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P E R S P E C T I V E

Direct-To-Consumer Advertising: Developing Evidence-Based Policy To Improve Retention And Comprehension

New standards are needed that focus on consumers, not health care professionals.

by **David L. Riggs, Stacy M. Holdsworth, and David R. McAvoy**

ABSTRACT: Pharmaceutical advertising was historically directed toward health care professionals and mainly communicated through medical journals. The arrival of direct-to-consumer advertising has sparked both praise and criticism. Although current Food and Drug Administration requirements for drug promotion were written from a health care professional perspective, the same regulations have been applied to advertising directed at consumers. This has led to questions regarding the appropriate method for communicating detailed medical information. Rigorous research is needed to evaluate and determine the most effective format for communicating benefit and risk information to consumers. New standards for drug advertising to consumers should be grounded in data derived from this type of research.

THE VALUE OF direct-to-consumer (DTC) advertising to patients has been demonstrated by survey research conducted by the U.S. Food and Drug Administration (FDA).¹ The FDA strictly regulates the content and form of this advertising. However, it remains unclear if patients are able to truly understand the advertising messages they read and hear about prescription medicines.² This is an issue of importance to regulators, the medical community, the pharmaceutical industry, and most importantly, to consumers.

Recent draft guidance from the FDA seeks to develop initiatives resulting in better-informed consumers.³ Current FDA regulations are geared toward promotion to health

care professionals, not to consumers, and, among other things, the new guidance illustrates that the existing regulatory structure would benefit from enhancements for a consumer audience.

These issues have stirred debate among academics on the impact of DTC pharmaceutical advertising. The *Health Affairs* Web Exclusives by Joel Weissman and colleagues and by Steven Woloshin and colleagues help to define this debate, and they illustrate the need for revised DTC requirements that are geared more toward consumers.⁴ Here we examine some challenges associated with delivering benefit and risk information to consumers, with an emphasis on the latter. While pursuit of more consumer-friendly advertisements is impor-

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tant, consumers are not and should not be in a position to make prescription medicine decisions on their own. Health professionals receive extensive training over many years on medicines and pharmacology and are licensed to prescribe medications based on this training. An advertisement should inform enough to lead to a meaningful discussion with a health professional but need not, and should not, take the place of the learned intermediary.

Benefit Information

To communicate efficacy information more effectively, Woloshin and colleagues propose that a “benefit box” be added to the brief summary page that is usually located on the back page of print advertisements. Although this is an intriguing concept, the authors’ solution is problematic, at least as proposed. Problems with the sampling methods, design flaws, and questionable assumptions leave open the possibility that the findings suffer from considerable bias, which makes the results difficult to interpret and casts doubt on the extent to which they can be generalized. The authors even acknowledge that their methods caused some respondents to underestimate drug effectiveness.⁵

Although a benefit box could prove useful to consumers, further research is needed that incorporates sound scientific designs and appropriate measures. What is needed for development of an effective DTC policy is research that begins with a prestated hypothesis tested using samples that can be projected to the population of study interest (as opposed to use of the convenience sampling methods by Woloshin and colleagues).

Risk Information

Just as Woloshin and colleagues noted that consumers may not understand the efficacy claims contained in pharmaceutical advertising, the FDA and others are clearly concerned that risk information is not being comprehended in its current format, even when the communication follows requirements set forth in the FDA’s advertising regulations.⁶ A conventional approach used by sponsors to satisfy the regulatory requirements for presentation

of risk information in print ads has been to reproduce safety language taken directly from the prescribing information given to physicians. This attempt to fulfill the brief summary requirement is not consumer-friendly, nor does it uniformly focus on the most important clinical risk information related to the product; thus, it is not likely to be useful for consumers. In fact, research suggests that many consumers either do not read the brief summary in its current format, are unaware of it, or do not recall it.⁷ These results emphasize the need for focused efforts to improve the format for communication of risk to consumers.

The pending FDA draft guidance on risk disclosures in print ads outlines alternative methods for fulfilling the brief summary requirement.⁸ According to the guidance, sponsors may comply with this requirement in one of the following ways: (1) continue using the current brief summary format, (2) use approved patient labeling (patient package insert, or PPI) in its entirety, (3) eliminate benefit and disease state information and only present risk information from the PPI, or (4) create a consumer-friendly “highlights” section derived from the proposed new rule for physician labeling.⁹ Although these approaches certainly appear to communicate in a more consumer-friendly manner, it is not clear whether these changes alone would increase the usefulness and improve retention and comprehension associated with consumer advertisements, and the FDA provides no data in this regard.

The draft FDA guidance also appears to trend toward a “less is more” approach in communicating risk information. It is not clear whether the guidance, when implemented, will result in a more effective delivery of risk information. However, such an approach may facilitate retention and comprehension of product risk information. In recently issued comments, the Federal Trade Commission (FTC) advocated a similar position.¹⁰

Presentation of safety information that focuses only on the product risk information most important to consumers may mean that consumers retain and comprehend the infor-

mation better. Numerous approaches might be appropriate for risk communication. While traditional methods have focused on a combination of risk presentation within the body of the advertisement as well as the accompanying brief summary page, varying formats may lend themselves to a more concise and straightforward delivery of the important safety information. For example, a risk information window in the body of an ad could contain the product's most important safety information and eliminate the need for an additional page of small-type text listing numerous contraindications, warnings, precautions, and side effects. Research comparing these options is needed.

Policy Development Needs

The FDA's research has been helpful in defining the problem; a different type of research is needed to create a solution. What is needed is for the FDA to develop an evidence-based policy using research that controls for different ad variables in a representative population. Such research should analyze both traditional and nontraditional methods of risk communication.

The recently released draft guidance suggests that sponsors include risk information ranging from side effects to all contraindications, warnings, and major precautions contained in the physician prescribing information. However, consumers may need to receive information on only the most important adverse events related to a product. Also, certain medical warnings and terms might not be amenable to conversion to consumer-friendly language (for example, "Do not take an MAOI inhibitor with this medication").

For these reasons, the FDA should base its final policy on research that defines and tests a full range of ways to present risk information. Research is needed that tests variations of the fair-balance presentation on the front page and the brief summary on the back page beginning with more safety data and moving toward less, to determine whether less information is

actually more.

However, the research must do more than just focus on different ways to disclose risk information, because the ad is read in a broader promotional context. The risk and benefit components of consumer ads must not be looked at in isolation (for example, Woloshin and colleagues focused exclusively on efficacy). The FDA rules require ads to contain "fair balance." It is essential that the "fair balance" definition be viewed in its literal inter-

pretation: a true (proportionate) balance of a product's efficacy and safety information. Because of this, any research undertaken to test a variety of risk disclosure options should be conducted by placing these variations within the body of an ad that also contains efficacy statements, with a goal of ascer-

taining the reader's overall understanding of risk and benefit. Such research should expose one set of readers to one ad variation and a different set to a different variation, with sample sizes large enough to test whether there are statistically significant differences between the ads tested. Results would provide data on the comprehension, retention, and readability of the various ads.

Such research would then form the evidentiary basis for developing advertising requirements that are driven by consumers, not by regulators or physicians. The FDA should defer its policy until this research can be completed. Research leading to a new evidence-based policy on DTC would help the FDA make objective choices on what information should be included in consumer ads. Evidence-based policy is essential if subjectivity and interpretive differences are to be minimized. Furthermore, evidence-based policy would facilitate consistency across all components of the FDA, including various review divisions and the Division of Drug Marketing, Advertising, and Communications.

Once the necessary research is in place and the FDA develops appropriate standards, then

"The FDA should base its final policy on research that defines and tests a full range of ways to present risk information."

the agency must decide whether to publish these standards in new rule making or through a guidance document. Although all affected parties would likely prefer the creation of informal guidance documents, given their convenience and timely application, it may be difficult to reconcile certain consumer-driven needs with what the law requires for pharmaceutical advertising, because those laws, when promulgated, were aimed at health care professionals.

The FDA should not introduce new consumer-driven, evidence-based standards through guidance that fails to meet the technical requirements of current regulations, justifying this by telling the regulated industry that such standards are appropriate pursuant to the FDA's prosecutorial discretion.¹¹ If this approach is adopted, there is no guarantee that ads will change at all. For DTC prescription drug ads to become more understandable, the FDA must generate the science that shows which ads accomplish this, then develop standards derived from these data, reconciling such requirements with a regulatory structure that is not now suited for consumer-friendly communications.

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NOTES

1. Food and Drug Administration, "FDA Releases Preliminary Results of Physician Survey on Direct-to-Consumer Rx Drug Advertisements," *FDA Talk Paper* (13 January 2003).
2. *Ibid.*
3. See Food and Drug Administration, "The Food and Drug Administration's Strategic Action Plan, Protecting and Advancing America's Health: Responding to New Challenges and Opportunities," August 2003, www.fda.gov/oc/mcclellan/strategic.html (5 April 2004); and FDA, "Guidance for Industry—Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements (Draft Guidance)" (Washington: FDA, January 2004).
4. J.S. Weissman et al., "Physicians Report on Patient Encounters Involving Direct-to-Consumer Advertising," *Health Affairs*, 28 April 2004, content.healthaffairs.org/cgi/content/abstract/hlthaff.w4.219 (28 April 2004); and S. Woloshin et al., "The Value of Benefit Data in Direct-to-Consumer Drug Ads," *Health Affairs*, 28 April 2004, content.healthaffairs.org/cgi/content/abstract/hlthaff.w4.234 (28 April 2004).
5. See Woloshin et al., "The Value of Benefit Data," discussion on Avastat in "Interpretations and Limitations" section, W4-242–W4-243.
6. FDA, "Guidance for Industry"; and 21 CFR, Part 202 (Prescription Drug Advertising).
7. See, for example, K. Aikin, "The Impact of Direct-to-Consumer Prescription Drug Advertising on the Physician-Patient Relationship," Presentation at FDA public meeting on direct-to-consumer promotion, Washington, D.C., 22–23 September 2003, slide 5, www.fda.gov/cder/ddmac/aikin/sld005.htm (15 April 2004). To the question, "How much of the brief summary do you read?" 56 percent responded a little/none in 1999, and 73 percent responded a little/none in 2002. See also E. Slaughter, "Consumer Reaction to DTC Advertising of Prescription Medicines, 1997 to 2002," Presentation at FDA public meeting, Washington, D.C., 22–23 September 2003, www.fda.gov/cder/ddmac/P1slaughter/index.htm (13 April 2004). In that study, 46 percent of respondents were not aware of or did not recall a brief summary.
8. FDA, "Guidance for Industry," 3–6.
9. PPI labeling was approved by the FDA to communicate product benefit and risk information in consumer-friendly language. For the proposed new rule, see "Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels," 65 *Federal Register* 81082 (22 December 2000).
10. Comments of the Staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the Federal Trade Commission in the Matter of Request for Comments on Consumer-Directed Promotion, Docket No. 2003N-0344 (2003).
11. The FDA appears to be headed in this direction. FDA, "Guidance for Industry," 3–6 ("FDA does not intend to object to a consumer-directed print advertisement for a prescription drug on the ground that it does not present risk information in compliance with the brief summary requirement.").