November 20, 2017

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

Re: Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements; Establishment of a Public Docket; Request for Information and Comments (FDA-2017-N-2936)

Dear Sir/Madam:

APhA is pleased to submit these comments to the Food and Drug Administration's ("FDA") request for information and comments, "Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements; Establishment of a Public Docket; Request for Information and Comments" (hereinafter "RFI"). The American Pharmacists Association ("APhA") was founded in 1852, and represents 64,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and other parties invested 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.

Like FDA, APhA is interested in enhancing direct-to-consumer (DTC) advertisements to provide clear and useful information to patients, and consumers more broadly. APhA appreciates FDA's Office of Prescription Drug Promotion's investigation regarding the effectiveness of a "limited risks plus disclosure strategy"[1] to inform future policy regarding DTC advertisements.

I. Methods of communication

As technology evolves, many alternative methods of communication have emerged, such as Twitter, Facebook, Snapchat, and Youtube, which may have different implications from a marketing perspective.[2] While several manufacturers may already utilize these avenues to communicate with users, FDA has not clarified how it would apply the proposed policy different mediums. APhA encourages FDA to regularly evaluate patient understanding of risk and benefit

[1] *See* Food and Drug Administration, Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements; Establishment of a Public Docket; Request for Information and Comments, available at: https://www.regulations.gov/document?D=FDA-2017-N-2936-0002
[2] *See* Kim, H. (2015). Trouble Spots in Online Direct-to-Consumer Prescription Drug Promotion: A Content Analysis of FDA Warning Letters, *International Journal of Health Policy and Management,* 4(12), 813-821.

in advertisements, and include the wide-variety of advertising methods and communication mediums.

In addition, APhA recommends FDA consider steps manufacturers can take to help assure complete and comprehensive information is available via alternative methods of communication, such as those noted above.

II. Communications to supplement patient understanding

The RFI indicates that advertisements may direct patients to contact their health care provider, as well as instruct them to read patient labeling for information about risks and side effects as information in the major statement will be limited. APhA believes DTC advertising policy should assure advertisements include complete, comprehensive, and understandable information that informs consumers of potential benefits and risks of the product.[3] Given that FDA is considering more narrowed risk communications, APhA is concerned the proposed policy may not assure complete and comprehensive information will be more readily available to consumers. For example, even when a patient asks their health care provider about the complete risks, the provider may not have patient-centered resources available to effectively communicate all of a product's risks, as the RFI is silent on additional education or modifications to supplement communications. APhA encourages FDA to work with manufacturers, patients, and health care providers, such as pharmacists, regarding additional materials manufacturers could provide to help health care practitioners more effectively communicate a broader range of risks and benefits to patients.

III. Evidence-based research

APhA appreciates FDA's decision to develop policy that considers evidence-based research. We encourage FDA to identify the process it will use to review and incorporate research into DTC advertising policy, especially as new policies are implemented.

IV. Practitioner and consumer education

The RFI does not identify FDA's plan to educate health care practitioners and patients regarding advertising changes. APhA recommends FDA provide education to health care practitioners and consumers regarding the new advertising framework. Separate education should be provided for health care practitioners and consumers, and education should address the meanings of each definition with examples, where comprehensive materials can be accessed and questions that different types of consumers may need to ask after seeing a DTC advertisement.

Thank you for your leadership and work on this issue. We look forward to supporting FDA's efforts to improve patients' access to affordable and safe medications through feasible

[3] American Pharmacists Association, House of Delegates Policy, Direct-to-Consumer Advertising of Medications, stating, "APhA supports legislative and regulatory activities permitting direct-to-consumer advertising concerning medical or health conditions treatable by prescription or nonprescription drug products. These advertisements must conform to rules and regulations that assure complete, comprehensive, and understandable information that informs consumers of potential benefits and risks of the product.", available at: https://www.pharmacist.com/policy-manual

implementation approaches. If you have any questions please contact, Jenna Ventresca, Director, Health Policy, by email jventresca@aphanet.org or phone (202) 558-2727.

Sincerely,

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO
cc: Stacie Maass, BSPharm, JD, Senior Vice President, Pharmacy Practice and Government Affairs