

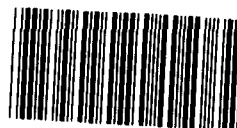
GAO

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

July 1991

PRESCRIPTION DRUGS

Selected Direct-to- Consumer Advertising Studies Have Methodological Flaws



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Program Evaluation and
Methodology Division

B-243615

July 22, 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 conduct a technical review of five studies (four reports) conducted by Scott-Levin Associates, a marketing research firm of Newtown, Pennsylvania.¹ The purpose of this review was to determine whether the methodology—with regard to sampling design, data collection, and analysis—used in these studies was sufficient to ensure the accuracy and generalizability of their claims that support for direct-to-consumer prescription drug advertising was increasing among both physicians and consumers. This report responds to that request.

Three out of five times in which a patient visits a doctor's office, the physician prescribes some form of drug therapy. As a result, nearly 700 million prescriptions are filled each year at a cost of almost \$42 billion. Consumers pay about 59 percent of these costs out-of-pocket without any form of third-party reimbursement.²

Pharmaceutical companies have traditionally ensured that physicians prescribe their products through advertising, marketing, and promotional activities directed at physicians. These activities include conducting symposia—some with “honoraria” of up to \$1,000 for attendance—and providing free gifts, lavish vacations, and cash payments. Some pharmaceutical companies, however, have begun targeting advertising for their products directly to consumers, as a response to increased competition in the pharmaceutical industry, especially from generic drugs. Protecting market share through direct-to-consumer advertising has been attempted despite what has been widely perceived as physicians' and consumers' attitudes against such advertising.

¹Direct Advertising to the Consumer: A Baseline Reading (Newtown, Pa.: Scott-Levin Associates, October 1986); Direct Advertising to the Consumer (Newtown, Pa.: Scott-Levin Associates, December 1987); Physician Response to Recent Direct-to-Consumer Campaigns (Newtown, Pa.: Scott-Levin Associates, February 1988); Direct Advertising to the Consumer: Consumer and Physician Reactions, 1989 Update (Newtown, Pa.: Scott-Levin Associates, December 1989).

²Neither Medicare nor medigap supplemental insurance policies pay for the cost of drugs outside hospitals.

Moreover, recent studies have made substantial claims to the effect that physicians' and consumers' opinions have shifted in favor of direct-to-consumer advertising. Scott-Levin Associates, a market research firm, reported in a January 22, 1990, press release " 'dramatic effects that foreshadow continued growth in the practice of advertising to consumer audiences' " and "continuing growth in support for the new advertising, by both physicians and consumers." This, in Scott-Levin's opinion, is "destined to become an increasingly important part of the pharmaceutical industry's marketing mix." (See appendix I.)

In view of the potential effect of such claims for increasing the amount of direct-to-consumer advertising, the House Subcommittee on Oversight and Investigations asked us—after the subcommittee had subpoenaed the documents from Scott-Levin—to conduct an evaluation of the adequacy of Scott-Levin's research as the basis for these claims.³

Results in Brief

We found that the Scott-Levin studies do not permit the valid or generalizable measurement of either physicians' or consumers' opinions about direct-to-consumer advertising. Further, the studies' data do not support conclusions about change (that is, whether support is growing or not). We also found that the studies' analytical interpretations of the responses are, in many cases, not consistent with conventional analyses of data used in opinion research.

Scope and Methodology

Our technical review of the studies included the following:

- an assessment of the sampling design, data collection instruments, and analysis;
- interviews with representatives of Scott-Levin to ensure our understanding of the procedures it used in conducting its studies; and
- an evaluation by experts we selected to determine whether these studies were within currently accepted standards for ensuring the validity and generalizability of opinion research (see appendix II).

³In addition, the subcommittee asked us to conduct a comprehensive review of all available literature and research to determine what is actually known regarding consumers' and physicians' opinions about direct-to-consumer advertising and what is known about its effects. See U.S. General Accounting Office, Prescription Drugs: Little Is Known About the Effects of Direct-to-Consumer Advertising, GAO/PEMD-91-19 (Washington, D.C.: July 1991). The subcommittee also asked us to assess the degree of confidence that can be placed in the various studies and their findings.

Because our focus was on the validity of the findings, we considered whether the studies were consistent with accepted standards for conducting opinion studies and did not consider whether (1) the studies were within accepted standards for conducting market research or whether (2) any market research requirements or obligations might have affected the manner in which the studies were conducted. We conducted this review between October 1990 and January 1991 in accordance with generally accepted government auditing standards, although we did not independently verify the accuracy of the data reported.

Principal Findings

Technical Review: Issues of Generalizability and Validity

When a portion (sample) of some larger group (universe) has been appropriately selected, it is possible to determine the characteristics of the universe by measuring those same characteristics in the sample. The manner in which the sample is selected (that is, the sampling design) ensures that the sample accurately represents the universe. Thus, the criteria typically used to evaluate a sample design are given in the following questions:

- Does the design allow the results of sample measurements to be extended or generalized to the universe?
- Will the likely response rates permit the measurement of what is intended to be measured?

Scott-Levin's Physician Survey Study Design

Using the same study design, Scott-Levin Associates conducted two surveys of physicians' opinions toward direct-to-consumer advertising in 1988 and 1989. The first step in the physicians' study design was to randomly select a sample of physicians from the universe of the American Medical Association's (AMA's) Physician's List.⁴ In 1988, 6,250 physicians were selected, and in 1989, 14,500 physicians were selected. The selected physicians then received mailed questionnaires and returned 8.4 percent in 1988 and 11.0 percent in 1989. Finally, the data from these samples were analyzed and interpreted, but no adjustments were made to compensate for those who did not respond to the questionnaires.

⁴AMA authorizes 11 addressing companies to maintain its Master List of 380,000 physicians and medical students for mailing purposes. Scott-Levin contracted with one of these companies to randomly select the physicians and mail them questionnaires that Scott-Levin had developed.

GAO's Analysis of the Physicians' Surveys

Generalizability

The findings from the physicians' surveys cannot be generalized to the universe of physicians in the United States for the following reasons:

- the percentage of physicians in the United States who were included in AMA's Master List is not known;
- the samples were limited, by design, to physicians with an office practice; and
- no adjustments were made to ensure that, in the event of low response rates, the sample would adequately represent physicians who were included on AMA's Master List and had an office practice.

Validity

The validity of the survey findings is questionable because response rates of only 11 percent or less are far below normal standards for opinion surveys, and an 89-percent nonresponse rate means it cannot be claimed that the findings are representative of the sample.⁵ Thus, even if Scott-Levin's findings accurately reflected the opinions of the physicians who responded, the responses of the 89 percent or more of the samples who did not respond is not known. Yet their views on direct-to-consumer advertising could have been far different from those who did respond.⁶ Because of this possibility, these studies cannot be used as the basis for conclusions about either the extent of physicians' support for direct-to-consumer advertising or how that support is changing.

Scott-Levin Consumer Surveys' Study Design

Using the same study design, Scott-Levin conducted consumer opinion studies in 1986, 1987, and 1989. The first step of this study design involved selecting a sample of consumers for its studies from a universe that consisted of a sample of consumer households. These consumer households agreed to participate in periodic surveys of their purchasing behavior and of their opinions about various marketed products. Consequently, the generalizability of Scott-Levin's findings depends upon the procedures used in selecting both samples—consumers and consumer households.

⁵The normal standard for an opinion survey response rate is 75 percent. See *Developing and Using Questionnaires*, PEMD methodology transfer paper 7 (Washington, D.C.: U.S. General Accounting Office, July 1986), pp. 132-33.

⁶The study reported that a follow-up telephone survey was conducted with those who did not respond. An analysis of those who did respond to the telephone survey (but not the mail survey) could indicate whether there were differences between the respondents and nonrespondents. However, the results of the telephone survey were not reported.

The first sample, consumers who agreed to participate in periodic surveys (household panel), was selected by National Family Opinion (NFO). NFO recruited consumers by offering approximately 3 million consumers various financial incentives, such as coupons, small household appliances, and cash, for their participation in periodic surveys. About 5 percent of those who were invited agreed to participate. Scott-Levin then used NFO's consumer household sample as its universe for selecting a nationally representative sample of consumers with regard to age, sex, and geographic location.

Scott-Levin's samples of consumers, numbering between 3,300 and 3,600, were mailed questionnaires. The response rate for the total sample was between 53 and 67 percent.⁷ Different subgroups within the total samples, however, had different response rates. For example, equal numbers of males and females were mailed questionnaires in 1987 and 1989.⁸ However, more females (68 percent) returned questionnaires in 1987 than males. In 1989, about the same percentage of females returned questionnaires (51 percent) as males.

GAO's Analysis of the Consumer Surveys

Generalizability

Because Scott-Levin's consumer sample was selected from NFO's consumer households sample, determining to which consumers Scott-Levin's findings generalize depends upon the type of consumers represented in NFO's sample. Although NFO adjusted its consumer household sample to match the demographic characteristics of the population of the United States, those adjustments may not have been effective for ensuring that the sample's opinions matched the population's.⁹ Consequently, there is no way to know whether the opinions that were measured represented those of U.S. consumers generally.

Validity

As in the case of the physician surveys, the response rates for the consumer samples were below normal standards. Thus, it is impossible to

⁷The effective response rate for Scott-Levin's consumer surveys is between 2.5 and 3.0 percent (that is, the effective rates equal 0.05 percent—NFO's response rate—multiplied by 0.53—Scott-Levin's response rate—and 0.05 percent multiplied by 0.67 percent). Both the response rates and effective response rates are below normal standards. See *Developing and Using Questionnaires*, pp. 132-33.

⁸The 1986 study did not provide the number of females in the sample.

⁹Demographically adjusted samples can accurately project purchasing behavior, but there is no evidence that they can project opinions about direct-to-consumer prescription drug advertising.

know whether the opinions of the nonrespondents were the same as those of the respondents. If the nonrespondents' opinions were different, then the findings reported by Scott-Levin must be invalid. Further, any change in support for direct-to-consumer advertising cannot be determined because both the composition of the samples and the question wording changed between surveys.

Technical Review: Data Collection Instruments and Analytical Interpretations in Survey Studies

A conventional analytical requirement for data collection instruments is that questions must be posed in such a way that positive responses are neither more nor less likely than negative responses (that is, there are no biases). Further, the findings must be based on the analysis and interpretation of the response data and correspond closely to those data. Thus, data collection instruments and analytical interpretations are typically evaluated by answering the following questions:

- Do the questionnaire items direct, suggest, or indicate how they should be answered by either wording or location and context (that is, does bias exist)?
- Are the analysis and interpretation of the response data appropriate?

GAO's Analysis of Physician Surveys

Do Physicians Believe That Direct-to-Consumer Ads Benefit Patients or Physicians?

Scott-Levin's 1989 report states that "direct-to-consumer ads are perceived by an increasing number of physicians as benefiting both consumers and physicians themselves. These positive reactions seem to indicate that experiences with consumer requests and/or dialogue have been satisfactory."¹⁰ The report, however, does not state that the question actually asked was, "Do you feel that consumer advertising of prescription drugs provides any benefits to consumers or physicians [emphasis added]?"¹¹

Because the focus of this question is about the provision of "any benefits," a positive response does not imply support for direct-to-consumer advertising. Also, the levels of endorsement for consumer advertising are lower than those implied, based on the results of the 1988 and 1989 surveys. In 1988, 37 percent of physicians responding indicated that

¹⁰Direct Advertising to the Consumer: Consumer and Physician Reactions, 1989 Update, p. xiv.

¹¹Direct Advertising to the Consumer: Consumer and Physician Reactions, 1989 Update, p. I-1.

they believed direct-to-consumer advertising provided any benefits for consumers; in 1989, 45 percent of physicians believed advertising provided any benefits for consumers. In 1988, 28 percent of physicians believed that direct-to-consumer ads provided any benefits to physicians; in 1989, 33 percent believed that there was any benefit for physicians. In light of an 11-percent response rate, these findings cannot be said to represent physician opinion or support—and growth in support—over the 2-year period. Between 55 and 63 percent of responding physicians did not find any benefits for consumers, and between 67 and 72 percent of physicians did not find any benefits for physicians.

What Are the Dimensions of Physician Interest in Direct-to-Consumer Advertising?

Scott-Levin's 1989 report states that "there has been a significant increase in doctors' perceptions of the value of direct-to-consumer advertising to both consumers and physicians."¹² The report does not discuss the level of agreement to questions about costs and benefits of direct-to-consumer ads in a given time period, as a statement about the "value" of direct-to-consumer advertising implies. Physicians were asked their beliefs about some of the effects of direct-to-consumer advertising and responded as follows:

- 69 percent of respondents disagreed that it is an important educational tool;
- 70 percent disagreed that it is valuable and worth while; 72 percent disagreed that it provides a source of reliable information on health care; and
- 77 percent agreed that it should be tightly controlled by the Food and Drug Administration.

Moreover, because these questions were asked only once (in 1989), the report cannot address whether there was an increase in the perceived value of direct-to-consumer advertising.

GAO's Analysis of Consumer Surveys

Are Consumers in Favor of Direct-to-Consumer Advertising?

Only one question was repeated in all three consumer surveys: "Traditionally, pharmaceutical companies have communicated information about prescription drugs only to health care professionals: Do you think

¹²Direct Advertising to the Consumer: Consumer and Physician Reactions, 1989 Update, p. 90.

they should also advertise or communicate information about prescription drugs to the general public?"

This question is biased in its design because it directs consumers to answer the question positively in three ways. First, by alluding to information about prescription drugs that health care professionals have been receiving, it implies that such information is important or useful information to have. Second, because this question was placed after an informational question that asked whether the respondent was aware of each of several recent advances or changes in the pharmaceutical industry, it emphasizes the changes that were occurring and the need to keep abreast of them. Third, by asking about the desirability of drug companies' both advertising and communicating prescription drug information in other ways, it captures the respondents who support advertising and those who oppose advertising but, nevertheless, favor receiving drug information.

Further, the responses are reported selectively in the analysis. The level of respondent consumer endorsement in Scott-Levin's 1986 report was 70 percent; in 1987, it was 75 percent; and in 1989, it was 60 percent. Yet Scott-Levin's 1986 report says that "consumers were asked their opinion about the concept of prescription drug advertisements direct to the general public. Seventy percent of the 2,016 respondents were in favor of this form of communication."¹³ The 1987 report states, "when asked their opinion as to whether pharmaceutical companies should promote their drugs directly to the public, 75 percent of the respondents replied in the affirmative."¹⁴ And its 1989 report says, "in general, consumers are in agreement that direct-to-consumer advertising provides informational and educational benefits. As in 1987, positive attitudes concerning the pharmaceutical drug industry are expressed and often relate to R[esearch] & D[evelopment], while price is the major negative response elicited."¹⁵ In sum, the drop in the 1989 level of endorsement, reversing a 2-year trend, was not reported.

Is Interest in Direct-to-Consumer Ads Increasing Among Consumers?

The 1989 report states that there was a "higher degree of interest" in direct-to-consumer advertising. However, that interpretation was based upon the following ambiguously worded question: "Listed below are some topics and conditions that prescription drug companies might

¹³Direct Advertising to the Consumer: A Baseline Reading, p. 44.

¹⁴Direct Advertising to the Consumer, p. 45.

¹⁵Direct Advertising to the Consumer: Consumer and Physician Reactions, 1989 Update, p. xiii.

choose as subjects of advertisements. (PLEASE CIRCLE ALL THAT YOU ARE INTERESTED IN.)”

It is not clear in this question whether respondents should indicate the health topics that they want to see advertised or the topics in which they are interested, regardless of whether they want to see them advertised.

Scott-Levin Comments

As you requested, we did not ask for written comments from Scott-Levin Associates on a draft of this report. However, the views of responsible Scott-Levin officials were sought during the course of our work and have been included where appropriate. We discuss their main points below.

Scott-Levin indicated that although it concurred with our description of the studies, it disagreed with our interpretation of several facts. First, it commented that the purpose of its market research was to measure trends in behavior, as opposed to academic research intended to measure attitudes. That is, Scott-Levin contended that its focus was on the increase in the number of physicians who encountered patients who had been exposed to direct-to-consumer advertising and how those physicians reacted to those patients.

Although a complete review of the differences between market and academic research is beyond the scope of this study, we agree that the focus of market research is often on the relationship between trends in consumer behavior and some objective standard such as total sales. We believe, however, based on the Scott-Levin studies’ own statements, that the studies did purport to measure and report on trends in physician and consumer attitudes. Further, we believe that if Scott-Levin intends to measure and report on attitude trends, the methods it uses should ensure, as precisely as possible, their valid measurement.

A Scott-Levin official indicated that the company was not concerned about the lack of national representativeness of the samples used in the company’s studies for two reasons. First, he said the company deliberately selected its samples to represent the universe of most likely drug purchasers and prescribers rather than the universe of consumers or physicians. Second, he noted that Scott-Levin refrained from generalizing to inappropriate universes from its samples.

However, in our opinion, Scott-Levin did attempt to generalize to the universe of national consumers and physicians with inappropriate samples. Moreover, while it is perfectly acceptable to restrict the universe sampled to those such as likely drug users or prescribers, the response rates in Scott-Levin's studies were so low that it is not possible to identify the universes to which generalizations are being made.

Scott-Levin indicated that the response rates it obtained in physician surveys were consistent with other physician studies that it conducted (that is, prescription audits). In addition, an official of the company said that low response rates were a necessary trade-off of avoiding "adverse selection." That is, Scott-Levin said that either offering physicians money or incentives or follow-up activities involving repeated contacts would lead to physicians' participating in their studies who differed systematically from the majority of physicians. Further, the company official indicated that it was his impression that those having extreme opinions were most likely to respond and their views tended to balance one another, reflecting the majority opinion.

We agree that adverse selection should be avoided in sampling designs. However, we have found no evidence that follow-up activities, such as repeated contacts, result in adverse selection. Instead, experts on mail surveys recommend repeated contacts for follow-up, and AMA uses repeated contacts without adverse selection. Further, we believe that Scott-Levin could offer incentives consistent with those offered by other companies surveying physicians with concern about adverse selection.

Finally, Scott-Levin commented that the sample compositional differences between the 1988 and 1989 consumer surveys probably tended to understate the awareness expressed about direct-to-consumer advertising. That is, because the percentage of women in the 1988 sample was greater than in 1989 and women tend to be more aware of health issues than men, the level of awareness found in 1989 may have been lessened by the decrease in the percentage of women.¹⁶

We agree that the same percentage of women in the 1989 sample as in the 1988 sample may have resulted in a greater level of awareness than was actually found. Nonetheless, this speculation does not affect our position that changes in the composition of surveys prevent measuring changes in the universes represented by those samples.

¹⁶J. H. Hibbard and C. R. Pope, "Gender Roles, Illness Orientation, and Use of Medical Services," *Social Science and Medicine*, 17 (1983), 129-37.

Unless you announce the contents of this report earlier, we plan no further distribution of it until 30 days from its date. We will then 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 Systems Areas, at (202) 275-3092. Other major contributors to this report are listed in appendix III.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Eleanor Chelimsky". The signature is fluid and cursive, with a large, stylized "E" and "C".

Eleanor Chelimsky
Assistant Comptroller General

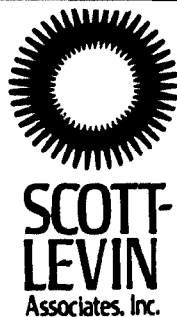
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Abbreviations

AMA	American Medical Association
GAO	U.S. General Accounting Office
NFO	National Family Opinion

Scott-Levin Associates Press Release



FOR INFORMATION & INTERVIEWS,

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FOR IMMEDIATE RELEASE

PRESCRIPTION DRUG ADS TO CONSUMER AUDIENCES ARE PRODUCING "DRAMATIC EFFECTS," RESEARCH SHOWS Scott-Levin Says "Quest for Silent Sufferers" Is Working

(NEWTOWN, PA.) January 22, 1990 — Once unheard of, the relatively recent phenomenon of prescription drug advertising that targets consumers — rather than doctors — is having "dramatic effects," and seems destined to become an increasingly important part of the pharmaceutical industry's marketing mix, says Scott-Levin Associates, Inc.

A leading healthcare research and consulting firm based in Newtown, Pa., Scott-Levin today released select findings of its newest national survey measuring a wide range of the advertising's effects on consumers and physicians.

The research, which replicated and expanded upon similar surveys the firm conducted in 1986 and 1987, examined the effects of various ad campaigns on such things as doctor visits, doctor-patient relations, prescribing behavior, and attitudes held by both physicians and patients toward the advertising and the drug manufacturers.

The three national studies document "dramatic effects that foreshadow continued growth in the practice of advertising to consumer audiences," said Joy Scott, chief executive officer.

Scott went on to predict that "direct-to-consumer advertising by the drug industry will soon explode in significance and visibility. It could become a mainstream part of our culture," she said.

"The industry's advertising is already transforming relations between doctors and their

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patients, and it will be a factor in business success — and failure — for a number of major manufacturers and their products in the years ahead,” Scott added.

The firm’s research shows that discussions with a doctor as a consequence of ad exposure doubled between 1987 and 1989, Scott said. In 1987, only 20% of consumers reported they had talked to a physician because of an ad, and in the new survey 40% reported doing so. She added that “many” (but not all) of the target audiences of recent ad campaigns reported even higher percentages of doctor visits.

Further, Scott announced that in the latest research over 70% of physicians acknowledged that a patient who requested a specific drug did, indeed, suffer from a condition that could be treated with the drug mentioned.

“The drug industry’s quest for ‘silent sufferers’ is clearly working,” Scott said.

Scott-Levin’s research also documents continuing growth in support for the new advertising, by both physicians and consumers. Scott said that since 1987 the percent of physicians who believe the advertising benefits consumers has grown from 37% to 45%. This increased support for direct-to-consumer advertising has involved “virtually every specialty,” Scott reported.

Similarly, a growing number of physicians also believes the advertising helps doctors, according to Scott-Levin research. Scott noted that whereas 28% of physicians perceived benefits to themselves in 1987, that number had grown to 33% in 1989, and was even higher for some specialties. Forty percent of allergists, for example, now report benefits to themselves from the advertising, compared to only 27% two years ago, she said.

At the same time, an “overwhelming majority of consumers judge prescription drug advertising very positively,” Scott announced. She said 72% of Americans say the advertising is an educational tool, and 71% agree that the advertising is worthwhile.

Scott suggested that one of the most interesting and important insights of her firm’s research concerns the long-term implications of the advertising’s effects on relations between American doctors and their patients.

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"This advertising is effectively encouraging doctors to accept the concept of 'self-diagnosis,' and to give heightened respect and consideration for the intelligence of their patients," Scott observed.

At the same time, she said the advertising is producing "a growing number of consumers who are choosing to take a more active role" in their own healthcare.

"These findings suggest that a significant transformation is taking place, that direct-to-consumer advertising is becoming not only an essential marketing tool for many manufacturers, but a force that is changing the very culture of healthcare," Scott said.

She added that the advertising will become especially significant because of the many manufacturers who plan to eventually market over-the-counter versions of drugs initially available only by prescription.

At the same time, she stressed that recent advertising campaigns for prescription drugs haven't been equally effective, and that the Scott-Levin research has uncovered "numerous subtleties to physician and consumer reactions that will become increasingly significant as the quantity and competitiveness of direct-to-consumer advertising grows."

Based in Newtown, Pa., Scott-Levin Associates, Inc. is a leading healthcare research, consulting, software and publishing company. The firm supplies proprietary research, multi-client research, consulting, software, publications and training services to over 100 clients worldwide, most of them pharmaceutical manufacturers.

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