



**American Pharmacists Association**<sup>®</sup>  
Improving medication use. Advancing patient care.

April 19, 2017

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

**Re: Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities (FDA-2016-D-1307)**

Dear Sir/Madam:

Thank you for the opportunity to provide comments on the Food and Drug Administration's request for comments, "Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities" (hereinafter, the "Draft Guidance"). Founded in 1852 as the American Pharmaceutical Association, the American Pharmacists Association (APhA) represents 64,000 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 offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

APhA appreciates FDA's decision to provide clarity regarding manufacturers' communications of health care economic information (HCEI) in reference to their prescription drugs and devices to payors, formulary committees or other similar entities (hereinafter, "Payors"). As medication experts and the practitioner most accessible to patients, pharmacists are frequently the health care provider patients approach with their medication-related questions. Pharmacists also play an important role in communicating with a patient's insurer on a wide range of topics and are affected by payor decision-making, especially decisions related to medication coverage.

**I. Additional information regarding truthful and non-misleading information**

APhA agrees with FDA that it is vital that information provided from firms to Payors about drugs and investigational products be truthful and non-misleading. Like FDA, APhA believes that truthful and non-misleading information is based on competent and reliable scientific evidence, and should be considered in the context of research practices developed by authoritative bodies and guidelines issued by external expert bodies, as described in the Draft

Guidance. APhA recommends standardizing the format of the information that should be clearly and prominently presented as discussed in Q.A.A.5 of the Draft Guidance. For example, APhA believes that standardizing how information, such as the study design and methodology, and additional material information for a balanced and complete presentation is displayed will make it easier for those reviewing the content to understand and compare.

FDA states that the Draft Guidance is not applicable to the dissemination of HCEI to other audiences, such as health care providers. Pharmacists are often the intermediary between patient and pharmacy benefit manager or payor when a coverage decision is being made. Since pharmacists play a role in medication selection and communicate coverage changes to patients, APhA believes that any materials submitted by manufacturers to Payors should be made available to pharmacists and other health care practitioners upon request.

## **II. Formulary design**

APhA is concerned that cost of medication is driving payor formulary decisions. APhA recognizes that a sustainable health care system must consider cost, but we are concerned that cost is not looked at comprehensively, thus ignoring overall cost-effectiveness and considerations such ease of use or dosing which affect patient adherence. In addition, patients can be negatively impacted by overly restrictive formularies because of decreased patient access or the supplanting of health care professionals' clinical judgment. While FDA does not have authority to regulate formularies, we request FDA remember the need for appropriate clinical judgement and patients' needs when establishing policy.

Finally, APhA believes that an influx of information from Payors regarding HCEI could cause formularies to change more frequently and consequently, affecting patients' access.. Coverage of medications is an important factor when patients are selecting insurance. APhA believes that FDA could reduce confusion and inconsistency in formularies/ coverage by limiting the timeframe and point(s) in the year that firms release HCEI to Payors.

Once again, we appreciate FDA's efforts to make more information available regarding the cost-effectiveness of prescription drugs and devices. APhA believes that manufacturer communications with Payors regarding evidence-based information has the potential to help reduce costs and improve formulary design when balanced with the need for unimpeded clinical judgment and care decisions. For additional information, please contact Jenna Ventresca, APhA's Associate Director, Health Policy, at [jventresca@aphanet.org](mailto:jventresca@aphanet.org) or 202-558-2727.

Sincerely,



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