AMCP Academy of Managed Care Pharmacy®

November 20, 2017

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

Re: Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements [Docket No. FDA-2017-N-2936]

Dear Sir or Madam:

The Academy of Managed Care Pharmacy (AMCP) thanks the Food and Drug Administration (FDA) for the opportunity to provide comments in response to the request for information titled *"Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements [Docket No. FDA-2017-N-2936]"* as published in the *Federal Register* on August 21, 2017. AMCP discourages the use of direct-to-consumer (DTC) advertising that promotes specific prescription drug products, and supports advertisements that educate the public about disease symptoms and available treatment options.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of health care dollars. Through evidence- and value-based strategies and practices, the Academy's 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

AMCP discourages the use of DTC advertising that promotes specific prescription drug products as studies have shown that DTC advertising can often be misleading because they typically fail to sufficiently warn consumers about the potential risks of using the product, fail to inform them about alternative treatment options, and fail to provide information about cost issues.[1] AMCP is also concerned about the ability of consumers to comprehend DTC advertising based on research findings that show only 12% of the US adult population is health literate and has the ability to obtain, process, and understand basic health information and services to make appropriate health

[1] Dumit, Joseph. "Pharmaceutical Witnessing: Drugs for Life in an Era of Direct to Consumer Advertising." The Pharmaceutical Studies Reader. N.p.: John Wiley & Sons, 2015. 35-40. Wiley Blackwell, 2015. Web. 31 Jan. 2017.

decisions.[2] Health literacy rates are even lower for individuals without a high school education, racial/ethnic minorities, the uninsured and publicly insured, and the elderly.[3]

While AMCP does not support DTC advertising for specific prescription products, AMCP does commend the FDA for taking the initiative to help improve how risk information in DTC advertising is presented to ensure that it is clear, adequate, comprehensive, useful, comprehendible, and memorable for consumers. Under FDA's proposal, the current *major statement* required for DTC advertising would be replaced by a *limited risks plus disclosure* strategy where DTC advertising would be limited to severe, serious, or actionable risks coupled with a disclosure to alert consumers that there are other product risks not included in the advertisement. In support of this proposed change, FDA conducted a study that found the *limited risks plus disclosure* strategy improved risk recall and recognition, improved benefit recognition, and did not adversely affect consumers' processing of drug risk and benefit information.[4]

AMCP is encouraged by FDA's proposal and believes that it is a step in the right direction to present a fair balance of risk information to avoid a misleading presentation regarding a drug's risk-benefit profile. However, prior to finalization and adoption of the *limited risks plus disclosure* strategy, AMCP recommends that FDA consider the following:

A. FDA should require that risk information be presented in a manner that aligns with the Agency for Healthcare Research and Quality (AHRQ) Health Literacy Universal Precautions[5]. Specifically, risk information should be presented in a manner that:
    a. Uses plain language;
    b. Limits information to 3-5 key points;
    c. Is specific and concrete, not general;
    d. Demonstrates using pictures and models that are applicable to the information being presented; and
    e. Repeats and summarizes the information.

B. FDA should include pharmacists in the disclosure statement. Pharmacists have comprehensive and unique education and training in the use of medications for the treatment, management, and prevention of diseases to contribute to the health care team. Studies and practice-based experience have shown that when pharmacists are involved as members of the health care team, patient outcomes improve, patients report higher rates

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[2] America's Health Literacy: Why We Need Accessible Health Information. An Issue Brief From the U.S. Department of Health and Human Services. 2008. Available at: https://health.gov/communication/literacy/issuebrief/.

[3] *Id.*

[4] Serious and actionable risks, plus disclosure: Investigating an alternative approach for presenting risk information in prescription drug television advertisements. Betts, Kevin R. et al. Research in Social and Administrative Pharmacy, Volume 0, Issue 0. Available at: http://dx.doi.org/10.1016/j.sapharm.2017.07.015.

[5] Agency for Healthcare Research and Quality Healthy (AHRQ) Health Literacy Universal Precaution Toolkit, 2nd Edition. Last updated. May 2017. Available at: https://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/index.html.

of satisfaction, and overall health care costs are reduced[6]. Furthermore, nearly 86% of Americans live within five miles of a pharmacy and therefore pharmacists are easily accessible to most Americans[7]. Therefore, AMCP recommends that the proposed disclosure statement be revised to read as follows:

> *"This is not a full list of risks and side effects. Talk to your health care provider* ***or pharmacist*** *and read the patient labeling for more information."*

C. FDA should conduct additional research and cognition testing on consumers. AMCP appreciates that FDA conducted initial research to understand the impact of the *limited risks plus disclosure* strategy, however there were limitations to the research. AMCP recommends that the FDA conduct more robust research that includes patients without a high school education, the uninsured and publicly insured, the elderly, and other underserved populations and individuals. The research should also include patients with several comorbid diseases and disabilities. Furthermore, testing should also be conducted that evaluates whether a revised approach to presenting risk information in DTC advertising impacts patient behaviors.

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with FDA. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-2600 or scantrell@amcp.org.

Sincerely,

Susan A. Cantrell, RPh, CAE
Chief Executive Officer

[6] Giberson S, Yoder S, Lee MP. Improving Patient and Health System Outcomes Through Advanced Pharmacy Practice: A Report to the U.S. Surgeon General 2011. Available at: https://www.accp.com/docs/positions/misc/improving_patient_and_health_system_outcomes.pdf.

[7] NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department