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**Are Consumers Well Informed
About Prescription Drugs?**

*The Impact of Printed
Direct-to-Consumer Advertising*

by

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The Public Policy Institute, formed in 1985, is part of the Research Group at AARP. One of the missions of the Institute is to foster research and analysis on public policy issues of importance to older Americans. This paper represents part of that effort.

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*Composite only; there is no such company or product.

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ARE CONSUMERS WELL INFORMED ABOUT PRESCRIPTION DRUGS?

THE IMPACT OF PRINTED DIRECT-TO-CONSUMER ADVERTISING

EXECUTIVE SUMMARY

BACKGROUND

In recent years, drug manufacturers have been enlisting consumers in efforts to influence physician prescribing. The appeals to consumers, encouraging them to approach their physicians about drug products, have come to be known as direct-to-consumer or “DTC” advertising. DTC advertising takes the form of direct mail solicitations, radio and television commercials, magazine and newspaper advertisements, and publicly placed messages on billboards and mass transit kiosks, for example. Drug manufacturers are also increasingly using the Internet to reach consumers directly with promotional information about prescription drug products. Drug companies invested an estimated \$1.3 billion in DTC efforts in 1998 and \$905 million in the first half of 1999.

While acknowledging that there may be a positive role for DTC advertising in patient education, consumer advocates have raised some concerns about the growing volume of DTC advertising. Consumer advocates generally cite concerns about the quality of the information in these ads, and concerns about the effect of DTC advertising and promotion on prescription drug costs. Drug companies, advertising experts, and others assert that DTC advertising plays a valuable role in educating the public about health matters generally, as well as about specific products; prescription drug manufacturers also suggest that there are consumer protections inherent in the legal requirement of a physician’s prescription that must be obtained before their products may be dispensed.

The U.S. Food and Drug Administration (FDA) regulates all prescription drug advertising under the Food, Drugs and Cosmetics Act (FDCA). This law requires prescription drug advertisements, including DTC ads, to be accurate and nonmisleading in their claims of safety and efficacy. Among other federal specifications, the advertisements must include a “Brief Summary” of a product’s indications, risks, and possible side effects. The FDA does not have a process for prior approval of DTC advertising, although the agency reviews proposed advertisements if a drug company requests it to do so.

To enforce the prescription drug marketing rules, the FDA has the power to issue injunctions against the publication or broadcast of a false or misleading advertisement. However, in practice, the agency relies primarily on its “warning letter” process or less formal means. Drug companies

typically withdraw advertisements that are the subject of a warning letter or other notification from the FDA. The agency has no authority to impose penalties or other sanctions against manufacturers who broadcast or publish false or misleading information in prescription drug advertisements.

PURPOSE

The purpose of the research reported here is to explore the impact of DTC printed advertising on consumers, with particular attention to older consumers. The research focuses on their perceptions related to 1) the impact of DTC advertising on consumer knowledge about health matters and medications that treat disease; 2) the information that these advertisements provide about the risks and possible side effects of the advertised products; and 3) the roles that doctors and pharmacists play as sources of information about medications.

METHODOLOGY

The data reported here were obtained through telephone interviews with consumers. Questions for the random national survey were based on the results of focus groups conducted in October 1998. The telephone survey was conducted by ICR, Inc., in December 1998. In total, 1,310 adults were contacted, with oversampling of consumers age 50 and over, weighted to represent the U.S. adult population. Sampling error is plus or minus 3 percentage points. Differences in survey responses are reported only when statistically significant.

KEY FINDINGS

1. Impact on Consumer Knowledge About Health Matters and Medications That Treat Disease

While DTC prescription drug advertising may be one source of information for consumers about their health and medications, DTC advertising appears to have limited educational value in the eyes of consumers. Many consumers consider DTC advertising to be one source, among many, from which they seek information about medications. However, the actual audience for printed DTC advertising, i.e., two-thirds of the population, does not always notice or take away key information in the advertising. For instance, one-third of the DTC audience apparently fails to notice the “small print” information, included in most printed advertisements, that advises readers about risks and potential side effects associated with the product. The likelihood of noticing this information appears to be related to age and education level, favoring younger readers and college-educated readers to some extent. Only 34 percent of those who have noticed this part of the advertisement say they “usually” read it.

Survey results also indicate that consumers generally perceive the ads to be potentially helpful to them in their discussions with their doctors. Three-quarters of consumers

generally agree that an ad could assist them in discussing treatment options with their doctors, if they needed the drug that is advertised.

2. Information Provided by DTC Advertisements About Risks and Possible Side Effects

Some consumer audiences, particularly older readers, find that printed DTC ads do not “clearly” convey that the product is available by prescription only. The fact that prescription products are inherently more risky than nonprescription products is reflected in the requirement of written approval from a physician in the form of a prescription. Twenty percent of consumers who have seen printed DTC advertisements say the advertisements “rarely” or “never” make it clear, or report that they “don’t know,” that a *prescription* drug is being advertised. Older consumers, i.e., those age 60 and over, are less likely than younger consumers to say that the ads usually clarify that a prescription is required (50 percent versus 67 percent).

Consumers are divided in their assessment of how well DTC ads inform them of risks and possible side effects of the products, but they are united in their views of what types of information are important. Overall, consumers who have seen printed DTC ads are evenly divided about whether they usually contain sufficient information about the risks and possible side effects of the products advertised. Asked if the ads contain enough information about risks and possible side effects, 50 percent of consumers overall say “yes,” 45 percent say “no,” and 5 percent answer “don’t know.” Younger consumers and more educated consumers are more likely to feel that the ads contain enough information on risks or side effects. Further, there is no strong consensus among consumers about the reliability of information about product risks and side effects. Consumers generally agree, however, on the types of information that printed DTC ads should contain. They want specific information about product indications, as well as descriptions of all potential side effects. Particularly strong preferences for this information are found among women, older consumers, and less educated consumers.

3. Roles of Doctors and Pharmacists As Sources of Information About Medications

For many consumers, health professionals are not a source of information about medications. Physicians and pharmacists play a mandated role as expert intermediaries between prescription drug marketers and consumers. However, survey results suggest that, for many consumers, these health professionals are not serving as sources of information about prescriptions. Only 54 percent of all consumers report that their physicians, when prescribing, or pharmacists, when dispensing, “usually” talk to them about a product’s risks or potential side effects. Even though they use more medications, older consumers are less likely than younger ones to report having these conversations; 17 percent versus 10 percent report “rarely” having such conversations with their physicians.

Finally, survey results suggest that consumers and their doctors may not always have the same level of awareness of prescription products available in the marketplace. Twenty-one percent of all consumers report having asked their doctors about prescription products with which the doctors were not familiar.

IMPLICATIONS FOR CONSUMERS

The findings of the survey suggest that many consumers face a “medication information gap” in the prescription medication marketplace, even though the proliferation of DTC advertising might be viewed as increasing the overall volume of available health care information. On the one hand, not all of the information contained in printed DTC advertisements reaches even those consumers who actually see the advertisements. On the other hand, health professionals also frequently fail to provide this information on a personalized basis to their patients. In some cases, patients may be aware of prescription products available, but they are not necessarily well informed either by advertising or their health care providers.

Implications for Older Consumers. Consumers age 60 and older appear to obtain less information from the ads than younger persons do. At the same time, older consumers also tend to report less interaction about medications with their physicians and pharmacists. Thus older consumers, along with other groups such as low-income and less educated persons, may be more vulnerable than other consumers to the “medication information gap” in the prescription drug marketplace. The vulnerability is further heightened for older consumers because they tend to use more prescription drugs than younger consumers do.

IMPLICATIONS FOR PUBLIC POLICY

There is a role for public policy in addressing the medication information gap. The findings from this study suggest two possible policy approaches. The first approach relates to public oversight of the quality of the information that DTC advertising provides to consumers. The second approach addresses the adequacy of the information consumers receive in their personal dealings with professionals who prescribe or dispense prescription medication.

Through its regulatory activities, the FDA monitors the accuracy and balance of DTC advertising. If given authority by Congress, an agency such as the FDA could take additional steps toward improving the quality of information provided by manufacturers in DTC advertisements. Options for additional regulatory oversight include: requiring prior approval by the FDA of advertising content; requiring all DTC advertisements to include standardized warning messages, comparable to requirements for cigarette advertising; developing and refining standards for information dissemination; and imposing sanctions for false or misleading DTC advertisements. Further research, especially research that evaluates DTC advertising content, would be helpful to inform the development of some of these options.

To complement these regulatory measures, FDA or another federal agency responsible for promoting public health could design and sponsor public information campaigns about prescription drugs in general, and about their use. Such campaigns could be devoted to promoting medication safety and effectiveness, and could target vulnerable populations where appropriate. Increased oversight of DTC advertising or government sponsorship of effective

public health campaigns about medications would require significant public investments. To pay for public education, policymakers could consider tapping existing revenues from the “user fees” that drug manufacturers pay to the FDA as part of the drug approval process.

As the findings of this study suggest, other factors besides DTC advertising contribute to consumers’ lack of information about their medications. Frequently, for example, physicians and pharmacists fail to discuss treatment alternatives and medication risks with their patients. It is more difficult to fashion a public policy response to this problem. Nonetheless, policymakers can play some role in responding to the concerns that have emerged. For instance, it may be appropriate for state medical boards to review their standards relating to physician prescribing and counseling, and place priority on compliance or enforcement. Similarly, Medicaid and Medicare policymakers might explore their opportunities as purchasers to promote improved communications between beneficiaries and their doctors and pharmacists.

ARE CONSUMERS WELL INFORMED ABOUT PRESCRIPTION DRUGS?

THE IMPACT OF PRINTED DIRECT-TO-CONSUMER ADVERTISING

INTRODUCTION

This Issue Paper presents findings and analysis of research about the impact of direct-to-consumer (DTC) prescription drug advertising on consumers, with a particular emphasis on consumers age 60 and older. Based on focus groups and survey data, the study explores consumer perceptions related to 1) the impact of DTC advertising on consumer knowledge about health matters and medications that treat disease; 2) the information that advertisements provide about the risks and possible side effects of the advertised products; and 3) the roles that physicians and pharmacists play as sources of information about medications.

BACKGROUND

Pharmaceutical manufacturers have traditionally promoted their prescription drugs to physicians and pharmacists, primarily through direct-mail solicitations, journal advertising, and personal sales contacts. In recent years, drug makers have also been enlisting consumers in efforts to influence physician prescribing. The appeals to consumers, encouraging them to approach their physicians about drug products, have come to be known as “direct-to-consumer” promotion or, more commonly, “DTC” advertising. DTC advertising takes the form of direct mail solicitations, radio and television commercials, magazine and newspaper advertisements, and publicly placed messages on billboards and in mass transit kiosks, for example. Advertisements have appeared in such unusual places as the available space on a paper luggage tag supplied by an airline, and the paper bag a drug store uses when providing prescription products to its customers. Drug manufacturers are also increasingly using the Internet to reach consumers directly with promotional information about prescription products.

DTC advertising has increased steadily throughout the past decade. Drug companies invested an estimated \$1.3 billion in DTC efforts in 1998 and \$905 million in the first half of 1999.¹ The increase in DTC advertising in the late 1990s has been explained in part by increased competition in the marketplace, brought on by growing numbers of new prescription products.² Marketers of new prescription drugs may also be encouraged by recent trends among consumers toward more

¹ Barents Group, *Factors Affecting the Growth of Prescription Drug Expenditures*, report for the National Institute for Health Care Management (NIHCM), July 1999; IMS Health, October 1999, reported in *American Health Line*, National Journal Publications, October 13, 1999. Based on these estimates and earlier reports, it appears that expenditures on DTC advertising have more than doubled since 1996. See the February 1999 issue of *MedAd News*, an industry trade publication, indicating that spending on DTC advertising was around \$600 million in 1996.

² See *MedAd News*, June 1997.

active interest in health and well-being, and a focus on “self-care.” Some DTC advertising may appeal to those consumers who are seeking information for themselves and family members about possible treatments for their health problems.³

The growing volume of DTC advertising has raised concerns among some consumer advocates and health care provider groups. Critics generally cite two different types of concerns. The first relates to the quality of the information that the ads provide about health and medication matters, especially in light of the safety issues inherently present in the use of prescription medications. The purpose of advertising, to induce purchases, is not fully consistent with the notion of effective disclosure about the potential hazards of product use.⁴ Here, there may be particular concern about the impact of DTC advertising on older consumers, who tend to have more serious health conditions and use more prescription medications. According to figures for 1996 cited by the Employee Benefit Research Institute, 8.6 prescriptions per year are written, on average, for each consumer age 65 to 74 and an average 11.7 prescriptions per year for each consumer age 75 and over, compared to just 4.2 prescriptions per year for those age 45 to 54.⁵ The impact of printed DTC advertising may be especially relevant when the lower literacy level of the aged population is considered.⁶

The second concern, one not addressed by this Issue Paper, is the potential effect of DTC advertising and promotion on prescription drug costs. Since the mid-1990s, national expenditures on prescription drugs have been rising sharply and steadily.⁷ By one estimate, total retail expenditures for prescription drugs increased by 84 percent between 1993 and 1998, or about 13 percent annually, on average.⁸ For the most part, this growth is attributed to increased utilization and the introduction of high-priced new products. However, some analysts cite increased DTC advertising as an additional factor. One report noted that “DTC advertising spending takes place in categories that have experienced significant increases in product utilization over time, largely as a result of the adoption and use of the drugs that are heavily marketed to consumers.”⁹ Nonetheless, it is difficult to estimate the precise impact of DTC promotion on overall costs of prescription drugs.¹⁰

³ *Prevention Magazine, National Survey of Consumer Reactions to Direct-to-Consumer Advertising, Year Two*, Rodale Press, 1999; see also Holmer, Alan F., “Direct-to-Consumer Prescription Drug Advertising Builds Bridges Between Patients and Physicians,” *Journal of the American Medical Association*, January 27, 1999.

⁴ See Hollon, Matthew F., M.D., “Direct-to-Consumer Marketing of Prescription Drugs: Creating Consumer Demand,” *Journal of the American Medical Association*, January 27, 1999.

⁵ Copeland, Craig, *Prescription Drugs: Issues of Cost, Coverage and Quality*, Employee Benefit Research Institute, April 1999.

⁶ Weinstein-Shr, Gail, *Literacy and Older Adults in the United States*, National Center on Adult Literacy, January 1995. This report makes note of an estimate from a 1975 study finding that adults over age 50 were the least literate, compared to younger age groups.

⁷ Smith, Sheila, et al., “The Next Decade of Health Spending: A New Outlook,” *Health Affairs*, July/August 1999; see also Barents Group, *op. cit.*

⁸ Barents Group, *op. cit.*

⁹ *Ibid.*, p. 13.

¹⁰ See Hunt, Michie, *Direct-to-Consumer Advertising of Prescription Drugs*, background paper for the National Health Policy Forum, April 1998.

A related issue is the potential impact of DTC advertising on drug prices. Such an impact may be generally assumed, but there is little publicly available data for assessing the effect of DTC advertising on drug prices overall or on the price of any specific product that is heavily marketed to consumers. While some analysts might contend that rising drug prices partially reflect the costs of mass marketing, others could assert that DTC advertising creates an active marketplace where competition would tend to keep prices lower.

Despite concerns about quality and costs, many consumer advocates hesitate to oppose DTC advertising outright, and some favor it, as one means, among others to provide drug information to consumers. When discussing the potential merits and drawbacks of DTC advertising, consumer advocates generally emphasize that it serves the public interest for consumers to have 1) readily available information that is accurate and useful; 2) the best possible conditions for making personal choices about health care treatment; and 3) informed access to innovations in a health care system characterized by busy professionals and expanding treatment options. Thus, the value of DTC advertising is often viewed through one or more of these lenses.

Health care providers have voiced additional concerns about DTC advertising. Some physicians assert that drug companies intrude too far into medical practice by suggesting treatment options directly to patients, who may lack the skill and training to diagnose health problems or select proper remedies. Some providers, such as managed care organizations and pharmacists, have criticized DTC advertising for leading to patient demands for products that are unavailable under formulary policies, or for boosting demand for prescription products that may not be necessary.¹¹

Drug companies, advertising experts, and others answer the concerns of consumers and providers by asserting that DTC advertising plays a valuable role in educating the public about health matters generally, as well as about specific products.¹² Some proponents of DTC advertising stress that consumers are protected by the requirement of obtaining a written prescription from their physicians. They further assert that it is the role of physicians and pharmacists, through personal attention to each patient, to address concerns about safe medication use and possible side effects.¹³

Research About DTC Advertising and Consumers. While the drug industry regularly monitors the impact of DTC advertising from a marketing perspective, independent researchers have only recently begun to explore the impact of DTC advertising on consumers. The results have been mixed. A survey sponsored by the National Consumers League (NCL) in 1998 found that most consumers (80 percent) have seen DTC advertisements, especially on television. Of those who have, 44 percent said they had talked to a doctor about the product advertised.¹⁴ In its 1998 study, *Prevention Magazine* found that 70 percent of consumers had seen a DTC advertisement, and 33 percent spoke with their doctor about an advertised product.¹⁵ In a similar

¹¹ See Vecchio, Anthony, "Direct Concerns: Pharmacists Wary of Surge in Consumer Rx Drug Ads," *Drug Topics*, July 21, 1997. See also Hollon, Matthew F., *op. cit.*; Hunt, Michie, *op. cit.*

¹² See, e.g., Holmer, Alan F., *op. cit.*

¹³ *Ibid.*

¹⁴ National Consumers League, *Health Care Information and the Consumer: A Public Opinion Survey*, 1998.

¹⁵ *Prevention Magazine*, *National Survey of Consumer Reactions to Direct-to-Consumer Advertising*, Rodale Press, 1998.

Printed DTC Advertisements: Organization and Regulation

As illustrated by the “Inhaleez” composite advertisement* on the following two pages, it may be helpful to think of a typical printed DTC advertisement – appearing in a magazine, for instance – as composed of three chief component parts.

- The first component is the creative portion of the advertisement, which may include photos or drawings of consumers in various inviting settings. The creative portion might also identify the advertised prescription product with a distinctive logo or type font, as well as other text designed to attract readers’ notice to the ad.
- The second component, which may overlap or appear visually integrated with the creative portion, is text containing marketing claims and more information about the product, such as: indications, risks, and safety precautions; references to diseases and symptoms that the product is designed to treat; and recommendations for the reader to consult a physician or other source for more information. Less typical DTC advertisements are the so-called “reminder” and “help-seeking ads,” which may not contain all of this information. Reminder ads do not make assertions about conditions or diseases the named product is intended to treat, while help-seeking ads mention symptoms but not a product name.
- The third component is the “Brief Summary,” which is the “small print” or “gray” portion found in most printed DTC advertisements. In most cases, this component is not integrated with the main part of the advertisement, but rather appears as a block of information on a facing or opposing page.

Federal regulatory provisions, which apply to the entire advertisement, may influence how a drug manufacturer and its advertising artists choose to design an advertisement. The Food and Drug Administration (FDA) requires the entire advertisement to be accurate and nonmisleading in its claims of safety and efficacy. Among other more specific requirements, the advertisement must include a “Brief Summary” with information about side effects, contraindications, and effectiveness. The typical DTC advertisement presents this Brief Summary information in a separate or distinct section that is characterized by small print and a high level of technical detail. *The FDA does not require the Brief Summary to have this format or appearance.*

FDA marketing regulations also dictate that the advertisement as a whole must present a “fair balance” of the product’s benefits and risks. For instance, a prescription drug advertisement may not overstate the extent of a drug’s clinical benefits while understating the frequency or severity of known side effects. As a practical matter, the “fair balance” requirement dictates that advertisers prominently present information about significant risks or safety concerns. The FDA would judge an advertisement’s “fair balance” in terms of its specific content and the impression that the advertisement gives when viewed as a whole.

*Ad is a composite only. There is no such company or product.



Inhaleez*
(Vican IP 65)

**Breathe EEZY...
Finally!**

DOES THE MERE THOUGHT OF FLOWERS, DUST, OR YOUR HOUSEHOLD PET MAKE YOUR eyes water, throat itch, and sinuses congest? **You're not alone:** More than one-third of Americans suffer from seasonal allergies each year.

Now there's relief. INHALEEZ is a safe, effective, long-lasting decongestant that can help improve the symptoms of seasonal allergies. **Now you can breathe eezy!**

INHALEEZ works quickly and reliably to counteract watery eyes, a scratchy throat, and blocked sinuses. Millions of Americans have tried **INHALEEZ** and loved it. **You will, too!**

Side effects include dizziness, nausea, and dry mouth. Do not use **INHALEEZ** if you are currently taking medications for heart disease or high blood pressure.

Why hesitate? Ask your doctor about INHALEEZ today, breathe eezy tomorrow!

Please see important summary of patient information on next page.

**Ad is a composite only. There is no such company or product.*

Inhaleez*
(Vican IP 65)

study the following year, 81 percent of consumers had seen an advertisement, but the percentage of consumers who had talked with their doctor remained about the same as the previous year (31 percent).¹⁶

Additional findings from both the NCL and the *Prevention* studies address consumer perceptions of the adequacy and presentation of the information in DTC advertisements. The NCL study found that 43 percent of consumers who have seen printed DTC advertisements read “little or none” of the small-print information typically included. The authors of the 1998 *Prevention* report concluded that “the ads may not be doing such a good job of providing [consumers] with the information they need to take charge of their own health. Consumers don’t think DTC advertising is clear and give it low marks for providing information about both side effects and benefits.”¹⁷ While the 1999 follow-up study resulted in much the same conclusion, it also found that many consumers (63 percent) say that DTC advertising helps them make decisions about medications or become involved in their own health care (76 percent).¹⁸

However, both *Prevention* reports and the NCL report highlight the potential value of DTC advertising in the overall context of growing consumer involvement and information seeking in matters related to health care and medical treatment. The NCL, in addition, probed consumers’ views and preferences about the types of medication information they have encountered.

Federal Regulation of DTC Advertising. The U.S. Food and Drug Administration (FDA) regulates all prescription drug advertising under the Food, Drugs and Cosmetics Act (FDCA).¹⁹ The FDA issues regulations and regulatory guidance, as well as directly enforcing the FDCA requirements in the marketplace.

The law requires prescription drug advertisements to be accurate and nonmisleading in their claims of safety and efficacy. To meet this requirement, the advertisements must include a “Brief Summary” that contains information about a product’s side effects, contraindications, and effectiveness. Depending upon the media, i.e., print or broadcast, the creators of DTC advertisements may meet the legal requirements by different means. In printed DTC ads, which are the subject of this Issue Paper, the “Brief Summary” frequently appears as a block of small-print information opposite or adjacent to the main, creative part of the ad. (See accompanying text box and illustration.) The FDA does not specify the format of the Brief Summary. Citing convenience and legal precaution, many prescription drug advertisers simply reprint relevant portions of the “professional labeling” inserts that are required, under separate FDA authority, to be included with the drugs when they are shipped by the manufacturer.

In addition to the information in the Brief Summary, FDA marketing regulations dictate that the advertisement as a whole must present a “fair balance” of the benefits and risks. For instance, a prescription drug advertisement may not overstate the extent of the drug’s clinical benefits while

¹⁶ *Prevention Magazine*, 1999, *op. cit.*

¹⁷ *Prevention*, 1998, *op. cit.*, p. 3.

¹⁸ *Prevention*, 1999, *op. cit.*

¹⁹ See 21 U.S.C. Section 352(n) for the relevant provisions of the FDCA; see 21 CFR Part 202 for FDA regulations. Nonprescription or “over-the-counter” drugs are regulated under separate authority by the Federal Trade Commission.

understating the frequency or severity of known side effects. To meet the “fair balance” requirement, advertisers select and present key facts about a product’s risk in a prominent size and location within the advertisement, although such information might also be found in some form in the Brief Summary.

In August 1999, the FDA issued a final “Guidance to Industry” that specifically addresses DTC advertising for radio and television. This guidance suggests that a broadcast advertiser may refer listeners and viewers to the location of a printed version of the advertisement for additional information about the product. Such a reference in the broadcast advertisement would partially meet the advertiser’s burden of providing adequately for dissemination of product labeling for the advertised product. While the agency has not published specific guidance about printed DTC information, the FDA has indicated that it may consider issuing new guidance for print media in the future.

The FDCA prohibits the FDA from requiring manufacturers to submit advertisements for regulatory review and approval prior to publication or broadcast. However, if requested by the manufacturer, FDA’s Division of Drug Marketing, Advertising and Communications will review and comment on proposed advertising before its sponsor distributes it.

To enforce the prescription drug marketing rules, the FDA relies on the enforcement tools generally at its disposal under the regulatory powers granted by Congress. These tools include the power to issue injunctions against the publication or broadcast of false or misleading advertisements. However, injunctive action in a prescription drug advertising case is rare. More commonly, if the FDA finds that a particular advertisement violates the law or regulations, the agency issues the sponsor a written notice of this finding. The most formal type of notice is called a “warning letter.”²⁰ As a practical matter, a manufacturer typically withdraws an advertisement that has been cited in a warning letter; the advertisement may be reissued when the cited deficiency is corrected. The FDA has no authority to impose penalties or other sanctions against manufacturers who broadcast or publish false or misleading information in prescription drug advertisements.

PURPOSE

The purpose of the research reported here is to explore the impact of DTC printed advertising on consumers, with particular attention to older consumers. The issues for research relate to consumer impressions and perceptions associated with the following questions:

1. What is the impact of DTC advertising on consumers’ knowledge about health matters and medications that treat disease?
2. Do DTC advertisements provide adequate information about the risks and possible side effects of the advertised products?

²⁰ Nordenberg, Tamar. “Direct to You: TV Drug Ads That Make Sense,” *FDA Consumer* magazine, January-February 1998. The notice can also take the form of an “untitled letter.” Warning letters, unlike untitled letters, are subject to public disclosure requirements and are generally posted on the FDA’s Internet Web site.

3. To what extent do physicians and pharmacists function as sources of information about medication risks and side effects?

The focus of the study is printed advertising, and the effects of broadcast media are not explored. In regulating broadcast DTC advertising, the FDA clearly favors broadcast campaigns that inform consumers of the availability of appropriate printed information, such as printed versions of advertisements for the product. Given the importance of printed information in the regulatory scheme, it is worthwhile to study the printed medium apart from other media.

Particular attention is paid to older persons. As noted earlier, older consumers constitute a large portion of the market for prescription drug products. Their high utilization of medications, which often includes multiple products, may make them particularly susceptible to medication problems such as side effects or poor interactions among drugs.

METHODOLOGY

The data reported here were obtained through telephone interviews with consumers. Questions for the random national survey were based on the results of focus groups conducted in October 1998. The telephone survey was conducted by ICR, Inc., in December 1998. In total, 1,310 adults were contacted, with oversampling of respondents age 50 and over. This weighted sample size permits the results reported here to be extrapolated to the national adult population. The survey results reported were analyzed for three age groups: 18 to 39 years, 40 to 59 years, and age 60 and older. Sampling error is plus or minus 3 percentage points for the entire sample and plus or minus 5 percentage points for the age subgroups.

The results of the research are limited in that the research questions are informed only by consumer perceptions, impressions, and opinions. The impact of DTC advertising on actual consumer knowledge, the adequacy of safety information, and the behavior of physicians and pharmacists have not been independently tested in this study.

DISCUSSION OF KEY FINDINGS

Key findings of the research are discussed below, with concluding comments about implications for consumers and for public policy. The discussion of findings is organized according to the issues identified for research: consumer perceptions related to 1) the impact of DTC advertising on consumer knowledge about health matters and medications that treat disease; 2) the information advertisements provide about the risks and possible side effects of the advertised products; and 3) the roles that doctors and pharmacists play as sources of information about medications. Differences in survey responses are reported only when statistically significant.

Detailed Findings from the national survey and an annotated questionnaire may be found in Appendices A and B. The findings of the focus groups are summarized in Appendix C.

1. Impact on Consumer Knowledge About Health Matters and Medications That Treat Disease

While DTC prescription drug advertising may be one source of information for consumers about their health and medications, DTC advertising appears to have limited educational value in the eyes of consumers. Focus group research for this study strongly indicated that DTC advertising is one source, among many, from which consumers seek information about medications. (See Appendix C.) However, the national random survey results reveal an audience for printed DTC advertising that is limited in certain respects. First, one-third of the population reports not having recently seen a DTC advertisement in print, and another 2 percent “don’t know.” Among the 65 percent of consumers who report at least having seen a DTC advertisement, a few clear trends emerge. First, the likelihood of reporting having seen a printed DTC advertisement increases with level of education. More than three-quarters (77 percent) of consumers with at least a college degree report noticing DTC printed ads, compared to 57 percent of those with some or all of high school completed. Further, the audience is somewhat segmented among the 65 percent who have seen the ads. For instance, women are more likely than men to have seen them (70 percent versus 59 percent).

One possible explanation for the gender difference is that women tend to be more active than men in seeking health-related information, so that they may be more attuned to printed DTC advertising.²¹ Similarly, the variation in education level is consistent with a hypothesis that better educated consumers make up a larger portion of reading audiences in general. In any case, the survey results tend to indicate that many consumers in identifiable segments of the population, especially less educated consumers, are not part of the actual audience for printed DTC advertising.

This actual audience for printed DTC advertising, i.e., two-thirds of the population, is further segmented in terms of the amount and type of information obtained from the advertising. First, survey results suggest that consumers may often fail to be informed of what the advertised product is intended to treat. Older readers (those age 60 and older) and those with lower education levels are more likely to say that the ads “never” tell them what the advertised product is for. Consumer perceptions on this point may be influenced by exposure to some of the so-called “reminder ads,” which by definition do not mention symptoms. However, this explanation is only partial at best, given that reminder ads are not typical. In any case, there was significant variability in consumer perceptions on this question. (Table 1).

In addition, one-third of the DTC audience apparently fails to notice the “small print” information included in most printed advertisements. As noted in an earlier section, this “small print” portion of the advertisement typically contains required “Brief Summary” information, although there is no federal requirement to provide this information in the detailed, small-print format in which it typically appears. One general explanation for consumers’ failure to notice the Brief Summary is simple lack of interest in reviewing advertisements in full, especially if the subject of the advertising has no personal relevance to individual consumers. Here again, however, there is

²¹ For an overview of research on this topic, see Kaplan, Sherrie H., et al., “Gender and Patterns of Physician-Patient Communication,” in *Women’s Health, The Commonwealth Fund Survey*, The Johns Hopkins University Press, 1996 (eds. Marilyn M. Falik and Karen Scott Collins).

significant variability in what groups of consumers report. The likelihood of noticing this information appears to be related to age and education level, slightly favoring younger readers and college-educated readers of the advertisements. Sixty-six percent of those in the 18-39 age group notice the small print, compared to only 48 percent of consumers age 60 and over. Seventy-two percent of consumers with at least a college degree notice this information, versus 55 percent of consumers with “some college” and 57 percent of consumers who have only completed some or all of high school. (The difference between 55 percent and 57 percent here is not statistically significant.)

TABLE 1							
Would you say the advertisements provide enough information to let you know what the drug is for?*							
(in percent)							
	ALL	AGE			EDUCATION		
	n=898	18-39 n=294	40-59 n=328	60+ n=258	High School or Less n=326	Some College n=240	College or More n=327
Usually	49	50	52	44	41	49	62
Sometimes	24	26	24	22	25	28	19
Rarely	13	16	10	11	16	12	10
Never	10	6	12**	15**	15***	7	6
Don't know	4	2	2	8	3	4	3
* Respondents who have seen printed prescription drug ads in the past six months.							
** Statistically significant difference, compared to “18-39” age group.							
*** Statistically significant difference, compared to “Some College” and “College or More” groups.							
Source: Direct-to-Consumer Prescription Drug Advertising Survey, conducted for AARP by ICR, Inc., in December 1998.							

Finally, 37 percent of consumers who do see the “small print” say that they “rarely” or “never” read it. Only 34 percent say they “usually” read it. The two most cited reasons for not reading the small print are lack of interest and the print size. Only a small percentage of consumers say that they do not read this information because it is too technical.

To summarize, there is a substantial audience, about 65 percent of consumers, that is noticing printed DTC advertising. The consumers who fail to see DTC advertising altogether, 35 percent, are also a sizable group. A closer look reveals that smaller groups of consumers notice *and actually obtain important types of information* from the ads.

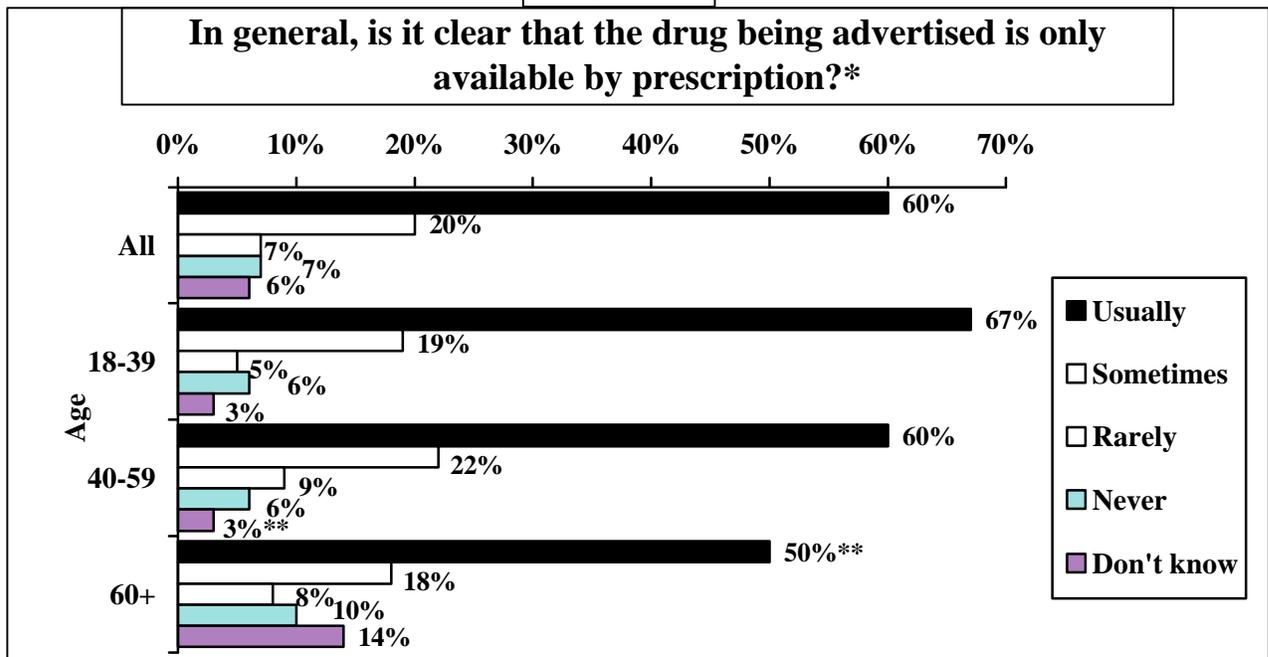
Survey results also indicate that consumers generally perceive the ads to be potentially helpful to them in discussions with their doctors. Three-quarters of consumers generally agree that an advertisement could assist them in discussing treatment options with their doctors, if the drug advertised was a medication that they needed. Given a slightly different statement, however, almost half (46 percent) agree that they would “never depend upon the information” in

an ad to help them talk to their doctors. Taken together, these results indicate strong consumer perceptions that printed DTC ads can be helpful, with perhaps slightly less tendency to “depend” upon DTC information exclusively or primarily.

2. Information Provided by DTC Advertisements About Risks and Possible Side Effects

Some consumer audiences, particularly older readers, find that printed DTC ads do not “clearly” convey that the product is available by prescription only. The fact that prescription products are inherently more risky than nonprescription products is reflected in the requirement of written approval from a physician in the form of a prescription. A majority (60 percent) of consumers who have seen printed DTC ads say that the ads “usually” contain sufficient information to convey clearly that the medication is available by prescription only. Nonetheless, 14 percent of consumers who have seen printed DTC advertisements say that the advertisements “rarely” or “never” make it clear that a *prescription* drug is being advertised. Older consumers, i.e., those age 60 and over, are less likely than younger consumers to say that the ads “usually” clarify that a prescription is required (50 percent versus 67 percent). (Figure 1). Higher income and more educated consumers are more likely to find that the ads are “usually” clear about this point.

FIGURE 1



* n= 898: Respondents who have seen printed prescription drug ads in the past six months.

** Statistically significant difference compared to 18-39 and 40-59 age groups.

Source: Direct-to-Consumer Prescription Drug Advertising Survey, conducted for AARP by ICR, Inc., in December 1998.

Overall, consumers who have seen printed DTC ads are evenly divided about whether the advertisements “usually” contain sufficient information about the risks and potential side effects of the products advertised. Here, too, there is notable variation according to age and education level.

Asked if the ads contain enough information about risks and possible side effects, 50 percent of consumers overall say “yes,” 45 percent say “no,” and 5 percent answer “don’t know.” Younger consumers and more educated consumers are more likely to feel that the ads contain enough information about risks or side effects. Sixty percent of the 18-39 age group say the information is sufficient, compared to 43 percent of consumers age 60 and over. Sixty-one percent of consumers with at least a college degree agree, compared to 42 percent of consumers with some or all of high school completed. (Table 2).

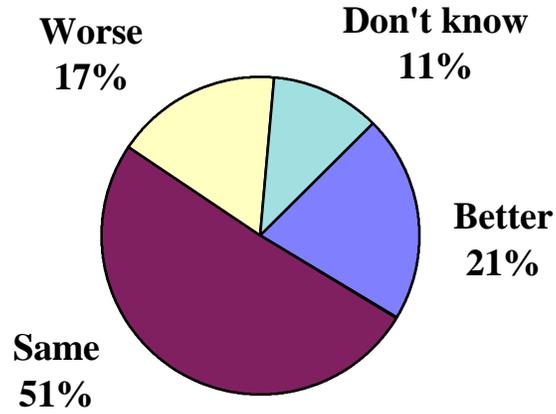
TABLE 2							
Do you feel there is usually enough information in these ads regarding possible risks or side effects of the medication?*							
(in percent)							
	ALL	AGE			EDUCATION		
	n=898	18-39 n=294	40-59 n=328	60+ n=258	High School or Less n=326	Some College n=240	College or More n=327
Yes	50	60**	43	43	42	51	61***
No	45	38	54	48	53	44	35
Don't know	5	2	3	9	5	5	4
* Respondents who have seen printed prescription drug ads in the past six months.							
** Statistically significant difference, compared to “40-59” and “60+” age groups.							
*** Statistically significant difference, compared to “High School or Less” group.							
Source: Direct-to-Consumer Prescription Drug Advertising Survey, conducted for AARP by ICR, Inc., in December 1998.							

Further, there is no strong consensus among consumers about the reliability of information that DTC advertisements present about product risks and side effects. Half the audience for printed DTC advertising takes the view that the ads are basically accurate in portraying degrees of risk and likelihood of side effects. The other half is divided in assessing whether the ads understate (21 percent) or overstate (17 percent) the risks and potential for side effects. A significant number, answering “don’t know” (11 percent), are unable to make an assessment. (Figure 2).

Consumers generally agree, however, on the types of information that printed DTC ads should contain. They want specific information about product indications, as well as descriptions of all potential side effects. Particularly strong preferences for such information are found among women, older consumers, and less educated consumers. Eighty-six percent of consumers say it is “very important” for DTC print advertisements to include a description of who should not take the drug. Fewer consumers, but still a strong majority, say that it is very important for the ads to include information about all of the possible risks and side effects (75 percent), even information about side effects that occur in rare cases (64 percent). (Table 3). Older consumers and less-educated consumers also prefer this information. Women are more likely than men to want information about rarely occurring events.

FIGURE 2

Generally, are the risks portrayed as worse than they really are, better than they really are, or about the way they really are?*



* n= 898: Respondents who have seen printed prescription drug ads in the past six months.

Source: Direct-to-Consumer Prescription Drug Advertising Survey, conducted for AARP by ICR, Inc., in December 1998.

3. Roles of Doctors and Pharmacists As Sources of Information About Medications

For many consumers, health professionals are not a source of information about medications. Physicians and pharmacists play a mandated role as expert intermediaries between prescription drug manufacturers and consumers. In focus groups conducted for this study, participants generally expressed their trust and reliance in physicians and pharmacists to function in this role. However, survey results suggest that, for many consumers, these health professionals are not serving as information sources about medications. Only 54 percent of all consumers report that their physicians “usually” talk to them about product risks or potential side effects when they are prescribing. One-fifth of all consumers say their physicians “rarely” or “never” talk to them about medication risks and side effects. Older consumers are less likely than younger ones to report having these conversations (17 percent versus 10 percent “rarely” having such conversations with their physicians).

Even fewer consumers overall report having discussions with their physicians, when they are prescribing, about other prescriptions (only 43 percent say they “usually” do) and nonprescription options (35 percent say they “usually” do). Here, too, older consumers are less likely to report such conversations.

TABLE 3										
Information Consumers Consider "Very Important" to be Included in DTC Printed Advertisements (in percent)*										
INFORMATION INCLUDED	ALL	AGE			HOUSEHOLD INCOME			EDUCATION		
		18-39 n=439	40-59 n=467	60+ n=377	<\$25K n=360	\$25K-49.9K n=411	\$50K+ n=376	High School or Less n=548	Some College n=329	College or More n=426
A description of the types of people who should not take the drug	86	85	88	84	84	87	89	84	87	87
The most common risks and side effects	82	81	86	78	80	85	83	79	84	84
All of the possible risks and side effects	75	74	77	74	75	77	73	77	78	70
Risks and side effects that occur in rare cases	64	57	70**	72**	69	65	56	70***	62	56
* All respondents.										
** Statistically significant difference, compared to "18-39" age group.										
*** Statistically significant difference, compared to "Some College" and "College or More" groups.										
Source: Direct-to-Consumer Prescription Drug Advertising Survey, conducted for AARP by ICR, Inc., in December 1998.										

Other results suggest that many consumers are not aware of the contacts and relationships that physicians have with prescription drug companies. More than one-third of consumers report that their doctors “rarely” or “never” talk to them about free samples or other items given to the doctors by drug companies. Consumers with incomes under \$25,000 are more likely to report that these discussions “never” take place, compared with higher-income consumers. Women are more likely than men to say that they talk to their doctors about pharmaceutical promotions.

Similar results were obtained when comparable questions were asked about discussions with pharmacists at the time of dispensing. The survey did not capture whether doctor-patient and pharmacist-client interactions are initiated by consumers or professionals. Thus, some of the variation in the data just described could be explained by variation in the degree to which different segments of the population actively seek information about health care. In any case, the overall results reveal that many consumers, including those who frequently read or at least see printed DTC ads, report that they fail to receive personalized professional attention about medication.

Finally, survey results suggest that consumers and their doctors may not always have the same level of awareness of prescription products available in the marketplace. Twenty-one percent of all consumers report having asked their doctors about prescription products with which the doctors were not familiar. The survey does not make a direct link between this type of physician-patient encounter and consumer exposure to DTC advertising and promotion.

IMPLICATIONS FOR CONSUMERS

The findings of the consumer survey suggest that many consumers face a “medication information gap” in the prescription drug marketplace, even though the proliferation of DTC advertising might be viewed as increasing the overall volume of available health care information. On the one hand, the information contained in printed DTC advertisements does not reach a third of consumers at all. Many of those who notice printed DTC advertisements do not notice or read the Brief Summary. To some extent, this finding may reflect the fact that many consumers lack an interest in learning more about a particular product, especially if the product is not relevant to their individual health concerns. However, many consumers report that the advertisements do not clearly convey that the product advertised is available only by prescription. This general assessment could be made by consumers regardless of their personal interest in products promoted through DTC printed advertising.

On the other hand, it does appear that health professionals also frequently fail to provide medication information on a personalized basis to their patients. In some cases, patients may be aware of prescription products available, but they may not be well informed either by advertising or their health care providers.

Implications for Older Consumers. Older consumers constitute the largest group of prescription drug users and are more likely than younger people to have multiple health conditions requiring medication. The survey results highlight areas of particular concern for them in terms of their access to relevant prescription medication information.

Consumers age 60 and older are about as likely as consumers overall to see printed DTC advertisements. However, this group appears to obtain less information from the ads. For instance, older consumers are less likely than younger consumers to find that the ads clearly indicate what the advertised products are for, or even indicate that the product is a prescription medication. In addition, older consumers are less likely to find that the printed ads contain enough information about risks and side effects. At the same time, older consumers also tend to report less discussion about medications with their physicians and pharmacists. Thus older consumers, along with low income and less educated consumers, may be more vulnerable than others to the “medication information gap.” Their vulnerability is further heightened because they tend to use more prescription drugs than younger consumers do.

IMPLICATIONS FOR PUBLIC POLICY

There is a role for public policy in addressing the medication information gap. The findings from this study suggest two possible policy approaches. The first approach relates to public oversight of the quality of the information that DTC advertisements provide to consumers. The second approach would address the adequacy of the information consumers receive in their personal dealings with professionals who prescribe or dispense prescription medication.

Oversight of Information Quality. Through its regulatory activities, the FDA has responsibility to monitor the accuracy and balance of DTC advertising. The agency has issued regulations and guidance on various aspects of prescription drug marketing, including DTC advertising. When an advertisement is found to be misleading or lacking in fair balance of benefits and risks, the FDA may take action to have the advertising withdrawn. To avoid an unfavorable regulatory finding, manufacturers may, and often do, seek FDA review of their DTC advertising prior to publication.

Despite regulations aimed at ensuring balance as well as technical accuracy, much of the important information contained in DTC advertising apparently fails to reach consumers, especially the most vulnerable ones such as those age 60 and older. With the proper authority, an agency such as the FDA could take additional steps toward improving the quality of information provided by manufacturers in DTC advertisements. Options for regulatory oversight include:

- Requiring all DTC advertisements to be approved by the FDA prior to publication in consumer-oriented media. Along with this process, the agency could be charged with developing specific criteria reflecting standards for the quality of information contained in DTC advertising.
- Requiring DTC advertisements to advise consumers of dangers inherent in prescription drug use, and the importance of a physician's recommendations for proper use of medications. Specific, standardized messages could be developed for this purpose, comparable to the approach used in regulating cigarette packaging and promotion.
- Subjecting manufacturers to civil penalties if the FDA determines that unbalanced, false, or misleading information has been presented in a DTC advertisement.

These suggested alternatives, especially the last two, should be informed by additional research evaluating various aspects of DTC advertising content. In the research reported here, consumers who had seen printed DTC advertisements were asked to assess the clarity and usefulness of the advertisements. However, consumer perceptions alone do not permit findings as to how well or how poorly sponsors provide required (or desirable) information, or whether they fail to provide such information altogether. Accordingly, implications for regulatory policy in this area should be considered with some caution.

In addition to possible regulatory approaches, policymakers may wish to consider public education as a response to the medication information gap. The FDA or another federal agency responsible for promoting public health could design and sponsor public information campaigns, targeting vulnerable populations where appropriate, and promoting medication safety and effectiveness. These campaigns could focus on the types of information that DTC advertisements typically omit, such as:

- The potential availability of generic brands.
- The continuing efficacy of less recent innovations or nonprescription products for many conditions.
- The option to forgo medication altogether for cosmetic concerns or common complaints such as mild seasonal allergies.

Through the Healthy People 2010 initiative, federal officials have already identified drug safety as a priority area for federally sponsored public health activities. It may be worth exploring whether the Healthy People campaign could integrate programs that respond to the types of quality concerns raised by DTC promotion.

Increased government oversight of DTC advertising and sponsorship of effective public health campaigns about medications would require significant public investments. To pay for public education, policymakers could consider tapping existing revenues from the “user fees” that drug manufacturers pay to the FDA as part of the drug approval process. Some portion of the user fees could be allocated for oversight of DTC advertising and for relevant public information. Such an initiative would create a policy link between the government’s responsibility to help bring safe, innovative products to market in a reasonable time, and a role for drug manufacturers in effectively providing objective information to consumers.

In any case, public and nonprofit agencies that engage in public education or produce public health messages must pay careful attention to the overall impact of DTC messages. The public will most likely continue to be targeted by privately sponsored promotional messages about health care. It appears that consumers appreciate this information and that they are potentially well served by having information about available treatment options. However, health care information from independent sources could also be valuable to consumers. Independent sponsors of information about medications have an opportunity, with their own messages, to respond to the impact of DTC advertising on consumers.

Making the most of that opportunity may involve an active and critical review of DTC advertising content as well as fully understanding the relevance and impact of DTC (or lack of relevance and impact) on different audiences. At the same time, it is worthwhile for public health educators to acknowledge the creativity and marketing sophistication behind the advertisements that increasingly catch the consumer’s eye. Highly effective DTC advertisements providing high-quality information may serve as good models for public messages.

Promoting Effective Communication Between Consumers and Health Professionals. As the findings of this study suggest, other factors besides DTC advertising contribute to consumers’ lack of information about their medications. Frequently, physicians and pharmacists fail to discuss treatment alternatives and medication risks with their patients. Given the complexity of the health care system and the pace of innovation, health professionals are continually challenged in their roles of educating consumers and protecting them from risks. The impact of DTC advertising on certain consumer audiences undoubtedly adds to the challenge. Nonetheless, it makes sense for health care professionals to be aware of the fact that DTC advertising is a source of information for many consumers. Those physicians and pharmacists who are aware of this fact have the opportunity to practice strategies for promoting safe medication use. Professional societies and training institutions clearly have a role in developing and supporting such strategies.

It is more difficult to fashion a public policy response in this area. Nonetheless, policymakers can play some role in responding to the concerns that have emerged. For instance, it may be appropriate for state medical boards to review their standards relating to physician prescribing, and place more priority on enforcing these standards. Similarly, public purchasers of health care

coverage (such as Medicaid and Medicare) might explore their opportunities to promote improved communications between beneficiaries and their doctors and pharmacists. Federal policymakers may wish to evaluate the impact of pharmacy counseling services mandated for Medicaid programs in 1990.²²

Further, a special focus on useful information for older consumers is warranted, given the importance of medication in their lives and the research reported here. Medicare policymakers in particular are challenged to address a range of issues related to beneficiaries and prescription drugs, including quality and safety, as well as financing a possible prescription drug benefit. In this connection, the impact of DTC promotion on drug costs will clearly be a topic of continued concern and investigation. The necessity and value of patient information and education must be considered in this context as well.

²² Omnibus Budget Reconciliation Act (OBRA) of 1990, Public Law 101-508.

APPENDIX A

DETAILED FINDINGS

A national telephone survey of consumers was conducted by ICR Inc., in December 1998. An annotated survey questionnaire is provided in Appendix B. In total, 1,310 adults were interviewed, with an oversampling of adults age 50 and older. Survey results are analyzed according to:

- Gender.
- Age (18-39; 40-59; 60 and older).
- Annual income (less than \$25,000; \$25,000-49,999; \$50,000 and more).
- Level of education (some or all of high school; some college; college degree and more).

Unless otherwise noted, reported differences are statistically significant within a 95 percent confidence interval. Findings are reported as reflective of the national adult population. Sampling error is plus or minus 3 percentage points for the entire sample and plus or minus 5 percentage points for the age subgroups.

The findings are organized into three sections, corresponding to the three research questions established for the study. The questions focus on consumer perceptions about:

1. The impact of DTC advertising on consumer knowledge about health matters and medications that treat disease,
2. The information that advertisements provide about the risks and possible side effects of the advertised products, and
3. The roles doctors and pharmacists play as sources of information about medications.

A short summary of the questions asked appears in italics at the beginning of each section.

1. Impact on Consumer Knowledge about Health Matters and Medications That Treat Disease

To gauge the impact of printed DTC advertising on readers' knowledge about health matters and medications that treat disease, interviewers asked respondents about their exposure to the information in DTC advertisements and their perceptions about the nature of the information provided.

Overall, 65 percent of all consumers (n=1310) report having seen a printed DTC advertisement in the past six months.

- Seventy percent of women and 59 percent of men report having seen a printed DTC ad.

- The likelihood of reporting having seen a printed DTC advertisement increases with education level. Those with a college degree and more are most likely (77 percent) to report having seen such an advertisement, followed by consumers with some college (66 percent). In contrast, only 57 percent of consumers with some or all of high school completed report having seen a printed DTC advertisement.

Of those who report having seen a printed DTC ad (n=898), just under half (49 percent) say that the ads “usually” contain enough information to convey what the advertised product is for. About one-quarter (24 percent) say the ads do this “sometimes.” Another 23 percent report that DTC print ads “rarely” or “never” contain this information (13 percent and 10 percent respectively). The remaining answer “don’t know.”

- More consumers age 60 and older (15 percent) and age 40-59 (12 percent) say that the ads never provide enough of this information, compared to consumers age 18-39 (6 percent). (There is no statistical significance in the difference between the 40-59 and 60-and-older groups.)
- Those with a college degree or more are more likely (62 percent) than those with only some college (49 percent) and those who have only completed some or all of high school (41 percent) to report that the ads “usually” provide enough information to convey what the product is for. (Here, the difference between 49 percent and 41 percent is not statistically significant.)

Of consumers who report having seen a DTC ad, nearly two-thirds (62 percent) also report having seen any small-print information accompanying the main part of the ad. Thirty-two percent report not having seen this part of the ad, and the remainder respond “don’t know.”

- Younger people are more likely than those age 60 and older to notice the presence of the small print. In the 18-39 age group, 66 percent notice the small print, compared to only 48 percent of those age 60 and older.
- Consumers with the highest level of education are more likely to notice the small print than are those with less education. Seventy-two percent of those with at least a college degree report noticing this information, compared to 55 percent of those who have “some college” and 57 percent of those whose highest level of education is high school or less. (Here, the difference between 55 percent and 57 percent is not statistically significant.)

Of those noticing the small print (n=547), the majority report that they “usually” or “sometimes” read it, while more than one-third say they “rarely” or “never” do so. Specifically, 34 percent report that they usually read this information; 29 percent read it sometimes; 18 percent read it rarely; and 19 percent never read the small print.

Consumers who notice the small print, but “rarely” or “never” read it (n=210), give various reasons for failing to read it. The most common reason given (36 percent) is lack

of interest in the information, while 33 percent say that the print is too small. Smaller numbers of consumers say the information is “too technical,” or report the perception that this information is not intended for consumers. A significant percentage of consumers (24 percent) cite “other” reasons that were not identified by the survey.

Eighty-four percent of consumers who notice the small print and read it “usually,” “sometimes,” or “rarely” (n=445) say the information is useful. Thirteen percent say the information is not useful, and the remainder “don’t know.”

- Women are more likely than men to find the small-print information useful (89 percent versus 76 percent).

Consumers who have seen a printed DTC advertisement (n=898) were asked about the usefulness of DTC advertisements in their interactions with their physicians. Two slightly different questions were posed. The first question asked how helpful the ad would be if the product advertised were one that the respondent actually needed. The second question explored the degree of reliance, in the doctor-patient context, that the respondent would place on a DTC advertisement.

Three-quarters generally agree with this statement: *If I needed the drug, the information provided in the ad would help me discuss my treatment options with my doctor.* Thirty-four percent “strongly” agree, and another 41 percent agree “somewhat.” Thirteen percent disagree “somewhat,” and 10 percent strongly disagree. The remaining answer “don’t know.”

About half generally disagree with this statement: *I would never depend on the information in a prescription drug ad to help me talk with my physician about treatment.* Thirty-one percent disagree “somewhat,” and 21 percent disagree strongly; 24 percent agree strongly, and 22 percent agree somewhat. The remaining answer “don’t know.”

2. Information Provided by DTC Advertisements About Risks and Possible Side Effects

Consumers who reported having seen a printed DTC ad (n=898) were asked a set of questions to assess their perceptions about the information contained in DTC ads. An initial question relates to whether the ads convey that the product is available only by a prescription. Additional questions probe consumer views about how well the ads communicate risks and potential side effects of the medications.

A majority of consumers who have seen printed DTC advertisements say that the ads clearly indicate that the advertised product is only available by prescription. Sixty percent say the ads “usually” make this clear, and 20 percent say they “sometimes” do; 7 percent say the ads are “rarely” clear about this, and another 7 percent say they “never” are. The remaining respondents (6 percent) say they don’t know.

- Younger consumers are more likely to say that printed DTC advertisements are usually clear that a prescription is required. Sixty-seven percent of those age 18-39 and 60 percent of those age 40-59 answer in this manner, compared to 50 percent of those age 60 and older. (Here, the difference between 67 percent and 60 percent is not statistically significant.) In addition, a significant percentage of consumers age 60 and older answer “don’t know” (14 percent), while this answer is much less common among younger consumers.
- Consumers with incomes over \$50,000 are more likely (67 percent) than those with incomes under \$25,000 (52 percent) to say that the ads are usually clear that the advertised product is only available with a prescription.
- Consumers with at least a college degree are more likely (70 percent) than those with only some or all of high school completed (53 percent) to say the ads are usually clear about this.

Overall, consumers who have seen DTC advertisements are evenly divided as to whether the ads contain sufficient information about possible risks or side effects of the advertised product. When asked if there is “usually” enough of this information, 50 percent say “yes,” while 45 percent say “no”; 5 percent answer “don’t know.”

- Consumers age 18-39 are more likely (60 percent) to feel that the ads contain enough information about risks or side effects, compared to 43 percent of those age 40-59 and 43 percent of those age 60 and older.
- Sixty-one percent of consumers with at least a college degree say that the information is sufficient, compared with 42 percent of those with only some or all of high school completed.

Consumers who report having seen printed DTC ads are also divided in their assessments of how reliably risks and potential side effects are presented. Fifty-one percent feel that the advertisements portray the risks and side effects of the medication as “about the way they really are.” Another 21 percent believe that the risks and side effects are portrayed as “better than they really are,” and 17 percent feel this information is portrayed as “worse than they really are.” Eleven percent respond “don’t know.”

- Consumers age 60 and older are more likely (20 percent) to respond “don’t know,” compared to 9 percent of those 40-59 and 8 percent of those 18-39. (Here, the difference between 9 percent and 8 percent is not statistically significant.)

Among all consumers, there is overwhelming agreement that it is “very important” for DTC print advertisements to include a description of who should not take the drug (86 percent) and of the most common risks and side effects (82 percent). A strong majority also thinks that it is “very” important for the ads to include information about all of the possible risks and side effects (75 percent). Sixty-four percent say it is very important for

advertisements to provide information about rarely occurring risks and side effects. More than 90 percent of consumers report that it is “somewhat” or “very” important for ads to contain information of this nature.

- Eighty-eight percent of women and 83 percent of men say that it is very important for the ads to describe the types of people who should not take the medicine. Also, women are more likely than men (68 percent versus 60 percent) to say it is very important to include information about risks and side effects that occur in rare cases.
- Only 57 percent of consumers age 18-39 say it is very important for the advertisements to contain information about rarely occurring events, compared to 70 percent of those 40-59 and 72 percent of those age 60 and older. (Here, the difference between 70 percent and 72 percent is not statistically significant.)
- Seventy percent of those with only some or all of high school completed say it is very important for DTC advertisements to contain information about rarely occurring events, compared to 62 percent of those with some college and 56 percent of those with at least a college degree (Here, the difference between 62 percent and 56 percent is not statistically significant.)

3. Roles of Doctors and Pharmacists As Sources of Information About Medications

All respondents (n=1310), whether or not they reported having seen a DTC advertisement, were asked a series of questions exploring their interactions with health professionals about their medications.

Conversations With Doctors. Fifty-four percent of consumers say their doctors “usually” talk to them about risks and side effects, when prescribing medication. Eighteen percent say their doctors do this “sometimes,” while 12 percent say their doctors “rarely” talk about risks and potential side effects of medication; 9 percent say their doctors “never” do so. The remaining answer “don’t know” or “do not have a doctor.”²³

- Seventy-seven percent of women and 66 percent of men report that this interaction usually or sometimes takes place when their doctors are prescribing.
- Seventeen percent of consumers age 60 and older say that their doctors rarely talk to them about the risks and potential side effects of medication when prescribing, compared to 10 percent in the 18-39 group.

Forty-three percent of consumers say that their doctors “usually” talk with them about “other prescription products that may be appropriate” when prescribing; 23 percent say

²³For the series of questions about interactions with doctors, members of the youngest cohort are more likely than those in either of the older age cohorts to report not having a physician. In addition, consumers in the oldest cohort are more likely than those in either of the younger ones to answer “don’t know” when asked about interactions with their doctors on the subject of medication.

their doctors do this “sometimes,” while 14 percent say “rarely” and 13 percent say “never.” The remaining answer “don’t know” or “do not have a doctor.”

- Forty-six percent of women say this interaction usually takes place, compared to 38 percent of men.
- Eighteen percent of consumers age 60 and older say their doctors never talk to them, when prescribing, about other appropriate prescription products, compared to 10 percent of those 18-39 who answer in this manner.

Thirty-five percent of all consumers say that their doctors “usually” talk with them about “other nonprescription products that may be appropriate” when prescribing; 23 percent say their doctors “sometimes” do so, while 16 percent say that this “rarely” takes place and 19 percent say it “never” does. The remaining answer “don’t know” or “don’t have a doctor.”

- Forty-one percent of women, compared to 30 percent of men, say their doctors usually talk with them about nonprescription products when prescribing; conversely, 22 percent of men say this interaction never takes place, compared to 16 percent of women answering in this manner.
- Forty-two percent of those age 60 and older say that their doctors rarely or never talk to them about nonprescription medications when prescribing, compared to 30 percent of those age 40-59 and 32 percent of those age 18-39 (Here, the difference between 30 percent and 32 percent is not statistically significant.)

Thirty-two percent of all consumers say that their doctors, when prescribing, “usually” talk with them about “free samples and other items the doctor may have received without charge from drug companies.” Another 25 percent say their doctors do so “sometimes,” while 12 percent say “rarely” and 24 percent say “never.” The remaining answer “don’t know” or “do not have a doctor.”

- Thirty-seven percent of women and 26 percent of men say this interaction usually takes place.
- Twenty-nine percent of consumers with income under \$25,000 and 26 percent of those with income between \$25,000 and \$49,999 say that their doctors never talk to them about free samples and other products provided by drug manufacturers, compared to 17 percent of those with incomes over \$50,000 who answer in this manner. (Here, the difference between 26 percent and 29 percent is not statistically significant.)
- Thirty-eight percent of consumers with at least a college degree say that this interaction usually takes place, compared to 27 percent of those with only some or all of high school completed who answer in this manner.

One out of five consumers (21 percent) say they have asked their doctors about a prescription drug that the physicians were not familiar with. Seventy-seven answer “no,” and the remainder say “don’t know.”

Conversations With Pharmacists. Forty-eight percent of all consumers report that their pharmacists “usually” talk to them about the risks and side effects of medicines prescribed. Another 18 percent report that this occurs “sometimes;” 8 percent say “rarely,” and 23 percent say “never.” The remainder answer “don’t know.”

- Fifty-two percent of women and 44 percent of men indicate that this interaction usually occurs. Conversely, 27 percent of men and only 19 percent of women said that this interaction never occurs.
- Forty-three percent of consumers age 18-39 say this interaction usually occurs, compared to 53 percent of those age 40-59 and 51 percent of those age 60 and older. (Here, the difference between 53 percent and 51 percent is not statistically significant.)

Sixty-five percent of all consumers say that their pharmacists “never” talk to them about “special offers available through drug company marketing programs.” Twelve percent say this interaction “sometimes” occurs, while 11 percent say it “rarely” occurs, and 8 percent say it “usually” occurs.

- Seventy-three percent of consumers with annual incomes over \$50,000 say that this interaction never takes place, compared to 60 percent of those with incomes in the range of \$25,000 to \$49,999 and 62 percent of those with incomes under \$25,000 (Here, the difference between 60 percent and 62 percent is not statistically significant.)

Eighty-three percent of all consumers agree that their pharmacists would “provide information about an advertised prescription product upon request.”

- Fourteen percent of consumers with only some or all of high school completed disagree, compared to 8 percent of those with at least a college degree.

APPENDIX B

AARP DIRECT-TO-CONSUMER PRESCRIPTION DRUG ADVERTISING SURVEY

ANNOTATED QUESTIONNAIRE

1. Have you seen advertisements for prescription drugs in newspapers and magazines in the past six months? (n=1310)

65%	Yes (Continue)
33%	No (Skip to Q10)
2%	Don't Know

2a. Thinking of the ads you have seen for prescription drugs in newspapers and magazines, in general, is it clear that the drug being advertised is only available by prescription? Would you say the ads are usually, sometimes, rarely, or never clear in this respect? (n=898)

60%	Usually
20%	Sometimes
7%	Rarely
7%	Never
6%	Don't Know

2b. Would you say the advertisements provide enough information to let you know what the drug is for? Would you say the ads are usually, sometimes, rarely, or never clear in this respect? (n=898)

49%	Usually
24%	Sometimes
13%	Rarely
10%	Never
4%	Don't Know

3. Do you feel there is usually enough information in these ads regarding possible risks or side effects of the medication? (n=898)

50%	Yes
45%	No
5%	Don't Know

4. **In general, how do you feel about the way the risks and side effects of the medication are portrayed in these ads? Generally, are the risks portrayed as worse than they really are, better than they really are, or about the way they really are? (n=898)**

17%	Worse than they really are
21%	Better than they really are
51%	About the way they really are
11%	Don't know

5. **I am going to read you two different statements about the prescription drug ads you have seen in newspapers and magazines. As I read each, please tell me whether you agree or disagree with the statement. (n=898)**

If I needed the drug, the information provided in the ad would help me discuss my treatment options with my doctor.

34%	Agree Strongly
41%	Agree Somewhat
13%	Disagree Somewhat
10%	Disagree Strongly
2%	Don't Know

I would never depend on the information in a prescription drug ad to help me talk with my physician about treatment.

24%	Agree Strongly
22%	Agree Somewhat
31%	Disagree Somewhat
21%	Disagree Strongly
2%	Don't Know

6. **In any of the ads for prescription drugs you have seen in newspapers and magazines, have you noticed any small-print information near or across from the advertisement itself? (n=898)**

62%	Yes (Continue)
32%	No (Skip to Q10)
6%	Don't Know (Skip to Q10)

7. Do you read the small-print information usually, sometimes, rarely, or never? (n=547)

34%	Usually
30%	Sometimes
18%	Rarely
18%	Never

8. Why do you (rarely/never) read the small-print information? (n=210)

33%	Print is too small to read
6%	Information is too technical for me to understand
8%	Information is for doctors or lawyers, not for consumers
36%	No interest in knowing more about the drug than what is in the main part of the ad
24%	Other

Note: Figures do not sum to 100% because multiple selections were permitted.

9. When you read it, is the small-print information useful? (n=445)

84%	Yes
13%	No
3%	Don't Know

10. Now I am going to read a brief list of the types of information that might be included in the advertisement itself. As I read each, please tell me if you think it is very important, somewhat important, not too important, or not at all important to include? (n=1310)

All of the possible risks and side effects. Is this very important, somewhat important, not too important, or not at all important information to include in an advertisement for prescription drugs?

75%	Very important
17%	Somewhat important
4%	Not too important
3%	Not at all important
1%	Don't know

The most common risks and side effects. Is this very important, somewhat important, not too important, or not at all important information to include in an advertisement for prescription drugs?

82%	Very important
12%	Somewhat important
2%	Not too important
2%	Not at all important
2%	Don't know

A description of the types of people who should not take the drug. Is this very important, somewhat important, not too important, or not at all important information to include in an advertisement for prescription drugs?

86%	Very important
8%	Somewhat important
1%	Not too important
3%	Not at all important
2%	Don't know

Risks and side effects that occur in rare cases. Is this very important, somewhat important, not too important, or not at all important information to include in an advertisement for prescription drugs?

64%	Very important
26%	Somewhat important
5%	Not too important
3%	Not at all important
2%	Don't know

11. Thinking about your own doctors, how often does your doctor talk to you about each of the following things when prescribing medication? (n=1310)

Risks and potential side effects of medications prescribed. Does your doctor talk to you about this usually, sometimes, rarely, or never?

54%	Usually
18%	Sometimes
12%	Rarely
9%	Never
5%	Do not have a doctor
2%	Don't Know

Other prescription products that may be appropriate for you. Does your doctor talk to you about this usually, sometimes, rarely, or never?

43%	Usually
23%	Sometimes
14%	Rarely
13%	Never
5%	Do not have a doctor
2%	Don't Know

Other nonprescription products that may be appropriate for you. Does your doctor talk to you about this usually, sometimes, rarely, or never?

35%	Usually
23%	Sometimes
16%	Rarely
19%	Never
5%	Do not have a doctor
2%	Don't Know

Free samples and other items the doctor may have received without charge from drug companies. Does your doctor talk to you about this usually, sometimes, rarely, or never?

32%	Usually
25%	Sometimes
12%	Rarely
24%	Never
5%	Do not have a doctor
2%	Don't Know

12. Have you ever asked your doctor about a prescription drug that he or she is not familiar with? (n=1310)

21%	Yes
77%	No
2%	Don't Know

13. Thinking about your own pharmacist, how often does your pharmacist talk to you about each of the following things? (n=1310)

Risks and potential side effects of medications prescribed. Does your pharmacist talk to you about this usually, sometimes, rarely, or never?

48%	Usually
17%	Sometimes
8%	Rarely
23%	Never
4%	Don't Know

Special offers available through drug company marketing programs. Does your pharmacist talk to you about this usually, sometimes, rarely, or never?

8%	Usually
12%	Sometimes
12%	Rarely
65%	Never
3%	Don't Know

14. Do you agree or disagree with this statement: "My pharmacist will provide information about an advertised prescription drug upon request."? (n=1310)

82%	Agree
12%	Disagree
6%	Don't Know

APPENDIX C

SUMMARY OF FOCUS GROUP RESULTS

Focus groups were conducted in the Fall of 1998 by Berrier and Associates, Inc. in Philadelphia and Baltimore. This summary is based upon a final report prepared for AARP by Berrier and Associates.

OBJECTIVES

Focus groups were conducted to gather preliminary information about the impact of DTC advertising on older consumers. The research questions related to 1) the impact of DTC advertising on consumer knowledge, 2) consumer assessments of the information provided by DTC advertising, and 3) the effects of DTC advertising on interactions between patients and physicians. Results of the focus groups were used in developing the national consumer survey conducted in December 1998. See Appendices A and B.

METHODOLOGY

Four focus groups were conducted on October 13 and 14, 1998. Participants included two groups of consumers age 55 to 64 and two groups age 65 and over. The total number of participants was 46. All participants were taking between one and four prescription drugs. All participants also were readers of magazines and newspapers containing DTC advertisements.

KEY FINDINGS

Sources of Information About Prescription Drugs. Participants identify multiple sources of information about prescription drugs, including physicians and pharmacists, printed and broadcast advertisements, and family and friends. Some participants said they browse the Internet for information on the products they are taking.

When asked about trustworthiness of information from health practitioners, some participants said they favor pharmacists as an information source. Several said that pharmacists are more knowledgeable than their physicians about prescription drugs because "it's their job." Other participants stressed that they trust their physicians more than pharmacists because the doctors know them personally and they are the ones who prescribe the medications.

Most participants expressed a high degree of satisfaction about the printed information that pharmacies may provide with prescription products. These sources of information were cited for their completeness and readability.

Participants were familiar with DTC advertising and most reported positive feelings about such advertisements. Some of the negative comments related to the presentation of information about side effects.

Perceptions About the Usefulness of DTC Advertisements. Most participants agreed that DTC advertisements relating to conditions they have are useful sources of information about those conditions. Some said that the advertisements help them understand the drugs they are taking or the conditions they have. Most agree that the ads provide substantial information about the drugs advertised. Participants believe that the information contained in DTC advertisements is reliable because the drug manufacturers are motivated to avoid lawsuits.

“Small-Print” Information. Most participants said that they generally do not read the “small-print” information frequently accompanying printed DTC advertisements because it is “too technical” and difficult to understand. Some said they do read this information in advertisements about products they are taking. Some participants expressed a belief that the “small-print” information is required by law; others believed that companies include this information in order to avoid lawsuits.

The Role of Physicians. Participants generally attached strong importance to the role of the physician as prescriber. Participants thought that physician involvement in prescribing medication adds an element of professional control in the drug marketing environment, and mitigates their concern about the accuracy and honesty of prescription drug advertisements. Several of the participants said they have had conversations with their physicians about an advertised product. Some said that they mention advertised drugs to their physicians, expecting the doctors to let them know if particular products are appropriate for them.

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