



American Pharmacists Association[®]

Improving medication use. Advancing patient care.

FDA PUBLIC MEETING: Over-The-Counter Monograph User Fees June 10, 2016

Statement of the American Pharmacists Association Stacie S. Maass, BSPHarm, JD Senior Vice President, Pharmacy Practice and Government Affairs

Good morning, I am Stacie Maass, Senior Vice President for Pharmacy Practice and Government Affairs for the American Pharmacists Association (APhA). APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, physician office practices, managed care organizations, hospice settings, and the uniformed services.

I would like to thank the FDA for holding a public meeting to gather stakeholder input on the potential development of a user-fee program for OTC Monograph Drugs as the desire to support timely and efficient FDA review of the efficacy and safety of OTC products' ingredients is a goal shared by many if not everyone in this room. APhA does not have official policy with regard to user fees or the establishment of a system to develop supplemental funding beyond congressional appropriations. However we appreciate being part of the discussion as medications, including OTC medications, are the cornerstone of what pharmacists do and as the most accessible health care professional, with 86% of Americans living within five miles of a pharmacy, pharmacists are most often the health care professional patients see most. While OTC product ingredients are reviewed by FDA with the intention that a health care professional's involvement isn't required prior to their use, the reality is every day, in every pharmacy in the US, pharmacists are asked questions about OTC products. Thus, it is not only the millions of American consumers but other health care professionals, especially pharmacists, who rely on FDA's review OTC ingredients and the accuracy of products' labeling to make recommendations regarding OTC products. An importance which is amplified by the vast number of OTC products on the market. In addition, OTC medications can interact with other OTC and prescription medications so the timely review of these products' ingredients has a far-reaching impact on health care.

Given the large number of OTC products on the market and the direct access hundreds of millions of consumers have to these medications, it is not lost on the stakeholders attending today's hearing the real and potential consequences of inadequately funding FDA's OTC monograph review process. Although, APhA strongly believes that any OTC monograph user fee program or supplemental funding needs to be tied to meaningful reform rather than simply using additional funding to address review timelines or other delays.

I would like to close by thanking FDA and the other stakeholders for their interest improving the OTC monograph drug review process, its timeliness and impact on innovation. While APhA has no specific recommendations regarding the establishment of user fees, APhA has long had policy supporting the need for patient access to safe and affordable medications so any potential system or mechanism needs to consider the patient's cost and access. APhA looks forward to being part of future discussions on this topic.

Thank you.