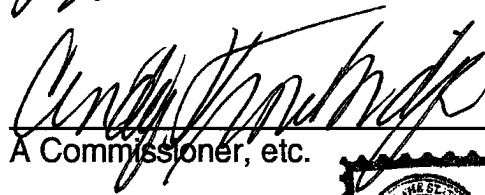


This is **Exhibit "E"** referred to in the Affidavit of
Dr. Richard Dolinar sworn before me this
23rd day of July, 2007.


A Commissioner, etc.



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

**In the Matter of
Request for Comments on Consumer-Directed Promotion**

Docket No. 2003N-0344

**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**

December 1, 2003*

***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

The Food and Drug Administration has requested comments regarding the advertising of prescription drug products directly to consumers (DTC advertising).¹ Among other things, the agency announced that it “will consider its own research and the research of others to explore whether, and, if so, how, the agency’s current regulatory approach should be modified, including whether the guidance on DTC broadcast advertisements should be withdrawn, continued, or modified to reflect the agency’s current thinking.”² The staff of the Federal Trade Commission’s Bureau of Consumer Protection, Bureau of Economics, and Office of Policy Planning (FTC staff) offer the following comments to assist the FDA in its deliberations.

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 In addition, Section 12 of the FTC Act more specifically prohibits the dissemination of false advertisements for foods, drugs, devices, services, or cosmetics.⁴ The FDA and the FTC generally share jurisdiction over prescription drug advertising, although 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

¹ 68 Fed. Reg. 47,920 (Aug. 12, 2003).

² *Id.* at 47,922.

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. The FTC considers the prevention of deceptive health-related advertising claims to be of utmost importance in promoting consumer welfare. The Commission thus has taken action in numerous cases involving deceptive health-related claims for foods, drugs, dietary supplements, and medical devices. 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.

In addition to its law enforcement experience, the FTC staff also has examined the effect of advertising regulation on consumers and competition.⁶ In particular, we have submitted comments to the FDA in response to previous requests for views on the economic impact of DTC advertising.⁷ We appreciate the opportunity to share our views on DTC advertising with the FDA.

Truthful, non-misleading DTC advertising benefits consumers. It can empower consumers to manage their own health care by providing information that will help them, with the assistance of their doctors, make better-informed decisions about their treatment options. For

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 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) (hereafter “*FTC 1996 DTC Comment*”), available at www.ftc.gov/be/v960001.htm.

example, advertisements can call consumers' attention to new drugs, help them communicate with medical professionals, spur them to get treatment, or serve as a reminder to take prescribed medication. Consumers receive these benefits from DTC advertising with little, if any, evidence that such advertising increases prescription drug prices. On the other hand, deceptive or misleading ads for prescription drugs can misinform consumers about the effectiveness of their medications.

In this comment, we analyze the overall economic effects of DTC advertising to assist the FDA in evaluating such advertising. We also make a number of suggestions about how the FDA's regulatory scheme for DTC advertising could be modified to communicate truthful, non-misleading information in a manner that is easier for consumers to understand and access:

- The brief summary requirement for broadcast ads -- a major statement of drug risks along with adequate provision for more complete risk information -- should be retained, although consumers should be directed to a more useful source of more complete risk information than the FDA-approved product labeling.
- The brief summary requirement for print ads should be consistent with the requirement for broadcast ads.
- The FDA should make clear that the fair balance requirement for DTC ads prohibits only ads that convey a deceptive impression of the risk and benefits from the overall presentation of information, rather than those that fail to achieve a mechanistic balance between risk and benefit information because they do not present such information with identical emphasis.
- Pharmaceutical manufacturers should be permitted to make truthful, non-misleading

price comparisons and other types of relative cost claims.

- The FDA should apply the same standards for endorsements and testimonials in DTC ads for prescription drugs as the FTC applies through its Guides Concerning the Use of Endorsements and Testimonials in Advertising to endorsements and testimonials for other products, including over-the-counter (OTC) drugs. In addition, as the FTC Guides undergo regulatory review, we encourage the FDA to submit comments on the use of endorsements and testimonials in DTC advertising.
- Internet advertising should be treated consistently with DTC ads in other media, and it would be beneficial if the FDA were to issue guidance addressing DTC ads available on the Internet.

The comment will first examine effects of DTC ads, specifically consumer and physician reactions and any demand effects. It will then analyze current DTC advertising regulations and offer recommendations on the brief summary requirement for both print and broadcast DTC ads. Finally, it discusses the fair balance requirement, comparative DTC advertising, endorsements and testimonials, and Internet advertising, as well as offers recommendations on these issues.

II. Effects of Direct-to-Consumer Advertising of Prescription Drugs

Empirical evidence suggests that the FDA's current approach to regulating DTC advertising generally confers benefits on consumers. Survey evidence suggests that DTC ads have provided consumers with useful information about the drug options open to them, which, in turn, has empowered consumers to interact with their physicians more effectively. Studies of the impact of DTC advertising on demand do not support the conclusion that it has led to the increased use of inappropriate drugs or increased drug prices.

A. Consumer and Physician Reactions to DTC Advertising: Survey Evidence

Major surveys conducted to assess the effects of DTC advertising on consumer attitudes, experiences, and behavior include those by the FDA,⁸ *Prevention*,⁹ the Harvard/Harris National DTCA Survey,¹⁰ the Henry J. Kaiser Family Foundation (Kaiser Family Foundation),¹¹ and the National Consumers League.¹² The general consensus from these and other surveys is that DTC advertising provides consumers with useful information, stimulates productive discussions between doctors and patients, and encourages consumers to learn more about previously undiagnosed conditions.

A consistent finding among the surveys is the significant degree to which DTC advertising provides consumers with useful information concerning their health. Ads achieve much of this informative role indirectly, by encouraging consumers to seek out more information from other sources about the advertised drug and the condition it ameliorates. In the 2002 FDA

⁸ See K. Aikin (FDA), *The Impact of Direct-to-Consumer Prescription Drug Advertising on the Physician-Patient Relationship*, presentation for the U.S. Food and Drug Administration Center for Drug Evaluation and Research “Research on Consumer Directed Advertising” Public Meeting (hereafter, “DTC Public Meeting”) (Sept. 22, 2003) (hereafter “FDA Survey”), available at www.fda.gov/cder/ddmac/aikin/index.htm.

⁹ *Prevention*, *Fifth Annual Survey: Consumer Reaction to DTC Advertising of Prescription Medicines* (2002/2003); see also E. Slaughter (Rodale, Inc.), *Consumer Reaction to DTC Advertising of Prescription Medicines 1997 to 2000: A Six-Year Tracking Study from Prevention and Men’s Health Magazine*, presentation for DTC Public Meeting (Sept. 22, 2003), available at www.fda.gov/cder/ddmac/P1Slaughter/index.htm.

¹⁰ J. Weissman (Mass. Gen. Hosp. Institute for Health), *Consumer and Physician Reports on the Health Effects of DTCA*, presentation for DTC Public Meeting (Sept. 22, 2003), available at www.fda.gov/cder/ddmac/P1weissman/index.htm.

¹¹ M. Brodie, (The Henry J. Kaiser Family Foundation), *Understanding the Effects of Direct-to-Consumer Prescription Drug Advertising*, (Nov. 2001).

¹² L. Golodner (National Consumers League), *Effectiveness of and Attitudes Toward Medication Advertising*, presentation for DTC Public Meeting (Sept. 22, 2003), available at www.fda.gov/cder/ddmac/P1golodner/index.htm.

survey, 43% of patients who recalled seeing a DTC ad said that it caused them to look for more information through a variety of sources, the most important of which was their own doctor.¹³ Significant numbers also reported seeking information from their pharmacist and from friends and relatives.¹⁴ In what will no doubt be an increasingly important source, the percentage of consumers seeking information on the Internet as a result of viewing a DTC ad increased from 18% in 1999 to 38% in 2002.¹⁵ Also, DTC ads may generate information searches in other ways. For example, someone who sees a DTC ad may talk about the drug with a friend or relative with the relevant condition,¹⁶ and that friend or relative may then consult a doctor.

Other surveys also report a positive consumer response to DTC ads. The *Prevention* survey found that viewing a DTC ad led 33% of consumers to initiate discussions with their physicians.¹⁷ The corresponding figure in the consumer survey conducted by the Kaiser Family Foundation was 30%.¹⁸ Especially noteworthy is the role of DTC ads in prompting consumers to consult their physicians for a previously undiagnosed condition. In the FDA survey, 18% of the patients surveyed said DTC ads caused them to talk to their physician about a specific medical

¹³ FDA Survey, *supra* n.8.

¹⁴ *Id.*

¹⁵ *Id.* The *Prevention* survey reports that 55% of consumers have consulted online sources for health information. *Prevention*, *supra* n.9.

¹⁶ See, e.g., G. Kassan (Parade Magazine), *Compliance, Caregivers and the Consumer*, presentation for DTC Public Meeting (Sept. 23, 2003), available at www.fda.gov/cder/ddmac/p7kassan/indexplain.htm (finding that 41% of caregivers who recalled seeing DTC ad showed or discussed the ad with someone who had the condition; 45% of sufferers shown a DTC ad by a caregiver were likely to show or discuss the ad with someone else with the condition).

¹⁷ *Prevention*, *supra* n.9.

¹⁸ Kaiser Family Foundation, *supra* n.11.

condition or illness for the first time.¹⁹ In the Harvard/Harris survey, 25% of consumers reported that the office visits prompted by a DTC ad resulted in a “new diagnosis.”²⁰

When asked about the overall effect of DTC advertising on their patients and their practice, doctors were fairly evenly divided as to whether they viewed DTC advertising positively (40%), neutrally (27%), or negatively (33%).²¹ However, in response to more specific questions about their experiences and interactions – questions more likely to shed light on the actual effects of DTC advertising – physicians’ answers suggested positive effects for patients from DTC advertising. For example, the most comprehensive physician survey, the FDA Physician Survey conducted in 2002, confirmed the informative role of DTC ads. The survey found that 73% of physicians surveyed agreed “strongly” or “somewhat” with the statement that patients who saw a DTC ad asked more thoughtful questions during their visits.²² A majority

¹⁹ FDA Survey, *supra* n.8. This represents a significant drop from the corresponding 27% figure reported for the 1999 survey.

²⁰ Weissman, *supra* n.10.

²¹ FDA Survey, *supra* n.8. Until 1992, the American Medical Association was opposed to product-specific DTC advertising. As such advertising became more common, however, the AMA reassessed its position. It recently testified that responsible DTC advertising can have a positive impact on health care if it is accurate and educational to consumers, balances benefits and risks, and promotes good health outcomes. The AMA also stated that it would like to see more independent research on DTC advertising, particularly, on its impact on the patient-physician relationship and on health outcomes and costs. DTC advertising is a controversial issue for AMA members, who recognize its positive effects but have concerns about some aspects of the advertising. *See Prepared Statement of the American Medical Association before the Senate Special Committee on Aging* (July 22, 2003), available at <http://aging.senate.gov/hr105nn.pdf>.

²² K. Aikin, *FDA’s physician survey on DTC Rx drug ads shows health benefits*, CDER News Along the Pike, Vol. 9:1 (Feb. 21, 2003), available at www.fda.gov/cder/pike/JanFeb2003.htm#Survey.

agreed that DTC ads promoted better awareness of both potential problems and alternative treatments among patients.²³

Although survey evidence does not show that DTC advertising causes significant problems for the doctor-patient relationship, physicians had mixed views about whether DTC ads generally improved their interactions with patients. For example, in response to the question whether there were beneficial effects on patient interaction from DTC advertising, 41% of the physicians responded “yes” and 59% responded “no.”²⁴ However, a large majority of physicians surveyed by the FDA (82%) reported that the DTC ads did not adversely affect their interactions with the last patient they treated who discussed an advertised prescription drug.²⁵ Of those that did report a negative effect, the most frequently cited problem (by 41% of the physicians) was the extra time spent correcting misimpressions caused by the DTC ad.²⁶

Notably, an important concern regarding DTC ads – that they lead to inappropriate prescribing – fails to find support in the surveys. Of physicians reporting a negative effect from DTC ads in the FDA study, only 5% listed “pressure to prescribe” as one of the reasons.²⁷

²³ FDA Survey, *supra* n.8.

²⁴ *Id.* “No” responses included those physicians who did not believe that the ads had any effect, either positive or negative, as well as physicians who believed the advertising had a negative effect.

²⁵ *Id.*

²⁶ *Id.* The next most common problem, cited by 26% of the physicians, was “drug not needed/did not have condition.”

²⁷ *Id.* Although a significant share of physicians reported perceiving some “pressure” to prescribe the advertised drug -- 52% of all general practitioners and 42% of specialists -- the overall pattern of responses to the FDA survey, and to the others discussed in the text, indicates that the majority of physicians view such pressures as relatively light. For example, only 8% stated that the patient tried to “influence the course of treatment in a way that

Overall, over 94% of the physicians stated that the DTC-advertised drug they prescribed was at least as effective as alternative drugs.²⁸

The surveys do reflect physicians' concerns about what they see as the tendency of DTC ads to foster misimpressions among patients. The most frequently cited concern raised in the FDA physician survey was the tendency of DTC ads to convey the benefits of a drug more effectively than its drawbacks.²⁹ In addition, a significant number of physicians in the Harvard/Harris survey reported that DTC ads reduced their patients' confidence in them.³⁰ Despite these negative assessments, the physician surveys overall indicate that DTC ads generate a number of important benefits for patients, and that these benefits tend to outweigh the drawbacks.³¹

would have been harmful to him or her." *Id.*

²⁸ Weissman, *supra* n.10. Overall, a prescription drug was prescribed in 39% of the visits involving a patient who requested a drug they saw advertised. The resulting drug prescribed was the "most effective" in 46.1% of the visits, and was "as effective" in 48.4%. In 5.5% of visits, a particular drug was prescribed although "other drug/treatment options were more effective; but [the physician] wanted to accommodate [the] patient's request." *Id.*

²⁹ FDA Survey, *supra* n.8.

³⁰ Weissman, *supra* n.10.

³¹ Moreover, some physician groups support DTC advertising because of its potential to reach important subgroups in the population that tend to be less informed about relevant health options. For example, the National Medical Association, representing African-American physicians, issued a statement generally supporting DTC advertising, based on a survey of its members, in part because of the role of DTC ads in educating patients about disease and treatment options. National Medical Association, *Position Statement of the National Medical Association on Direct to Consumer Advertising* (June 2002). Similarly, a representative of the National Alliance for Hispanic Health has testified in favor of DTC advertising. J. Delgado, *Recent Developments Which May Impact Consumer Access to, and Demand for, Pharmaceuticals, Prepared Witness Testimony: The Committee on Energy and Commerce* (June 13, 2001).

B. Demand Effects of DTC Advertising

Analysts have used extensive market data to shed light on two important questions concerning DTC advertising: (1) does it increase drug prices to consumers? and (2) does it encourage the consumption of drugs that are unnecessary or more expensive than available substitutes that are not advertised? A combination of data and methodological shortcomings have so far frustrated attempts to answer these questions. Nevertheless, the existing empirical analyses provide little or no basis to conclude that DTC advertising increases the price of drugs to consumers or encourages consumption of inappropriate drugs.

There have been no well-controlled econometric tests of the hypothesis that firms pass on the costs of DTC advertising through higher prices. Such studies are the best test of such a hypothesis. A number of less formal analyses, however, suggest that DTC ads have little or no price-increasing effect, although the lack of adequate controls rule out any definitive inferences from them.³²

³² Manning and Keith, writing on behalf of Pfizer, report that a rank ordering of brands according to DTC spending was not related to percentage increases in cost per prescription. R. Manning & A. Keith, *The Economics of Direct-to-Consumer Advertising of Prescription Drugs*, published by Pfizer Inc. in *Economic Realities in Health Care Policy*, 20:1, at 3-9 (June 2001). Calfee *et al.* note that statin drugs, among the leaders in DTC advertising, have exhibited a relatively low price increase of 7% in real terms between 1995 and 2000. J. Calfee *et al.*, *Direct-to-Consumer Advertising and the Demand for Cholesterol-Reducing Drugs*, XLV J.L. & Econ. 677 (Oct. 2002).

These types of studies are largely observational and do not account for other factors that may influence the price of prescription drugs. Calfee, for example, notes the downward pressure on the price of statins due to the emergence of generics -- an important consideration in analyzing price changes in other prescription drug markets as well. J. Calfee, *Public Policy Issues in Direct-to-Consumer Advertising of Prescription Drugs*, J. Pub. Pol'y & Marketing 179 (Fall 2002).

DTC advertising accounts for a relatively small proportion of the total cost of drugs, which reinforces the view that such advertising would have a limited, if any, effect on price. For example, while spending on DTC advertising has risen dramatically, it still represents only a small percentage of total sales. In 1996, spending on DTC television and print advertising amounted to \$791 million and 1.2% of overall prescription drug sales. By 2000, spending on such advertising had risen to \$2,467 million -- yet was still only 2.2% of overall prescription drug sales.³³ Similarly, expenditures on DTC advertising account for a small share (16%) of the pharmaceutical companies' total promotional budget, which is dominated by professional marketing activities such as detailing and sampling.³⁴

The informative nature of DTC advertising, as revealed by the consumer and physician surveys, also tends to undercut the argument that expenditures on DTC advertising are passed on to consumers in the form of higher drug prices.³⁵ Economic theory predicts, and a host of studies

³³ 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. The authors also note the skewed distribution of DTC expenditures across drug classes, with the 20 largest drug classes accounting for over 60% of total expenditures. As a result, the relative size of DTC ad expenditures will vary significantly across drug classes.

³⁴ *Id.* For example, in 1996, promotions to professionals totaled \$9,164 million (representing 14.1% of sales) and in 2000 promotions to professionals totaled \$15,708 million (14.0% of sales). *Id.* at 500. There is evidence that expenditures for detailing do affect the drug the physician prescribes. J. Donohue (Harvard Medical School), *Effects of DTC Advertising of Prescription Drugs on the Treatment of Depression*, presentation for DTC Public Meeting (Sept. 22, 2003), available at www.fda.gov/cder/ddmac/P2donohue/index.htm.

³⁵ Some studies suggest that increased drug expenditures are due to the complex interaction of many factors, such as how extensively a drug is promoted to professionals, whether it has preferential status with an insurer (*i.e.*, it is listed on the formulary), whether the advertising relates to a newly-approved use for a drug, and whether the supporting science is strong. See P. Azoulay, *Do Pharmaceutical Sales Respond to Scientific Evidence? Evidence from Anti-Ulcer Drugs*, 11 J. Econ. & Mgmt. Strategy 551 (2002).

confirm, that informative advertising can stimulate firms to compete on the basis of both price and quality.³⁶

Price-based advertising provides the clearest evidence of how advertising can lower the price of goods and is the basis of many of the empirical studies. Yet non-price advertising that provides useful information to consumers -- the primary type of DTC advertising -- may also exert a downward pressure on price. This can occur, for example, when the information provided by the ads stimulates an increase in product sales that results in lower per unit costs of production and marketing.³⁷

In the final analysis, the applicability of the general research on the influence of advertising on price depends on how DTC advertising interacts with unique aspects of how drugs are purchased, such as the role played by physicians and managed care in selecting the drugs to be prescribed and the role of price in that selection process.

In contrast to attempts to estimate price effects, researchers have recently begun to apply sophisticated econometric techniques to study whether DTC advertising expands the demand for prescription drugs. The results have been mixed. Calfee *et al.*'s study of statin drugs reports no demand expansion effect from DTC advertising for either sales within the therapeutic class, or for the particular drug being advertised.³⁸ But a number of more recent studies (not yet published) find that DTC advertising expands the overall demand for the relevant therapeutic

³⁶ See H. Beales & T. Muris, *State and Federal Regulations of National Advertising* (1993); Ippolito & Pappalardo, *supra* n.6.

³⁷ See Beales & Muris, *supra* n.36.

³⁸ J. Calfee *et al.*, *supra* n.32; see also Manning and Keith, *supra* n.32.

class of drugs, while typically failing to increase the market share of the specific drug being advertised.³⁹

Whatever the effects of DTC advertising on the demand for prescription drugs, there are no straightforward inferences regarding its impact on consumer welfare. To determine the net effect on consumer welfare, one would have to balance any negative effects, such as from over-consumption of prescription drugs, with the positive effects, such as those from increased appropriate consumption or the provision of useful information to consumers. The likelihood of significant over-consumption effects is minimized by physicians and (increasingly) managed care organizations acting as gatekeepers to determine which drug is ultimately prescribed.

In regard to benefits, of the possible positive effects from increased drug consumption, three stand out. First, heavily advertised drugs tend to be new and innovative and may be more effective or have fewer side effects than the older drugs they seek to replace.⁴⁰ Second, limited

³⁹ M. Wosinska, *Just What the Patient Ordered? Direct-to-Consumer Advertising and the Demand for Pharmaceutical Products*, Harvard Business School Marketing Research Papers No. 02-04 (Oct. 2002), available at ssrn.com/abstract_id=347005 (while DTC advertising expands total therapeutic class sales, it only increases the sales of the particular brand if the brand has a preferred status on the health insurer's formulary); T. Iizuka & G. Jin, *The Effect of DTC Advertising in the Prescription Drug Markets*, University of Maryland working paper (Sept. 2003); Rosenthal *et al.*, *Demand Effects of Recent Changes in Prescription Drug Promotion* (June 2003). For a useful review of these and other empirical investigations into the demand effects of DTC advertising, see General Accounting Office, *Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations: Report to Congressional Requesters* (Oct. 2002).

⁴⁰ Rosenthal *et al.*, *supra* n.33; Iizuka & Jin, *supra* n.39. See also F. Lichtenberg, *Are the Benefits of Newer Drugs Worth Their Cost?*, Health Affairs (2001) (citing M. Merlis, *Explaining the Growth in Prescription Drug Spending: A Review of Recent Studies*, (Aug. 2000)). New drugs are also less likely to face generic competition and thus would likely be more expensive. Any additional cost would have to be weighed against any improvement in efficacy.

evidence suggests that advertised drugs target under-treated conditions.⁴¹ When an advertisement motivates a consumer to treat a condition that they would not have treated otherwise, the consumer may obtain important health benefits. Third, new drugs in general may be cost-efficient forms of medical treatment relative to diagnostic and non-surgical procedures. Some research indicates that substituting new drugs for other diagnostic and non-surgical procedures may help consumers save money by lowering other medical costs.⁴²

C. Conclusions

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.

⁴¹ Iizuka & Jin, *supra* n.39; *Prevention*, *supra* n.9.

⁴² F. Lichtenberg, *Are the Benefits of Newer Drugs Worth Their Cost?*, Health Affairs (2001); P. Neumann, *et al.*, *Are Pharmaceuticals Cost-Effective? A Review of the Evidence*, Health Affairs (2000).

III. Analysis of DTC Advertising Regulations

A. Brief Summary Requirement

1. Background

In 1962, the Federal Food, Drug, and Cosmetic Act gave the FDA the authority to regulate prescription drug advertising.⁴³ At the same time, the Act was amended to require that prescription drug advertising contain a true statement of “information in brief summary relating to the side effects, contraindications, and effectiveness” of the drug.⁴⁴ The legislative history of the amendment indicates that this “brief summary” requirement arose from a concern about the adequacy of risk information in ads directed at physicians, not consumers.⁴⁵

FDA’s implementing regulations specify that the information about risks in this “brief summary” must disclose “each specific side effect and contraindication (which include side effects, warnings, precautions and contraindications and include any such information under such headings as cautions, special considerations, important notes, etc.)” contained in the drug’s

⁴³ “Advertisements” subject to 21 U.S.C. § 352(n) 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(l)(1).

⁴⁴ 21 U.S.C. § 352(n).

⁴⁵ *See, e.g.*, 108 Cong. Rec. 17,369 (1962) (“We found cases concerning drugs that were addictive and in which nothing was said about side effects . . . [which was] misleading to the physician. [The brief summary requirement] is a very important part of the bill. It will provide the physician with honest and useful information.”) (statement of co-sponsor Senator Estes Kefauver).

FDA-approved package labeling.⁴⁶ Thus, FDA's regulations require the brief summary to "disclose all the risk-related information in a [drug's FDA-approved] package labeling."⁴⁷

During the 1960s and 1970s, pharmaceutical manufacturers directed their drug advertising to physicians. To meet the brief summary requirement, manufacturers generally included in their ads the entire section of the FDA-approved product labeling that discusses the side effects and contraindications of the advertised drug. Although this information was written in complex medical terminology, physicians and other medical professionals had the scientific background necessary to understand it.

In the early 1980s, pharmaceutical manufacturers became interested in advertising drugs directly to consumers.⁴⁸ In 1982, the FDA asked the industry for a moratorium on DTC advertising while it considered the issue. The moratorium was lifted in 1985. The FDA concluded that "current regulations governing prescription drug advertising provide sufficient safeguards to protect consumers,"⁴⁹ that is, DTC ads would have to meet the same brief summary requirements as ads directed at physicians.

Following the FDA's decision, DTC advertising continued to grow, but the agency's decision had an effect on the types of DTC ads that pharmaceutical manufacturers used. It was impractical for pharmaceutical manufacturers to include all of the information needed to satisfy

⁴⁶ 21 C.F.R. § 202.1(e)(3)(iii).

⁴⁷ 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."

⁴⁸ 60 Fed. Reg. 42,581, 42,581-82 (Aug. 16, 1995) (reviewing history of DTC advertising).

⁴⁹ 50 Fed. Reg. 36,677 (Sept. 9, 1985).

the FDA's brief summary requirement in television and radio ads. Companies thus generally used print ads rather than broadcast ads to communicate with consumers about their products. To the extent they used broadcast ads, they tended to be "help-seeking" or "reminder" ads that were not required to meet the brief summary requirement.⁵⁰

Recognizing the inherent limitations in trying to incorporate brief summary information into broadcast ads, such as 30-second or 60-second television ads, the FDA in 1996 proposed less onerous brief summary requirements for these ads. To comply with these requirements, broadcast ads must: (1) include a "major statement" conveying all of the drug's most important risk-related information, and (2) provide brief summary information or make "adequate provision" for consumers to receive the FDA-approved product labeling.⁵¹ In 1996, the FTC staff filed a supporting comment explaining that the proposal to impose these less restrictive brief summary requirements for broadcast ads would "provide timely information regarding medical advances, remind consumers about good health practices, and supply information needed by consumers to understand and evaluate their physician's recommendations."⁵² The

⁵⁰ "Help-seeking" advertisements encourage consumers to talk to their doctors about health conditions without mentioning a specific drug treatment, and so they are not considered to be drug ads for purposes of the brief summary requirement. "Reminder" advertisements identify specific drugs, but not the drug's indications; the brief summary requirement does not apply to such ads. See 21 C.F.R. § 202.1(e)(2)(i)-(iii).

⁵¹ Broadcast ads "shall include information relating to the major side effects and contraindications of the advertised drug" plus make adequate provision for receipt of more complete risk information. 21 C.F.R. § 202.1(e)(1). "The major statement must include all of the most important risk information related to the product. Because risks vary from product to product, the amount of information disclosed for any particular product to meet this requirement will vary as well." FDA, Division of Drug Marketing, Advertising, and Communication, *Frequently Asked Questions*, (revised May 28, 2003), available at www.fda.gov/cder/ddmac/FAQS.HTM#DTC.

⁵² *FTC 1996 DTC Comment*, *supra* n.7.

comment also noted that the involvement of two medical professionals -- a doctor and a pharmacist -- performing unique gatekeeper roles makes it less likely that consumers would be harmed if complete risk information is not included in DTC broadcast ads themselves.⁵³

In 1999, the FDA issued guidance to provide further information regarding what a pharmaceutical manufacturer must do to make adequate provision for consumers to receive the FDA-approved product labeling in connection with a DTC ad.⁵⁴ A broadcast advertiser may satisfy the adequate provision requirement by meeting all four of the following components:

- (1) Provide a toll-free number for consumers to call and either have the FDA-approved product labeling read to them or mailed to them in a timely manner (*e.g.*, mailed within 2 business days for receipt within 4-6 days);
- (2) Provide the address of an Internet web page that permits consumers to access the FDA-approved product labeling;
- (3) Create and disclose an alternative mechanism for consumers without access to the Internet to have access to the FDA-approved product labeling, *e.g.*, include the information in concurrently running print ads or widely distributed brochures with the information; and
- (4) Include a statement directing consumers to physicians or pharmacists (or other health care providers) who may provide additional product information.

⁵³ *Id.* Moreover, DTC advertising may alert consumers to the existence of more effective drugs that are not available on a particular health care organization's formulary, leading to demand-side pressure for more effective remedies that would counter any pressure from the health care organization on the doctor to prescribe medications that are less costly but less effective, or less convenient.

⁵⁴ 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).

More than 64% of current DTC advertising is broadcast advertising,⁵⁵ and most pharmaceutical manufacturers meet their adequate provision requirement by satisfying the four criteria set forth in the FDA's 1999 Guidance Document.

2. FTC Staff Conclusions and Recommendations

The FTC staff recognizes that consumers should receive information about the risks of advertised drugs to inform them which medications might be appropriate for them. Advertising alone may not be the most effective vehicle for communicating complete risk information, however. The sheer amount of information in the FDA-approved product labeling that the brief summary requires be disclosed in DTC print ads and provided in connection with DTC broadcast ads may deter consumers from reading the information or make it difficult for consumers to understand it.⁵⁶ Moreover, some evidence indicates that these disclosure requirements are not particularly effective in conveying complicated scientific information.⁵⁷

The FTC staff thus generally supports the FDA's on-going efforts to find more consumer-friendly and less costly methods of communicating risk information to consumers. We offer the following suggestions as to how the FDA's approach to the brief summary

⁵⁵ In 2000, 64% of DTC spending was for television ads, with some additional spending on radio ads. The Henry J. Kaiser Family Foundation, *Trends in Direct-to-Consumer Advertising of Prescription Drugs* 5 (Feb. 2002).

⁵⁶ *FTC 1996 DTC Comment*, *supra* n.7, at 21-22 n.40-41 (reviewing studies demonstrating that size of print and volume of information may contribute to reduced consumer perception).

⁵⁷ One study, for example, demonstrated that consumers exposed to the brief summary in print ads scored lower in their understanding of risk than those who were exposed to risk information in other formats. L. Morris & L. Millstein, *Drug Advertising to Consumers: Effects of Formats for Magazine and Television Advertisements*, 39 *Food Drug Cosm. L.J.* 497, 501 (1984).

requirement could be modified to convey the sort of useful risk information that will prompt and facilitate discussions between consumers and medical professionals, without discouraging or unduly burdening the provision of information about benefits.

a. DTC Print Advertisements

In contrast to broadcast ads, FDA regulations continue to require that print DTC ads contain full brief summary information. Pharmaceutical manufacturers usually meet the brief summary requirement for 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 very fine “mouse print” text in magazines and other publications.

The FDA itself has recognized that using the FDA-approved product labeling to meet the brief summary requirement is of “questionable” value for consumers because these materials are “written in technical language intended for health care professionals and . . . relatively inaccessible to consumers.”⁵⁸ As FDA Commissioner Mark McClellan recently noted, the so-called brief summary is “not very brief, not much of a summary, so not very helpful.”⁵⁹

⁵⁸ 60 Fed. Reg. 42,581, 42,583 (Aug. 16, 1995) (summarizing disclosure requirements for print labeling and advertising in public hearing notice).

⁵⁹ FDA Commissioner Mark McClellan, Speech to National Association of Health Underwriters (Washington, D.C. Mar. 25, 2003); *see also* Robert Temple (Director, Office of Medical Policy, CDER), *Closing Remarks*, presentation for DTC Public Meeting, transcript at 226 (Sept. 23, 2003) (acknowledging that the brief summary “is neither brief nor a summary”), *transcript available at* www.fda.gov/cder/ddmac/DTCmeeting2003.html.

We agree. Most consumers do not read the brief summary information in print ads.⁶⁰

Many who do read it likely do not understand it: unlike medical professionals, many consumers do not have the education, training, and background necessary to evaluate critically the highly technical language of the FDA-approved product labeling.⁶¹ Consumers may simply ignore a page of mouse print they do not understand.

⁶⁰ The *Prevention* survey found that: “Only about 54 percent of consumers who say that they’ve looked at print ads say they even recall or remember seeing the brief summary page, 12 percent saying they read it thoroughly, and the rest saying only looking for key information or skimming it. Fully 46 percent don’t have any recollection of seeing the brief summary page at all.” E. Slaughter (Rodale, Inc.), *Consumer Reaction to DTC Advertising of Prescription Medicines 1997-2002: A Six-Year Tracking Study from Prevention and Men’s Health Magazines*, presentation for DTC Public Meeting, transcript at 83 (Sept. 22, 2003), transcript available at www.fda.gov/cder/ddmac/DTCmeeting2003.html; slides available at www.fda.gov/cder/ddmac/P1Slaughter/index.htm. National surveys conducted by the FDA found that consumers do not typically read “all or almost all” of the brief summary (dropping from 26% in 1999 to 16% in 2002) unless they were interested in the drug (dropping from 85% in 1999 to 45% in 2002). See FDA Survey, *supra* n.8; K. Aikin (FDA), *Direct-to-Consumer Advertising of Prescription Drugs: Patient Survey Results*, presentation to Health care Marketing Communications Council (Sept. 19, 2002), available at www.fda.gov/cder/ddmac/Presentations/KitHMCC2002out/index.htm.

Note that these results may overstate the extent to which consumers read the brief summary, if some respond that they read the brief summary because they believe that response is socially desirable. See W. Zikmund, *Exploring Market Research* 195 (2003); R. Fisher, *Social Desirability Bias and the Validity of Indirect Questioning*, 20 J. of Consumer Res. 303 (Sept. 1993); see also *Novartis Corp.*, 127 F.T.C. 580, 649 (1998) (Initial Decision) (social desirability affected willingness of some survey participants to acknowledge that ads influenced beliefs).

⁶¹ See *FDA Draft Guidance*, *infra* n. 63 at 3 (FDA approved product labeling “may be difficult for consumers to understand.”). According to the 2002 FDA consumer survey, 55% found the brief summary “somewhat hard” or “very hard” to understand. Aikin, *supra* n.60, available at www.fda.gov/cder/ddmac/Presentations/KitHMCC2002out/sld018.htm; see also M. Roberts (Catalina Marketing Corp.), *Alternatives to the Brief Summary*, presentation for DTC Public meeting (Sept. 23, 2003), available at www.fda.gov/cder/ddmac/P5Roberts/sld012.htm, [/sld013.htm](http://www.fda.gov/cder/ddmac/P5Roberts/sld013.htm), and [/sld014.htm](http://www.fda.gov/cder/ddmac/P5Roberts/sld014.htm) (standard comprehensibility tests indicate that most patient labeling is written at, at least, a tenth-grade reading level).

The current brief summary requirement for print ads also imposes unnecessary costs on drug manufacturers who desire to advertise their products. These costs are significant because advertisers must often pay for an additional page in a print publication to meet the brief summary requirement. The additional costs imposed on print ads may have several negative effects. The extra expense may lead advertisers to advertise less overall than they would have otherwise, depriving consumers of the information that they would otherwise have received from print ads.⁶² Many firms use both print and broadcast ads. The additional cost imposed by the current brief summary requirement for print ads – a cost not imposed on broadcast ads – may skew the choice that a manufacturer makes when choosing print or broadcast ads or the mix between the two. If print ads in some circumstances are the most effective vehicle to communicate information to certain consumers, they might receive less information. Similarly, if print ads are the most cost-effective vehicle for some firms to compete – particularly those without deep pockets – such additional costs might hamper competition.

The FDA has sought to address the issues that the brief summary requirement for print ads raise. In its 2001 Draft Guidance Document, the FDA acknowledged that consumers need different types and amounts of information about medical risks than medical professionals.⁶³

⁶² “Requiring additional information to qualify a claim or identify possible drawbacks of a product increases the cost of advertising. . . . If a significant fraction of each communication must be devoted to required disclosures, sellers may disseminate information about product advantages less widely.” J. Howard Beales, III, *Economic Analysis and the Regulation of Pharmaceutical Advertising*, 24 Seton Hall L. Rev. 1370, 1381 (1994).

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

The agency therefore encouraged drug manufacturers to use more consumer-friendly language in the brief summary in their print ads.⁶⁴ 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.⁶⁵ 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.⁶⁶ Nevertheless, some empirical evidence suggests that FDA-approved patient labeling, although shorter and less technical than FDA-approved product labeling, continues to be too long and complex for consumers to understand, as well as difficult to read when placed in the small type necessary to fit on a single page of printed text.⁶⁷

We believe that the FDA should replace the requirement that the DTC print ads include the FDA-approved product labeling with the requirement that such ads include a major statement of risks with adequate provision for consumers to receive more complete risk information from other sources. To increase consumer comprehension of important risk information in DTC ads, it is important to display the information in a clear and easily understandable format. By presenting the information in a more accessible format and form, this approach will make it more

⁶⁴ See *Draft Guidance*, *supra* n.63.

⁶⁵ *Id.* FDA-approved patient labeling is also called "Information for the Patient," "Patient Information," "Medication Guide," and "patient package inserts."

⁶⁶ *Id.* at 2.

⁶⁷ Roberts, *supra* n.61, available at www.fda.gov/cder/ddmac/P5Roberts/sld012.htm and /sld013.htm.

likely that consumers will actually see and understand the risk information provided. This change would make the brief summary requirement for DTC print ads consistent with the brief summary requirement for DTC broadcast ads. Although print generally accommodates more information than broadcast, consumers appear to receive little additional benefit from the risk information in the FDA-approved product labeling or perhaps the FDA-approved patient labeling, even though such labeling information can be conveyed in print media.⁶⁸ Moreover, if the brief summary requirement were the same for DTC broadcast ads and DTC print ads, then pharmaceutical manufacturers would choose the media for their ads based on how they can most effectively convey their message and thereby compete with other manufacturers, rather than based in part on the costs of complying with differing regulatory standards for different media.⁶⁹

b. DTC Broadcast Advertisements

The FDA's current approach to the brief summary requirement for broadcast ads – requiring a major statement of risks and making adequate provision for consumers to receive more risk information – provides consumers with sufficient risk information to empower them to

⁶⁸ In our previous comment, we recognized that “differences among media may affect the likelihood of deception from advertising claims and, therefore, the appropriateness of particular approaches to preventing deception.” *FTC 1996 DTC Comment*, *supra* n.7, at Section IV.B. Certainly, different approaches to communicating information and disclosures may be warranted based on differences between media. Although print is a more effective medium for the presentation of textual information than broadcast, it nevertheless may not be good public policy to impose greater disclosure requirements for print ads if the costs of providing the additional information exceed its benefits.

⁶⁹ History suggests that changes in regulatory standards for DTC ads can affect the relative cost of advertising in different media, thereby altering the media advertisers choose for DTC ads. For example, 85% of spending on DTC in 1995 was on print ads, with the remaining 15% of spending for ads on television. Kaiser Family Foundation, *supra* n.55, at 5. After the FDA decreased the cost associated with the brief summary for broadcast ads in 1996, advertisers switched much of their DTC spending from print ads to television ads. By 1999, 62% of spending on DTC was for television ads and 38% for print ads. *Id.*

have discussions with medical professionals about treatment options. Because this approach mandates only a limited amount of information to be included in the broadcast ad, the requirements do not seem unduly burdensome for advertisers. FTC staff, therefore, believes that the FDA generally should retain its current approach to the disclosure of brief summary information in broadcast ads. Indeed, as discussed above, we believe that the same approach should be extended to brief summary requirements for print ads.

Nevertheless, we believe that the FDA should revise its approach so that manufacturers will make adequate provision for consumers to receive risk information that they are more likely to read and understand. As discussed above, many consumers do not read FDA-approved product labeling or do not understand it. Thus, requiring advertisers to direct consumers to call a toll-free number or contact a website to receive this information probably confers minimal, if any, benefits. The FDA should consider revising the requirement that the FDA-approved product labeling be required so that consumers receive risk information that has been specifically designed for them and that is thus more useful to them.

For drugs for which the FDA has approved patient labeling, the FDA may want to consider requiring that advertisers give consumers a toll-free number to call and a website address to visit to obtain this information.⁷⁰ The patient labeling might provide consumers with

⁷⁰ The adequate provision requirement currently requires that pharmaceutical manufacturers provide an alternative means (such as a concurrently running print ad or the wide distribution of product brochures) to a toll-free telephone number and an Internet website to receive more complete risk information. Approximately 59% of American adults currently have access to the Internet, and about 95% of American households have a telephone. See Pew Internet & American Life Project, *Internet Use by Region in the United States* (Aug. 27, 2003); U.S. Census Bureau, *Historical Census of Housing Tables: Telephones* (1990 Census data). Because virtually all American consumers have access through the Internet or the telephone to a free and readily available means of obtaining more complete risk information about an advertised drug, there seems little need to impose on pharmaceutical manufacturers the

better risk information than the product labeling, at a relatively modest cost to advertisers. Nevertheless, given the concerns about how useful even the patient labeling is to consumers, we believe that the FDA should consider conducting consumer research to develop even more abbreviated and simpler forms of risk information that likely would be more beneficial for consumers.

In addition, for drugs for which there is no FDA-approved patient labeling,⁷¹ the FDA should retain its practice -- at least as an interim measure -- of allowing advertisers to direct consumers to FDA-approved product labeling through a toll-free number and website address. Although the product labeling provides only minimal benefit to consumers, making it available in this way does not appear to impose more than minimal costs or burdens on advertisers. As discussed above, however, we strongly encourage the FDA to expand its implementation of patient labeling or other more consumer-friendly alternatives.

B. Fair Balance Requirement

To comply with the Federal Food, Drug, and Cosmetic Act, DTC advertisements must also provide “fair balance.”⁷² FDA regulations state that prescription drug ads are misleading if the efficacy information regarding the drug is “not fairly balanced by a presentation of a

additional cost of concurrently running print ads or widely distributing product brochures. We would also note that consumers who want to maintain their privacy and obtain more complete risk information can call a toll-free number, not identify themselves, and receive the information over the telephone.

⁷¹ Apparently many drugs currently do not have FDA-approved patient labeling. For example, the FDA has approved patient labeling for only 24 of the 128 innovator drugs that the agency has approved since January 1998. See FDA, *Consumer Drug Information* (July 11, 2000), available at www.fda.gov/cder/consumerinfo.

⁷² See 21 C.F.R. § 202.1(e)(5)-(7).

summary of true information relating to side effects and contraindications of the drug.”⁷³ The purpose of the fair balance requirement is to prevent ads that create a net impression that overstates the efficacy or understates the risks associated with the advertised drug.

Although a mechanical application of the fair balance standard ensures proportionality between benefit and risk information, it could unnecessarily restrict the ability of advertisers to present truthful, non-misleading claims. For example, if a mechanistic approach were adopted, an advertisement might violate the fair balance requirement if it presented benefits clearly and conspicuously in 24-point type and presented risk information clearly and conspicuously in 18-point type. Such an ad may not be “fairly balanced” in terms of format, but it may, nevertheless, effectively communicate both benefit and risk information to consumers. Ads lacking in fair balance thus do not necessarily mislead or otherwise injure consumers.⁷⁴ On the other hand, an ad might present benefit and risk information in the same size and font, but it would be misleading if it discussed only minor risks without disclosing significant side effects.

The FTC staff recommends that the FDA clarify that, in interpreting and applying the fair balance requirement, the FDA prohibits only ads that convey a deceptive impression of the risk

⁷³ 21 C.F.R. § 202.1(e)(5)(ii). FDA regulations identify twenty types of advertising communications that it considers *per se* “false, lacking in fair balance, or otherwise misleading,” and an additional thirteen types of advertising that may be “false, lacking in fair balance, or otherwise misleading,” all of which would render the drug misbranded under 21 U.S.C. § 352(n). See 21 C.F.R. § 202.1(e)(6)-(7).

⁷⁴ To the extent that the fair balance requirement were interpreted to require equipoise between benefit and risk information, the requirement might lead consumers to overestimate the risks. For example, if a drug with many benefits and few risks must be presented in such a way that both risks and benefits garner equal attention, the relative distortion may mislead consumers.

or benefits of a drug from the overall presentation of information, rather than those that fail to achieve a mechanistic balance between risk and benefit information.

C. Comparative DTC Advertising

FDA regulations and practices may make it difficult for advertisers to engage in truthful, non-misleading comparative advertising, including comparative price advertising. For example, reminder ads, such as an ad reminding consumers to take an anti-depressant, are exempt from the brief summary requirement. Nonetheless, if truthful, non-misleading comparative price information is added to a reminder ad, then the ad must satisfy the FDA's brief summary requirement discussed above.⁷⁵ In 1996, FTC staff observed that this requirement may discourage advertisers from making comparative price claims in some ads.⁷⁶

We continue to believe that restrictions and burdens on truthful, non-misleading comparative advertising merit careful consideration.⁷⁷ Comparative advertising is an important

⁷⁵ See 21 C.F.R. § 200.200 (1994) (limited exemption from advertising and labeling requirements for reminder ads that communicate prescription drug price claims). The exemption is limited to ads whose "only purpose . . . is to provide consumers with information concerning the price charged for a prescription for a particular drug product." *Id.* The exemption apparently does not apply to comparative price claims or to comparative claims about economic factors other than price, such as the number of doctor visits required under one drug regimen as opposed to another.

⁷⁶ *FTC 1996 DTC Comment, supra* n.7. There is little need for such a requirement to prevent deception. Retail prescription drug price advertising has been allowed for years without such a requirement.

⁷⁷ For example, the FDA has extensive regulatory requirements even for price claims in reminder ads that are exempt from the brief summary requirement. Elements that must be disclosed, if the ad is to qualify as a reminder ad, include "the proprietary name of the drug product, if any; the established (generic) name of the drug product, if any; the drug product's strength [under certain conditions]; the dosage form; and the price charged for a prescription for a specific quantity of the drug product." In turn, the price stated in the advertisement must include "all charges to the consumer including, but not limited to, the cost of the drug product, professional fees, and handling fees, if any." 21 C.F.R. § 200.200.

source of information to consumers and assists them in making rational purchase decisions. It also encourages product improvement and innovation and can lead to lower prices in the marketplace,⁷⁸ certainly an important consideration in light of rising health care costs. For these economic benefit claims, the key question is the level of substantiation that should be required.⁷⁹ The Commission thus has encouraged companies to make truthful and non-misleading comparative claims, including comparative price claims, with appropriate disclosures to avoid deception.⁸⁰

We recognize that advertisers may face difficult challenges in making truthful, non-misleading comparative price claims in DTC advertising. For example, the prices that consumers pay for advertised drugs may vary widely because many consumers do not directly pay some or all of the cost of their drugs,⁸¹ although a substantial minority of them do⁸² and thus

⁷⁸ For a more complete discussion of the benefits of comparative advertising, see *FTC 1996 DTC Comment*, *supra* n.7.

⁷⁹ See *Comments of the Staffs of the Bureaus of Economics and Consumer Protection of the Federal Trade Commission in the Matter of Pharmaceutical Marketing and Information Exchange in Managed Care Environments*, Docket No. 95N-0228 (Jan. 16, 1996) available at www.ftc.gov/be/v960002.htm.

⁸⁰ Federal Trade Commission Statement of Policy Regarding Comparative Advertising, 16 C.F.R. § 14.15 (1979).

⁸¹ According to the FDA's survey, most consumers did not look for additional information about cost after seeing a DTC ad. As Dr. Aikin pointed out, however, this result may reflect "the fact that cost information is not that readily available." K. Aikin (FDA), *Direct-to-Consumer Advertising of Prescription Drugs, 1999-2002: Preliminary Patient Survey Results*, presentation for DTC Public Meeting, transcript at 26 (Sept. 22, 2003), transcript available at www.fda.gov/cder/ddmac/DTCmeeting2003.html.

⁸² See, e.g., The Henry J. Kaiser Family Foundation, *Prescription Drug Trends: A Chartbook Update 3* (2001) ("About 23% of the non-elderly population (those under age 65) lacked insurance coverage for prescription drugs in 1996, consisting mostly of those without any health insurance at all."). Moreover, even for those who have insurance, classes of drugs such as drugs used for cosmetic purposes may not be covered.

may be responsive to prescription drug pricing.⁸³ Nevertheless, if an advertiser can make the truthful, non-misleading claim that its advertised drug is less expensive than a competing drug, such as representing that its drug requires fewer doctor visits or fewer complementary treatments, then consumers and competition will benefit if such a claim is not prohibited or deterred. The FTC staff therefore recommends that the FDA carefully examine its regulations and policies to ensure that advertisers are able to make truthful, non-misleading comparative claims, including comparative price or other related cost claims, in DTC advertising.

D. Endorsements and Testimonials

One trend in DTC advertising in the last five years is the growing use of endorsers, particularly celebrities, as an element in advertising campaigns. Celebrity endorsers - - such as Joan Lunden (Claritin), Jennie Garth (Imitrex), Jack Nicklaus (Altace), and Rafael Palmeiro (Viagra) - - increasingly appear in DTC ads. The use of endorsers raises issues such as whether the endorser must have personally used and benefitted from the product and whether the

⁸³ A. Sorensen, *An Empirical Model of Heterogeneous Consumer Search for Retail Prescription Drugs*, National Bureau of Economic Research Working Paper 8548 (2001) (estimating that approximately five to ten percent of consumers search for lower drug prices at retail pharmacies, with price-shopping more common for medications that consumers purchase for continuing treatment), *available at* www.stanford.edu/~asorensen/papers/search.pdf; *see also* A. Sorensen, *Equilibrium Price Dispersion in Retail Markets for Prescription Drugs*, 108 J. Pol. Econ. 833, 834 (2000):

The central finding of this study is that observed price distributions are consistent with the predictions of models based on consumer search. The empirical approach hinges on the observation that incentives to price-shop are strongest for prescriptions that must be purchased frequently, such as medications used to treat chronic conditions. . . . This prediction is found to be true in the data. . . .

advertisement must disclose that the endorser has received compensation for appearing in a particular ad or for mentioning the product in an interview or talk show appearance.⁸⁴

Since 1975, the Commission has had guidelines governing advertisers' use of endorsements and testimonials, including expert and celebrity endorsements. The FTC's Guides Concerning the Use of Endorsements and Testimonials in Advertising⁸⁵ are designed to assist advertisers in conforming their endorsement and testimonial advertising practices to the requirement of Section 5 of the FTC Act that they not be deceptive or unfair.

The Guides state, for example, that endorsements must always reflect the honest opinions, findings, beliefs, or experience of the endorser.⁸⁶ Endorsements may not contain any representations that would be deceptive, or could not be substantiated if made directly by the advertiser.⁸⁷ An expert endorser must have the expertise that he or she is represented as possessing. An expert endorsement must be supported by an actual exercise of his or her expertise. This means that the expert's evaluation of the product must have been at least as

⁸⁴ See, e.g., M. Petersen, *Heartfelt Advice, Hefty Fees*, N.Y. Times (Aug. 11, 2002) (noting payment to Ms. Lauren Bacall for mentioning a friend's use of Novartis' Visudyne during an appearance on the *Today* television show); M. Petersen, *CNN to Reveal When Guests Promote Drugs for Companies*, N.Y. Times (Aug. 23, 2002) (reporting CNN's adoption of policy to query interviewees who will speak about medical issues whether they are being paid to promote a product).

⁸⁵ 16 C.F.R. Part 255. The Guides were promulgated under the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. §§ 41-58. The Guides are interpretations of laws administered by the Commission. To challenge a claim inconsistent with the Guides, the Commission would have to prove that it was unfair or deceptive in violation of the FTC Act.

⁸⁶ 16 C.F.R. § 255.1(a).

⁸⁷ *Id.*

extensive as someone with the same degree of expertise would normally need to conduct to support the conclusions presented.⁸⁸

The Guides also contain provisions that may be especially relevant to the use of celebrities to endorse prescription drugs. The Guides require that a material connection between an endorser and the seller of an advertised product -- that is, a connection that might materially affect the weight or credibility of the endorsement but that the consumer would not reasonably expect -- must be disclosed.⁸⁹ By the same token, the Guides recognize that consumers expect that experts or celebrity advertisers have been paid for their endorsement, unless the ad represents otherwise.⁹⁰

Both consumers and advertisers would benefit if the FDA applied the same approach with respect to endorsements and testimonials in advertising for prescription drugs as the FTC applies to those in advertising for other products, including OTC drugs. The differences between prescription and OTC drugs do not warrant different treatment with respect to endorsements and testimonials in ads for the two types of products. Moreover, because prescription drugs and OTC drugs may treat the same conditions, having the same rules apply to endorsements and

⁸⁸ 16 C.F.R. § 255.3(a)-(b); *see, e.g., Synchronal Corp.*, 116 F.T.C. 1189 (1993) (consent order) (holding both advertiser and expert endorsers liable for deceptive representations for a purported baldness remedy and cellulite treatment, and requiring expert to undertake an examination or test of a product at least as extensive as an expert in the field would normally conduct to support any endorsement).

⁸⁹ 16 C.F.R. § 255.5; *see, e.g., TrendMark Int'l, Inc.*, 126 F.T.C. 375 (1998) (consent order) (consumer endorsers' status as a distributor of weight loss product or as a spouse of a distributor is a "material connection" that must be disclosed); *Numex Corp.*, 116 F.T.C. 1078 (1993) (consent order) (expert endorser's status as corporate officer is "material connection" that must be disclosed).

⁹⁰ 16 C.F.R. § 255.5.

testimonials in advertising for these products would create a more level playing field on which the sellers of these products can compete.

We note that the Commission has announced that it will review the Guides Concerning the Use of Endorsements and Testimonials in Advertising.⁹¹ The Commission reviews all of its rules and guides periodically to seek information about their costs and benefits as well as their regulatory and economic impact. The FTC staff encourages the FDA and others interested in the use of endorsements and testimonials in DTC advertising to submit comments to the Commission during this regulatory review.

E. Internet Advertising

The Internet is a valuable resource for consumers looking for information about prescription drugs. According to a Pew Internet Project survey conducted in March 2002, 73 million American adults (62% of Internet users surveyed) use the Internet to look for health information.⁹² About two out of three of these users (64%) searched for information about prescription drugs, and more than half checked the Internet before visiting a doctor.⁹³ According

⁹¹ See 68 Fed. Reg. 2465 (Jan. 17, 2003). As part of this review, the Commission seeks comment as to whether its regulations and policy statements should be eliminated, retained, or retained with modifications to reflect changes in the marketplace, technology, or other considerations.

⁹² Pew Internet Project, *Vital Decisions: How Internet Users Decide What Information to Trust When They or Their Loved Ones Are Sick* (2002), available at www.pewinternet.org/reports/reports.asp?Report=59&Section=ReportLevel1&Field=Level1ID&ID=259.

⁹³ *Id.*; see also C. Rothkopf (Time Inc.), *The DTC Information Process*, presentation for DTC Public Meeting (Sept. 22, 2003), available at www.fda.gov/cder/ddmac/P1Rothkopf/index.htm (noting usage of pharmaceutical companies' websites as a source of information for disease conditions and treatments); A. Goldhammer (Pharmaceutical Research and Manufacturers of America), *The Internet and Useful Patient Information*, presentation for DTC Public Meeting (Sept. 23, 2003), available at

to the FDA's 2002 DTC advertising survey, as noted above, 38% of those surveyed cited the Internet as a source of information, up from 18% in the previous survey in 1999.⁹⁴

Prescription drugs can be advertised to consumers via the Internet in several ways. Aside from company websites, manufacturers can advertise elsewhere on the Internet by such means as banner ads, interstitials, pop-up ads, and e-mails.

Internet websites should be treated as DTC advertising, unless the site is also used to sell products or contains other indicia of labeling.⁹⁵ We believe that the FDA may be able to provide consumers with additional protection – and manufacturers with greater certainty – by spelling out basic guidelines for websites in a guidance document.⁹⁶ We recommend that these websites include the same brief summary information that all other DTC advertising would include under our recommendations above.⁹⁷ If the FDA decides to retain its distinction between the brief summary requirements for DTC print and broadcast ads, then we recommend that the standards

www.fda.gov/cder/ddmac/P7Goldhammer/index.htm (citing Nielsen/Net Ratings data that over 12 million consumers went to pharmaceutical manufacturers' websites during the first quarter of 2003).

⁹⁴ FDA Survey, *supra* n.8.

⁹⁵ For discussion of whether to characterize Internet websites as advertising or labeling, see, e.g., P. Moore & M. Newton, *Prescription Drug Advertising on the Internet: A Proposal for Regulation*, 2 W. Va. J.L. & Tech. 1.1 (1998), available at www.wvu.edu/~wvjolt/Arch/Moore/Moore.htm; L. Brannon, *Regulating Drug Promotion on the Internet*, 54 Food & Drug L.J. 599 (1998); P. Reichertz, *Legal Issues Concerning the Promotion of Pharmaceutical Products on the Internet to Consumers*, 51 Food & Drug L.J. 355 (1996); M. Scheineson, *Legal Overview of Likely FDA Regulation of Internet Promotion*, 51 Food & Drug L.J. 697 (1996).

⁹⁶ The FDA previously sought comment on treatment of the Internet, 60 Fed. Reg. 42,581 (Aug. 16, 1995), but has not issued guidance.

⁹⁷ For discussion of the FTC staff's recommendations regarding the requirements applicable to DTC advertising in print media, see *supra* Section III.A.2.

for print ads apply to websites: both media allow the communication of more information in text in a manner that broadcast advertisements do not.⁹⁸

We recognize that disclosure requirements for websites are more complicated than for traditional media. Among other things, websites can link to information on other web pages in the same domain or to other websites. Information on a web page may not be visible unless the reader scrolls down.⁹⁹ Moreover, the Internet can accommodate both static, text-based presentations as well as multimedia presentations that are more akin to broadcast advertisements.

The FDA may wish to consider developing an approach to the Internet that would require or encourage manufacturers to ensure that websites have certain minimum elements. For example, if a company website provides information about the benefits of a drug, the major statement of risks should be on the first web page that discusses its benefits, accompanied by an appropriate link to a source of more complete risk information that may be located elsewhere on the website. Consumers thus would receive the most important risk information about the advertised drug, with easy and ready access to more complete risk information, if they are interested in such information.

For other Internet advertisements, such as banner ads or pop-up ads, many ads in these formats will be reminder ads or help-seeking ads. These ads need not include a brief summary,

⁹⁸ In contrast to the print medium, large amounts of information can be presented on a website at very low cost.

⁹⁹ For a discussion of issues pertaining to Internet advertising and disclosures generally, see *Dot Com Disclosures: Information about Online Advertising* (Federal Trade Commission Staff Working Paper), available at www.ftc.gov/bcp/online/pubs/buspubs/dotcom/index.html.

consistent with the current treatment of similar ads in other media.¹⁰⁰ Other ads in these formats should be required to disclose the brief summary information to the same extent as ads in other media. Here, however, advertisers should be able to satisfy this requirement by sending consumers who click on the banner ad or pop-up ad to the first web page on the company's website that discusses the benefits of the drug, that is, the web page that will have the major statement of risks and an appropriate link to more complete risk information. Sending consumers who receive DTC ads online – who, by definition, have Internet access – to a web page with a major statement of risks and an appropriate link to more complete risk information should satisfy the brief summary requirement.¹⁰¹ Similarly, advertisers should be able to meet the brief summary requirement for commercial email by including an appropriate disclosure that additional information is available on a specific page of a website.

IV. Conclusion

DTC advertising can play an important role in providing information about prescription drugs that may spur consumers to seek help for a previously untreated condition, encourage them to talk with a doctor about a new drug, or otherwise take a more proactive role in minding their health. We therefore encourage the FDA to examine ways to facilitate the flow of truthful, non-misleading information in DTC advertising in a manner that is easy for consumers to understand and access.

¹⁰⁰ See *supra* n.50.

¹⁰¹ See FDA, *Guidance for Industry: Consumer-Directed Broadcast Advertisements*, at 2-3. (Aug. 9, 1999), available at www.fda.gov/cder/guidance/1804fnl.htm.

Respectfully submitted,

J. Howard Beales III, Director
Thomas B. Pahl, Assistant Director, Division of Advertising Practices
L. Mark Eichorn, Attorney
David K. Koehler, Attorney
Bureau of Consumer Protection

Luke Froeb, Director
Pauline M. Ippolito, Associate Director
Joseph Mulholland, Economist
Janis K. Pappalardo, Economist
Bureau of Economics

Todd J. Zywicki, Director
Maureen K. Ohlhausen, Deputy Director
Office of Policy Planning