



UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

BEFORE THE
OFFICE OF MANAGEMENT AND BUDGET

**In the Matter of Agency Information Collection Activities;
Submission for OMB Review; Comment Request;**

**Assessment of Physician and Patient Attitudes Toward
Direct-to-Consumer (DTC) Promotion Drugs; Survey**

Docket No. 01N-0078

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

September 24, 2001

* These comments are the views of the staff of the Bureau of Economics, Bureau of Consumer Protection, and Office of Policy Planning of the Federal Trade Commission. They do not necessarily represent the views of the Commission or any individual Commissioner. Inquiries regarding this comment should be directed to Janis Pappalardo (202) 326-3380, Bureau of Economics.

I. INTRODUCTION

The Food and Drug Administration (FDA) submitted a proposal to collect information about Direct-to-Consumer (DTC) prescription drug advertising to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.⁽¹⁾ The FDA proposes to administer two extensive surveys: (1) a consumer survey similar to one conducted by the FDA in 1999, and (2) a survey of physicians. The purpose of the surveys is to gain a better understanding of the effects of DTC advertising on consumer and physician attitudes and behavior. The OMB requested comments on the FDA's proposal.

In light of the Federal Trade Commission's (FTC) jurisdiction over advertising in other markets, the staff of the FTC's Bureau of Economics, Bureau of Consumer Protection, and Office of Policy Planning submit views on the proposed surveys. We wish to make three principal points:

1. We commend the FDA's efforts to gather data on the effects of DTC advertising on patients and physicians. Such systematic data are critical to improve our understanding of the role of advertising, and advertising regulation, on consumer welfare.
2. An important policy issue surrounding DTC advertising involves its possible effects on prescription drug costs. The addition of a few questions about patient insurance coverage and drug costs might make the results of these extensive surveys even more valuable to policy makers. We therefore recommend that the FDA consider adding some questions about these factors to the survey.
3. In order to test hypotheses about differences in the effects of DTC advertising across physician specialties, it may be helpful to enlarge the physician sample.

The FTC enforces the Federal Trade Commission Act, which among other things prohibits deceptive or unfair practices in or affecting commerce. One of the FTC's primary

responsibilities is to prevent deceptive and misleading advertising.⁽²⁾ The FTC considers the prevention of deceptive health-related advertising claims as one of its highest priorities, and has taken action in numerous cases involving deceptive health-related claims about food products,⁽³⁾ dietary supplements,⁽⁴⁾ and over-the-counter drugs.⁽⁵⁾ In implementing its mandate, the FTC has developed considerable expertise in understanding the role of advertising and labeling within the overall consumer information environment.⁽⁶⁾

The staff of the Commission also is experienced in examining the effects of laws affecting advertising on market performance, including the prescription drug market.⁽⁷⁾

While important differences between advertising for prescription drugs and advertising for other products might lead to different approaches, we believe that the staff's experience, particularly regarding marketing and economic issues, has a bearing on the issues on which the OMB seeks comment.

II. BACKGROUND INFORMATION

Pharmaceutical companies did not advertise prescription drugs directly to consumers prior to the early 1980s. During the 1980s and 1990s the FDA re-examined its policy toward DTC advertising, leading to several changes. In 1995, for example, the FDA requested comments on DTC promotion through print, broadcast, and other media. In response, the FTC staff submitted a comment that examined the pros and cons of DTC advertising, and emphasized the importance of a regulatory scheme that would balance ". . . the benefits and the risks of allowing pharmaceutical manufacturers greater latitude in their advertising. In particular, it is important to protect consumers from deceptive information but not to stifle truthful information that could benefit consumers." The comment further explained why the FTC staff believed that ". . . the net benefits of DTC advertisements can be increased by limiting current disclosure requirements and by adjusting disclosure requirements according to the characteristics of different advertising venues."⁽⁸⁾ The FDA issued a draft guidance in 1997.⁽⁹⁾ The guidance proposed mechanisms for providing multiple sources of product labeling information, which would decrease the cost of broadcast advertisements that discuss a product and its effects ("product-claim advertisements"). The FDA issued a final guidance adopting this approach in August 1999.⁽¹⁰⁾ At the same time, the FDA announced that it would evaluate the effects of the new policy within two years.

Expenditures for DTC television ads soared from \$220 million in 1996 to \$1.13 billion in 1999.⁽¹¹⁾ This growth has not come without controversy. Some doctors and insurance companies voice concern that ". . . flashy, well-produced ads are sending patients in search of the latest medications even when they don't need them. And harried doctors often prescribe the pills rather than battle - and possibly lose - their patients."⁽¹²⁾ Others express concern that DTC advertising raises the cost of prescription drugs, either because advertising expenditures raise pharmaceutical companies' costs or because advertising induces patients to purchase more - or more expensive - prescription drugs than they would purchase in the absence of advertising.⁽¹³⁾ In contrast, some physicians give DTC advertising credit for empowering consumers with information that enables them to seek effective treatment for problems sooner than they would have otherwise. For example, an endocrinologist in private practice recently testified that: "In my experience as an endocrinologist, direct to consumer advertising of prescription medicines is getting patients with diabetes into my office sooner, so they can be treated with effective medicines and avoid the dire complications of this disease."⁽¹⁴⁾ Congress is currently examining the pros and cons of DTC advertising.⁽¹⁵⁾

III. THE PROPOSED SURVEYS

A. The surveys will provide valuable information

The two surveys proposed by the FDA come at a critical time in the debate over the effect of DTC promotions on public health. We commend FDA for undertaking these surveys, which will provide valuable information on this

important subject. Although survey data inevitably have limitations, we believe that the surveys proposed by the FDA will help policy makers evaluate the effects of DTC advertising. The proposed consumer survey generally tracks the FDA's 1999 survey, which should allow analysts to examine how consumer responses to DTC advertising have changed over time. For example, FDA staff recently testified that "a major result" of the 1999 survey ". . . is that a significant minority of respondents said that a DTC ad has caused them to ask a doctor about a medical condition or illness that they had not previously discussed."⁽¹⁶⁾ The new survey will allow analysts to evaluate how responses to questions such as this may have changed since 1999. The physician survey will provide unique data to help policy makers assess the effect of DTC advertising on the patient/physician relationship.

The surveys ask questions designed to learn more about the extent of potential benefits or harm from DTC advertising. For example, Question 18 on the consumer survey asks: "Has an advertisement for a prescription drug **ever** caused you to ask a doctor about a medical condition or illness of your own that you had **not** talked to a doctor about before?" Responses to this question help to estimate one possible effect of DTC advertising.

In addition to questions about DTC advertising, the survey asks a series of standard demographic questions, such as questions about income, health status, and education. Consumer behavior surveys often include demographic information because such information can improve data analysis in two ways. First, such information can help control for differences among different respondents at a single point in time. Second, demographic information can help analysts comparing results from surveys administered at different points in time to determine if changes in demographic variables explain changes in consumer behavior. Economic models of consumer behavior typically require data on relevant demographic variables reflecting differences in preferences and income, because such demographic variables can be important predictors of consumer behavior. From an economic perspective, cost data are also important, because the prices consumers face generally affect consumer demand.

B. Questions addressing insurance and costs would be helpful

As valuable as the proposed surveys are likely to be, we believe that with a few modifications, they could become even more valuable. Among other things, these extensive surveys offer an opportunity to gain a better understanding of the role of perceived prescription drug prices on consumer responses to DTC advertising. For example, data on consumer insurance coverage for prescription drugs could help ascertain whether consumers with greater coverage (who would expect relatively low prescription drug costs) are more likely to visit a doctor because of DTC advertising, or are more likely to ask new questions about previously untreated conditions during routine visits. Information on the role of drug costs within the overall consumer information search process might also help analysts estimate the extent to which DTC advertising might lead to lower prescription drug prices. If, for example, consumers consider cost when prescription decisions are being made, then this would suggest that competition through DTC advertising might lead to lower prices, holding all else constant.⁽¹⁷⁾ Even if the survey data cannot provide precise information regarding consumer responses to variations in cost, information about the role of costs would help to offer a more complete understanding of how consumers respond to DTC promotions.

Survey research is as much an art as a science, and we do not know, without further research and pre-testing, which survey questions would most likely elicit the most informative results. In the spirit of offering a starting point for discussion, in the event that the FDA wishes to collect some data on consumer insurance status and the role of costs, we suggest the following:

1. Cost information - Consumer Survey

After Question 36 in the Consumer Survey, the FDA might consider adding a question to elicit information about consumer search for prescription drug cost information, such as:

"How often do you compare the prices of prescription drugs or other alternative treatments? Would you say always, almost always, sometimes, rarely, or never?"

This question might be followed by a more direct behavior question, such as:

"When you are aware that different drugs will cost you different amounts, how important is cost in making your final choice? Would you say extremely important, very important, somewhat important, not very important, not important at all?"

If the FDA wants more precise information about the point at which patients consider cost, the survey could include a followup question such as:

"How often do you discuss the cost of prescription drugs or other alternative treatments with your doctor? Would you say always, almost always, sometimes, rarely, or never?"

2. Prescription coverage - Consumer Survey

Following Question 58 in the Consumer Survey, the FDA might add one or two questions about prescription drug benefits, such as:

"Do you belong to an HMO or an insurance plan with a prescription drug benefit?" [Yes, No, Don't Know, Refused]

Those who have a benefit might be asked more about the extent of their coverage. For example, the FDA might want to ask:

"How much do you typically expect to pay for prescription drugs? Would you say a modest co-payment (say \$5 or \$10 per drug), about 25% of the retail price, about half of the retail price, more than half of the retail price [allow an "other" option and a "do not know" option]?"

3. Cost information - Physician Survey

In the Physician Survey, the FDA may wish to insert a question about costs following Question 23, such as:

"Was the patient concerned about the price of the drug?" or "Did the patient ask if a less expensive drug was available?"

A more general question about the role of cost in choosing drug therapies might be included as part of Question 4 in the Physician Survey. This question asks doctors to tell the interviewer how frequently patients initiate questions about a series of treatments ranging from OTC drugs to prescription drugs advertised on TV. The question could be revised to include a question about how frequently patients initiate questions about the cost of drug treatments. If the FDA wants information from doctors that might help assess the role of generic drug competition, "generic prescription drugs" could be added to the list of options.

An alternative way of addressing the cost issue would be to insert a general question before Question 39:

"How often do you discuss the cost of alternative drugs or other treatments with your patients? Would you say always, almost always, sometimes, rarely, or never?"

Given the intense policy debate over generic drugs, the FDA may wish to discover the extent to which DTC advertising influences patients' and physicians' choices between brand-name prescriptions and generic equivalents. To do so, the FDA would first need to add a question that would identify the frequency with which generic substitutes are available for DTC advertised prescription drugs. A second question could then ask how frequently patients insist on receiving advertised, brand-name drugs even when a generic equivalent is available.

C. An expanded physician sample could be useful

The FDA has embarked on an extensive consumer research project, which was obviously designed with great care. If the FDA wishes to test hypotheses about the differential effects of DTC advertising on physicians in different specialties, it should consider the benefits and costs of enlarging the size of the physician sample. FDA staff may also wish to consider whether it is possible to create a control group of physicians in a specialty that encounters very little DTC advertising, possibly by administering a modified survey to this group. If this cannot be done as part of this study, then the FDA may wish to consider how this might be done in the future. Some type of control would help analysts better understand, for example, if consumers who try to influence the course of medical treatment are more likely to be treated for maladies with high levels of DTC advertising versus low levels of DTC advertising. Such a control would help to define the effects of DTC promotions more precisely.

IV. CONCLUSION

We support the FDA's efforts to collect systematic data to evaluate the effects of DTC advertising. These data will improve our understanding of the role of DTC advertising on consumers and the patient/physician relationship. Data such as these, especially if evaluated along with data from other sources, such as market studies and copy tests, are necessary to determine how DTC advertising policies affect consumer welfare.

Respectfully submitted,

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Endnotes:

1. See FDA, Notice, Agency Information Collection Activities, 66 Fed. Reg. 42,664 (Aug. 14, 2001).
2. 15 U.S.C. §§ 45, 52-57. The FTC and FDA have overlapping jurisdiction with respect to the advertising, labeling, and promotion of foods, over-the-counter drugs, cosmetics and medical devices. Under a long-standing liaison agreement between the agencies, the FDA exercises primary responsibility for regulating the labeling of these products, while the FTC has primary responsibility for enforcing laws against false or misleading advertising of these products. Working Agreement Between FTC and FDA, 4 Trade Reg. Rep. (CCH) ¶¶ 9,851 (1971).

In 1962 Congress limited a portion of the FTC's authority over prescription drug advertising. Specifically, section 502(n) of the Food, Drug and Cosmetic Act precludes FTC jurisdiction under sections 12-17 of the FTC Act with respect to three items: drug name, formula, and summary of effectiveness and consequences of use. The Food, Drug and Cosmetic Act does not address FTC jurisdiction under these sections over statements other than those that fall into these three categories, nor does it affect the FTC's basic jurisdiction over advertising, including prescription drug advertising, under section 5 of the FTC Act. The 1971 liaison agreement between the two agencies reflects the understanding that the FDA would exercise primary responsibility for the truth or falsity of prescription drug

advertising. See Letter from the Federal Trade Commission to the Honorable John C. Dingell, August 15, 1983, for further discussion of the FTC's shared jurisdiction with FDA regarding prescription drug advertising.

3. *E.g.*, *Conopco, Inc.*, 123 F.T.C. 131 (1997) (consent); *Grey Advertising, Inc.*, 122 F.T.C. 352 (1996) (consent), *The Dannon Co.*, 121 F.T.C. 136 (1996) (consent and \$150,000 in disgorgement); *Eggland's Best, Inc.*, 118 F.T.C. 340 (1994) (consent); *Pompeian, Inc.*, 115 F.T.C. 933 (1992) (consent); *Campbell Soup Co.*, 115 F.T.C. 788 (1992) (consent); *Bertolli U.S.A., Inc.*, 115 F.T.C. 744 (1992) (consent).

4. *E.g.*, *FTC v. Lane Labs-USA, Inc.*, No. 00 CV 3174 (D.N.J. June 28, 2000) (stipulated final order and \$1 million judgment); *U.S. v. Home Shopping Network*, 99-897-CIV-T-25C (M. D. Fla. April 15, 1999) (consent and \$1.1 million civil penalty); *KCD Inc.*, 123 F.T.C. 1535 (consent and \$150,000 in consumer redress); *Schering Corp.*, 118 F.T.C. 1030 (1994) (consent); *U.S. v. General Nutrition, Inc.*, No. 94-686 (W.D. Pa. April 28, 1994) (stipulated permanent injunction and \$2.4 million civil penalty); *General Nutrition, Inc.*, 111 F.T.C. 387 (1989) (consent and \$600,000 for research); *FTC v. PharmTech Research, Inc.*, 576 F. Supp. 294 (D.D.C. 1983) (preliminary injunction), 103 F.T.C. 448 (1984) (consent).

5. *E.g.*, *Novartis Corp. v. FTC*, 223 F.3d 783 (D.C. Cir. 2000) (upholding Commission finding that marketer of Doan's pills had misrepresented that product is superior to other analgesics for treating back pain); *Johnson & Johnson Consumer Products*, 121 F.T.C. 22 (1996) (consent order); *FTC v. Redhead*, No. 93-1232-JO (D. Ore. June 20, 1994) (stipulated permanent injunction and redress for misleading claims for purported AIDS treatment).

6. Relevant FTC staff research includes: Pauline M. Ippolito and Alan D. Mathios, *Information and Advertising Policy: A Study of Fat and Cholesterol Consumption in the United States, 1977-1990* (1996); Pauline M. Ippolito and Alan D. Mathios, *Health Claims in Advertising and Labeling: A Study of the Cereal Market* (1989); and John E. Calfee and Janis K. Pappalardo, *How Should Health Claims for Foods be Regulated? An Economic Perspective* (1989).

7. FTC staff filed a comment with the FDA on DTC advertising in 1996: *Comments of the Staffs of the Bureaus of Economics and Consumer Protection of the Federal Trade Commission in The Matter of Direct-to-Consumer Promotion: Public Hearing Docket No. 95-N-0227* (Jan. 11, 1996), also found at www.ftc.gov/be/v960001.htm ("FTC Staff DTC Comment"). For other relevant FTC staff research and analysis, see Roy Levy, *The Pharmaceutical Industry: Competitive and Antitrust Issues in an Environment of Change* (1999); Alison Masson and Robert Steiner, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws* (1985); FTC Staff Report, *Drug Product Selection* (1979); Ronald Bond and David Lean, *Sales, Promotion and Product Differentiation in Two Prescription Drug Markets* (1977); and FTC Staff Report, *Prescription Drug Price Disclosures* (1976).

8. FTC Staff DTC Comment, *supra*, n.7, at 4.

9. 62 Fed. Reg. 43171 (Aug. 12, 1997).

10. 64 Fed. Reg. 43197 (Aug. 9, 1999), also available at www.fda.gov/cder/guidance/1804fnl.htm,

11. Chris Adams, "FDA Plans to Review Policy Allowing Direct-to-Consumer Drug Ads for TV," *Wall Street Journal*, Mar. 28, 2001, at B1.

12. *Ibid.*

13. See, e.g., Phillip R. Alper, *Direct-to-Consumer Advertising: Education or Anathema*, 282 *Journal of the American Medical Association* No. 13 (Oct. 6, 1999) (expressing concern over "the inflationary impact of DTC advertising, with which the costliest drugs are pitched with all the skill that the advertising budgets of pharmaceutical companies can buy"); Testimony of Sidney M. Wolfe, MD, Director, Public Citizen's Health Research Group, Before the Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism, Committee on Commerce, Science, and

Transportation, U.S. Senate In Public Hearings on Direct-to-Consumer Advertising of Prescription Drugs, July 24, 2001 (asserting "an urgent need for more fine-tuned, better-staffed and much tougher government regulation"), available at <http://www.senate.gov/%7Ecommerce/hearings/072401Wolfe.pdf>, at 1. For counter-arguments, see Merrill Mathews, *Who's Afraid of Pharmaceutical Advertising?*, Institute for Policy Innovation Policy Report #155 (May 17, 2001), available at <http://www.ipi.org/ipi/IPIPublications.nsf>.

14. Testimony of Richard Dolinar, Before the Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism, Committee on Commerce, Science, and Transportation, U.S. Senate In Public Hearings on Direct-to-Consumer Advertising of Prescription Drugs, July 24, 2001.

15. On July 24, 2001, the Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism, Committee on Commerce, Science, and Transportation, U.S. Senate, held hearings on this issue. See 147 Cong. Rec. S8141 (daily ed. July 24, 2001) (authority for hearing); <http://commerce.senate.gov/issues/consumer.htm#Hearings> (listing witnesses).

16. Statement of Nancy M. Ostrove, Ph.D., Deputy Director, Division of Drug Marketing, Advertising and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, Department of Health and Human Services, Before the Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism, U.S. Senate Committee on Commerce, Science, and Transportation, July 24, 2001, available at <http://www.fda.gov/ola/2001/drugpromo0724.html>, at 6.

17. DTC prescription drug advertisements tend to focus on qualities of the drugs, not price. Economic research, however, suggests that consumers often infer that firms engaging in extensive nonprice advertising will also offer a better deal on price. Empirical studies of the prescription drug, eyeglass, and liquor industries find that advertising tends to reduce prices even when advertising of prices is prohibited. See Kyle Bagwell and Garey Ramey, *Advertising and Coordination*, 61 *Review of Economic Studies* 153-72 (1994).