April 29, 2016

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

Comments of members of the Patient, Consumer, and Public Health Coalition on the "National Direct-to-Consumer Advertising Survey Docket No. FDA-2016-N-0544

As members of the Patient, Consumer, and Public Health Coalition, we appreciate the opportunity to comment on the "National Direct-to-Consumer Advertising Survey." In general, we support this survey, which will update information from surveys completed in 1999 and 2002.

The objective of this research is to gain information from the public about "their experiences with and attitudes toward direct-to-consumer (DTC) advertising of prescription drugs."[1] Topics covered by the survey include consumer's knowledge of FDA's authority over DTC ads, how often they're exposed to DTC ads, their beliefs and attitudes about DTC ads and the influence of DTC advertising on patient-doctor interactions. The survey will measure other characteristics such as demographics, insurance coverage, and prescription drug use. We want to make sure that the questions about beliefs and attitudes will include gathering information about consumers' views on how information about the benefits and risks is provided, if it could be provided in a more unbiased way, and how it influences their views of the product being advertised. Ideally, you can provide short DTC videos for respondents to watch and ask them questions about what benefit-risk information they recall from those ads.

The new study of DTC ads is designed to reach a wider range of respondents than the previous surveys by weighting the data to make it nationally representative. We agree that the survey should represent the demographic makeup of the United States in sufficient numbers to analyze subgroups based on race, ethnic backgrounds, and sex. The survey should be skewed to include a disproportionate number of Americans over 50, since they are the target of vast majority of DTC ads and are also the most likely to be exposed to those ads on TV and in magazines. Of course, younger adults (18 and over) should also be included. Ideally, the study would include a sufficient number of teenagers who are 14-18 years old, to gather meaningful information about that age group.

We agree with the FDA that the DTC advertising landscape has changed since the previous surveys. We are concerned that extremely brief social media ads will not include sufficient information about risks. Since DTC ads focus primarily on selling products, it is unacceptable for the risks of a product to be listed through a link that consumers may not click or the often-used phrase, "for more information, see this month's issue" of a particular magazine. The survey should directly ask respondents how much information about the risks of the medical products they notice from social media ads.

Regarding the survey procedures, we support the mixed-mode methodology where households will be asked to complete a 20-minute online survey with a paper questionnaire sent to those who do not respond on-line. The paper option will ensure that respondents who are not internet savvy will still be included. The survey is designed to have as many as five contacts sent by mail to adults aged 18 and older and this should ensure that the FDA achieves at least its 35 percent response rate for both the pilot study and the main study. These estimated response rate percentages are lower than the telephone surveys conducted in 1999 (65 percent or 960 respondents) and in 2002 (53 percent or 944 respondents)[2] but the total number of respondents (1,765) is estimated to be higher for the new survey.

FDA also plans to compare responses between this survey and FDA's 2002 survey. In 2002, "60 percent [of respondents] felt that ads do not provide enough information about risks."[2] That is a high percentage. We want to know if that percentage has gone up or down, and what steps FDA and industry are taking to provide more information about the risks of medical products. We are particularly interested in the number of people searching the internet for drug and health information, which jumped from 18 percent in 1999 to 38 percent in 2002. Back then, most

people were looking for information about risks associated with the medical products.[2] The new survey should ask people how often they search the internet regarding medical products and what information they are inquiring about.

Conclusions

We are very concerned about the impact of DTC ads on prescriptions, and are especially disappointed at the FDA's failure to follow through on the agency's previous proposals to put risk information on a more equal footing with information about benefits. Due to the FDA's continued acquiescence to companies' proposed ads, DTC ads use the power of an expensive advertising campaign to persuade patients to use medical products that may not be safe or appropriate for them. Rather than empowering consumers, direct-to-consumer ads expose consumers to the most effective persuasion that money can buy. To truly protect consumers, and reduce unnecessary healthcare costs, Congress and the FDA need to do more than survey the public about DTC ads. They need to propose laws and rules to limit the persuasive power and unbalanced information provided in DTC ads, especially for drugs that have not been tested for long-term safety on a large population.

American Medical Women's Association
Breast Cancer Action
Connecticut Center for Patient Safety
MAME
MISSD
MRSA Survivors Network
National Center for Health Research
National Organization for Women Foundation
National Physicians Alliance
National Women's Health Network
Quinolone Vigilance Foundation
The TMJ Association
Washington Advocates for Patient Safety
WoodyMatters

The Patient, Consumer, and Public Health Coalition is an informal coalition of nonprofit organizations representing the interests of millions of patients, consumers, health-care professionals, scientists, and public health experts. The coalition can be reached through Paul Brown at (202) 223-4000 or at pb@center4research.org.

[1] Federal Register (February 29, 2016). Food and Drug Administration, Agency Information Collection Activities; Proposed Collection: Comment Request; National Direct-to Consumer Adverting Survey.

[2] Food and Drug Administration (November 19, 2004). Patient and Physician Attitudes and Behaviors Associated With DTC Promotion of Prescription Drugs —Summary of FDA Survey Research Results, Final Report.