BEFORE THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

In the Matter of
Request for Comments on Agency Draft Guidance Documents
Regarding Consumer-Directed Promotion

Docket No. 2004D-0042

Comments of the Staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the Federal Trade Commission

May 10, 2004*

***These comments represent the views of the staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the Federal Trade Commission. They do not necessarily represent the views of the Federal Trade Commission or any individual Commissioner. The Commission has, however, voted to authorize the staff to submit these comments.**

I. Introduction

On February 4, 2004, the Food and Drug Administration ("FDA") issued three draft guidances designed to improve the information that consumers and health care practitioners receive in advertising about prescription drugs and certain medical devices.[1] The first guidance (the "Brief Summary Guidance") would permit advertisers to include more limited and focused "brief summary" information in direct-to-consumer ("DTC") advertisements for prescription drugs. The second guidance (the "Disease Awareness Guidance") would clarify when the FDA would treat a communication as a "help-seeking communication" over which it lacks jurisdiction. The third guidance (the "Device Broadcast Advertising Guidance") would apply the same regulatory standards to DTC broadcast ads for restricted medical devices that apply to DTC broadcast ads for prescription drugs.

The FDA has sought public comment on the three proposed guidances.[2] As explained below, the staff of the Federal Trade Commission's Bureaus of Consumer Protection and Economics as well as its Office of Policy Planning ("FTC staff") believe that the proposed guidances represent substantial progress toward the FDA's goal of finding the appropriate means to convey relevant risk information to consumers in a manner that they can understand. Specifically, the FTC staff concludes that:

- The FDA's proposed new options to meet the brief summary requirement for DTC print ads for prescription drugs might be a significant improvement over the current brief summary requirement. The FDA, however, should conduct consumer research to determine whether these proposed options, or other formats,

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1 *See* 69 Fed. Reg. 6308 (Feb. 10, 2004).

2 *Id.*

are the most effective means of providing drug risk information in DTC print ads.

- The FTC staff agrees with the FDA's suggestion that the Commission has jurisdiction over help-seeking communications related to prescription drugs under Section 5 of the FTC Act.

- The FTC staff supports the FDA's proposal to extend the same brief summary requirement for DTC broadcast ads for prescription drugs to DTC broadcast ads for restricted medical devices. The staff believes that adoption of this proposal will likely lead to increased advertising for restricted medical devices, thereby benefitting consumers and competition.

II. Background

The FTC enforces Section 5 of the Federal Trade Commission Act ("FTC Act"), which broadly prohibits "deceptive or unfair acts or practices in or affecting commerce."[3] Section 12 of the FTC Act more specifically prohibits the dissemination of false advertisements for foods, drugs, devices, services, or cosmetics.[4] Although the FDA and the FTC generally share jurisdiction over prescription drug advertising, the FDA exercises primary responsibility for such advertising pursuant to a memorandum of understanding between the two agencies.[5]

One of the FTC's primary responsibilities is to bring law enforcement actions against

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[3] 15 U.S.C. § 45.

[4] 15 U.S.C. § 52.

[5] Working Agreement Between FTC and Food and Drug Administration, 4 Trade Reg. Rep. (CCH) ¶ 9,851 (1971).

deceptive practices in national advertising. Through these law enforcement activities and through research conducted in support of its mission, the FTC has developed considerable expertise in analyzing the role of advertising in conveying health-related information to consumers and the effect of advertising regulation on consumers and competition.[6] In particular, the FTC staff has submitted three previous comments to the FDA relating to DTC advertising for prescription drugs.[7] In our comments, we have emphasized that truthful, non-misleading DTC advertising benefits consumers by providing them with useful information about their healthcare and treatment options. False or misleading ads for prescription drugs, however, can misinform consumers about the effectiveness and side effects of their medications.

III. The FDA's Brief Summary Guidance Requirements for DTC Print Ads

The Federal Food, Drug, and Cosmetic Act ("FDCA") requires that prescription drug advertising contain a true statement of "information in brief summary relating to the side effects, contraindications, and effectiveness" of the drug (the "brief summary requirement").[8] FDA's

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[6] *See, e.g.*, P. Ippolito & J. Pappalardo, *Advertising Nutrition & Health: Evidence from Food Advertising 1977-1997* (2002); P. Ippolito & A. Mathios, *Information and Advertising Policy: A Study of Fat and Cholesterol Consumption in the United States, 1977-1990* (1996); J. Calfee & J. Pappalardo, *How Should Health Claims for Foods Be Regulated? An Economic Perspective* (1989); A. Masson & R. Steiner, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws* (1985).

[7] *Comments of the Staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the Federal Trade Commission in the Matter of Request for Comments on Consumer-Directed Promotion,* Docket No. 2003N-0344 (2003) (hereafter "FTC 2003 DTC Comment"); *Comments of the Staff of the Bureau of Economics, the Bureau of Consumer Protection, and the Office of Policy Planning of the Federal Trade Commission in the Matter of Request for Comment on First Amendment Issues,* Docket No. 02N-0209 (2002); *Comments of the Staff of the Bureau of Consumer Protection and the Bureau of Economics of the Federal Trade Commission in the Matter of Direct-to-Consumer Promotion,* Public Hearing Docket No. 95N-0227 (1996).

[8] 21 U.S.C. § 352(n).

implementing regulations specify that the information about risks in the "brief summary" must "disclose all the risk-related information in [a drug's FDA-approved] package labeling."[9]

Pharmaceutical manufacturers usually meet the brief summary requirement for DTC print ads by including the entire section of the FDA-approved product labeling that discusses side effects and contraindications of the drug. The product labeling often runs to a page or more of "fine print" text in magazines and other publications.

In 1999, the FDA recognized the inherent limitations in trying to incorporate all of the brief summary information from the FDA-approved product labeling into DTC broadcast ads, especially television ads. The agency, therefore, issued a guidance stating that DTC broadcast ads only have to include a "major statement" of risks and make "adequate provision" for consumers to obtain the FDA-approved product labeling.[10] The FDA, however, did not change the requirements for DTC print ads.

The FDA has sought to address the issues that the brief summary requirement for print ads raises. In its 2001 draft guidance document addressing print ad disclosures, the FDA acknowledged that consumers need different types and amounts of information about medical risks than medical professionals.[11] The agency therefore encouraged drug manufacturers to use

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[9] 62 Fed. Reg. 43,171 (Aug. 12, 1997) (citing 21 C.F.R. § 202.1(e)(1) and (e)(3)(iii)). Note that the approved package labeling is also sometimes called the "package insert" or "product package insert."

[10] *See* FDA, *Guidance for Industry: Consumer-Directed Broadcast Advertisements* (Aug. 9, 1999), *available at* www.fda.gov/cder/guidance/1804fnl.htm; *see also* 64 Fed. Reg. 43,197 (announcing final guidance document).

[11] *See* FDA, *Draft Guidance for the Industry: Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements* (April 2001), *available at* www.fda.gov/cder/guidance/4114dft.pdf. Although guidance documents are not legally binding on the FDA or the public, they do provide the FDA's current thinking on an issue and provide

more consumer-friendly language in the brief summary in their print ads.[12] Thus, in lieu of providing the entire section of FDA-approved product labeling, a manufacturer can satisfy the brief summary requirement for print ads by reprinting FDA-approved patient labeling, if such labeling in available.[13] Although the FDA-approved patient labeling does not disclose every specific risk included in the product labeling, it is designed to present the drug's most serious and most common risks and is intended to be written at a level that is easier for consumers to understand than the FDA-approved product labeling.[14]

In 2003, the FDA requested comment on DTC ads, including whether its current regulatory approach should be modified. The FTC staff filed a comment recommending, among other things, that the FDA generally retain its brief summary requirement for DTC broadcast ads.[15] The staff comment also recommended that the FDA apply the brief summary requirement for DTC broadcast ads to DTC print ads: namely, (1) a major statement of the risks of the drug, and (2) adequate provision for consumers to obtain more complete risk information, preferably in the form of the FDA-approved patient labeling, if available.[16]

In the proposed Brief Summary Guidance, the FDA proposes to allow manufacturers two options to satisfy the brief summary requirement for DTC print ads. The first would require

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consistency and predictability. *See* 62 Fed. Reg. 8961, 8962-63 (Feb. 27, 1997).

[12] *See Draft Guidance, supra* n.11.

[13] *Id.* FDA-approved patient labeling is also called "Information for the Patient," "Patient Information," "Medication Guide," and "patient package inserts."

[14] *Id.* at 2.

[15] *See* FTC 2003 DTC Comment, 20-22.

[16] *Id*.

manufacturers to include risk information from the more consumer-friendly FDA-approved patient labeling in DTC print ads. Under this option, manufacturers would have to reprint the patient labeling in full plus those sections of the product labeling concerning contraindications, warnings, major precautions, and most common adverse reactions.[17]

The second option would require manufacturers to include in print ads risk information from the "Highlights" section of the FDA-approved product labeling.[18] This option would include information about contraindications, warnings, major precautions, and most common adverse reactions.[19] Because the Highlights section of the product labeling has been written for medical professionals, however, the FDA recommends that manufacturers rewrite the section in language that is understandable to consumers.

The FTC staff believes that requiring the disclosure of risk information in a more consumer-friendly format would be an improvement over the current brief summary requirement for DTC print ads.[20] The proposed change would mandate a more concise and consumer-

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[17] The FDA would not object, however, to the use of only the risk information from the FDA-approved patient labeling.

[18] In 2000, the FDA determined that FDA-approved product labeling was not effective in conveying risk information even to physicians and other medical professionals. *Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirement for Prescription Drug Product Labels*, 65 Fed. Reg. 81,082 (Dec. 22, 2000). To address this concern, the FDA issued a proposed rule that would require the FDA-approved product labeling to include a new section, "Highlights of Prescribing Information," that would set forth in a concise manner the information that is most important for safe and effective use. The proposed rule is not yet a final rule.

[19] Although the proposed rule that would allow the Highlights section has not yet become effective, the FDA would not object to the use of this section in DTC advertising.

[20] The FTC staff recognizes that the draft Brief Summary Guidance would not apply to all DTC print ads. The FDA has not approved patient labeling for most of the innovator drugs that it has approved in the past few years. *See* 2003 FTC Staff Comment at 27 n.71. Moreover, many manufacturers may not have developed a Highlights section for FDA-approved product

oriented statement of risks, which makes it more likely that consumers will read and understand this information than the current risk information cribbed from the FDA-approved product labeling. Moreover, to the extent that the proposed change would decrease the disparity between the brief summary requirements for DTC print ads and DTC broadcast ads, the current regulatory incentive to use DTC broadcast ads to compete may be decreased, although not eliminated.

The FDA has asked for consumer research concerning the costs and benefits of the brief summary options contained in the draft Brief Summary Guidance. The FTC staff is not aware of any empirical research demonstrating whether the options would be effective in communicating risk information to consumers, or the costs associated with using these options. We strongly support the FDA's willingness to conduct and consider such research.

The FTC staff encourages the FDA to test the likelihood that consumers will read[21] and understand drug risks in DTC print ads with: (1) no brief summary information; (2) the brief summary information contained in broadcast ads (i.e., a major statement of risks plus adequate provision to receive more complete information); (3) the proposed new brief summary information options[22] (adapted patient labeling or Highlights); and (4) the currently required brief summary information (i.e., FDA-approved product labeling). Such research would provide insight into the costs and benefits of including different amounts of risk information in DTC

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labeling, because the agency has not yet issued a final rule relating to the Highlights section.

[21] Given the length and complexity of the current brief summary disclosure, standard copy test procedures may not accurately gauge the attention consumers would give such an extensive disclosure under more natural conditions. The consumer research should therefore be designed, and the results interpreted, with this consideration in mind.

[22] The FDA may want to test whether the inclusion in these options of contraindication, warning, major precaution, and common adverse reaction information from the product labeling improves consumer understanding of risk.

print ads. As the amount of risk information in such ads increases, consumers who read and understand the information may benefit. On the other hand, the increased risk information may deter some consumers from reading the information or may make it more difficult for them to comprehend.[23] Moreover, including highly-detailed risk information may increase the cost of running DTC print ads, thereby decreasing manufacturers' incentive to run such ads.[24] The FTC staff believes that this broader research focus will assist the FDA in determining the costs and benefits of these alternative options for presenting risk information, thus providing the agency with an empirical basis for selecting the best method of conveying such information to consumers in DTC print ads.

IV. The FDA's Disease Awareness Guidance

The FDA has stated that it has jurisdiction under the FDCA over drug "advertising" and "labeling."[25] The agency has concluded that it does not have authority over help-seeking

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[23] *See* Murray et al., *Public Policy Relating to Consumer Comprehension of Television on Commercials: A Review and Some Empirical Results*, 16 J. Consumer Pol'y 145, 155, 160-161 (1993) (demonstrating that the number of words in a disclosure is negatively correlated with comprehension); Murphy & Richards, *Investigation of the Effects of Disclosure Statements in Rental Car Advertisements*, 26 J. Consumer Aff. 351, 355-356 (1992). Murphy and Richards find 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.

[24] *See* 2003 FTC Staff Comment at 23 n.62.

[25] The FDCA does not specifically define "advertising" or "advertisement." According to FDA regulations, "advertisements subject to Section 502(n) of the act include advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems." 21 C.F.R § 202.1(1)(1). The FDCA defines "label" to mean "a display of written,

communications – communications that encourage consumers to seek treatment for a disease or medical condition but do not mention a particular drug.[26] The draft Disease Awareness Guidance that the FDA recently issued seeks to clarify its standards for determining whether communications are such "help-seeking communications" rather than drug "advertising" or "labeling."[27] In particular, the draft guidance emphasizes that the FDA will consider a help-seeking communication and a product ad as "advertising" over which the agency has jurisdiction if the two communications are not perceptually distinct.

The draft Disease Awareness Guidance also suggests that the FTC has jurisdiction over help-seeking communications under Section 5 of the FTC Act.[28] The FTC staff agrees with the FDA's suggestion that the Commission would have jurisdiction over claims made in such communications even though they do not mention a particular drug. Under Section 5 of the FTC Act, the FTC could investigate and challenge help-seeking communications if they appeared to be "unfair or deceptive acts and practices."[29]

V. The FDA's Device Broadcast Advertising Guidance

When the FDA eased the brief summary requirement for DTC broadcast ads in the late

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printed, or graphic matter upon the immediate container of any article. . ." 21 U.S.C. § 321(k). "Labeling" means "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

[26] *See* 69 Fed. Reg. 6308 (Feb. 10, 2004).

[27] *Id.*

[28] *See* FDA, *Draft Guidance for Industry: "Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms* (Jan. 2004) at 4 n.4, *available at* www.fda.gov/cder/guidance/6019dft.doc.

[29] 15 U.S.C. § 45.

1990's, the agency expressly excluded DTC broadcast ads for "restricted" medical devices. These are medical devices (e.g., pacemakers, corrective contact lenses, hearing aids) that the FDA has determined cannot be used safely without medical supervision and therefore are available only pursuant to a prescription.[30] The draft Device Broadcast Advertising Guidance would now apply the same, less burdensome, brief summary requirement to DTC broadcast ads for restricted medical devices that it has been applying to DTC broadcast ads for prescription drugs.

The current brief summary requirement for DTC broadcast ads for restricted medical devices provides a substantial disincentive for manufacturers to use such ads. As discussed above, the FDA recognized that including all of the risk information from the FDA-approved product labeling in DTC broadcast ads for prescription drugs was so onerous that these ads were not a realistic option for manufacturers. We believe that the current brief summary requirement for DTC broadcast ads for restricted medical devices would be likely to have the same effect.

Easing the brief summary requirements for DTC broadcast ads for restricted medical devices is likely to cause a substantial increase in the number of these ads. When the FDA eased the brief summary requirement for DTC broadcast ads for prescription drugs, there was an extraordinary increase in these types of ads.[31] Indeed, there are anecdotal reports that restricted

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[30] According to FDA, the devices covered by the Device Broadcast Advertising Guidance are those it has designated as "restricted" either by regulation promulgated under Section 520(e) of the FDCA (21 U.S.C. § 360j(e)) or by premarket approval application approval order pursuant to section 515(d)(1)(B)(ii) (21 U.S.C. § 360e(d)(1)(B)(ii)).

[31] The FDA issued its proposed changes in brief summary requirements for DTC broadcast ads in late 1996 and issued a final guidance document with these changes in 1999. In 1996, the industry spent $791 million on DTC ads. In 2000, the industry spent $2.467 billion on DTC ads. M. Rosenthal *et al., Special Article: Promotion of Prescription Drugs to Consumers*, 346 New. Eng. J. Med. 498 (Feb. 14, 2002), *available at* www.nejm.org.

device manufacturers are already considering modifying the methods that they use to market their products in response to the issuance of the FDA's draft Device Broadcast Advertising Guidance.[32]

Based on our analysis of the effect of changes in FDA's regulatory scheme for DTC ads for prescription drugs, the FTC staff believes that consumers are likely to benefit from changes in FDA regulations that are likely to increase DTC broadcast advertising for restricted medical devices. In assessing the effect of FDA's measures to decrease the regulatory burden associated with DTC broadcast advertising for prescription drugs, the FTC staff stated that:

> The evidence currently available suggests that DTC advertising has had some positive effects for consumers. DTC advertising appears to provide drug benefit and risk information that prompts consumers to seek out information about medications and medical conditions, some of which may not have been diagnosed previously. The information that consumers acquire may allow them to have more fruitful, informed conversations with their doctors about treatment options and may permit them to make better-informed health care decisions for themselves. In some cases, however, DTC ads may create misimpressions about drug risks and benefits, and doctors may have to correct these misimpressions and not let them affect their prescribing decisions. Definitive conclusions regarding the precise nature of the impact of the FDA's current approach to DTC advertising on consumer welfare cannot be reached, however, until better empirical evidence is developed concerning the effects of DTC advertising on both drug expenditures and health outcomes.[33]

Given that prescription drugs and restricted medical devices are both products sold pursuant to a prescription from a medical professional, the FTC staff believes that adopting the same brief summary requirement that applies to DTC broadcast ads for prescription drugs to such ads for

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[32] R. Thomaselli, *Medical Devices to Hike Spending*, Advertising Age (Feb. 16, 2004).

[33] FTC 2003 DTC Comment at 15. The quoted language from the FTC 2003 DTC Comment refers to the effects of all DTC advertising for prescription drugs. Given that DTC broadcast ads account for more than 64% of DTC advertising for prescription drugs, *see* The Henry J. Kaiser Foundation, *Trends in Direct-to-Consumer Advertising of Prescription Drugs* 5 (Feb. 2002), it is reasonable to attribute these effects to DTC broadcast ads as well.

restricted medical devices would have similar effects.

V. Conclusion

In light of the important role that DTC advertising can play in keeping consumers better-informed about their healthcare and treatment options, the FTC staff supports the FDA's effort to improve the facilitation of truthful, non-misleading information in DTC advertising by issuing three draft guidance documents on consumer-directed promotion. The FTC staff believes that the proposed guidances provide needed clarification and consistency that will aid in this endeavor.

Respectfully submitted,

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