American Hospital Association

800 10th Street, NW
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100 Phone
www.aha.org

June 2, 2016

Paperwork Reduction Staff
Office of Operations
Food and Drug Administration
8455 Colesville Rd. COLE-14526
Silver Spring, Maryland 20993

Re: Market Claims in Direct-to-Consumer Prescription Drug Print Ads (OMB Control Number: 0910-NEW)

To Whom It May Concern:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations (more than 100 of which sponsor health plans), and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) study on market claims in direct-to-consumer (DTC) prescription drug print advertising.

The FDA proposes to study how different types of DTC advertising can affect consumer behavior and beliefs about product efficacy. Specifically, the FDA proposes to evaluate how consumers perceive drug products after viewing print ads with and without quantitative information about product efficacy. **The AHA strongly supports the FDA's evaluation of DTC advertising to better understand how such advertising drives consumer behavior. We urge the FDA, however, to broaden the scope of the study to include televised and internet advertising, as well as to test the impact of other product information on consumer behavior, such as price and comparative effectiveness data.**

Specifically, the AHA encourages the FDA to:

- **Evaluate the effects of televised and internet (including social media) advertising.** A significant portion of DTC advertising occurs via television. For example, in 2014, drug manufacturers spent more than 60 percent of the $4.5 billion in total DTC advertising on television ads.[1] Meanwhile, use of internet advertising is increasing.[2] Given that

[1] Millman, J., "It's true: Drug companies are bombarding your TV with more ads than ever," The Washington Post, March 23, 2015.
[2] Ventola, C. Lee. "Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?" Pharmacy and Therapeutics 36.10 (2011): 669–684. Print.

consumers may interpret information differently based on the advertising medium, we strongly encourage the FDA to examine the impact of quantitative claims about product efficacy presented in televised and internet-based advertising as well.

- **Test the impact of other quantitative information about a product, including price and comparative effectiveness data, on consumer behavior.** As discussed in more detail below, many physicians have expressed concern that DTC advertising can confuse consumers. We suspect that one aspect contributing to that confusion is the inability of consumers to understand a particular product's effectiveness compared to competing therapies. Therefore, we strongly suggest that the FDA test the impact on consumer behavior of advertising statements that compare a drug's efficacy to other available treatment options. For example, the FDA could examine the effects of marketing language that compares a pain medication to other drugs in its class, as well as to common non-drug treatments, such as physical therapy. In addition, the FDA should examine how cost information, displayed in conjunction with product efficacy information, impacts consumers' perception of a product.

Fully testing these facets of DTC advertising is important because of advertising's contribution to rising drug costs. DTC advertising directly contributes to high drug prices for patients. Drug manufacturers spend billions of dollars each year on drug promotion, which is often recouped through product sales. In 2013, nine of the 10 largest drug manufacturers reported spending $80.8 billion on marketing, representing an average of 23 percent of all revenue. To put this in perspective, these same companies spent $57.6 billion on research and development, or 16.5 percent of revenue.[3] **While pharmaceutical companies routinely cite research and development as the primary driver of high drug prices,[4] their spending patterns demonstrate that product marketing actually has a bigger impact.**

Additionally, according to physicians, drug ads may confuse consumers as to the best course of treatment and lead some patients to pressure their providers to unnecessarily prescribe newer, higher-cost drugs. Further, FDA research on physician perspectives on DTC advertising found that:

> Physicians thought the ads did not convey information about risks and benefits equally well. Seventy-eight percent of physicians believe their patients understand the possible benefits of the drug very well or somewhat, compared to 40 percent who believe their patients understand the possible risks, and 65 percent believe DTC ads confuse patients about the relative risks and benefits of prescription drugs. In addition, about 75 percent of physicians surveyed believed that DTC ads cause

[3] Spiro, T. et.al., "Enough is Enough: The Time Has Come to Address Sky-High Drug Prices," Center for American Progress, September 2015.
[4] "Prescription Drug Costs in Context," PhRMA, 2016. Accessed May 12, 2016 at: http://www.phrma.org/sites/default/files/pdf/prescription-medicines-costs-in-context-extended.pdf.

> patients to think that the drug works better than it does, and many physicians felt some pressure to prescribe something when patients mentioned DTC ads.[5]

High drug prices result in adverse consequences for patients and the health care system. Sudden and excessive price increases threaten access to and the affordability of critical drug therapies for patients. When patients cannot pay for their drugs, they do not take them; such medication noncompliance leads to unanticipated and avoidable health care utilization, including emergency department visits and hospitalizations.[6] These situations are harmful to patients and their families because they cause distress, additional costs and lost productivity; they are harmful to providers because they unnecessarily use scarce resources and have a negative impact on provider quality; and they are harmful to payers who must absorb much of the excess and avoidable costs.

The AHA appreciates that the FDA is evaluating the impact of certain marketing claims on consumer behavior. We believe that much more must be done to ensure that DTC advertising does not lead to inappropriately high drug costs and other adverse outcomes for patients, providers and payers. We support this study with the modifications described above and encourage the FDA to translate its findings into meaningful reforms to the DTC advertising guidelines.

If you have any questions about our comments, please contact Molly Smith, senior associate director for policy development, at mollysmith@aha.org or (202) 626-4639.

Sincerely,

/s/

Ashley Thompson
Senior Vice President
Public Policy Analysis and Development

[5] "The Impact of Direct-to-Consumer Advertising," The Food and Drug Administration, Accessed May 12, 2016 at http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143562.htm.
[6] "Avoidable Costs in U.S. Healthcare," IMS Institute for Healthcare Informatics, June 2013.