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Report to the Chairman, Subcommittee
on Oversight and Investigations,
Committee on Energy and Commerce,
House of Representatives

July 1991

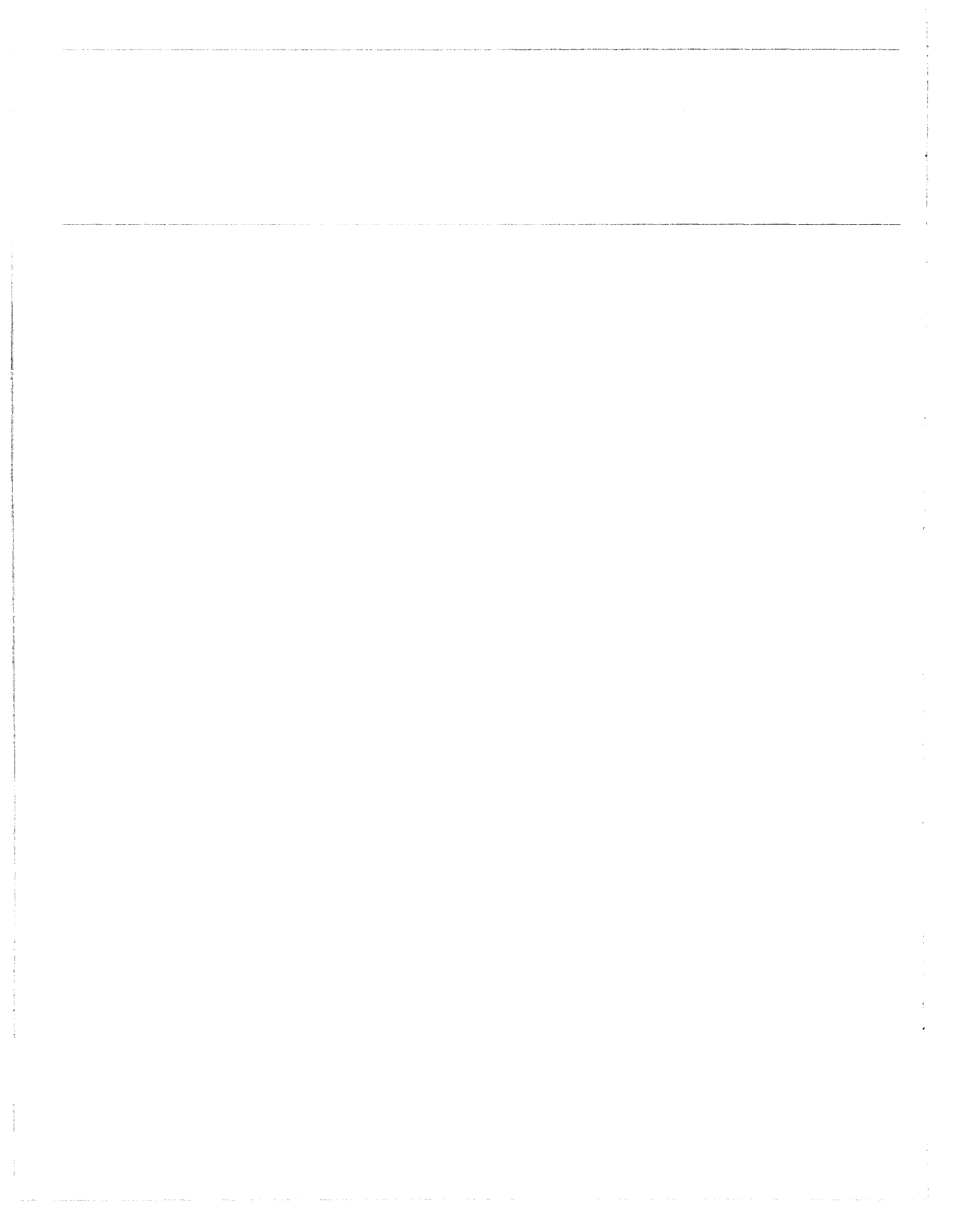
PRESCRIPTION DRUGS

Little Is Known About the Effects of Direct- to-Consumer Advertising



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**Program Evaluation and
Methodology Division**

B-243615

July 9, 1991

The Honorable John D. Dingell
Chairman, Subcommittee on Oversight
and Investigations
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

You asked us to undertake a comprehensive review and analysis of the information available on the effects of direct-to-consumer prescription drug advertising. This report responds to that request.

Until the early 1980s, drug companies and their advertising agencies seemed largely content to market their prescription drugs to physicians via medical journals and a vast network of office-to-office salespersons. Other marketing activities by drug manufacturers included conducting symposia—some with “honoraria” of up to \$1,000 for attendance—providing gifts, lavish vacations, and cash payments. Consumer advertising was generally viewed as costly and unnecessary because consumers were not seen as having an important voice in choosing what drugs were prescribed.

Since about 1984, however, concern over losing market share, especially to generic drugs, has led to increased and new forms of promotional activity directed at both physicians and consumers. Several companies have utilized various forms of direct-to-consumer advertising (DTCA) for their prescription drugs. These include institutional advertisements, public service announcements, reminder advertisements, comparative price information, and product-specific advertisements.¹

Recently, considerable controversy has arisen about the likely effects of DTCA. Opponents of direct-to-consumer prescription drug advertising argue that it can lead to increased health care costs, more confusion

¹Institutional advertisements refer to the company's name and position in the pharmaceutical industry, but do not mention their products by name; public service announcements describe health conditions about which consumers may want additional information and advice; reminder advertisements mention the product's name, but make no claims about its effectiveness; comparative price advertisements can only indicate that one named brand is the same as other brands, but costs less; and product-specific or product claim advertisements must include a brief summary from the package insert that lists risks and contraindications. The Food and Drug Administration regulates direct-to-consumer advertising and has prevented companies from making product-specific advertising that does not include such disclosure.

among consumers about medicines, and unhealthy pressure on the “doctor-knows-best” relationship between physician and patient. Further, they argue that advertising drugs by name will lead to increased prescriptions for the more costly brand-name drugs and undermine the prescriptions for the less expensive generic substitutes.

Proponents of direct-to-consumer prescription drug advertising argue that it will lead to lower drug prices for consumers by stimulating competition at the retail level. They also argue that advertising is a potent educational tool that can help consumers understand health issues. And even if consumers don’t understand completely, raising their awareness of potential health problems is, nonetheless, a major benefit. Additionally, these proponents point out that advertising, especially by television, can encourage people to participate actively, with their physicians, in making health care decisions.

Currently, the Food and Drug Administration (FDA) regulates direct-to-consumer prescription drug advertising based on its authority to regulate advertising to physicians.² However, the FDA has not yet developed a general framework for regulating DTCA. The failure to provide a regulatory framework based on direct advertising’s effects on consumers may lead to court challenges that could exempt DTCA from any FDA regulation and, thus, adversely affect consumers. To develop such a framework, the best available information about DTCA’s effects (benefits or detriments) and consumer and physician attitudes toward DTCA is needed.

Results in Brief

We found that available research does not provide an adequate basis for determining what the effects—or likely effects—of direct-to-consumer advertising may be. Methodologically rigorous and systematic studies have not been conducted in this area. Also, we found no credible studies that permit conclusions to be drawn about the extent to which consumers and physicians support or oppose DTCA, or about the potential for changing attitudes following increased exposure to direct advertising. Nonetheless, rigorous studies of the effects of DTCA and knowledge of both physicians’ and consumers’ views about it are necessary components of regulatory policy in this area.

²Code of Federal Regulations, part 202.

Objectives, Scope, and Methodology

Objectives

In response to your request, we reviewed and analyzed over 130 studies of direct-to-consumer prescription drug advertising. Specifically, your Subcommittee was interested in determining what is actually known about:

- the efficacy of direct-to-consumer advertising of prescription drugs with regard to its potential benefits or detriments and the confidence that can be placed in this knowledge based on the studies' methodologies and execution;
- the attitudes of consumers and physicians toward direct-to-consumer advertising of prescription drugs and the confidence that can be placed in this knowledge based on the studies' methodologies and execution; and
- the research gaps that exist in what is known about direct-to-consumer prescription drug advertising.

Scope

Because the staff of your Subcommittee had prepared a report in September 1984 that included available research until that date, we focused primarily on research conducted after 1984.³ However, we also reviewed 11 earlier major studies. We conducted our study between July and December 1990 in accordance with generally accepted government auditing standards.

Methodology

We used evaluation synthesis—a technique for systematically identifying, assessing, and combining information from different studies—to determine (1) the potential benefits or detriments of DTCA, (2) the attitudes of consumers and physicians toward DTCA, and (3) the confidence that can be placed in the studies' findings.⁴ Performing the evaluation synthesis consisted of the following steps:

³U.S. Congress, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, Prescription Drug Advertising to Consumers (Washington, D.C.: U.S. Government Printing Office, 1984).

⁴See The Evaluation Synthesis, Methods Paper I (Washington, D.C.: U.S. General Accounting Office, Apr. 1983).

- identifying relevant studies through computerized bibliographic searches and expert consultation;
- conducting a survey of stakeholders to verify the computerized bibliographic searches and to obtain proprietary and unpublished studies;
- reviewing studies to identify the potential benefits or detriments of DTCA and to determine how proponents' and opponents' attitudes toward direct-to-consumer advertising affected the citation of benefits or detriments;
- rating the studies' limitations with regard to research designs, data, and methods and classifying their findings by this overall rating; and
- synthesizing the information from the strongest studies to answer the questions.⁵

To determine what gaps exist in the available research, we examined the information we had developed from the evaluation synthesis and compared it to the information that would be needed to develop a regulatory framework.

Principal Findings

Effects of DTCA

Many benefits and detriments have been cited as possible effects of DTCA. These include consumer education, price reduction, and patient involvement in health care (cited as benefits) and "physician shopping," increased costs, and inadequate risk information (cited as detriments). However, few studies (N=4) have been conducted to determine if these possible effects occur. Moreover, the findings from those few that have examined the possible effects of DTCA have not been shown to apply to all types of advertising or all consumers.

Attitudes About Direct-To-Consumer Advertising

Studies of physicians' and consumers' opinions about DTCA have been only a little more numerous than studies of likely effects. Further, those attitude surveys that have been conducted (N=17) are limited in their usefulness for two reasons. First, opinions about DTCA depend in part upon differences in the type of advertising, media, and the content of the advertising, but the studies did not systematically address these issues. Second, the results of those studies may not adequately represent the opinions of most consumers or physicians toward DTCA because of

⁵Our ratings of the studies were validated by expert consultants (see appendix V).

flawed sampling design. As a result of their limitations, those studies do not measure either the extent to which opinions about DTCA are positive or negative or the short-term changes in those opinions. Some general information about consumers' and physicians' opinions, however, can be identified from these studies.

Physician Attitudes

The studies indicate that, generally, physicians oppose direct-to-consumer advertising because they believe it will undermine the physician-patient relationship. The extent of their opposition, however, depends on the type of DTCA, the media, and the content. For example, the findings of one study indicate that physicians are not opposed to DTCA that describes the symptoms of a disease, advises consumers to seek help from a physician, does not mention a product name, and does not make any product claims.

Consumer Attitudes

Most consumers are not aware of DTCA, and thus, their opinions about it are based on other experiences, such as advertisements for other products. In general, consumers support DTCA because they believe it will provide them with information and is an educational tool, like advertising for other products. This positive attitude, however, because it is not based on consumers' direct experience, could be quite volatile.

For most types of DTCA (for example, institutional advertisements and public service announcements), the controversy has calmed somewhat since 1986. However, this is not true for product-specific advertising. That is, proponents and opponents seem to have differentiated among the types of DTCA and have become less extreme in their views, except where product-specific advertising is concerned.

Gaps in Available Information

A number of knowledge gaps exist in this area as a result of the uncertain quality of the research. For example, likely effects (either benefits or detriments) have not been established. Information is lacking about whether different types of direct-to-consumer advertising, communicated by different media and containing different content, have different consequences. Other gaps, such as the effect of widespread advertising on drug prices, may not be possible to study before the actual implementation of widespread DTCA.

Summary

The available research on DTCA leaves too many important questions unanswered; thus, our review and analysis does not provide support for opponents or for proponents of DTCA. Stronger quality research could,

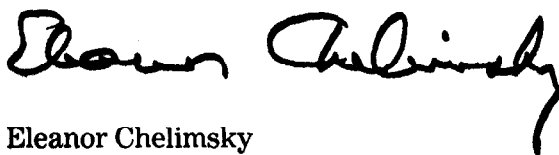
however, have determined what some of the DTCA effects are likely to be and certainly could have identified with more precision and confidence—using conventional survey procedures—the opinions of DTCA's principal stakeholders.

Agency Comments

As you requested, we did not ask for formal comment from federal agencies on this report. However, the views of responsible agency officials were sought during the course of our work and have been incorporated where appropriate. As we arranged with your office, we plan no further distribution of this report until 30 days from its date of issue, unless you publicly announce its contents earlier. At that time, we will send copies to officials of the Food and Drug Administration and Department of Health and Human Services. We will also make copies available to interested organizations, as appropriate, and to others upon request.

If you have any questions or would like additional information, please call me at (202) 275-1854 or Kwai-Cheung Chan, Director for Program Evaluation in Physical System Areas, at (202) 275-3092. Other major contributors to this report are listed in appendix VI.

Sincerely yours,



Eleanor Chelimsky
Assistant Comptroller General

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Abbreviations

AMA	American Medical Association
DTCA	Direct-To-consumer advertising for prescription drugs
FDA	Food and Drug Administration

Consequences of Direct-To-Consumer Prescription Drug Advertising

As first steps in the evaluation synthesis, we identified studies that directly tested whether the possible effects of DTCA actually occur and rated them on four criteria that we had developed to ensure the accuracy of the studies' findings. Then, we synthesized the information from the studies that met our criteria.

Identifying Relevant Studies

We conducted a computerized bibliographic search for any articles containing key words such as prescription, drugs, risks, and advertising. From an initial listing of over 240 studies, we identified about 130 that were relevant to direct-to-consumer advertising (DTCA) of prescription drugs and published after 1984. We then conducted computerized citation searches for investigations, investigators, and other key words that were referenced in the relevant studies we had already obtained. These computerized searches continued until we failed to identify any other studies.

Next, we reviewed the Subcommittee staff's 1984 report to identify the prescription drug manufacturers and related groups (advertising agencies, television networks, and market research organizations), trade organizations, consumer advocacy groups, and government agencies who were stakeholders.¹ We contacted these stakeholder organizations and the authors of the studies we had identified and asked them to (1) review our draft list of studies for omissions, (2) identify any proprietary studies of which they were aware, and (3) inform us of other individuals or organizations who might be knowledgeable about direct-to-consumer prescription drug advertising. Finally, we reviewed these relevant studies to identify those that had directly tested the effects of DTCA (that is, empirical studies).

DTCA's Likely Effects

To ensure the accuracy of the four studies included in the synthesis that addressed questions regarding DTCA's likely effects, we rated them on the criteria that follow:

- The process of measuring the impact must not contribute to the impact of DTCA;
- Participants in the study must be aware of DTCA and any of its important features or distinctions;

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Woodruff, David. "For Rogaine, No Miracle Cure—Yet." Business Week, June 4, 1990, p. 100.

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**Appendix I
Consequences of Direct-To-Consumer
Prescription Drug Advertising**

- Participants in the study must not have been selected in such a way as to increase the likelihood that any particular effect of DTCA would be found; and
- Those conducting the study must not “signal” the study participants that one response is more appropriate than another.

The first criterion addresses the problem of measuring a study participant’s recollection of promotional messages in different advertising formats with a true-or-false test. Such tests may allow participants to guess the correct answer and result in the same rate of recollection regardless of advertising format.

The second criterion focuses on ensuring that the participants’ responses are not due to their being unaware of DTCA. The third criterion is to ensure that any apparent effect of DTCA is not due to the selection of the participants. And the final criterion addresses the issue of how those conducting the study could influence the participants’ responses.

For each criterion met, a study was scored “1”; its total rating was expressed as a percentage of the four criteria. We included in the synthesis only studies that were rated at least 50 percent.² Table I.1 shows the studies’ ratings.

²Interrater reliability was greater than 0.80.

**Appendix I
Consequences of Direct-To-Consumer
Prescription Drug Advertising**

**Table I.1: Ratings of the Empirical
Studies of Possible Consequences of
DTCA^a**

Criterion	FDA84^b	P&D87^c	P&D88^d	T&S87^e
Dependent variable independent of treatment	1	1	1	1
Effective manipulation of independent variables	1	1	1	0
Random assignment	1	0	0	1
Experimenters blind to condition	0	0	0	0
Rating	75%	50%	50%	50%

^aEach rating is the average of the consultants' average rating and GAO's rating.

^bMorris, Louis A., Prescription Drug Advertising to Consumers: Brief Summary Findings for Television and Magazine Advertisements (Rockville, Md.: National Center for Drugs and Biologics, 1984).

^cPerri, Matthew, and W. Michael Dickson, "Direct to consumer prescription drug advertising: consumer attitudes and physician reaction," Journal of Pharmaceutical Marketing & Management 2(1), 1987, pp. 3-23.

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^eTucker, G. K., and M. Smith, "Direct-to-Consumer Advertising: Effects of Different Formats of Warning Information Disclosure on Cognitive Reactions of Adults," Journal of Pharmaceutical Marketing and Management 2(1), Fall 1987, pp. 27-41.

Synthesizing Studies That Tested Possible Consequences

Most of the possible consequences of DTCA have not been empirically tested. Those that have, have not been tested in all the ways in which those consequences could be manifested. For example, "pressure on the physician" could be manifested as shopping for a physician who will prescribe a drug or as an attempt to persuade one's physician to prescribe a particular drug. In the only study to empirically test this possible consequence, pressure was used to mean "verbal attempts to persuade."

The following are possible benefits of DTCA gleaned from the studies that have considered its possible consequences:

- Educational value,
- Improvement in the physician-patient relationship,
- Increase in patient compliance,
- Increase in the regularity of physician visits,
- Lower prices,
- Support for advertisers' first amendment rights,
- Support for consumers' right to information, and
- Other.

The following are possible detriments:

- Damage to the physician-patient relationship;³
- Inability of consumers to understand technical information,³
- Inadequate risk information,
- Increase in prices,
- Increase in liability actions,
- Loss of drug industry's liability protection,³
- Misleading nature of promotional materials,
- Overmedication and drug abuse,
- Pressure by patients on physicians to prescribe,³
- Waste of physicians' time, and
- Other.

The four studies that tested a few of the possible consequences of DTCA were limited by low generalizability.⁴ That is, even if one could be confident that any differences found between experimental conditions were not artifactual, those differences may not be found to any significant extent in the population at large.

Will Patients "Pressure" Their Physicians?

Only one study, Perri and Dickson (P&D87), addressed the question of whether patients will "pressure" their physicians as a result of DTCA or undermine the physician-patient relationship.⁵ This study was conducted in Georgia with a nonrandom sample of 200 patients. These patients were selected because their four physicians agreed to participate in the study and they were scheduled for periodic checkups or physical exams. Ten and three days before their scheduled visits, they were mailed print advertising for hypothetical drugs that indicated the ads contained "important health information for you." At the completion of the visit, the physicians gave their patients questionnaires, which they completed at home and returned.

Of the 200 patients, 155 were observed by the study's physicians, and 61 percent (N=94) provided usable data. Of these respondents, 70 percent (N=66) indicated that they had seen the ads, and 11 percent of these (N=7) could remember the name of the product. Eight and one-half percent of the 155 patients (N=13) inquired about the drugs. The authors estimate that between 4 and 13 percent of consumers are likely

³Empirically tested.

⁴Several studies, using data from FDA's 1984 study (Morris), were published separately in various journals.

⁵The results of this study were published in 1987 and 1988 in two different journals.

to inquire about drugs they learned about in DTCA. The four physicians indicated that they did not feel pressured by their patients.

Can Risk Information Be Communicated in Promotional Messages?

Two experimental studies addressed this question. In the first, conducted by the FDA in 1984, the same experimental procedures were repeated in four cities.⁶ However, the study's procedures did not ensure that the participants were representative of their cities' populations or that similar participants were studied in the four cities. Consequently, the findings are not generalizable to an entire city nor are differences in the findings attributable to citywide differences.

The FDA study involved showing consumers either television or magazine advertisements for two fictitious drugs, one to treat hypertension and one to treat arthritis. Ads were embedded in either a health-oriented TV program or a magazine containing health-related studies. Variations of the ads had been designed to reflect differing amounts of risk information (two or four items), emphasis (integrated throughout the ad, clustered at the end, and accompanied with a voice-over), and specificity of risk information (specific or general). Two control conditions, one containing no risk information and one involving full disclosure of the brief summary information, were also included.

Immediately after viewing the advertisements, the participants were asked to recall the main and additional points of the ads, respond to a true-and-false test of knowledge of the ad content, and fill out attitude questionnaires. The main point recalled was generally a benefit of the drug, though risk information was often mentioned as an additional point. The amount of risk information recalled increased with increases in the amount of that information presented. The ratio of benefits-to-risks recalled decreased as more risk information was included for both TV and print ads. The ratio was more balanced when the risk information had been presented in a specific rather than a general form. The ratio was higher for print ads than for TV ads. There was no consistent effect of emphasis.

In the magazine format, the full disclosure condition resulted in lower knowledge scores than did the other risk conditions for one drug. For the other drug, the ad with no risk information resulted in scores that were not significantly different from the full-disclosure ad. In the TV format, as the number of risks presented increased, the number recalled

⁶The results from this study were also published separately in seven journal articles.

increased. An announcer and print emphasis resulted in higher recall than the print alone; dispersed risk information yielded higher recall than emphasizing risks by grouping them.

The findings from this study were complex and indicated that a number of factors can affect how consumers react to risk information. Generally, however, this study demonstrated that although risk information can “compete” with the promotional message, if it is specific, it can be communicated in advertising.

Another study (Tucker and Smith, 1987) involved showing consumers, selected at random at a shopping mall, one of four advertising formats for a fictitious drug. The authors concluded that advertisements with any amount of risk information were appealing to consumers. However, consumers were more reassured when ads contained no risk information or only general risk information. This trade-off suggests that although consumers recognize the importance of risk information, they still prefer not having to weigh competing messages. The study did not consider the behavioral outcome of competing messages relative to consistent messages.

Do Consumers Understand DTCA?

Only the FDA study considered this question. It found on a recall test that between 28 and 36 percent of advertising points could not be recalled. In a true-and-false test, this study found that between 5 and 20 percent of the advertising messages were misunderstood. In a journal article that also presented these results, the authors indicated that their results were consistent with those found in similar studies.

Attitudes Toward Consumer Advertising

We conducted evaluation syntheses of studies of physicians' and consumers' attitudes toward direct-to-consumer prescription drug advertising to determine (1) what is known about them and (2) the extent to which confidence could be placed in the accuracy of study findings. From the previously identified relevant studies, we selected for more intensive review those that measured physicians' or consumers' attitudes toward DTCA. We then assessed their limitations (with regard to research designs, data, and methods) and synthesized the information from the strongest studies.

In addition, we reviewed nonempirical studies to identify possible consequences of DTCA, either benefits or detriments, and to determine how their authors' attitudes toward DTCA affected their citation of benefits or detriments. Our analysis included the computation and analysis of the relative frequencies with which benefits and detriments were cited in the studies.

Rating the Attitude Studies

To determine the extent to which confidence could be placed in the accuracy of a study's findings, we developed criteria for rating the attitude studies. Our criteria were as follows:

- post-1983 data must be used;
- nationally representative samples must be drawn;
- random sampling designs must be used;
- questions must be appropriately worded; and
- response rates must be at least 75 percent.

We established the first criterion, post-1983 data, to ensure that the studies reflected recent attitudes toward direct-to-consumer prescription drug advertising. To avoid including studies that did not represent all segments of the nation's consumers and physicians, we incorporated the second criterion. Random sampling designs, including a clearly specified universe from which the respondents are selected, must be used to ensure that information collected from the sample generalizes to the entire universe. The questions asked in the surveys should be clear, unambiguous, and unbiased so that the responses can be meaningfully interpreted.¹

¹Other criteria, such as conceptualization, instrument design, and data analysis were not applied because we wanted the least subjective and the most appropriate and unambiguous criteria.

**Appendix II
Attitudes Toward Consumer Advertising**

We scored a study "1" for each criterion it met and expressed its total score as a percentage of the five criteria.² We included in the syntheses of physicians' and consumers' attitudes all the empirical studies that we rated as meeting at least 60 percent of the criteria.³ Table II.1 shows the studies' ratings.

Table II.1: Ratings of Attitude Studies on the Selection Criteria

Criteria	Physicians										Consumers						
	AMA84 ^a	AMA88 ^b	CU88 ^c	A ^d	B ^d	C ^d	D ^d	E ^d	F ^d	G ^d	AMA84 ^a	AMA88 ^b	PN ^e	H ^d	I ^d	J ^d	K ^d
Post-1983 data	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Nationally representative	1	1	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0
Random sampling	1	1	1	0	0	0	0	0	0	0	1	1	0	0	0	0	0
Appropriate wording	1	1	1	1	1	1	0	0	1	1	1	1	1	1	0	0	0
Response rate, 75%	0	0	0	1	1	1	0	0	1	1	1	1	1	1	0	0	0
Rating ^g	80%	80%	60%	60%	60%	60%	20%	20%	60%	80%	100%	100%	60%	60%	20%	20%	20%

^aAmerican Medical Association, Physician and Public Attitudes on Health Care Issues, 1984.

^bAmerican Medical Association, Physician and Public Attitudes on Health Care Issues, 1989.

^cCutrer, Christine, Direct to consumer advertising of prescription drugs: Texas physician's perceptions, Master's thesis (Austin: Univ. of Texas, Dec. 1989).

^dProprietary marketing research study.

^ePerri, Matthew, and Arthur A. Nelson, "An Exploratory Analysis of Consumer Recognition of Direct to Consumer Prescription Drug Advertising," Journal of Health Care Marketing 7(1), Mar. 1987, pp. 9-17.

^fRatings are a consensus of three opinions.

Synthesizing the Attitude Studies

Physician Attitudes

There were 10 empirical studies of physicians' attitudes toward DTCA, two of which were rated below 60 percent and none above 80 percent on the selection criteria. All of the studies are limited in both scope and methodology. First, half of the studies are either not nationally representative (Cutrer, A, B, C, and F) or do not provide enough information to determine if they are (D and E). Second, random sampling was either not used in five studies (A, B, C, F, and G), or the universe sampled was

²A dichotomous rating was used, instead of a continuous one, so that judgments about the extent to which a study met a particular criterion would not have to be made.

³Interrater reliability was greater than 0.80.

not identified (D and E). Third, there is a strong possibility of bias in five studies because of low response rates (AMA84, AMA88, Cutrer, D, and E). Fourth, as a result of random sampling not being used and the possibility of bias due to low response rates, the generalizability of those studies is limited. Fifth, the ratings indicated that the wording of questions was not appropriate in two of the studies (D and E).

Besides these studies' limitations, reflected by their ratings on the selection criteria, none of them considered the different types of DTCA and different media that can be used to communicate it. Several studies, however, found that attitudes toward DTCA depended upon the type and the media.

Despite these limitations, several conclusions can be drawn from these studies about physician attitudes toward DTCA. This is because the studies' limitations pertain to their weak sampling designs and do not permit their findings to be extended to all physicians. However, because the same results were found in several studies that used different methods and were conducted at different times and locations, they may be applied, guardedly (and nonscientifically), beyond the samples studied.

Physician Opposition to DTCA

First, we found eight studies that, when synthesized, suggest that physicians generally oppose DTCA, although the extent of their opposition cannot be determined from these studies. The AMA studies, for example, indicate that for TV advertising, between 49 and 81 percent oppose DTCA.⁴ Similarly, the Cutrer study, limited to Texas, found that 64 percent thought that product-specific advertisements were bad and 56 percent thought they were harmful. Second, the extent of opposition varies with the type of advertising, the media, and the content. For example, Cutrer found that 60 percent of physicians thought that drug availability advertisements were appropriate. Third, the studies indicated that physicians who oppose DTCA believe that the physician-patient relationship will be undermined. Fourth, physician attitudes about DTCA vary with their specialty. The Cutrer study, for example, found that response rates differed by physician specialty, and the 1988 AMA study found that federal physicians and radiologists were less opposed to DTCA (71 and 62 percent, respectively).

⁴A response rate of 60 percent yielded 1,000 respondents, indicating that a sample of about 1,700 had been selected; about 810 were opposed, about 60 "did not know." If the maximum number of nonrespondents (about 800) supported TV advertising, then no more than 49 percent of the original sample could have been opposed.

**Studies Are Inconclusive on
Several Questions**

The studies are inconclusive with regard to several questions. For example, between 1984 and 1988, the AMA study did not find any significant change in physician attitudes. However, none of the other studies included in the synthesis permit the possibility of measuring changes in physician attitudes. The AMA's finding is not supported by other studies and, thus, whether change occurred must be considered inconclusive. In addition, the studies are inconclusive about the effect of practice type, age, and region of the country on physician attitudes toward DTCA.

Consumer Attitudes

There were seven empirical studies of consumers' attitudes toward DTCA, and three of these were rated as meeting only 20 percent of the criteria for inclusion in the synthesis (I, J, K). Similar to the physician studies, they are limited in both scope and methodology. First, only two studies (AMA84 and AMA88) were nationally representative, used random sampling, and obtained a response rate of at least 75 percent. These studies, however, asked only one question about supporting or opposing prescription drug advertising on TV (84 percent opposed in 1984 and 81 percent opposed in 1988). Despite these limitations, some credible information was found in the four studies included in the synthesis (AMA84, AMA88, PN, and H). In addition to their ratings on the selection criteria, none of these studies considered all types of DTCA communicated by different media.

**Consumer Awareness of Direct-
To-Consumer Advertising**

The studies indicate that consumer awareness of DTCA is quite low. Perri and Nelson, for example, found in 1987, that only 12 percent of the respondents in their study (N=17) reported recognizing an advertisement that had appeared in the Reader's Digest. One proprietary marketing study (Study H) also found that only a small percentage of consumers were aware of DTCA.

Consumer Support for DTCA

The nationally generalizable AMA study found that 63 percent of consumers oppose the television advertising of prescriptions drugs; however, the other studies included in the synthesis indicate that consumers do support nonspecific types of DTCA. In view of the finding that physicians have different attitudes toward different types of DTCA, it may be that the AMA study pertains only to TV advertising. These studies indicate that consumers believe DTCA will provide them with information. However, consumer attitudes toward DTCA are not based on direct experience and, for most consumers, may turn out to be quite volatile once they have experienced it.

Other Aspects of Consumer Attitudes

The studies do not address whether any changes might be occurring in consumer attitudes toward DTCA. Also, the studies are inconclusive with respect to how attitudes might vary among consumers with different demographic characteristics.

Identifying Possible Consequences

We reviewed 108 nonempirical studies to identify possible consequences of DTCA (benefits and detriments) and to determine how their authors' positions toward DTCA (opposed, neutral, supportive), the date and type of publications (general, medical, trade), and the type of advertising discussed (product-specific or DTCA in general) affected the relative frequencies with which benefits and detriments were cited in the various types of studies between 1984 and 1990.

Possible Benefits and Detriments

We identified 39 different possible consequences of DTCA, which had been suggested in 108 nonempirical studies. Of these studies, 66 percent neither supported nor opposed DTCA, 17 percent supported DTCA, and 18 percent opposed it. There were 268 citations with 19 consequences cited more than once. (Consequences that were cited once were grouped into "Other-Benefit" or "Other-Detriment" categories.) Thirty-nine percent of the 268 consequences cited in these studies were benefits, and 61 percent were detriments (see table II.2). Of the 54 consequences cited in studies supporting DTCA, 70 percent were benefits and 30 percent were detriments. Of the 67 consequences cited in studies opposed to DTCA, 16 percent were benefits and 84 percent were detriments. In the neutral studies, of 149 consequences, 38 percent were benefits and 62 percent were detriments.

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Table II.2: Benefits and Detriments of DTCA Cited in Nonempirical Articles

Possible consequence	Oppose	Neutral	Support	Total
Benefits	16%	37%	70%	39%
Educational value	55	40	21	35
Improvement in the physician-patient relationship	9	7	18	12
Increase in patient compliance	0	5	11	7
Increase in the regularity of physician visits	0	2	3	2
Lower prices	27	13	13	14
Support for advertisers' first amendment rights	0	11	8	9
Support for consumers' right to information	0	18	18	16
Other ^a	9	4	8	6
Total number of benefits	11	55	38	104
Detriments	84%	63%	30%	61%
Damage to the physician/patient relationship	14	11	25	13
Inability of consumers to understand technical information	13	14	7	13
Inadequate risk information	14	7	0	9
Increase in prices	14	17	19	16
Increase liability actions	4	1	0	2
Loss of drug industry's liability protection	2	1	6	2
Misleading nature of promotional materials	16	19	13	18
Overmedication and drug abuse	13	13	13	13
Pressure by patients on physicians to prescribe	4	4	0	4
Waste of physicians' time	0	2	0	1
Other ^a	7	10	19	10
Total number of detriments	56	92	16	164
Total number of possible consequences	67	147	54	268

^aIncludes those possible consequences that were cited only once.

Patterns of Benefit and Detriment Citation

Unsurprisingly, more benefits than detriments were cited in studies supporting DTCA, and more detriments than benefits were cited in studies opposing DTCA (see table II.3). We compared studies written through 1985 with those written after 1985. The same relationship was found in those written through 1985 for both product-specific DTCA and DTCA in general. However, in studies written after 1985, this relationship—more

Appendix II
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benefits cited in studies favoring DTCA and more detriments cited in studies opposing DTCA—was greatly diminished for DTCA in general, but remained strong for product-specific DTCA. Authors presented either the benefits or the detriments of product-specific DTCA. This change indicates that after 1985, authors were less extreme in their discussions of DTCA, with the exception of product-specific DTCA.

Table II.3: Possible Consequences of DTCA by Author's Position and Date of Publication

Possible consequence	Through 1985			General		
	Product-specific			Oppose	Neutral	Support
Benefit	8%	39%	100%	25%	34%	87%
Detriment	92	61	0	75	66	13
Total number of consequences	12	28	5	4	50	15

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After 1985								
Product-specific			General			Total		
Oppose	Neutral	Support	Oppose	Neutral	Support	Oppose	Neutral	Support
15%	37%	71%	22%	42%	56%	16%	37%	70%
86	63	29	78	58	44	84	63	30
33	38	7	18	31	27	67	147	54

As table II.4 shows, slightly less than half (48 percent) of 104 benefits were cited in trade publications, while about 19 percent were cited in general publications and 33 percent were cited in medical publications. Of 164 detriments, 18 percent were cited in general publications, with the remainder about evenly split between medical and trade publications. There was, however, no statistically significant association between the type of publication and the citation of benefits or detriments.

Table II.4: DTCA Benefit and Detriment Citations by Type of Publication

Type of publication	Citation		Total
	Benefit	Detriment	
General ^a	19%	18%	19%
Medical ^b	33	40	37
Trade ^c	48	41	44
Total number	104	164	268

^aDirected toward the general public through publications such as news magazines or newspapers.

^bDirected toward physicians or pharmacists and concerned with the practice of medicine or pharmacy.

^cDirected toward a business or legal audience and concerned with marketing, production, and the legal aspects of the pharmaceutical industry.

Gaps in the Current Knowledge About Direct-To-Consumer Advertising

Gaps in the current knowledge about the effects—or likely effects—of direct-to-consumer prescription drug advertising occur because few studies have been conducted and there are technical deficiencies in those that have been conducted. No credible studies of the extent to which physicians and consumers support or oppose DTCA or about the potential for changing attitudes following increased exposure to consumer advertising are available. Technically adequate studies of effects and knowledge of both physicians' and consumers' views are important components of a regulatory policy for consumer advertising. Finally, gaps exist because it may not be possible to conduct the research that would be needed to fill them unless widespread advertising actually occurs.

Few Available Studies

There are few available studies of either the effects of DTCA or physicians' and consumers' attitudes toward it. Few studies are available that test whether the possible consequences of DTCA actually occur. Thus, only a small number (N=4) of the possible consequences of DTCA have been tested. General information is known about physicians' and consumers' attitudes, but how they differ among consumers and physicians with different demographic or professional characteristics is not known.

Technical Inadequacies of Available Studies

Gaps in the current knowledge about direct-to-consumer advertising also exist because the empirical studies that have been conducted are technically inadequate. Both the studies testing the effects of consumer advertising and those of physicians' and consumers' attitudes were limited because they may not represent all types of advertising or all consumers and physicians. Only 5 of the 17 attitude studies could be rated as having met the criterion for national representativeness.

Barriers to Developing Information

Barriers to developing information about consumer advertising exist for two reasons. First, some issues, such as widespread advertising's long-term impact on consumer health, may not be possible to determine prospectively because of the large number of factors that affect health and the changing circumstances of health care. Second, other issues, such as the effect of widespread advertising's impact on drug prices, may not be possible to determine unless widespread advertising actually occurs.¹

¹Determining advertising's effects on the physician-patient relationship, and some of its other impacts, would require the collection of baseline data before such advertising becomes widespread and would also require time before any effects could be reasonably expected to develop and be measured.

Appendix III
Gaps in the Current Knowledge About Direct-
To-Consumer Advertising

However, there are issues, such as how best to communicate technical information in DTCA, that could be informed by competent research.

List of Studies

Anonymous nonempirical and proprietary empirical studies are not listed. An asterisk indicates an empirical study.

American Medical Association. Physician and Public Attitudes on Health Care Issues. Chicago: 1989.

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Colford, Steven W. "FDA Shows New Taste for Food Health Claims." Advertising Age 56(95), 1985 p. 3.

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