



**FDA Public Meeting on the Reauthorization of the Prescription
Drug User Fee Act (PDUFA)
Docket No. FDA-2010-N-0128**

**Remarks of Karin Bolte, Director Health Policy
American Pharmacists Association**

July 23, 2020

Good morning, I am Karin Bolte, Director of Health Policy at the American Pharmacists Association (APhA). APhA represents pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care across all practice settings.

APhA thanks FDA for inviting us to provide our perspective on the implementation of PDUFA VI to date and to offer some considerations as work begins on PDUFA VII.

APhA believes that FDA has made good progress on PDUFA VI's goals. For FY 2018 and FY 2019 to date, FDA met or exceeded the 90 percent performance level for 11 of 12 review performance goals. There is room for improvement in first review cycle approvals, however. While 89 percent of approved priority applications were approved on the first cycle in FY 2018 (the latest year for which data is available), only 61 percent of standard applications were approved on the first cycle. Improving first cycle approvals should be an area of focus for PDUFA VII.

**Improving Predictability of FDA Funding and Resource Capacity Planning
Utilization to Better Assess the Sustained Workload and PDUFA Resource Needs**

Changes in the PDUFA VI fee structure have improved the predictability of FDA funding, simplified user fee administration, and enhanced the flexibility of financial mechanisms to improve the management of PDUFA program funding.

APhA is pleased to see that FDA has collected 100.1% of the total planned target user fee revenue through the first two years of PDUFA VI. It is critical that FDA continues to be a good steward of its financial resources. We are encouraged by FDA's resource capacity planning (RCP) and modernized time reporting (MTP) implementation to date. Moving forward, we urge FDA to fully enable its RCP capabilities and to adopt its proposed capacity planning adjustment (CPA) methodology to better assess the sustained workload and PDUFA resource needs.

As FDA begins to consider PDUFA VII, we urge the Agency to include the following areas in the Commitment letter:

Continuing FDA’s Focus on Hiring and Retaining Highly Qualified Staff

PDUFA VI includes several commitments to improve the hiring and retention of critical review staff through modernization of FDA’s hiring system, augmentation of hiring staff capacity and capabilities, creation of a dedicated function focused on staffing the program, reporting on hiring metrics, and a comprehensive and continuous assessment of hiring and retention. On April 13, 2020, Booz Allen Hamilton published an [Interim Hiring and Retention Assessment Report](#) that noted continued deficiencies in FDA’s recruiting, hiring, and retention functions. While APhA appreciates the improvements FDA has made and the action plans the Agency has developed to address specific issues identified in the report, more progress needs to be made. For this reason, APhA believes that it is imperative that PDUFA VII maintain FDA’s focus on hiring and retaining highly qualified review staff.

Enhancing the Use of Real-World Evidence for Use in Regulatory Decision-Making

APhA commends FDA for its commitment to enhancing the use of real-world evidence (RWE) in regulatory decision-making. We appreciate the publishing of FDA’s [Framework for Real-World Evidence Program](#) (Dec. 2018) and its May 2019 Draft Guidance on [Submitting Documents Utilizing Real-World Data and Real-World Evidence to FDA for Drugs and Biologics](#). APhA recommends that FDA build upon this momentum by incorporating RWE commitments in PDUFA VII. In addition, APhA urges FDA to include pharmacists as a key stakeholder in this process because pharmacists are highly accessible healthcare providers 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

As part of PDUFA VII, APhA supports the continued development of approaches and processes for incorporating patient reported outcomes (PROs) in regulatory decision-making. We welcome the June 2020 publication of the [first](#) of four patient-focused drug development (PFDD) guidance documents addressing how stakeholders can collect and submit patient experience data and other relevant information from patients and caregivers for medical product development and regulatory decision making. APhA urges 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, APhA urges 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

APhA believes that a larger proportion of PDUFA VII user fees should be directed to postmarket surveillance. 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.

APhA commends FDA for its commitment to develop a more robust and rigorous Sentinel program. 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 Strategies (REMS), or other surveillance systems that retroactively collect data.

Addressing Drug Shortages

APhA appreciates FDA's and the CDER Drug Shortage Staff's efforts to address our nation's drug shortage problem, including early notification requirements, expedited inspections and reviews of manufacturing sites, the establishment of an Agency Drug Shortages Task Force and stakeholder listening sessions, and the publication of FDA's October 2019 [report](#) examining the root causes of drug shortages and potential solutions.

Despite these advances, drug shortages continue to occur, especially in the context of COVID-19, where we have seen shortages of critical drugs used to treat COVID-19 patients. For this reason, APhA urges FDA to continue to focus on alleviating drug shortages as part of the PDUFA VII reauthorization. APhA calls for widespread development of redundancy and risk mitigation strategies in the manufacturing process to ensure reliable and consistent availability of safe and high-quality drugs. APhA also urges greater transparency, accuracy, and timeliness of information and notification to health care professionals regarding drug shortages and anticipated shortages, product quality and manufacturing issues, supply disruption, and recalls.

Utilizing Biomarkers and Pharmacogenomics

APhA supports advances in the utilization of biomarkers and pharmacogenomic markers. As part of the patients' health care team, many pharmacists integrate pharmacogenomics into their practices to achieve optimal medication use, outcomes, and safety. As medications have become more complex and personalized, patient counseling and education regarding medication regimens are imperative to successful patient outcomes. Pharmacists have more medication-related education and training than any other health care provider, making them best suited to provide medication-related consults and services based on a patient's genomic information.

As we move into the next iteration of PDUFA, APhA supports the inclusion of pharmacogenomic analysis in the drug development, approval, and postmarketing

surveillance processes. APhA also encourages FDA and stakeholders to consider incentives to support enhanced coordination of care with pharmacists to ensure adequate patient access to education and ongoing support to improve medication adherence, safety, patient self-management, and understanding.

Closing

In closing, APhA again thanks FDA for the opportunity to provide our initial thoughts on PDUFA VII. We look forward to continuing to work with FDA, manufacturers, and other stakeholders as the reauthorization process continues.