Before the
Food and Drug Administration

In the Matter of	)	
	)	
Content of Risk Information in the Major	)	
Statement in Prescription Drug Direct-to-	)	Docket No. FDA-2017-N-2936
Consumer Broadcast Advertisements	)	
	)	
	)	
	)	

COMMENTS OF THE NATIONAL ASSOCIATION OF BROADCASTERS

1771 N Street, NW
Washington, DC 20036
(202) 429-5430
Rick Kaplan
Erin Dozier
Jerianne Timmerman
Antrell Tyson

November 20, 2017

TABLE OF CONTENTS

Before the
Food and Drug Administration

In the Matter of	)	
	)	
Content of Risk Information in the Major	)	
Statement in Prescription Drug Direct-to-	)	Docket No. FDA-2017-N-2936
Consumer Broadcast Advertisements	)	
	)	
	)	
	)	

COMMENTS OF THE NATIONAL ASSOCIATION OF BROADCASTERS

I. INTRODUCTION AND SUMMARY

The National Association of Broadcasters (NAB)[1] hereby files these comments in response to the request of the Food and Drug Administration (FDA or Administration) for information and comments on the content of risk information in direct-to-consumer (DTC) broadcast advertising for prescription drugs.[2] Specifically, the FDA seeks comment on the usefulness of limiting the risks in the major statement[3] to those that are severe, serious, or

[1] NAB is a nonprofit trade association that advocates on behalf of free local radio and television stations and broadcast networks before Congress, the Federal Communications Commission and other federal agencies, and the courts.

[2] FDA, 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, Docket No. FDA-2017-N-2936, 82 FR 39598 (Aug. 21, 2017) (Notice).

[3] Prescription drug advertising regulations require that broadcast advertisements containing product claims include information relating to the advertised drug's major side effects and contraindications in either the audio or audio and visual parts of the ad. 21 C.F.R. §202.1(e)(1)). This is often called the *major statement*. The regulations also require that broadcast advertisements contain a brief summary of all necessary information related to side effects and contraindications or that "adequate provision" be made for dissemination of the approved package labeling in connection with the broadcast presentation. 21 C.F.R.

actionable, coupled with a disclosure to alert consumers that there are other product risks not included in the advertisement.[4] NAB supports the Administration's adoption of such a "limited risks plus disclosure strategy."[5] As numerous studies and record evidence in other FDA proceedings show, the major statement under current rules is usually too long and complex for broadcast advertisements, causing reduced consumer comprehension, minimization of the most important risk information and potentially, therapeutic noncompliance caused by fear of side effects. Accordingly, the FDA should adopt a standard that will allow consumers to receive more meaningful disclosures. The FDA's proposed "limited risks plus disclosure" approach will enable DTC advertisements on broadcast media to provide clearer, more useful information to consumers.

II. DTC ADVERTISING YIELDS IMPORTANT CONSUMER BENEFITS THAT WILL BE ENHANCED BY A LIMITED RISKS PLUS DISCLOSURE APPROACH

Several consumer benefits arise from DTC advertising. As the FDA has acknowledged, DTC ads can raise awareness about medical conditions and treatment options, and spur consumers to action.[6] In an FDA consumer survey, 43% of respondents

---

202.1(e)(1)). This requirement to make "adequate provision" is generally fulfilled when a firm gives consumers the option of obtaining the FDA-required labeling or other information via a toll-free telephone number, print advertisements or product brochures, information disseminated at health care provider offices or pharmacies or online. *See* FDA, Guidance for Industry, Consumer-Directed Broadcast Advertisements (Aug. 1999), available at: https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm070065.pdf.

[4] Notice at 39599. *See also* 79 FR 9217 (Feb. 18, 2014).

[5] *Id.*

[6] FDA, *Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs – Summary of FDA Survey Research Results* (Nov. 19, 2004) at 2, available at: https://www.fda.gov/downloads/drugs/scienceresearch/researchareas/drugmarketingadvertisingandcommunicationsresearch/ucm152860.pdf (FDA Patient-Physician Study)("DTC

reported that a DTC ad caused them to look for more information either about the drug or their health, and 18% of respondents made an appointment to see a doctor about a medical condition they had never previously discussed.[7] Another study found that 25% of patients who visited their doctor after seeing DTC advertising received a new diagnosis, often for a high-priority health condition.[8] Data also show that DTC ads benefit consumers by encouraging patient adherence to treatment regimens,[9] reducing under-diagnosis and undertreatment of conditions,[10] promoting and improving dialogue with health care providers,[11] and reducing the stigma associated with certain conditions.[12]

---

advertisements prompted a sizable percentage of patients to seek additional information about the drug, the condition it treats, or health in general.").

[7] FDA Patient-Physician Study at 2.

[8] Auton F., *Opinion: The case for advertising pharmaceuticals direct-to-consumers*, Future Med. Chem. 2009; 1(4):587–592, 588 (citing Weissman J., *et al*., *Consumers' Reports on the Health Effects of Direct-to-Consumer Advertising* (2003), available at: http://www.npcnow.org/system/files/research/download/Consumer%20Reports%20on%20the%20Effects%20of%20DTCA.pdf).

[9] *See, e.g.,* FDA Patient-Physician Study at 69 (34% of physicians agreed that DTC increased the likelihood patients would use their medications properly; 32% agreed it would help patients adhere to their treatment regimen).

[10] *See* Ventola, C.L., *Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?,* Pharmacy and Therapeutics. 2011 Oct; 36(10): 669-674, 681-684, available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278148/#b31-ptj3610669 (discussing how ads for Procrit spurred chemotherapy patients who previously were not reporting fatigue symptoms or receiving treatment to report fatigue to their doctors, leading to treatment). *See also* FDA Patient-Physician Study at 79-80 (72% of physicians agree that DTC makes patients aware of possible treatments; 44% agree that it increases patient awareness of health problems earlier).

[11] *See, e.g.,* FDA Patient-Physician Study at 69 (56% of physicians believe that DTC advertising makes patients ask better questions; 51% believe it leads to better discussions about the patient's health).

[12] *See* Auton F., *Opinion: The case for advertising pharmaceuticals direct-to-consumers*, Future Med. Chem. 2009; 1(4):587–592, 590 (a Merck advertising campaign for finasteride (Proscar), a treatment for benign prostatic hyperplasia, is widely regarded as having successfully raised awareness of a medical condition that men had been reluctant to discuss with their doctors).

To realize the full benefits of DTC ads, consumers must be able to comprehend and absorb the risk information in the ads. Data show that the current regulations can result in risk statements that are too long and complex for broadcast advertisements, which can reduce consumer comprehension, minimize the most important risk information and potentially, result in therapeutic noncompliance caused by fear of side effects. Research on advertising and communication recognizes the limits of a consumer's ability to process information.[13] Indeed, the FDA has explained that "effectively disclosing risk information also requires a consideration of whether an advertisement or promotional material *over*

[13] *See, e.g, See* Betts K.R., *et al., Serious and actionable risks, plus disclosure: Investigating an alternative approach for presenting risk information in prescription drug television advertisements*, Research in Social and Administrative Pharmacy (2017) at 2, available at: http:// dx.doi.org/10.1016/j.sapharm.2017.07.015 (Limited Risks Study) (observing that "[e]ven if consumers engage and process a thorough presentation of risk information, they may not be able to interpret and use the information because of constraints on working memory or information processing style;" this would make additional risk information "physically present but functionally absent")(citing Jacoby J., *Perspectives on information overload,* J Consum Res. 1984;10(4): 432e435. http://dx.doi.org/10.1086/208981; Wilson E.A., Wolf M.S., *Working memory and the design of health materials: a cognitive factors perspective,* Patient Educ Couns. 2009;74(3):318e322, available at: http://dx.doi.org/10.1016/j.pec.2008.11.005. *See also* Murray N.M. *et al*., *Public Policy Relating to Consumer Comprehension of Television Commercials: A Review and Some Empirical Results*, 16 J. Consumer Pol'y 145, 155, 160-161, 164-165 (1993) (demonstrating that the number of words in a disclosure is negatively correlated with comprehension and that lack of viewer opportunity to process information disclosed in television advertising can contribute to reduction in comprehension); Murphy, J. & Richards, J., *Investigation of the Effects of Disclosure Statements in Rental Car Advertisements*, 26 J. Consumer Aff. 351, 355-356 (1992)(finding that if the amount of information presented exceeds consumers' ability to process it, the quality of consumer decision-making may be negatively affected). Murphy and Richards further state that "[a]lthough any efforts by regulators to facilitate informed decision-making may be laudable, failure to ensure that the chosen method of presentation is appropriate for consumer use can make those regulations worthless or even detrimental to consumer interests. If consumers are unable to understand or recall the information in the legally mandated form another disclosure technique…may be more efficacious." *Id*. at 373.

warns."[14] For example, an ad that includes a list of less important side effects "may lead to under-emphasis of the most important and serious risks."[15] Similarly, because it believes that "exhaustive lists of minor risks distract from and make it difficult to comprehend and retain information on the more important risks," the FDA issued draft guidance for print ads that "suggests approaches to communicating less, but better, information . . ."[16] Through its industry guidance and research, the FDA has repeatedly sought to balance the need for risk information with the harms of too much information.

A recently completed study by the FDA's Office of Prescription Drug Promotion (OPDP) further underscores the need to update risk disclosure requirements to better reflect consumers' ability to comprehend and recall risk information.[17] The study examined the impact of a typical major statement versus a limited risks plus disclosure statement on the ability of consumers to recall important risks and benefits of a drug following exposure to a DTC television advertisement.[18] The study concluded that "[t]he revised risk statement

---

[14] FDA, Draft Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion (May 2009), at 2, available at: https://www.fda.gov/downloads/drugs/guidances/ucm155480.pdf (emphasis added).

[15] *Id.*

[16] *Id.* at 13. *See also* FDA, Revised Draft Guidance for Industry, Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs (Aug. 2015), at 4, available at: https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm069984.pdf.

[17] *See* Limited Risks Study.

[18] Participants viewed one of four ads: (i) a completely unedited ad; (ii) ad with an unedited list of risks plus a disclosure stating: "This is not a full list of risks and side effects. Talk to your doctor and read the patient labeling for more information."; (iii) an ad with a limited statement of risks, without the disclosure statement; and (iv) an ad with a limited statement of risks with the disclosure statement. *Id.* at 4. The study also examined risk and benefit perceptions, ad-prompted actions, recognition of the disclosure statement, and evaluations of both the disclosure and risk statement.

improved overall processing of the television ad, as evidenced by improved risk recall and recognition and improved benefit recognition."[19] The Limited Risks Study observed that DTC television ads are currently exposing consumers to large amounts of information, "which may restrict their ability to process the information most relevant to them."[20] Given the findings of their empirical research, the authors concluded that "[r]egulatory authorities and sponsors may facilitate consumers' ability to process important product information by considering including only risks in the major statement that are serious and actionable and including a disclosure to indicate that not all risks are presented."[21]

The results of the Limited Risks Study strongly support a rule modification that will allow for a "limited risks plus disclosure approach." As other commenters have previously observed, this approach still allows patients to obtain full risk information from their health care providers, as well as "product labeling, product websites, magazine advertisements, and patient brochures."[22] Consumers would still be instructed that the specified risks are not comprehensive and that they should consult other sources and talk with their physicians or pharmacists.[23] The approach offers clear benefits by improving consumer comprehension, allowing consumers to focus on the most important risk information, and reducing the potential for therapeutic noncompliance caused by fear of side effects. In addition to these consumer benefits, modifying the rules will ensure that the FDA is using a

[19] Limited Risks Study at 1.

[20] Limited Risks Study at 10.

[21] Limited Risks Study at 10.

[22] *See* Comments of the Pharmaceutical Research and Manufacturers of America (PhRMA) in Docket No. FDA-2014-N-0168 (April 21, 2014) at 4-5.

[23] *Id.* at 5, *citing* 21 C.F.R. §202.1(e).

narrowly tailored means to advance its substantial interest in preventing consumers from being misled by DTC advertising, as required by the First Amendment.[24]

III. A LIMITED RISKS PLUS DISCLOSURE APPROACH WILL ALLOW BROADCAST STATIONS TO DELIVER CLEARER, MORE USEFUL INFORMATION TO THEIR AUDIENCES

Broadcast advertising can be an extremely valuable way for consumers to learn about medical conditions and available treatment options through DTC ads. Unlike other media outlets, broadcast television and radio offer free over-the-air services that do not require a subscription or any other payment. Broadcast television and radio are ubiquitous, with a presence in virtually every U.S. household. Radio stations reach an average of 266 million Americans per month (97%).[25] Television stations reach an average of 230.9 million Americans per month (94%), who are viewing an average of 6 hours and 22 minutes per day.[26] With its significant reach, broadcasting can be an excellent medium for advertisers to reach consumers and for consumers to learn new information about drug therapies.

However, broadcasters sometimes face challenges in competing effectively for DTC advertising. The length and complexity of the major statement required by current regulations can have a deterrent effect on advertisers, since every ad aired must have a significant portion of audio exclusively focused on product risks, rather than promoting the product. This problem is most pronounced for radio advertising, which is audio only and the

---

[24] FDA regulation of the content of DTC advertising is lawful only to the extent necessary to advance the government's interest in ensuring that consumers are not misled by such ads. *See, e.g., Sorrell v. IMS Health, Inc.,* 131 S. Ct. 2653, 2659 (2011) (finding "[s]peech in aid of pharmaceutical marketing" to be "a form of expression protected by the Free Speech Clause of the First Amendment" and giving "heightened" scrutiny to restrictions on that speech). *See also* Comments of The Washington Legal Foundation in Docket No. FDA-2014-N-0168 (April 21, 2014) at 7 (the FDA's current rule cannot be narrowly tailored if a less burdensome rule would better inform consumers).

[25] *Nielsen Total Audience Series Q1 2017*.

[26] *Id*.

very nature of the medium does not allow product risks to be presented together with any imagery.

Broadcasters should be able to compete on equal footing with other media outlets for DTC advertising. A limited risks plus disclosure approach would reduce the amount of advertising air time devoted solely to identifying risks, making radio stations a more viable advertising option and increasing competition in the advertising marketplace. More importantly, consumers who rely on broadcast radio will benefit from ads that better inform them about the risks and benefits of using a particular drug.

IV. CONCLUSION

NAB urges the FDA to modify its rules to allow advertisers to use a limited risks plus disclosure approach in DTC drug advertising. The rule change will enhance the consumer benefits of DTC advertising by making ads easier to comprehend, making the most important risks more apparent, and reducing the potential for therapeutic noncompliance from fear of side effects. Modifying the rules also will allow broadcast viewers and listeners to get clearer, more relevant information and spur competition in the advertising market by making radio a more viable outlet for DTC advertising. Finally, adopting a less burdensome regulation will make the FDA's rules more narrowly tailored to their intended purpose of ensuring that consumers are not misled by DTC advertising, consistent with the First Amendment.

Respectfully submitted,

NATIONAL ASSOCIATION OF BROADCASTERS
1771 N Street, NW
Washington, DC 20036
(202) 429-5430

Rick Kaplan
Erin L. Dozier
Jerianne Timmerman
Antrell Tyson

November 20, 2017