomes. Premier urges the FDA to address three critical areas to ensure success in reducing disparities for medical devices:

1. Standardizing data collection
2. Harnessing the power of real-world evidence
3. Balancing Innovation and Competition

Premier is a leading healthcare improvement company and national supply chain leader uniting an alliance of 4,400 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. Premier's sophisticated technology systems contain robust standardized data gleaned from nearly half of U.S. hospital discharges, 812 million hospital outpatient and clinic encounters and 131 million physician office visits. Premier is a data-driven organization with a 360-degree view of the supply chain, working with more than 1,300 manufacturers to source the highest quality and most cost-effective products and services. Premier's work is closely aligned with healthcare providers, who drive the product and service contracting decisions using a data driven approach to remove biases in product sourcing and contracting and assure access to the highest quality products.

Premier is working with life sciences organizations, community organizations, patient advocacy groups and health systems to co-create solutions that can help reduce disparities, improve outcomes and deliver equitable healthcare for all. At the foundation of this work is patient centricity, a philosophy and approach engaging patients (inclusive of caregivers, families and communities), partnering with and empowering them to gain greater control over decisions and actions affecting their health. Premier believes that reducing

disparities across health outcomes will require a diverse and inclusive healthcare environment where all patients can thrive and have the opportunity to achieve optimal health outcomes. This will take everyone from life sciences organizations to health systems to the FDA working together to develop solutions that can be customized to patients' needs and delivered to the right patients at the right time at the right cost.

I. Standardizing Data Collection

To support efforts to advance health equity, Premier believes that disparities in care must be identified with robust health equity-related data that is standardized across clinical trials, health systems, real-world evidence data sets, payer data and other clinical data sets. This data must include accurate and consistent collection of factors that affect people's lives and result in health disparities across race/ethnicity, age, ability, geography, economic status and other social conditions. These factors include access to healthcare, bias/discrimination and other social drivers of health such as education and economic opportunities. Bias and discrimination – or the unfair treatment of people or groups based on characteristics such as race, age, gender identity or sexual orientation – exists in many systems in society including healthcare.

Absent standardized data collection methods and recognized agreement regarding health equity definitions and measurement, each sector of healthcare risks speaking its own language resulting in a siloed and fragmented approach to a problem that requires a holistic and cohesive approach. A lack of standardized data impedes consistent decision making across the healthcare continuum and unfortunately can result in further harm to the goal of addressing health equity. A lack of standardized data collection methods can also create confusion for manufacturers applying for the health equity designation by not understanding what is required of them thereby resulting in missed opportunities and potential increases in costs if they are asked to redo certain studies.

Prior to finalizing the draft guidance, Premier urges the FDA to define the data elements it intends to utilize to measure health equity in medical devices under the Breakthrough Devices Program. In creating a standardized data collection mechanism, the FDA should work with the private sector to understand available data collection mechanisms and establish a standardized method that creates the least burdensome approach for the healthcare sector.

II. Harnessing the Power of Real-World Evidence

A key component to any new FDA accelerated approval pathway is the ability to measure success of the pathway in improving patient outcomes. As such, harnessing the power of real-world evidence to ensure medical devices entering the market under the health equity designation of the Breakthrough Devices Program are meeting their intended goals of benefitting communities impacted by health disparities is critical. With this information, researchers and clinicians are better able to analyze disparities and support communities and health systems to develop solutions including connections to community resources, treatment options and access to care.

Prior to finalizing the draft guidance, Premier urges the FDA to outline requirements and expectations for manufacturers granted a health equity designation to conduct real-world evidence studies to understand the practical implications of their devices on improving health equity. In addition, Premier urges FDA to outline a process for revoking the health equity designation of a medical device that either 1) fails to conduct the necessary real-world evidence studies in a timely manner; and/or 2) fails to demonstrate an impact on health equity in real-world evidence studies.

III. Balancing Innovation and Competition

To support market competition, which incentivizes innovation while reducing overall costs, Premier believes it is necessary to reduce the gaming of FDA requirements or other attempts to unfairly delay competition. For example, as seen in other areas of FDA regulation such as the Orphan Drug Pathway, some manufacturers 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. Similarly, it is possible that manufacturers leverage the health equity designation as an opportunity to bring their products to market and delay introduction of competing products to market.

As FDA considers how to best incorporate healthy equity into the Breakthrough Devices Program, Premier cautions FDA to ensure the approach strikes the appropriate balance between innovation and patient access while minimizing unintended consequences such as leveraging the pathway to thwart market competition. Specifically, prior to finalizing the draft guidance, the FDA should outline policies and procedures for manufacturers that initially seek a health equity designation and then seek a broader non-health equity designation. For example, additional information can be requested of manufacturers seeking the health equity designation, such as disclosing additional indications the manufacturer intends to seek FDA approval for. Requiring disclosure of this information may deter some manufacturers from abusing the health equity designation. In addition, Premier urges the FDA to report suspected cases of anticompetitive behaviors to the Federal Trade Commission (FTC).

IV. Conclusion

In closing, Premier looks forward to continuing to work with the FDA to finalize this guidance and assist in our common goal of creating a more accessible and equitable healthcare system. 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.