August 22, 2016

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

***Re: Prescription Drug User Fee Act; Public Meeting; Request for Comments***
***[Docket No. FDA–2016–N–1895]***

Dear Sir or Madam:

The undersigned pharmacist organizations thank the Food and Drug Administration (FDA) for the opportunity to provide comments on the reauthorization of the Prescription Drug User Fee Act (PDUFA) for fiscal years (FY) 2018 through 2022 as published in the *Federal Register* on July 19, 2016. Collectively, our organizations represent over 100,000 pharmacists across the full spectrum of health care practice settings.

Our organizations applaud the FDA for its continued commitment to protect the public health by assuring the safety and efficacy of medications in the United States, and for taking into account the evolution of health care

as it considers the next five years. Specifically, our organizations commend the FDA for inclusion of the following provisions in the reauthorization of PDUFA:

- Enhancing Use of Real-World Evidence for Use in Regulatory Decision-Making (page 26)
- Enhancing the Incorporation of the Patient's Voice in Drug Development and Decision-Making (page 27)
- Advancing Postmarketing Drug Safety Evaluation Through Expansion of the Sentinel System and Integration into FDA Pharmacovigilance Activities (page 35)

**Enhancing Use of Real-World Evidence for Use in Regulatory Decision-Making**
FDA acknowledges that using real-world evidence (RWE) will become increasingly important in evaluating the safety and effectiveness of medications. FDA commits to convening public workshops to understand issues related to RWE, initiating pilot programs, and publishing draft guidance on how RWE can contribute to the assessment of safety and effectiveness in regulatory submissions by the end of FY 2021.

Our organizations commend the FDA for its commitment to enhance the use of RWE in regulatory decision-making and for the systematic approach outlined for identifying and studying the key issues prior to issuing draft guidance. Our organizations urge the FDA to include pharmacists as a key stakeholder during this process because pharmacists are pharmacoeconomic experts and have been collecting, analyzing, and using RWE in their practice settings for many years.

**Enhancing the Incorporation of the Patient's Voice in Drug Development and Decision-Making**
FDA acknowledges the importance of facilitating the advancement and use of systematic approaches to collect and utilize patient reported outcomes (PROs) to more consistently inform drug development, and when appropriate, regulatory decision-making. The FDA commits to strengthening staff capacity to focus on this issue and publish a series of draft guidance documents to allow for meaningful assessment of PROs.

Our organizations commend the FDA for its commitment to develop approaches and processes for incorporating PROs in regulatory decision-making. Our organizations urge the FDA to include pharmacists as a core member of the integrated review teams during drug development and application review where a sponsor intends to use PROs as part of the development program. In addition, our organizations urge the FDA to consider how PROs reported to pharmacists can be incorporated, as pharmacists are easily accessible to patients and collect PRO data through the provision of pharmacy services such as medication therapy management, disease management, and patient counseling.

**Advancing Postmarketing Drug Safety Evaluation Through Expansion of the Sentinel System and Integration into FDA Pharmacovigilance Activities**
The FDA acknowledges the importance of pharmacovigilance practices to ensure the ongoing safety of medications once approved. The FDA commits to augmenting the quality and quantity of data available via Sentinel through expansion of data sources, enhanced communication with sponsors, and evaluation of additional ways for sponsors and the public to conduct safety surveillance.

Our organizations commend the FDA for its commitment to develop a more robust and rigorous Sentinel program. Our organizations agree that performing active, diligent postmarketing pharmacovigilance is critical for proactively identifying possible areas of concern for medications and ensuring the ongoing safety of medications post-approval. The Sentinel program plays a critical role in providing proactive surveillance through a distributed data approach that cannot be replaced by the Adverse Event Reporting System (AERS), Risk Evaluation and Mitigation Evaluation Strategies (REMS), or other surveillance systems that retroactively collect data.

In summary, our organizations share a commitment to patient safety and quality patient care, and as such, we commend the FDA for its work on the reauthorization of PDUFA. Thank you for the opportunity to provide feedback and for your consideration of our comments. We encourage the FDA to use our organizations as a resource as it continues this work.

Sincerely,

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