NCL 100 YEARS CONSUMER ADVOCACY National Consumers LEAGUE

NATIONAL CONSUMERS LEAGUE

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July 19, 2001

Dockets Management Branch
(HFA - 305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 01D-0162; Draft Guidance for Industry on Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements

Dear Sir or Madame:

The National Consumers League (NCL) appreciates this opportunity to comment on the Food and Drug Administration's (FDA) Draft Guidance for Industry on Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements. Draft Guidance for Industry on Using FDA-Approved Patient Labeling In Consumer-Directed Print Advertisements, 66 Fed. Reg. 20468 (April 23, 2001). NCL is a national nonprofit consumer advocacy organization founded in 1899 to represent consumers in the marketplace and the workplace. NCL welcomes FDA's efforts to improve the quality of the information about prescription drug products directed to consumers.

NCL has been involved with the issues surrounding prescription drug advertising for many years. NCL offered testimony at the FDA's public hearing on direct-to-consumer (DTC) promotion in 1995. NCL has also conducted research into consumer perceptions and the impact of prescription drug promotion.

In January 1996 and again in September 1998, NCL invited stakeholders to roundtable meetings to discuss DTC promotion. The goal of these roundtables was to reach some consensus on various aspects of this issue. FDA participated in these roundtables as an "observer." We distributed reports on these roundtable discussions to FDA and others. Copies of the reports of NCL Roundtables I and II are attached. Among the conclusions drawn from the roundtables:

> While DTC promotion benefits consumers by providing them with information about the availability and characteristics of drugs they might not have otherwise known, it is generally more effective in communicating benefits than risks.

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DTC promotion can convey only a limited amount of information due to time and space constraints; additional information sources offering balanced information must be available to consumers.

For print advertising, most brief summaries do not convey useful information to consumers and the requirements should be reformed to assure that the information conveyed is less detailed and more consumer friendly.

Brief summaries should be re-formatted to better provide important usage and safety information in consumer-friendly language. The brief summary should reflect the recommendations of the 1996 Keystone Committee and include the most serious and most frequent side effects and information about the disease the drug is intended to treat and what the drug does and does not do.

Health care professionals should receive different messages than consumers do.

DTC promotion should not be false or misleading, should be fairly balanced, may refer consumers to other sources for further information.

DTC promotion is a component to empowering consumers with information about the prescription drugs they use. Advertising can inform consumers about goods and services in the marketplace, including even products as potent as prescription drugs. To fulfill this vital role, however, prescription drug promotion must be fairly balanced and adequately inform consumers of the risks of drugs to avoid misuse, noncompliance, and adverse effects. With balanced, clear information, most consumers can understand and evaluate drug benefit claims and form accurate opinions about prescription drugs.

The healthcare environment has changed dramatically in recent years and this trend will continue. Today, a physician is not the only or even necessarily, the primary, source for information about a patient's own health care. Patients gather information through the media and Internet, from family and friends, and in their workplace. Consumers may not always develop close relationships with their physicians when they are receiving their medical care through clinics, emergency rooms, and managed-care systems.

Still, even amidst these changes, it is health care professionals who are responsible for ensuring that consumers understand how to safely and effectively use drugs. Only the health professional can evaluate whether the drug is appropriate for a particular patient. The health professional must discuss the risks and benefits of medications and other treatment options with the patient. The patient should also take responsibility for personal health decisions. NCL

encourages stronger relationships between patients and their physicians, pharmacists, nurses, and other healthcare professionals.

In 1995, NCL commended FDA for its commitment to aiding this dialogue about prescription and over-the-counter drugs between professionals and consumers. We do so again today. Allowing drug advertisers to fulfill the brief summary requirement by providing FDA-approved patient labeling will improve the quality and comprehension of information flowing to patients. NCL urges FDA to adopt the Draft Guidance quickly.

In 1995, NCL also reminded FDA that the existing regulations on the DTC promotion of prescription drugs were outmoded and not helpful to consumers. NCL urged FDA to adopt new standards specifically for prescription drug advertising directed to the consumer, rather than to the health care professional. Similar recommendations came out of the 1996 and 1998 roundtables. NCL repeats this call again.

The current regulations are ill-suited to communicate mportant risk information to consumers. While DTC promotion is usually quite good at communicating a product's benefits, it is less effective in communicating a drug's risks. The best DTC promotion is not necessarily the one that is the most exhaustive in its recitation of risk information. The brief summaries (and, with this Draft Guidance, the FDA-approved patient labeling) that accompany print advertising are quite comprehensive and often complex. They are also generally presented in very small type. They are often written in technical language only a medical professional would understand. They are formatted so that it is difficult for a consumer to distinguish the likelihood and severity of adverse events. These documents may recite all of a drug's risk information; however most patients cannot and do not read it, and if they do so, many cannot understand what they read.

The current regulatory scheme is especially difficult for those with limited reading and comprehension abilities. Those with limited education and people whose first language is not English are particularly vulnerable. The elderly, who take most of the prescription drugs, often cannot read the very small print. In this respect, the Draft Guidance is a positive step, but does not go far enough. FDA-approved patient labeling is very detailed. When condensed into a format that can fit on a single page for a print advertisement, patient labeling is likely to appear much as the current brief summary does -- dense, long, and technical.

Above all, risk information must be presented in a format and language that is consistent, useful, and easy for the consumer to read and understand. Regulations that mandate different presentations of the same risk information in varying levels of detail do not serve consumers well. For instance, whether a consumer receives a brief summary or full package labeling for a drug should not turn on whether the promotion triggering the disclosure is deemed advertising or promotional labeling. In NCL's view, the format for presenting risk information for prescription drugs should be standardized, as it is for over-the-counter drugs, dietary supplements and foods. The "Drug Facts," "Supplement Facts" and "Nutrition Facts" formats provide excellent models for the presentation of important risk and usage information for prescription drugs. It is a format that consumers are now familiar with and one that has helped them make informed choices for these products.

NCL further advocates consideration of the model set out in the Guidance on Consumer-Directed Broadcast Advertisements. Under that Guidance, DTC broadcast advertisements must:

- not be false or misleading;
- communicate that the advertised product is available only by prescription and that only a prescribing healthcare professional can decide whether the product is appropriate for a patient;
- present a fair balance between information about effectiveness and information about risk;
- include a major statement conveying all of the product's most important risk information in consumer-friendly language;
- communicate all information relevant to the product's indication (including limitations to use) in consumer-friendly language; and
- include reference in the broadcast to the adequate provision the sponsor had made for the dissemination of the drug's package labeling[1], through such means as pharmacists and physicians, calling a toll-free number, and visiting a Web site.

The DTC Advertising Broadcast Guidance does not require the dissemination of all pertinent risk information about the drug in an advertisement. Rather, the Guidance assures that consumers receive the most important risk information by requiring the major statement, thereby choosing importance over completeness. Completeness is addressed in that the broadcast further explains how consumers can gather more information through other, easily accessible means. NCL believes that moving print media requirements toward the standards applicable to broadcast with strict standards that fairly balance risk and benefit will increase the likelihood that consumers will actually read the risk information presented, understand it, and remember it.

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[1] NCL continues to be troubled by FDA's requirement that drug sponsors provide full product labeling if a drug promotion is disseminated as either "labeling" or through broadcast media. Although brief summaries and FDA-approved patient labeling are detailed and difficult to understand, full product labeling is worse. Full product labeling is specifically written for the health care professional and is incomprehensible to most consumers. There is no benefit to a requirement that it be disseminated to consumers. Most consumers will not attempt to read a document that is so lengthy and technical, and so, may miss vital information about a prescription drug. NCL urges FDA to eliminate this burdensome requirement and mandate, in the alternative, provision of consumer-friendly risk information.

Health care communications between the professional and patient are changing. Visits to a physician are more infrequent, and when they do occur, are often shorter, more hurried, and less personal. This is a challenge for the medical profession that drug promotion regulations cannot remedy by increasing the amount of information that must be squeezed into an advertisement. Drug sponsors must do their part by presenting truthful, accurate information that does not overstate a drug's benefits and includes the most important risk information.

NCL thanks FDA for this opportunity to comment upon an important step in improving communication about prescription drugs. We urge FDA to take the next steps toward broader reform immediately.

Sincerely,

Linda Golodner

LINDA F. GOLODNER
President

Enclosures

NATIONAL CONSUMERS LEAGUE

ROUNDTABLE ON DIRECT-TO-CONSUMER PROMOTION OF PRESCRIPTION DRUGS

FINAL REPORT

On January 17-18, 1996, the National Consumers League brought together representatives from consumer organizations, the health care professions, the pharmaceutical industry, the medical publishing industry, the advertising profession, the Food and Drug Administration (FDA), and the Federal Trade Commission (FTC) for a Roundtable on Direct-to-Consumer Promotion (DTCP) of Prescription Drugs.[1] The purpose of the Roundtable was to engage a wide range of interested and affected parties in a discussion of this unique and growing form of promotion and to seek consensus on the appropriate regulatory framework for DTCP.

The Roundtable serves as convincing evidence that interested parties, when brought together for reasoned discussion, can achieve general agreement on many fundamental issues regarding the regulation of DTCP. The National Consumers League remains committed to seeking a national consensus on an appropriate regulatory regime for DTCP.

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INTRODUCTION

The Food and Drug Administration has stated that it is currently reexamining its policies on the promotion of prescription drug products directly to consumers through print, broadcast, and other types of media, such as online services and the Internet. Traditionally, advertising of prescription drugs has been directed primarily to health care professionals,[2] and today drug companies continue targeting those who prescribe drugs to patients.

1. Representatives of the FDA and the FTC participated as observers only and do not necessarily endorse the conclusions of the Roundtable.
2. Throughout this report, the term "health care professional" refers to physicians, pharmacists, nurses, physician-assistants, and other medical personnel.

However, following FDA's lifting of a voluntary moratorium on DTCP in the early 1980's, there has been an upward trend in the use of consumer-oriented messages. This trend has become more dramatic in recent years. In 1994, the most recent year for which information is available, drug advertising directly to consumers increased 47% from the previous year, according to Competitive Media Reporting, a company that tracks ad spending. This notable shift to provide consumers with greater information about prescription drugs was brought on by two major forces: (1) the general trend of consumers to assume greater responsibility for their health and, therefore, seeking more information about medications and health care choices, and, (2) the growth of managed care systems in which costs are controlled in part by maintaining limited formularies.

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The health care environment and the vehicles through which consumers receive information have changed dramatically in the last decade. New health care priorities and realities restrict the traditional health care professional/patient relationship. Today, consumers make more of their own health care decisions than ever before. They are often treated by a variety of physicians, sometimes through an impersonal clinic, emergency room, or a managed care system that does not provide a consumer with the opportunity to develop a close relationship with a physician or other health care professional. In this environment, consumers demand and need more information about prescription drugs.

ROUNDTABLE FINDINGS AND CONCLUSIONS

There was general agreement among the Roundtable participants that DTCP is not inherently misleading and that it provides significant benefits that outweigh the potential risks to consumers and society inherent in this form of promotion.

1. <u>DTCP Benefits</u>

   Through DTCP, consumers can learn about availability and characteristics of drugs they might not otherwise have known. By reading help-seeking ads, which describe symptoms, conditions, or diseases but do not discuss specific prescription

drug products, consumers might recognize symptoms they are experiencing and seek diagnosis and treatment. DTCP may also serve as a reminder to consumers about the importance of continuing to take their prescription drugs as directed. This may result in increased compliance.

By being exposed to DTCP, consumers may be encouraged to discuss symptoms and medications with their health care professionals. Serving as a safety net, health care professionals can evaluate whether the drug is appropriate, and discuss non-drug or comparable drug alternatives with the consumer, involving the patient in his or her care.

2. DTCP Risks.

In some instances, DTCP may mislead consumers into believing that a product has greater potential benefits than it actually has. Advertising promotes the sale of a product, and therefore tends to do a good job of communicating the product's benefits, sometimes overstating them. At the same time, however, DTCP is not very effective at communicating the risks of a prescription drug, such as side effects and adverse drug reactions. False, deceptive and misleading advertising is detrimental to consumers, and laws prohibiting such activity must be strictly enforced.

False, deceptive and misleading advertising is detrimental to consumers...

Although some Roundtable participants believed that the pharmaceutical industry's use of DTCP results in higher drug costs, others argued that such promotion leads to lower drug costs, because it promotes competition in the marketplace.

WHO SHOULD REGULATE DTCP?

Under the Federal Food, Drug, and Cosmetic Act, FDA has responsibility for regulating the labeling and advertising of prescription drugs. FDA's regulations on promotion of prescription drugs, however, were designed to apply to advertising directed at health care professionals, apparently with little or no thought given to consumer-oriented messages.

The Roundtable participants recommended that regulations be drafted that pertain specifically to consumer-directed promotional materials.

The participants had varied views on whether the FDA should continue to regulate DTCP. While some believed that FDA remains the most appropriate regulatory entity, others suggested that regulatory authority be transferred to the FTC. Some suggested that DTCP should be overseen by a non-governmental entity.

participants recommended that regulations be drafted that pertain specifically to consumer-directed promotional materials.

1. Arguments in Support of Regulation by FDA

   Two arguments were made in support of regulation by FDA: (1) FDA is a public health agency that has medical expertise and is familiar with the pharmaceutical industry and pharmaceutical promotion; and (2) shifting regulatory control to another agency, such as the FTC, would result in less regulatory control over the content of DTCP, which could result in a higher level of misleading information.

2. Arguments in Support of Regulation by the FTC

   Three arguments were presented in support of regulation by the FTC: (1) The FTC has a more flexible approach than FDA to the regulation of advertising, both in terms of the regulatory process and in terms of substantiation requirements; (2) the FTC has greater experience than FDA in the regulation of promotion based on consumer perception; and (3) unlike FDA, the FTC has no authority over approval of drugs for marketing. There is a significant fear within the pharmaceutical industry that challenging FDA policies and actions related to DTCP may result in retaliation against companies with regard to products that are awaiting FDA approval.

3. Arguments Supporting a Non-governmental Approach

   Some Roundtable participants suggested self-regulation by the National Advertising Division (NAD) of the Council of Better Business Bureaus. They believed

the NAD could review DTCP and take appropriate enforcement action. Some Roundtable participants suggested that health care professionals and consumers be represented on the NAD.

Some Roundtable participants recommended that a consumer advisory board be established to review DTCP to determine whether it meets appropriate standards and communicates useful information. These participants believed that quick review of DTCP would be essential, and decisions of the board should be binding upon FDA. Some participants suggested that the National Consumers League house and coordinate the consumer advisory board.

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THE APPROPRIATE REGULATORY FRAMEWORK

1. Help-Seeking and Reminder Advertisements

Help-seeking promotional materials, which describe symptoms, conditions, or diseases but do not identify specific prescription drug products, are generally not regulated by FDA. The agency will regulate help-seeking ads if they create an association between the disease or condition and an identifiable product or type of product.

Reminder promotional materials contain the name of the drug, but they do not contain any information related to the use or therapeutic characteristics of the product. They are a means of reinforcing name recognition and brand loyalty.

There was general agreement[3] among the Roundtable participants that the current regulatory approaches to help-seeking advertisements are appropriate and beneficial, subject to the recommendations discussed below.

3. Throughout this report, "general agreement" refers to the majority of Roundtable participants supporting a particular viewpoint.

The participants recommended that a new type of DTCP, a "modified help-seeking advertisement," be permitted. In a "modified help-seeking ad," the consumer would receive information not only on the medical condition being treated, but also on the product, which would be identified. (See discussion of "Modified Help-Seeking Advertisements").

2. Product-Claim Advertisements

Product-claim promotional materials contain safety and efficacy claims about a specific prescription drug product. FDA's regulations require, among other things, that these materials present balanced information on the drug. Claims of drug benefits, such as safety and efficacy, must be balanced with relevant disclosures of risks and limitations of efficacy. This balanced presentation of drug therapy is commonly referred to as "fair balance."

DTCP should bear a statement that the product is a prescription drug and that consumers should consult their health care professionals...

a. General Standards

The Roundtable participants recommended the following general standards for product-claim advertisements:

(1) DTCP must not be false or misleading. False, deceptive, and misleading advertising is detrimental to consumers, and laws prohibiting such activity must be strictly enforced.

(2) DTCP should bear a statement that the product is a prescription drug and that consumers should consult their health care professionals. This will encourage consumers to discuss symptoms with their health care professional, who will determine the appropriate therapy.

(3) DTCP may appropriately refer consumers to a source of further information about the product, such as a toll-free number offered by the manufacturer or a notice of availability of information at local pharmacies.

(4) Most participants agreed that a requirement of fair balance should be retained, but were reluctant to propose a definition or detailed standards,

preferring to see a greater effort on the part of FDA to come up with reasonable and workable standards. Many expressed concern that FDA requires too much information under the fair balance requirement. Some participants suggested that there is no need for fair balance because, in their view, the prohibition against false or misleading advertising is adequate and the concept of fair balance is not workable as a regulatory standard.

(5) The use of icons and pictograms in DTCP should be encouraged, but optional. Icons and pictograms have the potential to improve DTCP and make it easier for consumers to understand. They should relate to the text and be located near the text they help explain. Consumer education on the meaning of pictograms can help prevent the problem of multiple interpretations.

(6) "Infomercials" are program-length television or radio programs that could be used to promote prescription drugs to consumers. "Advertorials" are the equivalent of "infomercials" in the print media. All Roundtable participants generally agreed that these forms of promotion must clearly and conspicuously disclose that they are advertisements. For example, "advertisement" should be printed in large, conspicuous letters on the screen at all times during an informercial.

"Advertorials" are the equivalent of "infomercials" in the print media...(and) must clearly and conspicuously disclose that they are advertisements.

b. **Brief Summary**

The Federal Food, Drug, and Cosmetic Act specifies that advertisements must contain "other information in brief summary relating to side effects, contraindications, and effectiveness..." This requirement is generally fulfilled by including the sections of the approved labeling that discuss the product's adverse event profile, contraindications, warnings, and precautions. The brief summary is usually in very small type on the page following the main ad and often is in language more appropriate for a health care professional. Consequently, most brief summaries are not useful for the great

majority of consumers. In addition, the requirement for a brief summary functions as a barrier to DTCP in the broadcast media, because it cannot be presented in a 30-second, or even a 60-second commercial. The requirement also increases the cost of print advertisements by requiring companies to buy extra pages of advertising space.

Recognizing that the brief summary is "neither brief, nor a summary," the Roundtable participants generally agreed that in its current form, the brief summary should be eliminated. While some wanted to eliminate the brief summary requirement entirely, others wanted to retain the concept of a clear, brief format.

Roundtable participants generally agreed that in its current form, the brief summary should be eliminated.

For example, risk information could be organized into headings and bullets, which improve readability and guide consumers through the information. An easy-to-read brief summary will help consumers to better assess risks and benefits of the advertised drug.

c. **Product Comparison Advertisements**

Product comparison advertisements compare drugs, or classes of drugs, with each other. Opponents of this comparative format argue that consumers do not have the contextual knowledge required to critically evaluate comparative claims, and that they therefore pose greater risks of misleading consumers. However, the Roundtable participants generally agreed that product comparison advertisements should be permitted, because consumers can evaluate comparative claims that are properly framed.

d. **Different Media**

The Roundtable participants generally agreed that DTCP is appropriate in the broadcast media (television and radio) just as in the print media. The broadcast media may communicate DTCP messages to marginally literate consumers and those who cannot read English.

The participants agreed that, if necessary, FDA should revise its regulations to permit DTCP on the broadcast media.

Most participants agreed that the requirements for print DTCP should be essentially the same as those for broadcast. However, there was a strong minority view that in some instances DTCP in the print media should be required to contain more information, especially with regard to risks. Some participants suggested that advertisements in the print media should be required to include a boxed section on "Questions to Ask Your Health Care Professionals." Providing questions to ask, such as those developed by the National Council on Patient Information and Education, would help consumers to have an informed discussion with their health care professionals about the advertised product.

...a new type of DTCP, a "modified help-seeking advertisement," be permitted by FDA in print and broadcast media.

e. Modified Help-Seeking Advertisements

The Roundtable participants recommended that a new type of DTCP, a "modified help-seeking advertisement," be permitted by FDA in print and broadcast media. This type of ad would direct the consumer to a health care professional in much the same manner as a traditional help-seeking ad. In the modified help-seeking ad, however, the consumer would receive information not only on the medical condition being treated but also on the product, which would be identified.

This form of advertisement would be written in consumer-friendly language and would contain the following elements:

- Identification of the product
- Listing of at least one use or indication
- Information on some or all "significant" risks or general warning (see discussion below)
- Help-seeking message describing the disease or

condition and encouraging the consumer to consult a health care professional

•Toll-free number for further general information or a reference to the availability of information at local pharmacies.

Most participants agreed there should be some information provided on specific risks that are "significant," but could not arrive at a definition of "significant risk." Ideas included contraindications, significant side effects, and risks to significant numbers of patients. Instead, the participants left it to the appropriate federal regulatory agency to define the term. Participants were unable to agree on whether informa-tion must be provided on all "significant" risks or only some "significant" risks.

...balancing of information provides a framework for consumers to understand and evaluate drug benefit claims.

There was general agreement that the appropriate federal regulatory agency should require this risk information to be presented with a prominence and readability reasonably comparable to the benefits of the product disclosed in the advertisement. Such balancing of information provides a framework for consumers to understand and evaluate drug benefit claims. This allows them to have an informed opinion about prescription drugs.

Some participants felt that the new "modified help-seeking ad" should not contain any specific information on risks. They suggested as an alternative that a general warning be included, such as:
All drugs have risks. This drug may not be right for you; you should discuss this product with your health care professional.

This warning would be required to be "clear and prominent," presented in a manner that is calculated to be noticed, read (or heard), and comprehended by consumers. Some participants were concerned that listing risks and adverse effects would cause a level of fear that might deter consumers from discussing a medication with their health care professional.

3. The Regulatory Process

a. Structure and Organization

There was no general agreement with regard to a proposal for structural or organizational change at FDA. Some participants suggested that there be an office overseeing promotion that is separated from the Centers[4] in order to allay industry fears that the Centers may retaliate against companies that challenge agency promotion policies by slowing down or withholding approval of those companies' products.

The Roundtable participants recommended that FDA and industry increase efforts to agree on basic principles for regulating DTCP.

b. Pre-Dissemination Review

In a July, 1993 letter to the industry, as well as in numerous prior and subsequent public presentations given by FDA staff, the agency has requested that drug manufacturers voluntarily submit proposed direct-to-consumer promotional materials prior to use, allowing FDA the opportunity to review and comment upon them before they reach consumers. Although FDA states that it encourages but does not require pre-dissemination review, many in industry believe that this is a de facto requirement that cannot be ignored.

Considering this topic, the majority of Roundtable participants agreed that FDA should eliminate this perception. Some attendees suggested that FDA issue a public statement that submission is voluntary and optional and that companies need not seek the agency's advice (see page 12). While some suggested that the agency go further and eliminate even the option of pre-dissemination review of DTCP, most participants agreed that such review should be available for those in industry who request it.

Some participants, especially consumer organizations, however, felt strongly that pre-dissemination review by FDA is

Although FDA states that it encourages but does not require pre-dissemination review, many in industry believe that this is a de facto requirement that cannot be ignored.

4. FDA is divided into the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), the Center for Food Safety and Applied Nutrition (CFSAN), and the Center for Veterinary Medicine (CVM), which have jurisdiction over product approvals in their respective areas of expertise.

an important safeguard to protect consumers from misleading advertising. A few suggested that FDA strongly encourage submission only for certain classes of drugs, such as drugs with "black box" warnings[5] or other special concerns. They also suggested that FDA commit to meeting certain time deadlines for reviewing DTCP.

c. Guidelines and Regulations

In conclusion, the Roundtable participants recommended that FDA move as expeditiously as possible to provide a statement of policy that would encourage and facilitate the flow of helpful information, including guidelines or a proposed regulation on DTCP.

FDA published a notice in the Federal Register that addresses many of the key conclusions and proposals of the NCL Roundtable.

ADDENDUM
ROUNDTABLE ISSUES AND PROPOSALS IN FDA'S POLICY-MAKING PROCESS

May 14, 1996, FDA published a notice in the Federal Register that addresses many of the key conclusions and proposals of the NCL Roundtable. 61 Fed. Reg. 24314 (the "May 14 Notice"). Some of the FDA representatives who attended the NCL Roundtable were involved in the preparation of the notice.

The first issue addressed in the notice is pre-dissemination review. As discussed above in Part 3b (Appropriate Regulatory Framework), the majority of Roundtable participants agreed that FDA should eliminate the perception that pre-dissemination review is required and some attendees suggested that FDA issue a public statement that submission is voluntary and optional, and that companies need not seek the agency's advice. The agency provides this statement in the May 14 Notice:

> [I]t appears that the agency's request that manufacturers voluntarily obtain advice on proposed DTC materials has been misinterpreted as a requirement. FDA reiterates that it does not now require, nor has it ever required, manufacturers to submit DTC promotional labeling and advertising for preclearance.

5. Some warnings that relate to the risk of death or serious injury are required by FDA to be placed in a prominently displayed box in the labeling.

Id. at 24315.

The notice also addresses the requirement of the brief summary. As discussed above in Part 2b, the Roundtable participants generally agreed that the brief summary, in its current form, should be eliminated, with some participants suggesting it be replaced with a format such as a Medication Guide (the name given FDA's proposal to extend its current requirements for approved patient labeling to broader classes of drugs). The agency states in the May 14 Notice:

> FDA believes that ... FDA-approved patient labeling generally meets the brief summary requirements, and, because it is written for patients, is a more appropriate vehicle for communicating risk information to consumers than the technically-written brief summary. FDA is requesting comment on its intention to consider patient labeling as adequate to fulfill the brief summary requirement ....

Id.

FDA is requesting comment on its intention to consider patient labeling as adequate to fulfill the brief summary requirement...

The Roundtable participants also recommended, as discussed above in Part 2e, that FDA eliminate the brief summary in a proposed new advertising format that would be more compatible with the limitations of the broadcast media. In the place of the brief summary, such advertisements would contain a more limited statement of risk information in the major statement (either information on some or all significant risks or a general warning statement). The May 14 Notice requests public comment on this proposal:

> If FDA required or permitted more limited risk information in the place of the current brief summary, what specific information should be included? What criteria should be used by manufacturers and the agency to identify the "major" risk information for any particular product?

Id. at 24316.

With regard to the suggestion by some Roundtable participants that the new advertising format provide only a general warning, the agency states:

> Such disclosures, however, are susceptible to habituation or "wear-out," which results in the viewer quickly teaming to ignore the message, thus lowering its

> effectiveness.... FDA solicits comments on the effectiveness of such standardized general disclosures at transmitting risk information.

Id.

Some Roundtable participants also suggested in this regard that it may be appropriate to require the print media to contain more risk information than the broadcast media. The May 14 Notice requests comment on this issue:

> [S]hould print media contain longer and more complete information [disclosures] than broadcast media because such information could be made readily available at minimal cost and consumers of print media may be more willing, able, and desirous obtaining more complete information?

Id.

Thus, the key concerns and proposals brought forward at the Roundtable have either been accepted by FDA or become focal points of the policymaking process. This further substantiates the view of the National Consumers League and of the Roundtable participants that the interested parties, including the government, can forge agreement on many fundamental issues regarding regulation of DTCP.

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ROUNDTABLE

Speaker Presentations

FDA REGULATION OF DIRECT-TO-CONSUMER PROMOTION OF PRESCRIPTION DRUGS

By David G. Adams
Olsson, Frank & Weeda, P.C.

I. INTRODUCTION

It is a form of promotion that is viewed with skepticism by many health care professionals and government regulators, and is prohibited in most developed countries.

The history of consumer-oriented promotion for prescription drugs defines the current policy conundrum facing FDA. Traditionally referred to as direct-to-consumer or DTC advertising, it includes both advertisements and promotional labeling that are intended to be provided directly to consumers rather than indirectly through health-care professionals such as physicians and pharmacists. Its significance as a marketing tool largely post-dates the drafting of the relevant statutory provisions and agency regulations governing prescription drug promotion, and was not a focal point in the development of that legal framework. It is a form of promotion that is viewed with skepticism by many health care professionals and government regulators, and is prohibited in most developed countries. Yet, it is a growing phenomenon in the U.S. pharmaceutical marketplace that has sparked considerable interest among consumers as well as among a growing number of health care professionals.

Given FDA's acknowledgment that its regulations governing promotion of prescription drugs were not designed specifically to address DTC promotion, the agency has shown continuing although sporadic interest over the years in developing a regulatory regime that would be based on a reasoned assessment of the distinctive issues involved in this form of communication. The first notable effort occurred in the early 1980's with a call for a voluntary moratorium on DTC promotion pending a series of public meetings and discussions. Following two years of review, the agency concluded that DTC promotion could be appropriately regulated under the agency's existing regulations and lifted the moratorium. The second effort occurred in the early 1990's with the circulation of a draft policy statement prepared by agency staff. This effort also appears to have been

abandoned following intense scrutiny and opposition by both the regulated industry and Congress.

Currently the agency is involved in an effort to examine these issues anew and consider whether, finally, to address the special regulatory considerations surrounding DTC promotion. In the midst of this discussion, it is prudent to examine the legal and policy conundrum faced by the agency over the years, the current challenges, and the possibility of a new approach.

II. TYPES OF DTC PROMOTION

DTC promotion, as the term is generally used by FDA and as used in this discussion, refers to three types of communications which provide the consumer with varying types and amounts of information.

Help-Seeking Communications. Help-seeking advertisements and labeling are communications that suggest that, for persons with a certain disease or condition, there may be a helpful therapy available and that such individuals should ask their health-care providers for information. These communications are sometimes referred to as institutional promotion because they generally mention the name of the company sponsoring the communication but do not identify the therapy. These communications are not regulated by FDA as prescription drug promotion under the theory that no drug is identified.

Reminder Communications. Reminder advertisements and labeling, sometimes referred to as brand-recognition promotion, involve a communication that provides the name of the therapy without providing any information about the nature or purpose of the therapy. This form of promotion is defined in FDA regulations and is exempted from most regulatory requirements.

Product-Claim Communications. The third and most controversial form of DTC promotion is that which identifies a product and provides information about the nature or purpose of the product. This form of communication prompts the agency's review under the full panoply of legal requirements for labeling and advertisements, discussed below.

The trend in DTC promotion has been toward using product-claim communications and providing the consumer with more rather than less information. This trend accelerated suddenly in the early 1980's and was met with initial resistance by the health-care community, government regulators, and many within the regulated industry. As the trend has continued over the years, resistance by the health-care community has lessened considerably, consumers have shown greater interest and strict regulatory oversight has yielded to a more flexible and confident approach. Currently there is a significant effort by the United States Food and Drug Administration to formulate a policy that will address the many issues and questions surrounding this growing phenomenon. The cornerstone of this initiative will be the agency's interpretation of its legal authority.

The trend in DTC promotion has been toward using product-claim communications and providing the consumer with more rather than less information.

III. THE LEGAL CONUNDRUM

The difficulties faced in using DTC promotion as a marketing and educational tool result in part from the scope and rigor of the legal and regulatory framework, from the fact that the applicable statutory provisions do not contain specific provisions related to DTC promotion and that FDA's regulations were not drafted with DTC promotion in mind. Although DTC promotion in the print media has found a place for itself under the terms of the current regulatory regime, promotion in the broadcast media continues to be severely curtailed.

To fully understand the basis for many of the current issues involving DTC promotion, it is important to have an understanding of the legal framework and its practical effects. The first element of this understanding must be the expansive scope of FDA's asserted regulatory authority.

A. The Scope of Regulation: Labeling and Advertisements

The array of activities regulated by FDA under its authority over labeling and advertisements is quite broad. Under the Federal Food, Drug, and Cosmetic Act (FDC Act), labeling is defined as "all labels and other written, printed, or graphic matter (1) upon any article

or any of its containers or wrappers, or (2) accompanying such article." Focussing on the concept of materials "accompanying" a product, the agency reached far beyond materials that physically accompany a product. The agency sought to regulate a broader range of materials that supplement or explain a regulated product. Based on numerous judicial precedents, FDA stated in testimony before Congress in 1976: "Labeling has been defined quite broadly in the [FDC Act] and by the Courts and includes virtually all printed materials about drugs placed into interstate commerce and supported by a drug firm."

Although FDA gained authority over prescription drug advertisements, in addition to labeling, in 1962, Congress failed to provide a definition of the term advertisement, stating only that advertisements do not include certain communications that are regulated as labeling. In interpreting the term advertisement the agency has presumed that Congress intended the concepts of labeling and advertisements to have parallel meanings that would include information originating from the same source as the product that is intended to supplement or explain the product. FDA distinguishes the concepts of labeling and advertisements largely by the medium employed by the vendor. If such communications are in written, printed, or graphic form and are disseminated by the pharmaceutical company, they are generally regulated as labeling unless they are disseminated through the media. If they are disseminated through the print or broadcast media or if they are disseminated in some form other than written, printed or graphic (e.g., oral presentations), they are generally regulated as advertisements.

FDA's regulations were not drafted with DTC promotion in mind.

Thus, the agency has created a virtually seamless regulatory regime in which most communications intended for the marketplace to supplement or explain a prescription drug will be subject to regulation either as labeling or as an advertisement. This broad assertion of jurisdiction has had a significant effect in the marketplace, for both promotion to health care professionals and DTC promotion. FDA has made its presence felt in such varied contexts as textbooks and articles published in scientific journals, live scientific and educational symposia, press conferences and press materials, consumer research, discussions between company personnel and consumers, and even appearances of

celebrities on television.

B. The Regulatory Hurdles and Barriers

The labeling provisions of the FDC Act include, among other things, requirements that labeling not be false or misleading in any particular, and provide full disclosure of all material facts related to the product or its use. The provisions governing prescription drug advertisements contain fewer, and more general requirements, the most significant being a brief summary relating to side effects, contraindications, and effectiveness, which has been amplified under current regulations to require a lengthy and substantive discussion of the product and fair balance in overall presentation. These provisions have formed the basis for a number of regulatory strictures and impediments for DTC promotion.

the agency will consider... whether the more vulnerable members of the public may be misled.

Non-misleading content. Under the language of the statute and its regulations, FDA would preclude any labeling or advertisement that is false or misleading in any particular. In determining whether a communication is misleading in any particular, the agency will consider whether the communication fails to reveal a fact that the agency deems material to the discussion of the product, whether the context of any particular statement in the advertisement may cause confusion, and whether the more vulnerable members of the public may be misled. The agency's regulations for prescription drug advertising list many other examples of how an advertisement may be misleading.

Adequate and well-controlled studies. Although the agency interprets the prohibition of misleading labeling and advertisements as requiring substantiation of claims, the key substantiation requirement for prescription drug promotion was provided in the new drug provisions of the of the FDC Act. Under these provisions, FDA approval of new drugs must be based on "substantial evidence" of effectiveness. Substantial evidence is defined to include adequate and well-controlled clinical investigations upon which experts could reasonably base a determination that the drug is effective. Under the agency's application of this standard, manufacturers are required to demonstrate proof of efficacy based on replicated, statistically

significant findings. Because (1) virtually all prescription drugs are regulated as new drugs and (2) all prescription drug advertising and promotional labeling claims for new drugs must be consistent with approved labeling, FDA requires that all efficacy claims in DTC promotion be supported by adequate and well-controlled studies. Moreover, FDA drug advertising regulations require that drug comparison claims involving either safety or efficacy must be supported by adequate and well-controlled studies. Even outcomes claims and quality-of-life claims that FDA may not regard as new efficacy claims must, in the agency's view, be supported by adequate and well controlled studies.

FDA requires that all efficacy claims in DTC promotion be supported by adequate and well-controlled studies.

Fair balance. An important standard employed by FDA in regulating prescription drug advertisements is fair balance between claims of a drug's benefits and relevant disclosures of risks and limitations on efficacy. The regulations require that risk information be presented with comparable prominence to the claims made about the drug's benefits . FDA interprets this regulation to require that the balancing information appear not only in the package insert or brief summary discussed below, but "in the body copy of the promotional material in language understood by consumers." In the case of a broadcast advertisement, the regulations specifically require disclosure of major risks (side effects, precautions, warnings, and contraindications) as an integral part of the advertisement. FDA refers to this disclosure as the "major statement." The promotional material must be viewed as a whole to determine whether it has fair balance, considering not only the textual material, but also its presentation (e.g., headlines, prominence).

The brief summary and package insert. FDA requires a full statement of prescribing information in all prescription drug labeling and advertisements. The full-disclosure labeling requirement is generally met by the inclusion of the FDA-approved package insert with any drug labeling. With regard to advertisements, the statute requires a "brief summary related to side effects, contraindications, and effectiveness." The agency's regulations address the brief summary requirement in detail and require, among other things, a discussion of the side effects and contraindications for any indication in an advertisement.

Promotional labeling is required to contain the full package insert. In practice, the brief summary used in advertisements closely resembles the package insert, including the sections from the approved package insert on adverse events, contraindications, warnings, and precautions. Neither is likely to be read by consumers and even FDA admits that "the value of this information for consumers is questionable." Yet, the agency applies this requirement in a manner that virtually precludes product-claim messages for consumers in the broadcast media.

Pre-dissemination agency review. FDA does not have any statutory authority to require pre-dissemination approval of prescription drug advertising except special circumstances. The agency's preapproval authority over advertising is limited to circumstances in which FDA has notified a firm that it has disregarded important safety information and the firm has failed to take appropriate corrective action. FDA regulations require that sponsors of approved premarket approval applications must submit advertising and promotional labeling to FDA at the time of initial use or dissemination. FDA has strongly advised drug companies to submit DTC promotional materials to the agency prior to dissemination and most do so.

FDA has strongly advised drug companies to submit DTC promotional materials to the agency prior to dissemination and most do so.

IV. THE MORATORIUM

In the early 1980's the agency witnessed a significant growth in DTC promotion. With the appointment of a new Republican Commissioner, Arthur Hull Hayes, M.D., FDA began to examine its policy of applying regulations to DTC promotion that were designed for promotion to health care professionals. Perceiving a softening of the agency's application of these regulations to prohibit broadcast advertising to consumers, Democratic Congressional oversight activities were swift in coming. Although Dr. Hayes continued to argue that a new policy analysis was in order with regard to DTC promotion, the rapid growth of the phenomenon and of the political issue of deregulation created a need for agency action. On September 2, Commissioner Hayes issued a formal policy statement declaring a "voluntary moratorium" to allow time for a dialogue among consumers, healthcare professionals, and industry and to allow time to

conduct and interpret research on DTC promotion. After a series of public meetings, FDA lifted the moratorium on September 9, 1985. Finding little support for DTC promotion from consumers and, surprisingly, from the pharmaceutical industry, and faced with considerable opposition from the health care professionals, the agency abandoned its proposal to consider new regulations for DTC advertising and stated its intent to continue to apply the general regulations for prescription drug advertising.

V. THE 1990 DRAFT POLICY STATEMENT

In 1990, in response to a request for information from a Congressional subcommittee, FDA provided Congress with a document it described as a "draft policy statement on direct-to-consumer advertising...

In 1990, in response to a request for information from a Congressional subcommittee, FDA provided Congress with a document it described as a "draft policy statement on direct-to-consumer advertising dated April 5, 1990." The agency requested that the document not be made available to the public because the agency expected that the document "will undergo further revision before becoming an official agency policy." Although Congress apparently did not make the document public, it did provide a document described as a "Proposed Policy Statement on Prescription Drug Advertising" issued by the Director of FDA's Center for Drug Evaluation and Research and dated July 17, 1990 (CDER Draft), to Congressional Research Service (CRS) for analysis. In a 1991 memorandum to the Committee (CRS Memorandum), the CRS described the document as follows:

> [T]he proposal would require governmental (HHS) preclearance of prescription drug advertisements directed to consumers. A stated objective of the policy is to allay concerns about the potential undermining of the education of patients that might possibly result from the limited and biased nature of advertising. The proposal cites agency intent to consider an advertisement to be product-claim advertisement [sic] (PCA) if it encourages the audience to ask its doctor of a particular prescription drug treatment. The agency clarifies [FDA's] intent to discourage and severely restrict product-claim advertising directed to consumers.

Portions of the 1990 CDER Draft quoted in the CRS memorandum evidenced a deep skepticism on the part of the agency with regard to DTC promotion:

[T]he agency is concerned about the potential of PCA's to mislead the public, somewhat less concerned about product mention ads, and still less concerned about help-seeking ads. Because consumers lack medical training, the FDA believes that PCAs directed to consumers are much more likely than physician-directed ads to be false or misleading.

Dr. Kessler stated that "[t]he risk of overuse and consumer confusion has to be balanced against the benefits that can be achieved by informing the public about the existence of a therapy."

The CRS Memorandum further quotes the agency as viewing advertising directed to consumers as outside of the marketing arena "contemplated" by the statute and regulations, and concluding:

[T]herefore, the FDA deems advertisements directed to consumers represent [sic] the "extraordinary circumstances" contemplated in Section 502(n) of the Act, and it intends to promulgate regulations requiring prior approval of such advertisements. In the interim, the agency requests that all firms seek informal agency review and concurrence before running such advertisements.

Although the CDER Draft has apparently not yet been disseminated to the public at large, the substance of the document was apparently obtained by the trade press in early 1991, near in time to the swearing in of Dr. David Kessler as the new FDA Commissioner. The timing was significant because of Dr. Kessler's well publicized concerns over misleading promotion of prescription drugs and intent to initiate a more aggressive enforcement policy. Although the enforcement initiative was primarily focussed on advertising to physicians, the new Commissioner stated that he was concerned with the "proliferation" of DTC promotion. Dr. Kessler stated that "[t]he risk of overuse and

consumer confusion has to be balanced against the benefits that can be achieved by informing the public about the existence of a therapy."

VI. PETITIONS AND LAWSUITS

The reports of the 1990 CDER Draft were followed by the filing of several citizen petitions, and one of the petitioners has recently filed a lawsuit against FDA based on its petition. Two of the petitions were filed by Washington D.C. law firms; one was filed by the Washington Legal Foundation (WLF), a public advocacy entity opposed to restrictions on commercial speech. The petitions directly challenged the 1990 CDER Draft, as well as policies already in force by the agency, as beyond the agency's authority under the FDC Act and as unconstitutional. The petitioners also challenged the proposal for pre-dissemination agency approval of DTC advertisements, arguing that such a requirement would constitute an unconstitutional prior restraint on commercial speech protected under the First Amendment.

the district court agreed with WLF that significant constitu-tional issues were raised by FDA's restrictions on prescrip-tion drug advertising.

The constitutional arguments presented in the WLF Petition have assumed greater weight following a judicial opinion in litigation brought by the WLF with regard to FDA regulation of promotion of off-label (unapproved) uses of prescription drugs in which the Foundation raised similar Constitutional arguments. In the suit, the WLF alleges that FDA policies have deprived physicians of vital information related to patient care, and have interfered with the ability of physicians to present scientific information to others and to receive professional education supported by the regulated industry. In dismissing the government's motion to dismiss, the district court agreed with WLF that significant constitutional issues were raised by FDA's restrictions on prescription drug advertising.

One of the petitioners, Sonnenreich, Roccograndi & Woo, P.C., has recently brought a lawsuit against the agency based on its petition regarding direct-to-consumer promotion. In a lengthy complaint, the plaintiff restates the propositions it had argued in its citizen petition and asks the court to declare that FDA's policies and regulations on DTC advertising violate the constitution and are invalid and that FDA has no authority under the statute to regulate DTC advertising.

VII. THE CURRENT DIALOGUE

Well before the Sonnenreich lawsuit was filed, FDA had published a notice in the Federal Register expressing the view that the agency's relevant policies and regulations on DTC promotion should be fully examined in a public forum and new policies considered. This initiative resulted less from concern over the impact of DTC promotion or over the absence of special regulations for this phenomenon than from the agency's greater level of comfort with its ability to regulate DTC promotion and ensure that balanced non-misleading information could be provided to consumers in various formats.

For example, in the context of reviewing DTC communications for Rogaine, the agency found it could deal comfortably with various new types of communications including infomercials, videotapes, and 800 numbers, as well as traditional help-seeking and reminder communications. Both industry and the agency were able to develop approaches for DTC promotion that worked. Similarly, the agency's experience with DTC promotion of nitroglycerine patches revealed that the agency was willing to allow a reminder communication that communicated more than the name of a product: the agency permitted a description of the type of product and dosage form as well as the suggested use of the product through the product's name.

In its August 1995 Federal Register notice, the agency did not mention the 1990 CDER Draft. The agency proposed no new policy and instead called for written comments and a public meeting to hear oral testimony. At the public meeting, both agency officials and witnesses voiced skepticism regarding DTC promotion. There was also, however, considerable agreement among government officials and witnesses that a new policy was in order that would allow for some reasonable form of product-claim advertisements.

VIII. CONCLUSION

The absence of a significant focus on DTC promotion in the development of the statutory provisions and FDA regulations governing DTC prescription drug promotion weighs in favor of a full legal and policy review by FDA of DTC promotion. After several prior, unsuccessful attempts to do so, the agency is currently conducting a serious initiative in a public process. This affords industry, consumers, health-care professionals, and other interested parties an unparalleled opportunity to engage the agency and work with it to develop a reasoned approach to regulating DTC promotion. The current initiative is all the more pressing in light of the recently filed lawsuit against the agency on DTC promotion. Despite the lawsuit, there is an opportunity for a reasoned, public, and cooperative policy-making process. It will offer a greater likelihood of a regulatory outcome deemed reasonable by the interested parties. It is, thus, imperative that interested parties participate vigorously at this juncture and seek to find common ground and present ideas that will encourage flexibility and creativity on the part of the agency.

Despite the lawsuit, there is an opportunity for a reasoned, public, and cooperative policy-making process.

SUMMARY OF RESEARCH CONCERNING DTC DRUG PROMOTION

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Public Health Analyst, Food and Drug Administration
Division of Drug Marketing, Advertising and Communications

Today I've been asked to discuss a summary of research concerning DTC drug promotion. I would also like to preface my remarks with the disclosure that today's limited time means that I can't discuss fully all of the information or concerns I'd like you to be aware of this morning. Please understand that this doesn't mean that the agency is not considering seriously all research it's aware of.

...although there may be much research that is potentially relevant to the issue of direct-to-consumer promotion of prescription drugs, there is actually disappointingly little that is directly relevant.

The truth is that although there may be much research that is potentially relevant to the issue of direct-to-consumer promotion of prescription drugs (hereinafter referred to as DTC), there is actually disappointingly little that is directly relevant.

Basically, I'd like to discuss research that specifically targets DTC. So ... let's begin with the issues involved. In a 1991 report to the Chairman of the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, the General Accounting Office cited 108 nonempirical studies that discussed the possible consequences – both positive and negative – of consumer-directed advertising of prescription drugs. More articles have appeared since that time. Some of these analyses discuss the presumed benefits of DTC promotion – the more frequent being that DTC will lower pharmaceutical prices, educate consumers, and allow consumers to become more active in their own health care, consequently improving the patient-physician relationship. Other analyses discuss the presumed costs of DTC promotion – the more frequent being that DTC will raise pharmaceutical prices, encourage consumers to pressure their physicians to prescribe particular products, thus negatively interfering with the patient-physician relationship, will lead to excessive medication of an already over-medicated society and will mislead and/or confuse consumers. Not surprisingly, the GAO report points out that more benefits than detriments were cited in analyses supporting DTC, and more detriments than benefits were cited in analyses

opposing DTC. A few analyses attempt to derive models of DTC advertising and to predict and validate on the basis of existing practice the characteristics of products – their market, life cycle, etc. – that are associated with DTC advertising.

But, is there empirical research that addresses the potential benefits and costs predicted to result from DTC? There is some, although it is limited in both scope and validity. There is, for example, survey research concerning patients' desire for information. Back in 1983 or thereabouts, CBS sponsored a national household survey that found that about three-fourths of consumers wanted more information than they had about their prescription drugs, and only one-third felt well-informed about this matter. Moving ahead to 1994, an FDA- and HCFA-sponsored national survey of patients who received new prescriptions suggested that almost half of these patients (45%) do not receive any substantial patient information about the dispensed drug beyond what is on the product's container label. These data are certainly suggestive that more consumers want information than appear to be getting it. They don't, on the other hand, address whether consumers want the information in the form of promotional materials.

There are, however, some data suggestive that consumers are not excessively put off by current promotional materials. Recently, FDA received testimony from market researchers at a large advertising agency that has conducted numerous proprietary qualitative and quantitative (i.e., copy tests) studies of DTC materials. They assert that the vast majority of consumers in their studies (an average of 97%) say that the DTC materials they've seen are informative and educational, although only one-fourth consider the materials objective and less than half consider them to be reliable.

There's also some research, both published and proprietary, that suggests that DTC may not affect too deleteriously the patient-physician relationship. A small non-rigorous study by Perri & Dickson (1987) showed little effect of their DTC manipulation – admittedly a weak one – on this relationship. Further, aggregate average data resulting from numerous DTC quantitative and qualitative market tests since 1991 suggest that of the approximately half of tested consumers who said they'd take action after reading an ad, the majority (83%)

patients who received new prescriptions suggested that almost half of these patients (45%) do not receive any substantial patient information about the dispensed drug beyond what is on the product's container label.

expected such action to be a discussion with their physician at their next scheduled appointment. Less than one-fourth (17%) of those expecting to take action anticipated calling their physicians or setting up a specific meeting to discuss the product.

It's also worthwhile to note that the results obtained from attitudinal studies can be used to support vastly different positions, depending on which studies and which results are highlighted. For example, there are many studies, from the early 80's through 1992, that show that large percentages of health care professionals - - consistently over half of the respondents queried – object to DTC advertising. This has been shown in studies conducted by the American Medical Association, Scott-Levin Associates and academic researchers.

although (health) professionals may be opposed to the *concept* of consumer advertising of prescription drugs, they are open to the potential benefits of (presumably) fairly executed advertising, for at least certain prescription products.

On the other hand, there are also studies showing that health professionals did not object to specific or prototypical DTC advertisements. Taken together, these data suggest that although professionals may be opposed to the *concept* of consumer advertising of prescription drugs, they are open to the potential benefits of (presumably) fairly executed advertising, for at least certain prescription products. In other words, depending on whether one examines reactions to an abstract concept, or to specific concrete examples of that concept, very different data may be obtained.

I should also note, however, that the usefulness of many attitudinal and copy test studies for guiding policy, as opposed to guiding marketing strategy, is severely limited in a number of ways. The methodologies are often less than ideal, due to the use of non-probability samples and the achievement of low response rates, even in the larger studies. This casts doubt on the validity and generalizability of the findings. Small, geographically restricted samples and low response rates often plague the smaller studies as well. Copy tests pose generalizability concerns because of the use of convenience samples and self-selection biases. Qualitative research is especially subject to self-selection bias.

The more rigorous studies in the DTC area have tended to investigate specific format or content variations; there are few of these. In 1983, Lou Morris and his colleagues at the FDA conducted a large experimental study of the effects on consumers' knowledge and

attitudes of DTC print and television advertisements for two fictitious drugs. The results are reported in a number of publications appearing in the late 80's. Briefly, this study examined a number of factors: the media used; the amount of risk information included; the specificity of the risk information; and the degree of integration of the risk messages. One control ad for each product included thorough risk information along the lines of a consumer-friendly "brief summary," presented at the bottom of the magazine ad and scrolled at the end of the TV ad. An additional control group included no risk disclosure. Knowledge of the benefits and risks was evaluated, as were attitudes about the products, DTC in general, overall perceptions of risk and benefits, likelihood of requesting the medication, etc.

In general, the more risk information presented, the better knowledge was about the ad points, and the more balanced the perceived benefit-to-risk ratio. Risk length did not appear to affect attitudes.

Specific risk messages – those that targeted specific side effects of the two fictitious products – resulted in greater recall and a more balanced perceived benefit-to-risk ratio. An interesting result is that ads containing general risk disclosures resulted in more positive attitudes about the drugs and a greater appreciation of the physician in the evaluation and prescribing of prescription drugs. But, in terms of knowledge, *the general risk disclosure ads didn't differ from the no disclosure ads.* This finding suggests a weakness of the general risk disclosures in communicating an appreciation of the risks of using these products.

For those of you who believe the kind of detailed information included in brief summaries does not effectively communicate information to consumers, I would point out that, in the magazine ads, the thorough risk disclosure produced inferior knowledge scores to most other forms of risk disclosure examined.

An experimental study by Tucker (1986) is generally consistent with these data. This study consisted of an experimental examination of 4 formats for a fictitious prescription flu vaccine. The formats consisted of a general warning disclosure, a prototypical brief summary with headings, a narrative brief summary withoutheadings, and a control condition which contained no risk information. The

...thorough risk disclosure (the kind of detailed information included in brief summaries) produced inferior knowledge scores to most other forms of risk disclosure examined.

traditional brief summary format was judged as significantly more informative than the "no risk" control; the other two formats did not differ significantly from any others. Given the FDA study results, especially interesting was that both the "no risk" and "general risk" disclosures were judged as higher on what Tucker named a "security" factor than either of the formats containing the detailed risk information, suggesting, together with the FDA data, that general disclosures are more likely to communicate a message of reassurance than an actual risk message.

I hope this gives you a flavor of some of the research that's been done in this area. I would also point out that FDA has consistently been research-oriented and is eager to know of any work that any of you may be doing in this area. Thank you.

general disclosures are more likely to communicate a message of reassurance than an actual risk message.

MORRIS (1984) FACTORS

- Media (magazine vs. television)
- Amount of Risk Information (2 vs. 4 risk concepts)
- Risk Specificity (specific vs. general disclosures)
- Risk Emphasis (integrated vs. separated/emphasized)
- Controls
  --no risk
  --thorough risk

GENERAL RISK DISCLOSURES

- Short

"All drugs have side effects you should know about."

"Only your doctor can determine if should be prescribed for you."

- Long (added) --

"Be sure you know any precautions and how to use ____before you use it."

"Before you use any drug, ask your doctor about possible interactions with other drugs or food.

TUCKER (1986)
Four Format Variations

- Prototypical Brief Summary (with headings)
- Narrative Brief Summary (no headings)
- No Risk Disclosure
- General Risk Disclosure
"All prescription medications have side effects. Consult your physician to see if Fluvax would be safe and effective for you."

Opportunities for Information and Education in Consumer-Directed Health Promotion

N. Lee Rucker, M.S.P.H.
Associate Executive Director
National Council on Patient Information and Education
Washington, D.C.
January 17, 1996

The National Council on Patient Information and Education ("NCPIE"), which was founded in 1982, is a coalition of health professional, pharmaceutical manufacturer, educational and consumer organizations focused on improving communication between health care practitioners and their patients about prescription medicines.

NCPIE provides educational resources to health professionals and consumers to improve their communication about and understanding of prescription drugs.

There are three things that I will discuss with you today. First, just what do we know about consumers' thinking on direct-to-consumer advertising of prescription drugs? Second, I will explain two NCPIE tenets that go hand-in-hand with DTC ads, that of the medicine education team and the "teachable moment." Finally, I will discuss NCPIE's proposed national medicine education campaign.

I would like to bring to your attention two doctoral dissertations (both 1995) that specifically looked at consumers' responses to DTC ads for prescription drugs. One, by Lisa Ruby Basara, Ph.D. (with Rhone-Poulenc Rorer), studied DTC ads' effects on prescription volume and on "consumer information-seeking behavior." (The volume/sales data portion of her research will appear in *Pharmaceutical Executive* in Feb. 1996.) Of the nearly 1400 consumers who responded, over one-fourth of them recalled seeing at least one of seven DTC ads. Over four percent of all respondents called the toll-free 800 number given in the ad. Those consumers differed from those who did not call only in their self-perceptions of knowing more than other people about prescription drugs, Basara found.

The other author studied the effects of DTC ads on an elderly population (Tom Christensen, Ph.D., now with North Dakota State

Univ., Fargo). He found that DTC ads are most useful if individuals are motivated to process the information. "If they're less motivated, they may be more swayed by promotional aspects of the ad content vs. important clinical aspects," he said. Christensen cautioned that practitioners should "be aware of different avenues of influence when communicating with patients exposed to DTC ads."

I would now like to turn to NCPIE's tenets that I mentioned earlier. First is the medicine education team – which includes physicians, pharmacists, nurses, the pharmaceutical industry, managed care organizations, the FDA and patients. The patient is the team leader or the "Medication Manager," because he/she is positioned to make critical start/stop decisions. These decisions ultimately promote or undermine the particular therapy's effectiveness.

Along with the medicine education team is the concept of the "teachable moment," i.e., taking full advantage of appropriate opportunities to inform and educate patients aboutprescription medicines. Ideal situations may occur in the waiting area, examination room, at an exit interview, as part of hospital discharge planning, or during a home visit.

Direct-to-consumer ads for prescription drugs may present wonderful teachable moments. Indeed, as one researcher concluded, DTC advertising "may serve more as a catalyst for doctor-patient discussions rather than a catalyst for demand" (Everett, cited in Christensen dissertation, pps. 41-42). Teachable moments are encouraged by common statements in DTC ads such as, "Ask your doctor/pharmacist if this drug may be right for you," and "What are the side effects of [drug X]?"

This brings me to what the FDA could do now to advance consumers' receipt of "useful" drug information. Since it bases its proposed "Medication Guide" program on its NDA/ANDA control over manufacturers, the FDA could study different contents and formats of printed drug information by requiring manufacturers to evaluate them in their DTC advertising. We know that manufacturers are willing to allocate resources to try to educate consumers via DTC ads; let's take advantage of that teachable moment by eliminating the requirement to include a brief Package Insert in DTC ads, and instead

Direct-to-consumer ads for prescription drugs may present wonderful teachable moments.

use a PPI/MedGuide prototype on an investigational basis. This would provide an ideal opportunity to try out various presentations and contents, and to get reliable evaluations that could be useful to all members of the medicine education team.

Another opportunity for information and education in consumer-directed health promotion would be for ads to include a screened box or designated space for a set of questions that consumers would be encouraged to ask their health care professional each time a medicine is prescribed or dispensed. These enabling questions would stimulate a dialogue between the patient and his/her health care provider regarding instructions for use, precautions, and side effects. Basic questions which NCPIE has promoted for several years include:

There are many opportunities for information and education in consumer-directed health promotion.

1. What is the name of the medicine, and what is it supposed to do?
2. How and when do I take it – and for how long?
3. What food, drinks, other medicines or activities should I avoid while taking this medicine?
4. Are there any side effects, and what do I do if they occur?
5. Will this new medicine work safely with the other prescription and over-the-counter medicines that I am taking?
6. Is there any written information available about the medicine?

In closing, I encourage pharmaceutical manufacturers, the FDA, the National Consumers League and others here today to work with NCPIE to develop a multi-media campaign to ensure that these types of medicine information and education questions reach consumers as often as possible. With your support and assistance, such an education campaign can succeed. There are many opportunities for information and education in consumer-directed health promotion. It is now incumbent on each of us to seize these opportunites.

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Note: Pages 2-3 of these remarks were adapted from a prepared text by Wm. Ray Bullman, NCPIE Executive Director, who was originally scheduled to present at the Roundtable.

BRINGING PEOPLE TOGETHER WITH SOLUTIONS

The Role of Industry in Direct-to-Consumer Advertising

By Matthew Seymour
President, CommonHealth Direct

I want to thank you for giving me the chance to speak with you today, to discuss the appropriate role of direct-to-consumer advertising of prescription products and services in today's healthcare marketplace. There is an opportunity for all of us to come out on the winning side of the direct-to-consumer debate if we are willing to listen to the needs and concerns of everyone affected by this advertising and stay focused on what is best for the health of our nation's consumers.

CommonHealth Direct is the direct marketing division of CommonHealth USA, the largest marketing and communications resource in the healthcare industry.

In my opinion, direct-to-consumer advertising of prescription products and services has the potential to be very, very good for everyone – doctors, manufacturers, advertising agencies, consumer publications, and, most importantly, consumers.

I am passionate about this subject because I know we can make this a win-win situation that will improve the lives of all healthcare consumers and still allow private enterprises to realize fair rewards for their efforts.

I truly believe that pharmaceutical manufacturers and healthcare communications companies are in business for the long haul, not to make a quick profit and run. There is no question that drug companies are in business to be profitable.

But while profit in the next quarter is definitely on the minds of pharmaceutical executives under pressure from impatient stockholders, these executives also know that consumers are much more valuable if they are satisfied with the products and services they receive and willingly enter long-term relationships with manufacturing companies. A person suffering with a headache who is satisfied with the price and performance of a drug company's pain reliever will not only continue to use it when the need arises, but will be more inclined to influence

I know we can make this a win-win situation that will improve the lives of all healthcare consumers

their friends and family members to use it as well.

Another benefit of long-term relationships, and one that is strengthened by consumers taking responsibility for their own healthcare, is a higher level of compliance among patients.

We believe that direct-to-consumer advertising increases consumer compliance. If consumers are treated at the earliest stages of diseases, that means better health for patients, better outcomes for physicians, and lower long-term care costs for managed care organizations and governmental health agencies. And, again in return for delivering value, it means higher sales for pharmaceutical manufacturers.

Most pharmaceutical manufacturers are still not sure exactly what to make of direct-to-consumer advertising.

The question for prescription drug manufacturers is how to develop long-term, value-for-value relationships with consumers who can't make the ultimate prescription choices by themselves.

Unlike traditional one-to-one marketing relationships, there are a host of other parties involved in the pharmaceutical product transaction, from physicians to pharmacists to managed care companies to spouses and other influencers, making the relationship-building process much more challenging, to say the least. It is no longer practical or effective to deliver a single message to a single audience.

Direct-to-consumer advertising presents an opportunity for pharmaceutical companies to deliver messages that will initiate relationships with healthcare consumers, to the benefit of everyone involved. It is not the complete answer for healthcare marketers, but it is a piece of the relationship-building puzzle and everyday it is becoming a larger part of the marketer's strategy.

Most pharmaceutical manufacturers are still not sure exactly what to make of direct-to-consumer advertising. They see the enormous potential of reaching a mass audience that is demanding more influence over their own healthcare decisions, but these drug companies have spent so many years communicating with physicians and other healthcare professionals, they don't know how to talk to consumers.

They don't understand that consumers want and need different kinds of information than doctors. Few pharmaceutical companies have experiences to draw upon for developing meaningful consumer relationships.

Our task, then, is to create communications that not only inform doctors about the latest healthcare therapies, but also let consumers know they have personal options and start them thinking about the significance of those choices. Doctors want pharmaceutical products that reduce pain and heal their patients. They measure effectiveness in terms of lab results and symptom relief. They choose a drug for its features – or lack of features, in the case of potential side-effects or possible drug interactions – but always with a focus on effecting optimal and measurable outcomes.

But consumers have a different agenda. They want to feel good. Does the average person care that an elevated cholesterol level means more sticky plaque forming on artery walls, eventually leading to arteriosclerosis?

But consumers have a different agenda (than doctors). Doctors want to know what a drug will do. Consumers want to know what it will mean.

The answer is no. Consumers do, however, care that high cholesterol means potential heart attacks, and that in turn may mean having to give up tennis or golfing or romping with their children and grandchildren. Doctors want to know what a drug will do. Consumers want to know what it will mean. Doctors ask, will this drug significantly lower cholesterol levels? Patients ask, if I take this drug, can I continue playing tennis into my golden years?

Here, then, is the challenge for advertisers: To educate doctors about the drug features they require to produce satisfactory patient outcomes, and, at the same time, show consumers how their lives might be improved by use of appropriate pharmaceutical therapies. It is the advertiser's task to bring such diverse audiences with different needs together to a place where they can meet and discuss the issues important to each.

We're not pushing drug use here. No one advocates the inappropriate use or misuse of pharmaceuticals. Over-promising is unacceptable. What we must be allowed to do, however, is let consumers know that there are options that can substantially improve the quality of their lives if they are suffering from certain conditions.

If you don't have epilepsy, it won't matter to you that there is a new product that may be more effective than current anti-epilepsy therapies. But if you are a person with epilepsy, and this new drug may reduce or eliminate the seizures you still experience despite your

current therapy, having that information may be invaluable. You probably don't care how it works, only that it will allow you to drive, to work in certain professions or to play some sports that you avoid because of your fear of debilitating seizures. *A drug's features mean better health. Its benefits mean a better life.*

So you walk into your doctor's office carrying a consumer ad from a popular news magazine. You ask about this new epilepsy product. Your doctor has been exposed to this new drug through traditional professional advertising and educational programs. You discuss the potential benefits and side effects and decide together whether this new therapy is right for you.

Doctors, consumers, pharmaceutical manufacturers and government agencies all have to deal with another force in today's healthcare environment -- managed care organizations.

You walk out of the office happy, knowing that the exchange between you and your doctor has been raised to a higher level. Your doctor has a better understanding of your condition from your perspective, and you have a better understanding of the treatment option that has been chosen. And yes, the pharmaceutical manufacturer rings up a sale, but only after delivering real value to both the doctor and consumer.

Of course, nothing is ever that simple. Doctors, consumers, pharmaceutical manufacturers and government agencies all have to deal with another force in today's healthcare environment --managed care organizations. Returning to the epilepsy drug example, if you belong to an MCO, there is a chance this new product isn't on their list of reimbursed drugs. For MCOs, the bottom line is a major consideration. In the short term, that may mean some advertised drugs may not be available to consumers who want and need them.

However as competition for patients increases among managed care organizations, I believe they will offer higher value to their members. If consumers demand certain products, managed care organizations will bow to their demands or risk losing customers.

To be fair, managed care organizations are constantly walking the tightrope between value and quality, trying to balance cost and effectiveness. Keeping the cost to consumers low is important not only to MCOs, but to their members as well. Like everyone, MCOs want the best products at the best prices. Direct-to-consumer advertising may help that cause by increasing patient compliance and reducing overall

costs. MCOs win both in the short and long term when members stick to their prescribed therapies, are satisfied with the outcomes and ultimately avoid the higher costs, both financial and in suffering, of treatment in the later stages of disease. Satisfied members also means long-term financial health and stability for the MCOs.

Building demand for their products is another motivation that drives pharmaceutical manufacturers to advertise directly to those who have the greatest power, the healthcare consumers. The fact is, a 1992 survey by Scott-Levin Associates found that 88 percent of physicians had patients who had come into their offices asking for specific drugs by name, and when those requests were made, 99 percent of the doctors found the therapies appropriate and wrote prescriptions. Ninety-nine percent. That tells me that direct-to-consumer ads must be effective in reaching those people who need help most. People recognize themselves and their symptoms in the ads, and take the initiative to influence their own healthcare and elevate their quality-of-life. And in almost every case – 99 percent of the time – doctors agree with their patients' assessments when specific requests are made.

Would those consumers have been empowered without consumer advertising? Would they have known what options were available for treatment of their specific conditions? Absolutely not. Despite what some self-proclaimed consumer advocates would have us believe, access to information deemed accurate and clear by the FDA is a beneficial thing, and a knowledgeable consumer is indeed powerful.

So where are we headed from here? How can we optimize the benefits of direct-to-consumer advertising and minimize exaggerated claims or fraudulent advertising? The key may be in the role that the Food and Drug Administration carves out for itself. If it chooses to endorse direct-to-consumer advertising of prescription products, requiring that it be accurate rather than complete, then it will be performing an important – a necessary – regulatory service for the American people. If it decides to do away with the complete disclosure -- also known, ironically, as the brief summary – in favor of monitoring ads for accuracy and clarity, then it will be taking a giant step toward facilitating better dialogue between healthcare professionals and their patients.

Building demand for their products is another motivation that drives pharmaceutical manufacturers to advertise directly to those who have the greatest power, the healthcare consumers.

The information that is currently required in direct-to-consumer ads is appropriate for physicians, but not very helpful to consumers. It is therefore better suited to professional advertising. Drug companies are limited in the amount of useful information they can convey because the FDA requires that they use so much space delivering information consumers don't need or can't comprehend.

This is not the fault of the FDA, by the way. Since the explosion of consumer advertising, the FDA has been using guidelines developed for professional advertising to regulate consumer advertising. The FDA realizes that is not realistic or useful, and is currently considering changing those guidelines. We can all make a difference in the amount and quality of information we are receiving by offering our perspectives to the members of the FDA. They want to hear from us to ensure that the concerns of all groups are considered and, hopefully, all their needs satisfied.

Since the explosion of consumer advertising, the FDA has been using guidelines developed for professional advertising to regulate consumer advertising.

For our part, the healthcare communications companies will learn better ways to elicit dialogue between doctors and consumers, and optimize these interpersonal transactions. If the FDA guidelines are revised, direct-to-consumer advertising will evolve into a mechanism that educates consumers about their healthcare options and results in more consumer responsibility for their own choices.

As for the future managed care organizations, we believe they will be able to balance the need for both high-quality and cost-effective healthcare. They will include the best products on their formularies, or they will lose customers. When consumers demand value from healthcare transactions, MCOs will deliver or perish – just like physicians and advertising agencies.

Drug manufacturers will continue to spend billions on research and development of new products that elevate the quality-of-life for healthcare consumers. They will spend less on traditional physician strategies and more on earning loyalty from the consumers of their products. The plain fact is that pharmaceutical companies are beginning to face the wider demands of being in the healthcare business rather than being focused on simply developing and manufacturing drugs. In the future, they will succeed only to the extent that they improve their customers' health, as defined by those customers. And cost will always

be a significant factor in assessing quality-of-life decisions for consumers. It will be in the best interests of pharmaceutical companies to try to keep down the costs.

I paint a rosy picture. But I truly believe everyone will win when clear, accurate information is allowed to flow freely to healthcare consumers through direct-to-consumer advertising.

When consumers demand value from healthcare transactions, MCOs will deliver or perish -- just like physicians and advertising agencies.

FDA'S DIRECT-TO-CONSUMER PROMOTION INITIATIVE

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National Consumers League Roundtable on Direct-to-Consumer Promotion of Prescription Drugs
January 17, 1996

I appreciate the opportunity to talk to you today about what FDA has been doing, and what we plan to do, with regard to direct-to-consumer promotion (DTCP) of prescription drugs.

We realize that the time has come to step back and look at the big picture and determine what the agency's role should be in DTCP.

For over fifteen years, FDA has been struggling with putting into place an appropriate regulatory scheme and policy with respect to direct-to-consumer promotion of prescription drugs, (for both humans and animals) biological products, and medical devices.

Recently, the agency has stepped up its efforts at trying to determine an appropriate regulatory scheme and policies.

We have looked at our past efforts, such as the request for a voluntary moratorium in the early 1980's, and the attempts to apply regulations that may be more appropriate for advertising and promotion to health professionals, rather that to consumers.

The world around us is changing.

With the information superhighway and other emerging technologies, the communication of information is everywhere.

With health care costs rising in this country, patients (consumers) are more interested in their own health care and are hungry for drug and disease information.

We realize that the time has come to step back and look at the big picture and determine what the agency's role should be in DTCP.

Recently, the agency turned to the public to get their input as to whether, and if so how, the agency's current regulatory approach should be modified.

We turned to many of you here today, consumers and consumer groups, health professionals and health professional groups, researchers, advertisers, and others.

In August 1995, the agency published a notice in the Federal Register, which listed a series of questions and issues that were of

particular interest to the agency.

We asked questions such as:

•"Is the (brief summary) form of disclosure effective for consumers?" "Is it informative?"

•"Should there be alternative requirements for risk disclosure, and if so what should they be?"

•"What role do (reminder) advertisements play in consumer promotion?" "Are such advertisements useful for consumers?"

On October 18 and 19, 1995, the agency held a pubic hearing to hear oral testimony responding to these, and other, questions and issues.

The agency also accepted written comments on the questions and issues until December 29, 1995.

We are still reviewing the written comments.

With respect to the oral testimony, we heard, loud and clear, the general perspective is that the brief summary is neither brief nor a summary.

we heard, loud and clear, the general perspective is that the brief summary is neither brief nor a summary.

As Bob Temple put it as he summarized the hearing, "The brief summary is not popular and has no explicit friends."

We also heard different opinions and views about whether DTCP communicates useful information to consumers, whether it is intended to communicate useful information, whether it is just a starting point or a stimulus to get people into the doctors office, and whether the objective of DTCP is plainly to sell more drugs.

We heard that the agency should not pre-clear DTC advertising. The agency, however, does not require preclearance for DTC advertising.

It is our belief that, currently, companies do so in order to get agency advice on DTCP campaigns.

Because we are still reviewing the comments, I cannot say what we are going to do with respect to a regulatory scheme for DTCP.

I can, however, tell you that we have heard the criticisms the complaints, and the suggestions.

I can also tell you that we plan to act <u>expeditiously</u> to develop a scheme that takes into account several points:

First and foremost: What makes sense to the consumer? Consumers' needs have to be kept in mind – in terms of understandability of the information in the DTCP and consumers' level of comprehension, and what kind of information consumers need to have.

Second, the internet and other emerging technologies are avenues for DTCP.

Any scheme has to go beyond simple print and broadcast media as modes of communication.

The scheme must be forward-thinking and attempt to cover future technologies.

Consumers' needs have to be kept in mind -- in terms of understandability of the information in the DTCP and consumers' level of comprehension...

Third, we have to take into account what impact modifying the DTCP policies will have on consumers and the health care professions in terms of the delivery of health care in the U.S.

Fourth, whatever policy is developed needs to be consistent with First Amendment values and the free flow of information.

Our first step of information collection is just about over.

This meeting will be helpful in that respect.

We (meaning the other FDA attendees and myself) are here in a "learning mode" to listen to your discussions and hear what you have to say.

As I said, we have stepped up our efforts in this arena.

It's not just rhetoric this time.

I hope our recent actions demonstrate our desire to hear what you, the public, has to say about DTCP and how we truly are looking at the big picture, in terms of the regulatory scheme and policies.

I hope to tell you more about where the agency is going with regard to DTCP in the near future.

Thank you.

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

IN THE MATTER OF DIRECT-TO-CONSUMER
PROMOTION; PUBLIC HEARING
DOCKET NO. 95N-0227

SELECTED COMMENTS OF THE STAFF OF THE BUREAU OF CONSUMER PROTECTION AND THE BUREAU OF ECONOMICS OF THE FEDERAL TRADE COMMISSION

JANUARY 11, 1996*

*These comments are the views of the staff of the Bureaus of Consumer Protection and Economics of the Federal Trade Commission. They do not necessarily represent the views of the Commission or any individual Commissioner.

I. Introduction.

The FTC enforces the Federal Trade Commission Act, which among other things prohibits deceptive or unfair practices in or affecting commerce. One of the FTC's primary responsibilities is to enforce the law prohibiting deceptive practices in national advertising.[1] The FTC considers the prevention of deceptive health-related advertising claims to be of utmost importance, and has taken action in numerous cases involving deceptive health-related claims about OTC drugs,[2] food products,[3] dietary supplements,[4] and medical devices.[5] In implementing its mandate, the FTC has developed considerable expertise in the role of advertising in the consumer information environment.

Truthful and non-misleading advertising can help consumers manage their own health care.

While important differences between advertising for prescription drugs and advertising for other products might lead to different approaches, we believe that the staff's experience, particularly regarding marketing and economic issues, has a bearing on many of the DTC advertising issues on which the FDA is seeking comment.

Truthful and non-misleading advertising can help consumers manage their own health care. Advertisements can, for example, provide timely information regarding medical advances, remind consumers about good health care practices, and supply information needed by consumers to understand and evaluate their physician's recommendations. On the other hand, deceptive or misleading advertisements in the prescription drug area can impose particularly high costs on consumers. The FTC staff believes that the Commission's Deception Policy Statement and its Statement on Advertising Substantiation may assist the FDA in evaluating prescription drug advertisements.

II. The Potential Effects of DTC Advertising on Consumers and the Marketplace.

Assessments of DTC regulatory options are likely to depend on one's understanding of DTC advertising's effects on consumers and the marketplace.

A. Incentives to Provide Consumers with Information About Alternative Drug Therapies.

With the growth of managed care organizations, consumers are expected to become more actively involved in their health care decisions and to demand more information on alternative therapies.[6] The recent growth of DTC pharmaceutical advertising expenditures[7] is consistent with the view that consumers are demanding more product information.

Substantial information about drug therapies is provided to consumers by independent parties. Newspapers report on new drugs,[8] books describe drug options,[9] magazines discuss alternative therapies,[10] and public health organizations provide a wealth of information.[11]

Despite the existence of these sources, economic reasoning suggests that advertising can be an important supplemental source of information.[12]

Firms have strong incentives to provide information about disease conditions and possible treatments if they can associate the information with products they sell.

Incentives to advertise are enhanced when firms can initiate new campaigns quickly. For example, the sooner information on product improvements reaches consumers, the sooner firms can begin through sales to recoup research and development investments and advertising expenditures. Similarly, the incentive to advertise is likely to be greater when firms can respond rapidly to advertising by competitors.

B. Prescription Drug Advertising as a Unique Source of Some Information that Can Enhance Consumer Welfare.

Prescription drug advertising, like any type of advertising, represents only one component of the total consumer information environment, which includes the media, package inserts, reference books, doctors, and pharmacists. Advertising, like any of these components, is better at some tasks that others.

Different forms of advertising may have different advantages and disadvantages as means of communicating information. Complex information is often communicated more effectively through print

Different forms of advertising may have different advantages and disadvantages as means of communicating information.

media than through broadcast media. Internet advertising may be particularly efficient at reaching small sub-populations with a strong interest in certain types of drugs.[13] Deceptive claims in the prescription drug area can have serious consequences.

Although prescription drug advertising shares many characteristics of advertising in other markets, prescription drugs have several characteristics that make the analysis of prescription drug advertising to consumers distinctive. For example, product safety and efficacy is a particularly important issue in this advertising market. At the product level, this concern is addressed by the requirement that all prescription drugs be pre-approved by the FDA for safety and efficacy.

Concerns about product safety and efficacy are reflected in control of access to prescription drugs. Doctors must prescribe them, and they must be dispensed by pharmacists.

Better informed consumers will be better able to understand and discuss their individual needs with their doctors and pharmacists, Thus, advertising can help consumers make decisions about their health care and health care costs.

C. Potential Effects of Prescription Drug Advertising on Price and Quality Competition.

Advertising is an important catalyst for price and quality competition. Advertising can put downward pressure on prices by spurring competition among alternative therapies.[14] To the extent that prescription drugs compete with OTC drugs,[15] prescription drug advertising potentially can lead to lower average prices for both product categories.

Quality competition can also be motivated by advertising. Advertising can help foster product improvements by delivering information to consumers on quality variables that they may not otherwise know.

D. Considerations Regarding Regulation.

We believe that truthful and non-deceptive DTC advertising can contribute to consumers' health information environment and consumer welfare.

Recent consumer research evidence suggests that DTC

advertisements are likely to encourage people to seek advice from their doctors,[16] which may result in improved health care.

We encourage balancing the benefits and the risks of allowing pharmaceutical manufactures greater latitude in their advertising. It is important to protect consumers from deceptive information but not to stifle truthful information that could benefit consumers. The net benefits of DTC advertisements can be increased by limiting current disclosure requirements and by adjusting disclosure requirements according to the characteristics of different advertising venues.

IV. Considering DTC Prescription Drug Advertising Issues in Light of the FTC's Approach.

A. The "Brief Summary."

The FTC's experience in enforcing the law pertaining to deception indicates that it is often difficult to effectively communicate information to consumers. More complicated messages are more difficult to convey to consumers in an understandable manner. Fine print disclosures, whether in print or broadcast advertising, are often insufficient to effectively communicate important information.[17]

The "brief summary" that currently appears in consumer directed prescription drug advertising is obviously highly technical, complicated, and lengthy. It is often presented in fine print, in language that is designed for health care professionals rather than lay persons. We believe that the information contained therein is therefore unlikely to be readily focused on and understood by consumers.

B. Tailoring Regulation to the Advertising Medium.

Print advertising is more conducive to communicating relatively complex information thaN TV advertising because people can read print advertisements at their own speed, and even re-read the information if so inclined. Similarly, advertising on the Internet can be read at one's own pace and can be saved or printed for future reference. A claim read quickly in a broadcast advertisement might present a different likelihood of deception than does the same claim appearing in a print or on-line format. If necessary, abbreviated disclosures in broadcast media could be supplemented through requirements that more detailed information be made available on request and that consumers be made aware of this option.

It is important to protect consumers from deceptive information but not to stifle truthful information that could benefit consumers.

C. Identifying the Source of an Advertisement.

Consumers' evaluation of information may be affected by an inaccurate perception regarding its sponsorship. A potential for deception therefore exists when consumers do not know that what appears to be a news broadcast or other programming is really an infomercial, or that what appears to be independently supplied information is really supplied by a product's manufacturer.

D. Regulation of Price Advertising.

FDA's existing brief summary requirements may have the inadvertent effect of unnecessarily restricting the dissemination of price information. While the FDA regulations exempt certain types of price claims from the brief summary requirement, the exemption is narrow[18] and apparently would apply only to advertisements of the price of a specific quantity of a drug, and not, for instance, to comparative price claims, coupons or other forms of price reduction information.

We therefore suggest that FDA evaluate whether its limitations on the exemption for price claims are necessary and desirable.

FOOTNOTES

[1] 15 U.S.C. §§ 45, 52-57. The FTC and FDA have overlapping jurisdiction with respect to the advertising, labeling, and promotion of foods, over-the-counter drugs, cosmetics and medical devices. Under a long-standing liaison agreement between the agencies, the FDA exercises primary responsibility for regulating the labeling of these products, while the FTC has primary responsibility for enforcing laws against false or misleading advertising of these products. Working Agreement Between FTC and Food and Drug Administration, 4 Trade Reg. Rep. (CCH) Para. 9,851 (1971).

[2] See, e.g., Johnson & Johnson Consumer Products, Inc., File No. 9433277 (Oct. 11, 1996) proposed consent); Olsen Laboratories, Inc., C-3556 (Feb. 6 1995); FTC v. Pantron 1 Corp., No 88-6696 RG (JRx) (C.D. Cal July 27, 1992) (judgement), rev'd in part and aff'd in part, (9th Cir Aug 25, 1994); St. Ives Laboratories, Inc., C-3366 (Jan 24, 1992); U.S. v. Sterling Drug, Inc., No. CA 90-1352 (D.D.C. June 12, 1990) (consent decree); Walgreen Co., 104 F.T.C. 548 (1984), aff'd, 791 F.2d 189 (D.C. Cir 1986), cert. denied, 479 U.S. 1086 (1987).

[3] See, e.g., Eggland's Best, Inc., C-3520 (Aug. 15, 1994) consent); Gracewood Fruit Co., C-3470 (Oct. 26, 1993) (consent); Pompeian, Inc., C-3402 (Oct. 27, 1992) (consent); Campbell Soup Co., D. 9223 (Aug. 18, 1992) consent); Pacific Rice Products, Inc., C-3395 (Aug. 17, 1992) (consent); Bertolli U.S.A., Inc., C-3396 (Aug. 17, 1992) (consent)

[4] See, e.g., Home Shopping Network, Inc., D. 9272 (Mar. 3, 1995) Complaint issued; matter in administrative litigation); Bee-Sweet, Inc., C-3550 (Jan. 17, 1995) (consent); Schering Corp., D. 9232 (Sept. 16, 1991) (Initial Decision), (Oct. 31, 1994) (consent); FTC v. Redhead, No. 93-1232-JO (D. Ore. June 20, 1994) (stipulated permanent injunction); U.S.v. General Nutrition, Inc., 114 F.T.C. 31 (1991) (consent); General Nutrition, Inc., 111 F.T.C. 387 (1989) (consent); FTC v. PharmTech Research, Inc., 5f76 F. Supp. 294 (D.D.C. 1983) (preliminary injunction), 103 F.T.C. 448 (1984) (consent).

[5] See, e.g., Lifestyle Fascination, Inc., C-3513 (Aug. 5, 1994) (consent); FTC v. LaserVision, Inc., No. 94-1691 WJR (C.D. Cal, Mar. 15, 1994) (stipulated permanent injunction); In re Dahlberg and the FTC, No. 4-94-CV-165 (D. Minn. Nov. 21, 1995) (consent decree); Numex Corp., C-3463 (Oct. 7, 1993) (consent); Conair Corp., C-3431 (June 14, 1993) (consent); Viral Response Systems, Inc., D. 9245 (July 31, 1992) (consent); Haverhills, C-3322 (Jan. 25, 1991) (consent); Removatron International Corp., 111 F.T.C. 206 (1998), aff'd, 884 F.2d 1489 (1st Cir

1989); Sun Industries, Inc., 110 F.T.C. 511 (1988) (consent).

[6] See H.W. Singer, Direct-to-Consumer Advertising, 14 Med. ad News 10, 30 (October 1995); W. Borow, The AMA Explains its About-Face on Direct-to-Consumer Advertising, Med. Marketing & Media, at 68, September 1993.

[7] Singer, supra note 1i, at 30. According to the trade press, drug companies spent a total of $11.6 million on DTC campaigns in 1989. In 1994, they spent $242,4 million. During the first five months of 1995, they spent $141.2 million.

[8] See, e.g., J. Schwartz, FDA Approved Drug for Treatment of AIDS: 3TC Compound Used in Combination with AZT, Washington Post, Nov. 21, 1995, at A3.

[9] Three prescription drug reference books were listed among the thirty-nine top selling reference books in 1994; The Physician's Desk Reference Family Guide to Prescription Drugs (205,000 copies), The 1994 Physicians' Desk Reference (110,000 copies), and The Essential Guide to Prescription Drugs 1994 (52,948 copies). See Publishers Weekly, March 7, 1994, at S26.

[10] See, e.g., Your Health; New Treatment for Ulcers - and Other Stomach Pains, Consumer Reports, Aug. 1995, at 552-553, (comparing ulcer treatments using antibiotic therapies to ulcer treatments using H2 blockers).

[11] See, e.g., Washington Post Magazine, Nov. 12, 1995 (insert between pages 26 and 27 sponsored by the American Cancer Society and the Ad Council urging women to get mammograms and providing an "800" number for people to call for further information).

[12] Many scholars have discussed prescription drug advertising from an economic and marketing perspective. See, e.g., M.J. Sheffet and S.W. Kopp, Advertising Prescription Drugs to the Public: Headache or Relief? 9 J. Pub. Pol'y & Marketing 42 (1991); A. Masson, "Direct-to-Consumer Choice: Proceedings of the Second International Conference on Research in The Consumer Interest p. 159-168 (R.N. Meyer ed., 1991); J.H.Beales, III, Economic Analysis and the Regulation of Pharmaceutical Advertising, 24 Seton L. Rev. 1370 (1994).

[13] For example, according to the trade press, cyberspace provides an efficient means of communicating to people with Lou Gehrig's disease. See, P. Weisz, Out of the Lab and into the Screening Room: Direct-to-

Consumer Ads are Now at $200 Million and Growing, Brandweek, at 31, April 18, 1994.

[14] See, e.g., L. Benham, The Effect of Advertising on the Price of Eyeglasses, 15 J.L. & Econ.337 (1972); J.F. Cady, An Estimate of the Price Effects of Restrictions on Drug Price Advertising, 14 Econ. Inquiry 493 (1976); K.B. Leffler, Persuasion or Information? The Economics of Prescription Drug Advertising, 24 J.L. & Econ. 45 (1981); J. Cady, An Estimate of the Price Effects of Restrictions on Drug Price Advertising, 14 Econ. Inquiry 493 (1976); W. Jacob et al. Improving Consumer Access to Legal Services: The Case for Removing Restrictions on Truthful Advertising. Staff Report to the Federal Trade Commission (1984).

[15] The degree of competition between OTC and DTC drugs likely varies across therapeutic categories. The level of competition is likely to be particularly strong in categories where some prescription drugs are switched to OTC status. For a description of this process see P. Temin, Realized Benefits from Switching Drugs, 35 J.L. & Econ. 351 (1992).

[16] See, S. Everett, Lay Audience Response to Prescription Drug Advertising, J. Advertising REs. 43-49 (April/May 1991); M. Perri and W.M. Dickson, Consumer Reaction to a Direct-to-Consumer Prescription Drug Advertising Campaign, 8 J. Health Care Marketing 66 (June 1988).

[17] See, e.g., Foxman et al., Disclaimer Footnotes in Ads: Discrepancies between Purpose and Performance, 7 J. Pub. Pol'y & Marketing 127, 134 (1998) (mis-comprehension level after exposure to smaller-print footnotes is higher).

[18] Buckingham Products, Inc., 110 F.T.C. 37 (1987)

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DTC Prescription Drug Promotion Roundtable
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Names in italics are representatives of the FDA and FTC who participated as observers only and do not necessarily endorse the conclusions of the Roundtable.

NATIONAL CONSUMERS LEAGUE DTC PRESCRIPTION DRUG PROMOTION ROUNDTABLE
AGENDA

Embassy Row Hotel
2015 Massachusetts Avenue, N.W.
Washington, D.C.

WEDNESDAY, JANUARY 17, 1996

11:00-11:15 WELCOME AND OPENING REMARKS

Linda F. Golodner, President, National Consumers League

11:15-12:45 PLENARY SESSION -- BACKGROUND & EDUCATION

David G. Adams, Esq.
Olsson, Frank and Weeda
"History of FDA Regulation of DTC Promotion of Prescription Drugs"

Nancy M. Ostrove, Ph.D.
FDA
"Summary of Research Concerning DTC Drug Promotion"

Linda F. Golodner
National Consumers League
"The Consumer's Interest in DTC Promotion in Health Care Communication"

N. Lee Rucker, M.S.P.H.
NCPIE
"Opportunities for Information and Education in Consumer-Directed Health Promotion"

Matthew R. Seymour
CommonHealth Direct
"The Role of Industry in DTC Drug Promotion"

Joan Z. Bernstein, J.D.
FTC
"The FTC's Perspective on the Regulation of DTC Drug Promotion"

Ilisa Bernstein, Pharm.D., J.D.
FDA
"FDA's DTC Promotion Initiative"

12:45-1:30 **LUNCH**

1:30-2:45 **ROUNDTABLE BREAK-OUT SESSION**

(Three groups – each group addresses same question(s). The groups have been preselected to ensure some degree of balance and diversity.)
Overall Moderator: George Strait, ABC Medical Correspondent

A moderator/facilitator team has been assigned to each break-out group. Please check the list of break-out groups and your nametag for your team assignment, and proceed to the appropriate room.

Team 1
Moderators: David G. Adams
Olsson, Frank, and Weeda, P.C.

Sandra B. Eskin
American Association of Retired Persons

Team 2
Moderators: Karin L. Bolte, Esq.
National Consumers League

Richard M. Cooper, Esq.
Williams and Connolly

Team 3
Moderators: Nancy L. Buc, Esq.
Buc, Levitt, and Beardsley

N. Lee Rucker, M.S.P.H.
National Council on Patient Information and Education

The purpose of the roundtable is for each break-out group to (1) identify the medical, legal, and policy issues involved in DTC prescription drug promotion; (2) consider the need for a new regulatory approach; and (3) describe what such a new approach might look like. Consideration of the attached questions should assist each group in preparation of its "talking points": See Outline of Issues for Discussion.

2:45-3:00 **BREAK**

3:00-4:15 **RESUME BREAK-OUT SESSION**

Develop "talking points,"conclusions, minority views, and recommendations.

4:15-4:30	**BREAK**
4:30-6:00	**PLENARY SESSION** Moderator: George Strait Each break-out group will present its conclusions, minority views, and recommendations. The conclusions will be combined into a single document which will provide the basis for the next day's work on designing the most appropriate regulatory approach to DTC prescription drug promotion.

THURSDAY, JANUARY 18, 1996

8:30-8:45	**SUMMARY OF DAY 1 CONCLUSIONS** Linda F. Golodner, National Consumers League A summary of the "talking points," conclusions, minority views, and recommendations from the Wednesday afternoon Plenary Session will be developed and circulated.
8:45-10:30	**ROUNDTABLE BREAK-OUT SESSION** (Pre-selected groups - not same group as Day 1. Please Check your Team assignment, and proceed to the appropriate room.) Having identified the significant issues in DTC prescription drug promotion and possible new regulatory approaches, the group's task for today's sessions is to design the regulatory scheme that will best address these issues. Each break-out group will consider the combined results of Wednesday's work.
10:30-10:45	**BREAK**
10:45-12:30	**PLENARY SESSION** Moderator: George Strait Each break-out group will present its final blueprint for the regulation of DTC prescription drug promotion. This will include a list of goals, next steps, and recommendations.
12:30-1:30	**LUNCH**
1:30-2:30	**PLENARY SESSION (CONTINUED)**
2:30-3:00	**CLOSING REMARKS AND WRAP-UP** Linda F. Golodner, National Consumers League

National Consumers League

Direct-To-Consumer Promotion of Prescription Drugs Roundtable II

September 28-29, 1998
Washington, DC

Table of Contents

INTRODUCTION

On September 28-29, 1998, the National Consumers League held its second Roundtable on Direct-To-Consumer Promotion of Prescription Drugs. Similar to the first Roundtable, held in 1996, Roundtable II brought together representatives from consumer organizations, health care professionals,[1] the pharmaceutical industry, the medical publishing industry, the advertising profession, the Food and Drug Administration (FDA), and the Federal Trade Commission (FTC)[2]. The purpose of this Roundtable was to address the current state of affairs regarding direct-to-consumer promotion of prescription drugs (DTCP). As the FDA prepares to issue final rules for commercials on television, and to address regulations of DTC print ads, NCL felt it important to examine what has been done since the last Roundtable, assess where the public is now, and focus on what still needs to be done for the future.

The main intent of the Roundtable was to develop a consensus document to present to FDA as recommendations for revised print and broadcast guidelines. In order to gain consensus, NCL presented an outline to all participants prior to the Roundtable covering the main points of the DTC guidelines: the brief summary, adequate provisions, and fair balance. Participants were then divided into different groups and asked to develop recommendations which were presented to the group as a whole at the end of day one. A summary of all the groups' recommendations was developed that evening and presented to the whole group the following morning, where it was further discussed and refined. A few weeks after the Roundtable, a draft consensus document was sent to all the participants for further review and comments. These comments were distilled into the final consensus document that is presented in this report.[3]

In order to properly gauge consumer attitudes and perceptions of DTCP, NCL commissioned two consumer surveys: one random-sample telephone survey and one mall-intercept. The surveys sought to find out where consumers were getting health information and how this information influenced their health decisions and attitudes. The results of both are included in this report.

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[1]Throughout this report, the term "health care professional" refers to physicians, pharmacists, nurses, physician-assistants, and other medical personnel.

[2]Representatives of the FDA and FTC participated as observers only and do not necessarily endorse the conclusions of the Roundtable.

[3]Not all of the participants responded to the request for comments to the draft consensus document. However, 20 percent did respond.

NCL ROUNDTABLE CONSENSUS

Introduction

The recommendations and conclusions below represent a consensus of opinions of the participants of the National Consumers League *Direct-To-Consumer Promotion of Prescription Drugs* Roundtable, held on September 28-29, 1998.

Prescription drugs are powerful products with tremendous healing potential that often have serious risks and side effects, and are only available through a health care professional. What product-specific, direct-to-consumer promotion of prescription drugs (DTCP) should encompass and how it should be regulated is an important concern. DTCP is beginning to have a significant influence on the public and may influence drug selection and use decisions by health care professionals and consumers.

DTCP of Prescription Drugs: Information for Consumers

- DTCP is an effective vehicle that motivates consumers to seek information, especially from health care professionals. More needs to be known about health consequences of this form of promotion as well as its affect on the patient-health professional relationship.

- Promotion and advertising can only convey a limited amount of information about medications due to time and space constraints. Additional information sources offering a balanced appraisal of the medication's safety and effectiveness must be available for consumers.

- Any DTCP campaign may be limited for some audiences, e.g., elderly, less literate, and non-English speakers, and should consider the impact on those populations.

- Health care professionals should receive different messages than consumers regarding medications. While health care professionals should receive more technical information, consumers need easy-to-understand, consumer-friendly, useful information about the benefits and risks of the medicine. Consumers also need usable information about their condition and medication when they receive their prescription medicines.

Current Brief Summary

- For print ads, there was agreement that the brief summary, presented in its entirety, frequently written in small type and technical language, does not communicate useful information to consumers.
  - Information needs to be less detailed and more consumer friendly.
  - For those consumers who desire more information, it should be made available

through alternative sources such as web sites, 800 phone numbers, and pamphlets at physician offices, clinics and pharmacies. When an 800 number is a source of information, the provider should give unbiased and accurate information and should not use the contact for promotional purposes. There should be full disclosure to consumers of any information captured through a web site or 800 number, with an opportunity for the consumer to opt out of the program or not be subjected to follow-up phone calls or mailings.

- The FDA should, separate and apart from its Draft Broadcast Guidance, clarify in a Federal Register notice that its drug advertising regulations will not be interpreted to require dissemination of the complete brief summary as part of a print promotion for a pharmaceutical product. However, useful, consumer-friendly information must be disseminated in conjunction with any and all print or broadcast ad campaigns.

Alternatives to the Brief Summary

- For print ads, the current brief summary format used by most advertisers should be replaced with a more consumer-friendly presentation of information. Alternatives include:

  - For print ads, the current brief summary format used by most advertisers should be replaced with a modified format[4] with a more consumer-friendly presentation of information. Some of the group suggested eliminating the brief summary requirement, and in its place, incorporating the pertinent information in to the body of the ad itself, similar to broadcast ads. The majority felt this would be insufficient. Others thought print ads should remain separate and distinct from broadcast ads with a more consumer-friendly brief summary as a vital component.

  - For print ads, the brief summary should be re-formatted to better reflect its purpose, to provide a summary of the most important usage and safety information in consumer-friendly language. The brief summary format should reflect the recommendations of the 1996 Keystone Committee, which were approved by HHS Secretary Shalala that includes the most serious and most frequent side effects. This uniformly-structured format should provide information about the disease the drug is intended to treat, and what the drug does and does not do. The ads should have a basic framework regarding how the important and necessary information is conveyed, with flexibility for advertisers to design the ads. A useful format is the "question and answer" format with

[4]FDA rules state that the term "MedGuide" cannot be used for information other than FDA-approved patient information. However, during the discussions at the Roundtable, the modified format that was discussed was explicitly described as a modified "MedGuide-type" format.

information presented in a consistent, logical order.

Standard Information Messages

- A series of generalized standard messages is desirable, including general information about efficacy, compliance, risk, contraindications, and interactions between drugs and food and drugs.
  - Messages should rotate frequently to avoid "wear out." They could also be integrated completely in the ad.
  - A possible approach is to provide very specific parameters for standard information messages and allow manufacturers to design their own. These messages should convey the concept of who should and should not take these medications to avoid unnecessary physician visits or increased expectations about benefits of the medications. But, the physician should make the ultimate decision.
  - Some participants, but not a majority, believed these generalized statements could replace the brief summary entirely for certain, limited classes of drugs. This was particularly true for "help-seeking ads," which include little or no promotion of particular drug products. Other participants stated these general statements should be included in addition to an abbreviated "brief summary" or whatever risk disclosure replaces it. Another suggestion was that risk information be "set off" in a box.

Broadcast Advertisements

- Some participants concluded that the same standards should apply to print and broadcast media ads. Other participants concluded that requirements for print and broadcast ads should be functionally equivalent, but not necessarily the same.
- For broadcast ads, consumers should receive useful, comprehensive information.
  - Alternatives to providing the drug's full approved labeling are probably useful to most consumers and should be sought. Sponsors should make "adequate provision" for the dissemination of nonpromotional, consumer-friendly information, and it was suggested that it could be the information required in a new brief summary. The full package insert should be made available to any consumers upon request, however, that briefer, more consumer-friendly formats would be acceptable.
  - Some participants concluded that some broadcast advertising provides an inadequate major statement of a drug's risks and side effects, and that the ads as

they are now are too promotional and often oversell the benefits while downplaying risks and side effects. For example, visual images are often at odds with the audio text. All images (both audio and visual) should be complementary. Some participants believed the audio and visual risk information should be presented concurrently, e.g., with scrolled text that parallels the voice-overs.

- Other participants concluded that the mechanisms for "adequate provision" need to be more user friendly, and not, for example, difficult-to-understand messages from a toll-free number.

Fair Balance

- Participants favored retaining the "fair balance" requirement.
  - Some participants called for FDA to make its fair balance decisions and its basis for such decisions more transparent.
  - Some participants stated that proper context was important and that the overall impression of an ad should not conflict with the approved indications. For example, visual images should not portray activities or illnesses for which the medication is not approved to treat.
  - Some participants believed that where risks appeared with approximately the same frequency as with a placebo, specific identification of this type of risk information might be unnecessary. In lieu thereof, there should be a general statement such as "There are risks associated with taking all prescription drugs. Speak to your doctor or pharmacist about the risks associated with ...."
  - DTCP cannot provide consumers with sufficient background information to fully understand the spectrum of risks, safety, and potential effectiveness of drugs.

Recommendations for Consumer Education and Research

- Industry and health care professionals should consider supporting broad public service campaigns to provide consumers with basic information so they can better understand DTCP claims.
- There is a need for better and more information regarding disease conditions and the appropriate role of medications.
- Research into DTCP is necessary and important in the following areas:
  - The extent to which consumers comprehend important health information

conveyed in a variety of formats, such as the current brief summary, full package labeling, approved patient labeling, major statements of risks in broadcast advertising, and modified MedGuide.

- Whether DTCP improves or lessens public health.

- The effect of DTCP on compliance with prescribed medication.
- What effect DTCP has on the physician-patient relationship.
- Results of such research should be made available through publication in the professional and lay press.

- Pharmaceutical manufacturers should provide educational programs for health care professionals prior to or concurrent with promotions in order to complement DTCP ad campaigns to consumers, so that communication about appropriate use of pharmaceuticals between health care professionals and consumers is effective.

Resources for Enforcement

- FDA is working to enforce DTCP requirements and should be adequately funded to monitor ads and continue to protect the public health. FDA is under-funded and cannot fully enforce its regulations because of increased workload responsibilities and inadequate resources.

- Agencies such as AHCPR should be funded to study the health consequences and outcomes from DTC ads.

APPENDICES

APPENDIX A

DIRECT-TO-CONSUMER PROMOTION OF PRESCRIPTION DRUGS: CURRENT STATUS

DTC Promotion Has Exploded and Continues to Grow

DTCP has increased dramatically. According to John Kamp of the American Association of Advertising Agencies (AAAA), there was no DTCP in the mid-1980's. Since that time, DTCP has grown to be the 13th largest advertising category. DTCP experienced triple-digit growth between 1995 and 1996.

AAAA estimates that nearly one billion dollars ($875 million) was spent on DTCP in 1997. IMS America, which tracks pharmaceutical company sales and spending, estimates DTCP spending of at least $1.3 billion in 1998, an increase of 50% over the previous year.

The type of advertising has also changed dramatically. In 1996, for the first time, consumer-directed advertising spending surpassed spending for medical journal advertising. In 1996, magazines comprised 81 percent of the mix of DTCP, while only 11.4 percent was spent on television advertising. By the beginning of 1998, magazine spending had dropped to 40 percent and television promotion increased to 50 percent.

Regulatory Update

1. *Broadcast DTCP*

Current regulations require that for broadcast advertising, the advertiser must either provide a brief summary of all necessary information related to a drug product's side effects and contraindications, or make "adequate provision" for the dissemination of the drug product's approved package labeling. (21 C.F.R. § 202.1 (e)(1)). In August 1997, the Food and Drug Administration (FDA) released a draft guidance that set forth four methods for making adequate provision for the dissemination to consumers of the drug's full package labeling (62 Fed. Reg. 43,171.August. 12, 1997). Adequate provision includes:

a. A toll-free number to call to obtain full package labeling in a timely manner by telephone, fax, or mail;

b. Concurrent advertising in print media;

c. Information on obtaining full package labeling from physician's offices, pharmacies, libraries, and other public places; and

d. An Internet web site address.

2. *Print Advertising*

FDA is in the process of re-evaluating its DTCP regulations for print media. The agency began the process in 1995 when it published a document explaining the background of DTCP, requested feedback on a number of DTCP-related issues and questions, and announced a public hearing regarding DTCP (60 Fed. Reg. 42,581. August 16, 1995). Among the issues on which FDA sought comment:

a. The regulation of help-seeking advertisements;

b. The value of reminder advertising;

c. The problems with required disclosures, including that the brief summary of the drug product's side effects and indications which must accompany print advertising is relatively inaccessible to consumers; and

d. Whether DTCP is fairly balanced (60 Fed. Reg. at 42,582-83.).

FDA sought additional comment on the brief summary in a Federal Register notice issued after NCL's Roundtable I, held in 1996 (61 Fed. Reg. at 24,314. May 14, 1996).

FDA intends to issue a new guidance regarding DTCP, but the process is ongoing (62 Fed. Reg. 14,912, 14,917. March 28, 1997). FDA has received many comments expressing concerns about the value for consumers of the complex, detailed information in the brief summary for print advertisements and has begun to address whether an alternative format could provide more useful information. While this process is pending, FDA has urged product advertisers in both print and broadcast media to provide non-promotional, consumer-friendly information that is consistent with the approved product labeling (62 Fed. Reg. at 43,172).

3. *Action Plan for the Provision of Useful Prescription Information*

In 1995, FDA published a proposed rule aimed at increasing the quality and quantity of written information about prescription medicines to consumers (60 Fed. Reg. 44,232. August 24, 1995). The proposed rule, entitled "Prescription Drug Product Labeling: Medication Guide Requirements," is commonly referred to as the 'MedGuide" proposal. FDA would have required manufacturers to produce "MedGuides" for certain medicines, would have encouraged written information leaflets to be produced and distributed for all drugs, and would have set targets for the distribution of the leaflets with new prescriptions. The MedGuide also set forth criteria by which written information would be deemed to be "useful."

In August 1996, Public Law 104-180 was enacted and called upon interested parties to meet and develop a plan that would achieve the goals of the MedGuide proposal, but without regulatory mandates. In December 1996, the Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information submitted the action plan to Secretary of Health and Human Services Shalala. The

action plan set forth guidelines that were similar to the MedGuide proposal in many respects. Most importantly, the action plan defined what constituted "useful prescription medicine information." Such information should be: (1) scientifically accurate; (2) unbiased in content and tone; (3) sufficiently specific and comprehensive; (4) presented in an understandable and legible format that is readily comprehensible to consumers; (5) timely and up-to-date, and (6) useful. The plan also set forth timetables for the provision of useful information to patients receiving new prescriptions.

Secretary Shalala approved the action plan in January 1997. The timetable calls for distribution of useful patient information to 75 percent of individuals receiving new prescriptions by the year 2000, and 95 percent of individuals receiving new prescriptions by 2006.

Summary of Current Research Findings

Current research into DTCP suggests the following hypotheses:

- DTCP can notify patients about available drugs
- DTCP encourages patient visits to physicians
- DTCP increases patient requests for drugs
- Consumers state that they want more information, but are frequently confused by what they receive
- Physicians have a negative reaction to DTCP
- Conveyance of risk information in DTCP is difficult
- Making additional disclosures may be problematic because of information overload and because visual disclaimers may have minimum impact
- DTCP can improve patient compliance

Research is needed in the following areas:

- What do consumers actually take away from DTCP--do they glean important information?
- What is the best way to convey important information to consumers in DTCP?
- How are consumers interpreting DTCP claims--do they understand that these are promotional ads?
- Is DTCP rasing health care costs, especially for prescription medicines? If it is, are these positive developments (consumers are seeking appropriate health care), or negative developments (consumers are being prescribed inappropriate medication and increasing physician visits)?
- Is DTCP altering drug product liability?
- Consumers say they are reading the brief summaries, but are they comprehending or recalling the information presented?
- Is there fair balance of the presentation between the benefits and risks of DTCP ads?

APPENDIX B

SUMMARY OF REQUIREMENTS FOR DIRECT-TO-CONSUMER PROMOTION OF PRESCRIPTION DRUGS

NATIONAL CONSUMERS LEAGUE ROUNDTABLE II
SEPTEMBER 28-29, 1998

- The Food and Drug Administration (FDA) regulates the advertising and promotion of prescription drugs.

- With some exceptions, the Federal Food, Drug, and Cosmetic Act, administered by FDA, deems any prescription drug to be misbranded and unlawful unless all advertisements and similar materials include a "brief summary" relating to side effects, contraindications, and effectiveness.

- FDA requirements distinguish between promotion through advertising (e.g., material appearing in newspapers and magazines and through broadcast media) and promotion through "labeling" (e.g., written, printed, or graphic material that "accompanies" a drug product). As noted, advertisements must be accompanied by a "brief summary." Promotional labeling must be accompanied by the product's complete package labeling. The package labeling is part of FDA's drug approval process, is very detailed, is written in technical language, and is intended for physicians and other healthcare practitioners.

- FDA's prescription drug advertising regulation requires the "brief summary" to disclose each relevant side effect and contraindication that is described in the FDA-approved product labeling, with minimal summarization.

- The brief summary must also be included in advertisements in broadcast media unless the advertiser makes "adequate provision" for the dissemination of the drug product's complete package labeling.

- FDA's regulation also requires that prescription drug advertisements and promotional labeling provide "fair balance" -- a balanced presentation of the drug's risks and benefits.

- FDA's prescription drug advertising regulation was adopted in the 1970s, when little or no direct-to-consumer prescription drug promotion was taking place. FDA recognizes that its regulation is outmoded and needs to be modernized to deal effectively with direct-to-consumer promotion.

- FDA issued an informal draft guidance in August 1996, which defines other means of making adequate provision for dissemination of the drug's full package labeling for ads in broadcast media. These methods include an 800 number; concurrent advertising in print media; and materials available in pharmacies, doctors' offices, and libraries, and on the Internet. FDA encourages advertisers to provide consumers with non-promotional, consumer-friendly product information as well.

- For some drug products, such as oral contraceptives and estrogen replacement products, FDA requires patient labeling, written in language that is intended to be easily understood by the average consumer.

- FDA is prohibited by statute from requiring preapproval of prescription drug advertising except in "extraordinary circumstances."

* This document is for background purposes only. It is a basic summary of the law and is not intended to provide legal advice. Interested persons should consult with their own regulatory counsel.

APPENDIX C

The Regulation of Direct-to-Consumer Promotion of Prescription Drugs

Nancy M. Ostrove, Ph.D.
Division of Drug Marketing, Advertising, and Communications, FDA
September, 1998

FDA Jurisdiction

- Agency said that current regulations provide sufficient safeguards to protect consumers (1985)
- Regulatory focus is on *content* of materials, not its general existence
- *No law nor regulations prohibit DTC promotion in general, or for specific products or product classes*

General Ad Requirements as Specified in Regulations

- Must not be false or misleading
- Must present a fair balance between effectiveness and risk information
- Must reveal "material" facts

Specific Disclosure Requirements

- Food, Drug, & Cosmetic Act (502(n)) requires that prescription drug ads include "information in brief summary relating to side effects, contraindications, and effectiveness"
- The Act left specifics to regulations

"Brief Summary"

- Regulations require that the "brief summary" information include "each specific side effect and contra-indication" (i.e., all the risk concepts)
- Manufacturers historically complied by reprinting risk-related sections of product labeling
  - verbatim reprinting not required

"Brief Summary": Print vs. Broadcast

- For print ads, regulations appear to give no leeway to reduce required information
- For broadcast, media limitations implicitly acknowledged through provision of alternative means of disseminating additional information

Broadcast Ad Requirements

- ***Must*** **have information about "major side effects and contraindications"**
  - **in audio, or audio plus visual**
- **Can *either* have:**
  - **presentation of brief summary, or**
  - **"adequate provision" for disseminating product labeling**

Broadcast Advertisement Draft Guidance

- **Took advantage of leeway already in regulations**
- **Reinforced requirements that ads**
  - **must be truthful and not misleading**
  - **appropriately communicate product's indication**
  - **adequately communicate most important risk information**

Diverse Audiences?

- **Differing levels of use of/comfort with sophisticated technology**
- **Active vs. passive information seekers**
- **Sensitivities to divulging personal information**

Clarified "Adequate Provision" for DTC Ads

- Gave one possible, multi-faceted approach to reach diverse audience with required product information
  - toll-free phone number for information to be mailed, faxed, or read to caller
  - concurrently available print information
  - internet address
  - reference to MD, RPh (or DVM) as source of more product information

Guidance Development

- Comment period closed October 14
- 25 comments received
  - additional 5 comments received since
- Comments will be addressed in publication of final guidance
- Request for research and planned evaluation two years after finalization

Comment Sources

- Manufacturers/PhRMA (9)
- Advertising advocates/vendors (8)
- Health professional associations (4)
- Consumer associations (2)
- Individual health professionals and consumers (6)

General Comment Issues

- Positive step: primarily manufacturers and groups representing advertising/communications
- Negative step: primarily individuals, consumer group, health care professional associations
  - similar concerns as raised in past

Specific Comment Issues

- Shouldn't need to include all 4 components mentioned in guidance
  - print component most problematic
  - should allow greater flexibility
- Overall brief summary concept still needs to be addressed (for print ads)

General Considerations in DTC Promotion

- Accurate communication of product indications, including:
  - limitations on indications, e.g., relevant patient population
  - concomitant therapies/ treatment
  - use of appropriate language in claiming likelihood of benefit, especially for products with relatively low efficacy

Most Important Risks

- Contraindications
- Major warnings, especially boxed warnings
- Significant precautions/drug interactions
- Frequent side effects

Additional Considerations

- Reasonably comparable communication of risks
  - Consumer-friendly language for both benefits and risk (readability)
  - Prominence of presentation
- Needed context for claims/risks
- Information needed for an informed patient-physician discussion

DTC Broadcast Ads: Regulatory Actions

- Product-claim television or radio ads have appeared for over 25 Rx products since August, 1997
- 1997
  - 3 "untitled" letters
  - 1 Warning letter (radio ad in P.R. only)
- 1998
  - 11 "untitled" letters

Bases for Broadcast Ad Letters - 1

- Comparability of presentation of risk vs. benefits information/fair balance
  - simultaneous disclosure of messages in competing modalities
  - minimizing/omitting risk information, especially boxed or bolded information
  - relative prominence, speed, audibility
  - distracting visuals

Bases for Broadcast Ad Letters - 2

- Communication of indication/efficacy
  - unsubstantiated broadening of efficacy
  - incomplete communication of indication
  - inadequate communication of limits of use
  - unsubstantiated superiority claim
- Prescription drug status
- Illegible established name

Bases for Broadcast Ad Letters - 3

- Inadequate mechanism for ensuring dissemination of product labeling
  - assurance of dissemination to consumers not wanting to divulge personal information (print component missing or obscured)
  - health care provider not referenced as source of product information

APPENDIX D

Remarks of John Kamp
Senior Vice President
Washington Office
American Association of Advertising Agencies

I'm delighted to talk to you about some of the things that are happening today as advertising agencies and their clients deal with the challenges and opportunities created by the ability to more effectively advertise prescription drugs directly to consumers.

Let me preface my remarks with a few comments about the FDA, especially the staff of the Division of Drug Marketing, Advertising, and Communications (DDMAC). You all know that the AAAA has been among the sharpest critics of FDA marketing policy, especially on "Off Label" professional communication and on the pre-August 1997 DTC television regulations. But don't confuse criticism of FDA policy with our view of the professionalism of the staff.

Particularly, I note with pleasure that the head of DDMAC, Mini Baylor-Henry, and the chief reviewer of DTC advertising, Nancy Ostrove, have taken time from their busy schedules to join us this morning to help us struggle with the public policy questions of this meeting. And, regardless of policy disagreements, the AAAA and its members have been impressed that the DDMAC staff consistently responds to calls and questions quickly and courteously. Thank you Mini, Nancy, and your staff.

Here are four of the major lessons for agencies and clients as they seek to inform consumers of health care choices using DTC advertising:

1. **Agencies and clients are learning very fast that broadcast advertising is very expensive, and not always the most efficient way to target their messages.** You all know that total DTC advertising expenditures in measured media exceeded one billion dollars in 1998, and that much of that nearly 50 percent increase from 1997 is being spent on television. Some, but not all of the dollar increase can be attributed to the August 1997 rule changes by the FDA that enabled more efficient television advertising. Now, many ad professionals are telling me that we may have reached the top of TV spending with established drugs. Advertisers are looking very carefully at the efficiencies of print for targeting and delivering messages.

2. **Agencies and clients are finding that the Major Statement disclosures required by the FDA are often hampering clear communication. Indeed, the disclosures are so confusing to prospects as to frustrate even the FDA's public policy goals.** Today's complicated messages often confuse and unnecessarily scare people away from the doctor visits that could result in effective treatment. Ad professionals know that effective TV ads have to be simple, straightforward, and even repetitive. Complicated messages must be reserved for labels, brochures, and in this case, doctors visits. The FDA should stop trying to tell advertisers and agencies how to communicate with potential customers, and instead, stick to their regulatory areas of expertise.

3. **Drug clients must not ignore doctors and other health care professionals when developing DTC campaigns.** Unfortunately, some DTC campaigns were launched without

sufficient consultation with the drug companies' major customers, the health care professionals that prescribe and oversee patient care. I think this lesson may have been learned, but not without some controversy on both sides.

4. **Direct-To-Consumer advertising works.** You and I both know that companies haven't made a billion-dollar investment in DTC advertising on a whim. Just like Coke telling us each a million times that Coke is the "Real Thing, " drug companies advertise because it works. It informs consumers about products, and enough prospects use that information to make the investment pay for the company. But for purposes of this conference, let's just pretend that we don't care if drug companies make profits. We'll even pretend that we baby boomers don't care if drug companies make a few bucks on existing drugs so they can invest that money in the research that creates the new drugs that extend our lives and improves the quality of our health.

Putting aside the profits that enable research, drug advertising works in the realm of public policy. Look at the studies released recently by Time and Prevention magazines. Those, and a new study about to be released by the Coalition of HealthCare Communications done by the Beta Research Corporation, are amazingly consistent on several factors that offer a compelling public policy case in favor of DTC advertising.

On the basis of these studies, it is clear that over 55 million people in America--nearly 20 percent of the population--have talked to their doctors recently armed with information gleaned from DTC advertising. In those doctor-patient conversations, nearly 9 out of 10 doctors confirmed the patient's concern about the advertised medical condition by making a positive diagnosis--an outstanding success rate by any standard.

Then, about 80 percent of those received some kind of treatment; sometimes the drug they saw advertised, other times another drug or non-drug treatment. Again, that's a pretty good success rate for anyone who wants to see timely diagnosis and treatment of medical disorders. There is, more, Of the 55 million people who sought treatment, over five percent were diagnosed and treated for an entirely different disorder than the one which lead them to visit their doctor in the first place. That's a great public policy bonus: people needing treatment sought help and received it. Call it what you want, luck, serendipity, the law of unintended consequences, good fortune, surprise; call it whatever suits you. I call it good public policy.

The studies all demonstrate that because of DTC, more U.S. citizens are getting their medical conditions diagnosed and treated. And, we can assume that much of this is happening earlier rather than later. Earlier treatment is almost always less expensive and more effective.

In sum, DTC advertising works for he American people. It saves money, lengthens lives, and improves the quality of our lives. That's win-win public policy. Let's keep that in mind for the remainder of this conference as we seek to guide policy makers in their decisions. Thank you.

APPENDIX E

DTC - Research Review

Louis A. Morris, Ph.D.
Tish Pahl, J. D.
National Consumers League
September 28-29, 1998

What Do We Need to Know?

- Depends on perspective
  - advertiser - how effective is campaign and how does DTC fit in? (increase sales, share, etc.)
    - communication goals, tactical element, ROI
  - public policy - what are the individual and cumulative effects of DTC?
    - What people need to know, how to communicate it, and what direct and indirect effect does it have?
    - Assume truthful, balanced ads needed for consumer protection: what is actually communicated?

Consumer Wants

- CBS/FDA/Other (general re: Rx Drugs)
  - risk (side effect) information biggest "communications gap"
- Time Survey (DTC in particular): (%)
  - all risks 84
  - all needed information 76
  - an 800 # 66
  - time to study 65
  - keep children from seeing 64

Consumer Ad Awareness

- General Ad Awareness (Prevention) - 70%
- Specific (%) - (know indication)
  - 73 - Prozac (72) 32 - Premarin (62)
  - 61 - Claritin (62) 21 - Prilosec (CBS's best)
  - 47 - Allegra (54) 18 - Imitrex (41)
  - 38 - Pravachol (21) 11 - Glucophage
  - 35 - Zocor (34) 8 - Sporenox
  - 34 - Valtrex

Communication Adequacy

- "Somewhat Clear" (Prevention)
  - 71% Spring 1997 (before guidance)
  - 66% Spring 1998 (after guidance)
- "Good/excellent" Informing About (%):

Magazines	Television	
36	30	Annoying SE
40	33	Serious Warnings
57	55	Product Benefits

Does DTC Increase Dr. Visits*?

- Correlational data:
  - Zyban - 60% increase in visits
- Consumer surveys
  - Time - 28% seeing ad discussed with HCP
  - Prevent - 33% talked to MD, 13% for 1st time
- Change in sales after DTC:
  - Pravacol - 34% increase in share
  - Claritin - 39% increase in share
  - Fosamax - gained 40% share after launch

*assorted news reports

Increase Requests for Drugs? (1)

- MD Surveys:
  - IMS/Scott-Levin: increase in requests:
    - 41% in 1997, 65% in 1998
    - 30% in 1989, 78% in 1993
  - Sherr and Hoff: 85% at least 1 req in past mo:
    - Claritin - 29%, Allegra/Zantac - 10%, Prosac - 6%, Zyrtec/Redux - 5%
- Retrospective Patient Study:
  - Wyatt: 45-60% Allergy suffers became aware of Allegra through Ads (85% TV; 12% Mag)
  - 10-20% Allegra users aware through ads

Increase Requests for Drugs?(2)

- Prevention Survey - 33% overall
  - already taking med (42% vs. 21%)
  - women (57% vs.29%)
- Scenario Study:
  - Everett: 35% would ask for back pain drug
- Behavioral Study:
  - Peri and Dickson: sent ads for fictitious drugs to 155 patients scheduled to see MD
    - 2 mailings, 10 and 3 days before visit
    - 8.4% asked MD about the drug

Nature of Request

- Prevention:
  - 28% Ask for Rx
  - 70% Ask for more information
    - (33% asked asked MD about drug, 13% condition)
  - 22% (of those seeing a DTC ad) sought info from a source other than the MD
  - 38% (of those talking to MD) sought info from another source

If Request Refused?

- Surveys:
  - Time: 32% believe can choose med w/o MD
    - 28% would switch MD to get med
- Scenario Studies:
  - Everett:6% would switch MDs if refused
  - Maddox et al.: Canadians - backlash:
    - If told they requested drug, uncomfortable discussing with MD compared to when MD suggests drug

Consumer Attitude Surveys

- Much is proprietary, some public:
  - Early: FDA, Scott-Levin, small studies
  - Recent: Time, Prevent, Scott-Levin, FDA-plan
- Scott-Levin (reported by CBS):
  - 49% DTC as an educational tool
  - 42% DTC-TV reliable source of info
  - 25% DTC-TV gives info cannot get elsewhere
  - 9% DTC-TV should be banned

Prevention Survey: DTC

- 74% - allows more involvement in own care
- 67% - educate about risks and benefits
- 61% - confuses about risks and benefits
- 55% - makes Rx medicines seem harmless
- 59% - help make own decisions re Rx meds
- 38% - cause tension between MD and Pat
- 34% - (of those taking med) feel better about taking having seen DTC ad

Consumer Attitude Surveys

- News-bites but insufficient detail:
  - Time: 32% believe can choose med w/o MD
    - 28% would switch MD to get med
- Attitudes still being "constructed"
  - what "stimulus" being evaluated
  - what "context"
  - how to interpret general attitude measures
  - what beliefs predict behavior?

What is Communicated?

- Survey:
  - Prevention - risks and benefits
  - Time - TV better for awareness, mag for action
- Copy test:
  - FDA Study: benefits likely, risk possibly
  - FDA enforcement: symbolic information
- Anecdotal:
  - Specific, vivid risks, detract from benefits

Communication Implications?

- Content unlikely to predict take-away
- Case by case analysis, experimental studies needed
- How do risks and benefits interact to influence communication?
- Are tertiary messages communicated? (e.g., adequate provision sources)
  - Effects of repeated exposures?

Truthfulness, Balance, Disclosure

- Roth:
  - 1/3 of ads lack fair balance (unclear what definition was used)
- General Concerns (not DTC-specific)
  - Multiple streams of info (see pictures, hear/see words, hear background)/ Limited take away (only 49% of supers are comprehended)
  - Explicit and Implicit Claims
  - Limited internal "context-availability"
    - Disclosure as a remedy?

Adequate Provision Methods

- Consumer Recall (Prevention) (%):
  - 87 MD/RPh
  - 71 Toll-free number
  - 48 Web-site
  - 24 Magazine/newspaper
  - 23 PDR (false positive)
- Read brief summary (%)
  - 45 All
  - 22 Some

Physician Attitudes - General

	Negative Attitudes (%)	
• 1986	79	(Pharmacy Times)
• 1997	61	(IMS Survey)
• 1998	65	(IMS Survey)
• 1998	80	(American Family Physicians)

Physician Attitudes - Specific

- Time: Positive:
  - 85% notifies about available drugs
  - 67% encourage MD visits
  - 61% provide needed information
  - 40% help MD give best treatment

Physician Attitudes

- Time: Negative
  - 88% Patients request unnecessary meds
  - 74% Pressure doctors to write Rx's
  - Patients are confused:
    - 69%about med risks
    - 68% about Rx and OTC difference
    - 56% due to information overload

Compliance/Persistence

- Most Ads targeted at Initial Visit
  - no analyses, may be a side effect?
- Health Resources
  - ads distributed with Rx info
  - Pilot Study (K-Dur) - IMS Compliance Data
    - more likely to refill Rx on time (about 1 day earlier than controls)
    - more likely to continue to refill Rx

Increase or Lower Prices?

- Penna (Cigna) MCO:
  - Antihistamine costs from $.48 to $1.19 PMPM
  - Antiulcer/Depression: $1.04 to $1.75 PMPM
  - Benefit redesign/DTC backlash
- Kopp and Sheffet - econometric analysis:
  - Retail gross margins decreased 50% for drugs with DTC
  - Limited to drugs with a no-DTC period, 65% advertise early in life cycle

What Evidence Suggests: Hypotheses

- DTC increases MD visits
- DTC increases patient requests for drugs
- People want risks but info may be confusing
- Physicians still don't like it (fluid)
- Risk information may be problematic
  - may also detract from benefits
- Additional disclosures may be problematic
  - information overload, supers have min impact

What Evidence is Needed: Too Early to Form Hypotheses

- How are TV claims interpreted?
- Cost-effectiveness societally?
- Liability changes?
- Impact on consumer as influencer, user
- Cumulative effects (trivialization)
- What is a "positive/negative" outcome?
  - Eye of the beholder, consensus needed
  - Need research agenda

APPENDIX F

NATIONAL CONSUMERS LEAGUE

HEALTH CARE INFORMATION AND THE CONSUMER

A PUBLIC OPINION SURVEY

National Consumers League
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NATIONAL CONSUMERS LEAGUE
PUBLIC OPINION SURVEY
HEALTH CARE INFORMATION AND THE CONSUMER
AUGUST 27, 1998

Methodology

The National Consumers League commissioned Opinion Research Corporation International to conduct a national telephone survey. It was conducted during the period August 27-30, 1998 among a national probability sample of 1,013 adults comprising 507 men and 506 women 18 years of age and older, living in private household in the continental United States.

Opinion Research Corporation utilizes an unrestricted random sampling procedure to assure the most advanced probability sampling technique in the selection of households for telephone interviewing. The national probability telephone sample includes both unlisted and listed numbers. Completed interviews are weighted by four variables: age, sex, geographic region, and race, to ensure reliable and accurate representation of the total population, 18 years of age and older.

Results of any sample are subject to sampling variation. The magnitude of the variation is measurable and is affected by the number of interviews and the level of the percentages expressing the results. With the sample size of this survey, most results fall within the +/- tolerance of 2-3%.

SURVEY RESULTS

Sources of Health Information

The first series of questions focus on what sources consumers use to learn about health. When asked ***What sources of information do you use to learn about health?*** the responses were :

Magazines.....34%
Health Care Professional.....33%
Television.....28%
Newspapers.....24%
Books/Medical books.....22%
Internet.....12%

Family/Friends/Word of Mouth.11%
Pamphlets/brochures..... 5%

Some of the interesting findings were that more females (41%) and those aged 35-44 (37%) and those earning from $25-$35,000 annually (45%) with some college (40%) or with college degrees (41%) mentioned magazines as a source of information. Those most likely to mention health care professionals are female (38%) and persons aged 55-64 (37%) or over 65 (45%). Those earning $15-25,000 annually (36%) and persons aged 45-54 (34%) mentioned television as a source of health information. Those more likely to use the Internet are age 25-34 (18%), live in the West (16%), earn more than $50,000 (19%) and are a college graduate (17%).

Prescription Drug Advertisements

Four out of five consumers indicate that have seen or heard an advertisement for a prescription drug. 84% of the women interviewed said they had seen or heard an ad; 87% of those from 55-64 years of age; 89% of those who ear more than $50,000 and 86% from an dual income household. Those who have had some college or have completed college (82 and 84%) indicate that they have seen or heard such an advertisement.

Of the total number of people who have seen or heard an advertisement, the places where they have seen or heard the advertisement were:

Television.....88%
Magazine.....50%
Newspaper.....23%
Radio.....20%

More younger people aged-34 years old (92%) have seen television ads. Those in the Northeast (59%) say they have seen magazine advertisements for prescription drugs.

It was important for us to find out if people read the "brief summary" in print advertisements. We asked: ***Print advertisements -- those that appear in newspapers and magazines -- include a page that is often in technical language and small print about the risks, possible interactions and side effects for the advertised drug. How much of this page do your read?*** Responses were:

Almost all.....32%

Some.....24%
Very little.....21%
None or don't read.....22%

Those who are more likely to read **almost all** are female (39%) and those in the income range of $25-50,000 (38%). Those who read **very little or none** of the brief summary are male (51%); those aged 18-24 (46%); from the West (48%), and those with the least education.

When asked ***Do you think that advertisements of prescription drugs increase consumer knowledge about MEDICINES?*** respondents answered:

Always.....23%
Sometimes.....53%
Rarely/never..... 22%

Those **least** likely to think that ads increase consumer knowledge about medicines were college graduates (28%), those who earn $50,000 or more (27%), and males (28%). Those who most frequently responded **always or sometimes** were female (80%); from the South (80%), age 18-24; those who are high school graduates (80%) and earn $15-35,000 (81%) a year.

Of those who have seen or heard an advertisement for a prescription drug, we asked if they had ever talked to a doctor about a **MEDICINE** that they heard about through an advertisement in a newspaper, magazine, or on the radio or television. **44% said yes. 55% said no.** Half of the females had spoken to their doctor and the older the respondent, the more likely to talk to their doctor. Of those 55-64, 49% said yes, and those 65+, 55% said yes. Those who make more money ($35,000 and up and those with dual incomes) (about 50%) said yes.

When asked ***Do you think that advertisements of prescription drugs increase consumer knowledge about DISEASE?*** respondents were more skeptical. They replied:

Always.....16%
Sometimes.....52%
Rarely/never.....31%

Those **least** likely to think that the ads increase consumer knowledge about disease were male (36%); from the Northeast (39%), earned more than $50,000 (37%), or were a college graduate (39%). Those who **sometimes** felt the ads increased consumer knowledge were female (54%); older (55-64 - 57%) (65+ - 54%); and did not live in a metropolitan area (56%).

When asked if they had ever talked to a doctor about a **DISEASE** they had heard about through an advertisement in a newspaper, magazine, or on the radio or television, the replies were:

Yes.....23%
No.....77%

Those **most likely** to talk to their doctor about a disease they had heard about through an ad were 18-24 year olds (37%); and those who were black (41%). Those **least likely** to talk to their doctor about a disease they had heard about through an ad were male (81%), 25-34 year-olds, and white (79%).

We then asked ***What was the result of your conversation with your doctor?*** Respondents replied:

It helped us talk about the drug/disease.....30%
The doctor prescribed the drug.....22%
I did not get a prescription for the drug.....13%
The doctor said the drug was not right for me or my condition.....12%
I did not get a prescription for the advertised drug, but got one for the same problem..... 5%

Very few respondents indicated that the doctor was unwilling to talk about the advertised drug, did not like the information I gave or that it caused tension between the doctor and the patient. Those **most** likely to respond that "It helped us talk" were 18-24 year olds (49%), black (42%), and had not completed high school (40%). Those whose doctors **prescribed** the drug were 45-54 year olds (33%) and those with a high school education (29%).

Taking care of your own health

We asked a series of questions about how people are taking care of their own health and whether they are taking dietary supplements or herbal medicines. Most often cited activity was exercising or walking (76%), watching diet (low fat; low cholesterol, "watch what I eat") (28%).

Respondents were then asked if they had taken herbal, vitamin, or mineral supplements in the past 12 months. 54% said yes (59% female); 45%, no. Those taking supplements are from every age group and generally the older one gets, the more likely to take a supplement. (61% of those age 55-64 responded yes.) Those from the West (61%) were more likely to respond yes than those from the Northeast or North Central part of the country. Those with higher incomes and with some college or college graduates were more likely to take supplements. What are the supplements that people are taking?

Vitamins.....64% [Vitamin E (22%) and Vitamin C (19%) are the most popular.]
Minerals.....21% [Calcium (13%) is the most popular.]
Herbal Supplements....39% [Ginseng (10%), Ginkgo (8%), and St. John's Wort (8%) are the most popular.]

Those most likely to take **vitamins** are 35-64 (about 69%) and it didn't matter if you have children or no children in the household. Those 55-64 and those who have had some college are more likely to take Vitamin E. Vitamin C is also very popular among those age 45-64. 20% of women take a **calcium** supplement; of those 65 and older, 22% do so.

More women (43%) than men (33%) take **herbal supplements**. The younger you are the more likely to take herbal supplements. Have of those age 18-24 take them; 46% of those who are black and almost half (49%) of those who have some college. Those who live in the West (43%) and Northeast (43%) are more likely to take herbal supplements than those in the North Central or Southern part of the country.

Next, repondents were asked a series of statements about herbal supplements:

Herbal supplements are generally safe.....46% generally or totally agree

Herbal supplements are effective in maintaining overall health and well-being.....37% generally or totally agree

herbal supplements are effective in preventing or protecting against some diseases.....36% generally or totally agree

Herbal supplements are good value for the money.....29% generally or totally agree

Herbal supplements are generally effective.....34% generally or totally agree

Herbal supplements have been approved for safety and effectiveness by the FDA.....26% generally or totally agree
23% totally disagree

40% of those 18-24 agree; 32% from the West; 33% Hispanic; more people with lower incomes and less education (34% of those without a high school education).

Claims made by the manufacturers of herbal supplement are confusing.....35% generally or totally agree; 40% Hispanic; mostly those with teenagers In the household (44%).

Herbal supplements are as effective as prescription or over-the-counter medicines.....23% generally or totally agree; 37% generally or totally disagree; 32% of those without a high school education

Respondents were asked what would make them feel more confident about the safety or effectiveness of herbal supplements.

More studies conducted about their safety and effectiveness.....78% (81% 18-24 year olds)

Approved for safety and effectiveness by the FDA.....76% (86% 18-24 year olds)

Manufactured by a well-known company.....54% (60% in the South; 62% of Those in the $15-25,000 income bracket

Do consumers receive useful information with their prescription drug ?

By the year 2000, the Food and Drug Administration is committed to determine whether consumers receive useful information when they receive their prescription drug. The National Consumers League shares that goal. In this section of the survey, we first asked ***Have you obtained a prescription drug from a pharmacy for yourself or someone else within the last year...***76% responded yes.

Women.....84%
Age 55-64.....83%
Age 65+.....86%
$50,000+.....84%
Dual Income.....83%
Some college.....81%

For those who have obtained a prescription drug in the last year, we asked ***When you get your prescription drug, could you tell me which of the following is MOST useful to you?***

Very complete information written in medical terms providing all possible side effects, risks, and possible interactions associated with taking the medicine.

52% responded that this would be the most useful; women (58%); age 65+ (56%); Hispanic and without a high school education (62%).

Summary of the most important, but not all, risks, side effects and possible interactions that could be associated with taking the medicine, including easy-to-read information about your condition or disease.

32% of the public responded that this would be the most useful; male (39%); age 55-64 (38%);

Summary of the most important, but not all risks, side effects and interactions that could be associated with taking the medicine.

12% resonded that this would be the most useful; age 35-44 (16%); Northeast (18%).

We then asked respondents to ***think about any written information, other than the label or any stickers on the container, that you might have received with your most recent prescription. Was the information...***

A few sentences or phrases printed by a computer at the pharmacy? 32%

A one page sheet about the medicine? 31%

A preprinted leaflet from a pharmaceutical company? 18%

A folder newsletter with information about your medicine and condition? 8%

Didn't receive anything 5%

We then asked how carefully did you read the written information

72% said that they "carefully read al of the information." Of those 65+, 83% said they read the information carefully;

10% said that they "carefully read **some** of the information

12% skimmed the information and 5% said tht they did not read any of the information.

Respondents were asked about the written information that they received. 54% said that it **"was easy to understand**;" of those 65+, 75% said that it would easy to understand; 48% indicated that it **"was very useful in teaching me about the medicine."** 47% said that it was **"very detailed and complete**." 46% said that it "**frankly discussed the side effects."** 15% said that **"Left me wondering if there was more I needed to know about the medicine."**

Question 1. What sources of information do you use to learn about health? (DO NOT READ LIST. RECORD AS MANY AS APPLY)

1. BOOKS/MEDICAL BOOKS.....22%
2. DOCTOR.....25%
3. FAMILY/FRIENDS/WORD OF MOUTH.....11%
4. INTERNET.....12%
5. MAGAZINES.....34%
6. NEWSPAPERS.....24%
7. NURSE.....4%
8. OTHER HEALTH CARE PROFESSIONAL.....6%
9. PHARMACIST.....1%
10. NEWSLETTER ATTACHED TO MY PRESCRIPTION.....1%
11. RADIO.....3%
12. TELEVISION.....28%
13. PAMPHLETS/BROCHURES.....5%
14. OTHER (SPECIFY).....6%
15. NONE/DON'T WANT OR NEED HEALTH INFORMATION...3%
16. DON'T KNOW.....2%

Question 2. Have you ever seen or heard an advertisement for any PRESCRIPTION drug?

1. YES.....80% -->CONTINUE
2. NO.....18%
3. DON'T KNOW.....2% -->SKIP TOQ.10

Question 3. Where have you seen or heard to advertisement? (READ LIST. RECORD AS MANY AS APPLY)

1. Television.....88%
2. Radio.....20%
3. Magazine.....50%
4. Newspaper.....23%
5. OTHER (SPECIFY).....5%
6. DON'T KNOW.....1%

Question 4. Do you think that advertisements of prescription drugs increase consumer knowledge about MEDICINES? Would you say that...(READ LIST)

1. Always.....23%
2. Sometimes.....53%
3. Rarely.....14%
4. Never.....8%
5. DON'T KNOW.....2%

Question 5. Do you think that advertisements of prescription drugs increase consumer knowledge about DISEASE? Would you say that...(READ LIST)

1. Always.....16%
2. Sometimes.....52%
3. Rarely.....22%
4. Never.....9%
5. DON'T KNOW.....1%

Question 6. Print advertisements--those that appear in newspapers and magazines--include a page that is often in technical language and small print about the risks, possible interactions and side effects for the advertised drug. How much of this page do you read? Would it be...(READ LIST)

1. Almost all.....32%
2. Some.....24%
3. Very little.....21%
4. None or don't read.....22%
5. DONT' KNOW.....1%

Question 7. Have you ever talked to your doctor about a MEDICINE you heard about through an advertisement in a newspaper, magazine, or on the radio or television?

1. YES.....44%
2. NO.....55%
3. DON'T KNOW.....1%

Question 8. Have you ever talked to your doctor about a DISEASE you heard about through an advertisement in a newspaper, magazine, or on the radio or television?

1. YES.....23%
2. NO.....77%
3. DON'T KNOW.....1%

Question 9. What was the result of your conversation with your doctor? (DO NOT READ LIST. RECORD CHOICES WHICH MOST CLOSELY DESCRIBE RESPONDENTS' ANSWER)

1. THE DOCTOR SAID THE DRUG WAS NOT RIGHT FOR ME OR MY CONDITION.....12%
2. THE DOCTOR PRESCRIBED THE DRUG.....22%
3. I DID NOT GET A PRESCRIPTION FOR THE ADVERTISED DRUG, BUT GOT ONE FOR THE SAME PROBLEM.....5%
4. I DID NOT GET A PRESCRIPTION FOR THE DRUG.....13%
5. IT HELPED US TALK ABOUT THE DRUG/DISEASE.....30%

6. IT CAUSED TENSION BETWEEN ME AND MY DOCTOR.....1%
7. THE DOCTOR WAS UNWILLING TO TALK ABOUT THE ADVERTISED DRUG.....2%
8. THE DOCTOR DID NOT LIKE THE INFORMATION I GAVE.2%
9. OTHER (SPECIFY).....6%
10. NOTHING/NO RESULT.....6%
11. DONT' KNOW.....6%

Question 10. What kinds of activities, if any, are you currently doing to take care of your health? (DO NOT READ LIST. RECORD AS MANY AS APPLY)

1. CHIROPRACTOR.....1%
2. EAT LOW FAT/LOW CHOLESTEROL FOODS/ WATCH WHAT I EAT.....28%
3. EXERCISING OR WALKING.....76%
4. MASSAGE THERAPY.....1%
5. MEDITATION OR YOGA.....1%
6. REGULAR DOCTOR VISITS/CHECK-UPS.....4%
7. STRESS REDUCTION/TRYING TO RELAX.....3%
8. TAKE HERBAL SUPPLEMENTS.....1%
9. TAKE MEDICATION/OVER-THE-COUNTER OR PRESCRIPTION DRUGS.....3%
10. TAKE VITAMIN SUPPLEMENTS OR MINERAL SUPPLEMENTS.....6%
11. TRYING TO LOSE WEIGHT.....3%
12. OTHER (SPECIFY).....11%
13. NOTHING.....9%
14. DON'T KNOW.....1%

Question 11. You may have already mentioned this, but have you taken herbal, vitamin or mineral supplements in the past 12 months?

1. YES.....54% -->CONTINUE
2. NO.....45% -->SKIP TO Q. 13
3. DON'T KNOW.....1%

Question 12. Which type of herbal, vitamin or mineral supplements have you taken? Any others? (DO NOT READ LIST. RECORD AS MANY AS APPLY)

1.	MULTIVITAMIN	44%
2.	VITAMIN A	4%
3.	VITAMIN B	9%
4.	VITAMIN C	19%
5.	VITAMIN E	22%
6.	VITAMIN K	1%
7.	VITAMIN (SPECIFY)	4%
8.	CALCIUM	13%
9.	IRON	3%.
10.	ZINC	4%
11.	MINERAL (SPECIFY)	6%
12.	ANTIOXIDANTS	4%
13.	BETA CAROTENE	3%
14.	ECHINACEA	5%
15.	GARLIC	5%
16.	GINSENG	10%
17.	GINKGO BILOBA	8%
18.	GOLDENSEAL	1%
19.	MELATONIN	1%
20.	ST. JOHN'S WORT	8%
21.	HERBAL SUPPLEMENT (SPECIFY)	10%
22.	STRESS TABS	1%
23.	COMBINATION VITAMIN/MINERAL	3%
24.	COMBINATION HERBAL	1%
25.	OTHER (SPECIFY)	15%
26.	DON'T KNOW	5%

Question 13. I'm going to read you a few statements about herbal supplements. Herbal supplements are products such as St. John's Wort, Ginseng, or Ginkgo Biloba. Tell me whether, overall, you agree or disagree based on what you know or have heard or seen. Please use a scale of 1 to 5, where "1" means you "totally disagree" and "5" means you "totally agree." If you are unsure howto answer a particular statement, please tell me. Overall, do you think...(READ AND ROTATE STATEMENTS)

1. Totally disagree
2.
3.
4.
5. Totally agree
6. UNSURE

	Level of Agreement
Herbal supplements are generally safe	26%
Herbal supplements are a good value for the money	17%
Herbal supplements are effective in preventing or protecting against some diseases	19%
Herbal supplements are effective in maintaining overall health and well-being	20%
Herbal supplements have been approved for safety and effectiveness by the Food and Drug Administration	15%
The claims made by the manufacturers of Herbal supplements are confusing	23%
Herbal supplements are as effective as prescription or over-the-counter medicines	12%

Question 14. Which of the following kinds of things, if any, would make you feel more confident about the safety or effectiveness of herbal supplements? (READ AND ROTATE LIST)

1. YES, WOULD MAKE ME FEEL MORE CONFIDENT
2. NO, NOT MAKE ME FEEL MORE CONFIDENT
3. DON'T CARE
4. DON'T KNOW

	YES SUMMARY
More studies conducted about their safety and effectiveness	78%
Approved for safety and effectiveness by the Food and Drug Administration	76%
Manufactured by a well-known company	54%

Question 15. Have you obtained a prescription drug from a pharmacy for yourself or someone else...(READ LIST)

1. Within the last year.....76%. -->CONTINUE
2. More than a year ago.....13%
3. DON'T KNOW.....11% -->SKIP TO NEXT SECTION

Question 16. Next, when you get your prescription drug, could you tell me which of the following is MOST useful to you? (READ ENTIRE LIST BEFORE RECORDING ONE ANSWER)

1. Very complete information written in medical terms providing all possible side effects, risks, and possible interactions associated with taking the medicine.....52%
2. Summary of the most important, but not all, risks, side effects and interactions that could be associated with taking the medicine.....32%
3. Summary of the most important, but not all, risks, side effects and possible interactions that could be associated with taking the medicine, INCLUDING easy-to-read information about your condition or disease.....12%
4. DON'T KNOW.....3%

Question 17. Now, I would like you to think about any written information, other than the label or any stickers on the container, that you might have received with your most recent prescription. Was the information...(READ LIST. RECORD ONE ANSWER)

1. A few sentences or phrases printed by a computer at the pharmacy.....32%
2. A one page sheet about the medicine.....31%
3. A folded newsletter with information about your medicine and condition.....8%
4. A preprinted leaflet from a pharmaceutical company.....18% -->CONTINUE
5. OTHER (SPECIFY).....2%
6. DIDN'T RECEIVE ANYTHING.....5% -->SKIP TO NEXT SECTION
7. DON'T KNOW.....3% -->CONTINUE

Question 18. How carefully did you read the written information? Would you say you...(READ LIST)

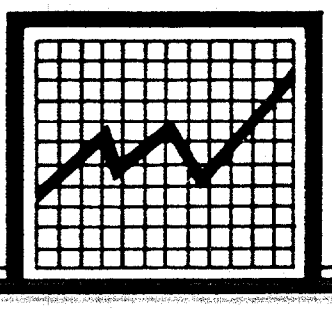
1. Carefully read all of the information.....72%
2. Carefully read some of the information.....10%
   -->CONTINUE
3. Skimmed the information.....12%
4. Did not read any of the information.....5%
   -->SKIP TO NEXT SECTION
5. DON'T KNOW.....1%
   -->CONTINUE

Question 19. Now, I would like you to give me your impressions of the written information you received. I am going to read a series of statements. On a scale of 1 to 5, where "1" means you "totally disagree" and "5" means you "totally agree," please tell me how much you disagree or agree with each statement. The written information I received about my prescriptions...(READ AND ROTATE STATEMENTS)

1. Totally disagree
2.
3.
4.
5. Totally agree
6. DON'T KNOW

	Level of Agreement
Was very useful in teaching me about the medicine	48%
Was easy to understand	54%
Left me wondering if there was more I needed to know about the medicine	15%
Was very detailed and complete	47%
Frankly discussed the side effects	46%
Was not useful and did not tell me much about the medicine	10%
Was too technical and difficult to understand	10%
Was unclear about the side effects	13%

FINGERHUT OPINION



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NATIONAL CONSUMERS LEAGUE

MALL INTERCEPT PROGRAM ON PRESCRIPTION DRUGS

Provided By:

Victor Fingerhut, President
Fingerhut/Granados Opinion Research

Over a period of four (4) days in ten (10) mall dispersed throughout the country, 250 interviews were conducted on the public's perceptions of prescription drug advertisements and inserts. The interviews covered general awareness and attitudes, as well as gauging the effectiveness of three specific types of material. Two hundred (200) of the interviews were taken from the general population and an additional 50 interviews were conducted with senior citizens. All of the participants in the survey had obtained a prescription within the last year.

GENERAL AWARENESS AND ATTITUDES

The public gathers information of health issues from a wide variety of sources. The most often mentioned means of information is *doctors*, other often mentioned responses were *books*, *magazines*, *pharmacists* and *television*.

Eighty-five (85) percent are aware of *having seen or heard an advertisement for any prescription drug*. *Television* was mentioned most often as the medium in which the advertisement was seen or heard followed by *magazines*, *radio* and *newspapers*.

Question: *Have you ever seen or heard an advertisement for any prescription drug*?

	General Population	Senior Citizens
Yes	85	84
No	11	16
Don't Know	4	--

Over three-quarters of those surveyed think that advertisements of prescription drugs *always* (21 percent) or *sometimes* (55 percent) increase consumer knowledge about medicines. Twenty-four (24) percent responded that the ads rarely (20 percent) or never (4 percent) increased consumer knowledge about medicines.

Question: *do you think that advertisements of prescription drugs – always, sometimes, rarely or never – increase consumer knowledge about medicines?*

(General Population)

Always	21	\ 76 percent
Sometimes	55	/
Rarely	20	
Never	4	

(Senior Citizens)

Always	17	\ 77 percent
Sometimes	60	/
Rarely	10	
Never	14	

The responses were similar when the term "disease" was substituted for "medicines". Sixty-one (61) percent answered that advertisements of prescription drugs always (11 percent) or sometimes (50 percent) increased consumer knowledge about disease.

Interestingly, **over half (56 percent) of the people had *talked to their doctor about a medicine they heard about through an advertisement in a newspaper, magazine or on the radio or television.***

Question: *Have you ever talked to your doctor about a medicine you heard about through an advertisement in a newspaper, magazine, or on the radio or television?*

	General Population	Senior Citizens
Yes	56	55
No	44	45

Slightly less, 42 percent, had *talked to their doctor about a disease they heard about through an advertisement in a newspaper, magazine or on the radio or television* (45 percent of seniors).

Of those who talked to their doctor, 31 percent said their conversation *helped us talk about the drug/disease*, 22 percent replied that *the doctor prescribed the drug*, while 20 percent responded that *the doctor said the drug was not right for me or my condition.*

For seniors, 28 percent said *the doctor said the drug was not right for me or my condition*, 19 percent answered *I did not get a prescription for the advertised drug, but got one for the same problem*, and 16 percent replied *the doctor prescribed the drug.*

Seventy-three (73) percent have at least once *taken the time to read the fine print, in either a prescription advertisement or package insert*, with 47 percent saying they read both. Twenty-four (24) percent of seniors said they have read both, and 79 percent have at least once *taken the time to read the fine print, in either a prescription advertisement or package insert.*

When asked *how often* they read the fine print of an advertisement for a prescription drug which interest them, 24 percent said *always* (45 percent of seniors), 28 percent answered *most of the time* (25 percent of seniors), and 24 percent replied *about half of the time* (15 percent of seniors). The remaining 24 percent responded *seldom* or *never*.

When queried about the fine print in an insert provided from the drug's manufacture the overall percentage were similar to those who read the fine print of advertisements. However, a greater percentage (35 percent) *always* read the fine print, 23 percent said *most of the time* and 14 percent answered *about half of the time*.

Two-in-five (41 percent) thought the detailed information provided in prescription drug advertisements is *confusing and written too technically*, while a majority (57 percent) said the information was *easy to understand*. More seniors (64 percent) thought the information was *confusing and written too technically* than thought it was *easy to understand*.

EFFECTIVENESS OF SPECIFIC MATERIAL

(Methodology)

Three types of informational material which would be given to prescription drug users by their pharmacist were tested. Each piece presented information including the benefits, side effects and usage for a particular drug. The different items varied in detail and style. The survey participants were each tested on all three formats and material. Three different drugs were employed to ensure that information retained from one items was not given as a legitimate response to a question on another item. In other words, each participant was questioned about three different pieces of material each detailing a different drug.

For purposes of the survey, the material was identified as: AD-X, AD-Y, and AD-Z. (Samples of materials can be found in the appendix.)

AD-X was a 8 ½ by 14 inch sheet of paper with preprinted information on one side in three columns, with one column contained an advertisement for a prescription drug, and the next two columns containing general health related information. On the reverse side was specific information on the drug being prescribed. The information was listed in plan type with three to six initial bullet points listing the most critical information followed by a paragraph on correct usage and a paragraph on side effects and warnings.

AD-Y was a one or two page full color description of the prescribed drug with graphics and pictures. The material was presented with colorful headlines and bold type. On the back was a full page of fine print concerning the drug.

AD-Z was a pamphlet or one page sheet which described in black and white in standard type the drug prescribed. Sections of this item were titled about your medicine, before using this medicine, proper use of this medicine, precautions while using this medicine, and possible side effects of this medicine.

In addition the three drugs were labeled DRUG-A, DRUG-B, and DRUG-C.

DRUG-A was Rezulin which is a diabetes medication.

DRUG-B was Zithromax which is an antibiotic for children's ear infections.

DRUG-C was Claritin which is an antihistamine.

Overall, the three different types of material were viewed similarly by the public.

The public was fairly good at discerning the *most important* item from the information they reviewed, and as a whole they were able to pick out the more important answers for *how the drug should be used* and *the risks or possible side effects of using this drug*. While these responses varied somewhat by the information stressed in a specific piece of material (AD-X, Y, Z), none of the formats produced a difference which would suggest one of the formats was superior or inferior in the usefulness of the information provided.

AD-X, which had specific information about the prescribed drug on one side of the page and general health tips and drug advertisements on the other side of the material sometimes produced responses that were derived from the general health tips or the advertisement and not related to the specific drug information. On occasion, because participants were questions about three different types of material concerning three different drugs, erroneous responses were given that related to material or drugs other then the one they were being questioned about.

In order to judge the ability of the material to communicate important information to the consumer, following the review of each of the ads, a series of ten (10) questions were asked on whether people in certain conditions should take the medication. The conditions ranged from pregnancy to obesity and included medical conditions such as diabetes, glaucoma and high blood pressure.

For every condition there were a high number of *should not use* responses for circumstances not mentioned in the material. For example, 13 to 30 percent said *obese* individuals *should not use* the drug in question, however, none of the material mentioned obesity.

In spite of the high percentage of false positive responses, in every instance where a condition was prominently detailed in the material, the number of *should not use* responses rose significantly.

To get to the heart of the effectiveness of the particular pieces (AD-X, Y, Z) to convey useful information to consumers, a series of eleven questions were asked. The participants were asked to rate statements on a scale of 1-to-5 with one (1) signifying total disagreement and five (5) signifying total agreement.

The marginal results (included with this report) show the detailed results for the nine combinations of drug types and material for each question. However, in order to analyze the data two different methods of summarizing the results were implemented.

The first method was to calculate a *mean* score for each question. The mean is determined by multiplying the number of responses by the answer category number (1-5) and dividing by the total number of responses. The result is the number which represents the cumulative responses. For example, if there was an even distribution of responses (say 10 people chose 1, 10 people chose 2,....10 people chose 5) the mean score would be 3 – half way between one (1) and five (5).

The advantage of using this method is all of the results for a question can be represented in one number. The disadvantage is it tends to flatten the results and it is necessary to look at one or two decimal places to see *any variance* between the drugs and material tested.

With that in mind, a second method was implemented to attempt to expose more subtle differences. The percentage of responses for answer number four (4) and five (5) were added together into one *net agreement* number.

The extensive tables in Appendix A illiterate the answers for <u>each question</u> in four (4) matrixes.

The first contains the <u>mean scores</u> for the <u>general population</u>,

the second contains the <u>mean scores</u> for senior citizens,

the third has the <u>net agreement</u> numbers for the general population, and

the last matrix has the <u>net agreement</u> numbers for senior citizens.

The last line of each matrix shows the relative ranking of the average score compared to those with the same population and scoring method in the other questions.

Upon careful review of each question by looking at the mean scores and net agreement percentages for the general population and senior citizens no pattern develops in which one type of material is favored over another. Whether analyzing each question by the mean scores or the net agreement numbers, the answers remain very close and the small variances are not consistent between drug and material types.

In other words, the three types of material tested were viewed similarly. For example, those who thought the material *was easy to understand* felt that way regardless of whether the were answering for AD-X, Y or Z.

Broad Conclusions

(1) Overall, three and four were perceived positively by a majority of the respondents — whether drawn from the general population or by senior citizens.

(2) Insofar as there *were* distinctions by age groups, seniors tended to slightly be *less positive* and slightly *more critical* of the ads overall.

(3) Despite the fair amount of "technical" information found in the ads, most respondents from both the general population and among senior citizens indicated the ads were comprehensible.

Thus, over 70 percent of both groups said the ads were "easy to understand."

At the same time, only about 20 percent described the ads as "too technical."

Indeed, respondents were more likely to say that the ads did not tell enough ("did not tell me much about the medicine") about the drug being advertised.

(4) An important conclusion of (3) is that the survey indicated that consumers are neither dumb nor overwhelmed by information presented by pharmaceutical companies – and are open to receiving significant amounts of clearly presented information.

(5) The ads were also successful in conveying an *appearance* of honest and completeness.

Overall, between 60-75 percent of the respondents gave the adds positive marks for

- completeness, and
- trustworthiness.

A similarly high reading was also given the ads for

- frankly discussing the side effects.

Analytical Note: Whether this is an *accurate* perception of the information conveyed in these ads I, of course, a matter lying *outside* the purview of these mull intercept surveys.

The survey results, however, are *unambiguous* in that the respondents believe the ads were – by and large – accurate and truthful.

(6) When we move to the matter of differences among and between various ads, the survey indicated some level of variances.

However, overall these variances were quite modest. Indeed the survey findings suggest that in the future – a wider range *of formats and presentations be tested.*

(7) The relative ranking of the questions show remarkable uniformity between the four (4) methods used to display the data. As such, the highest score consistently was given to *was easy to understand* regardless of how the data is illustrated, and the lowest score was consistently *was too scary.* The only question which had a variance in ranking greater than one was *frankly discussed the side effects* which senior citizens had a measurably higher level of agreement (ranking) than the general population.

(8) As noted in the tables below, Ad format Y (the full color ad with graphics and pictures) proved to the highest net positive reaction among both the general population and senior citizens.

Thus, the relative ranking of the three ad types for the general population and senior was as follows:

General Population

	Ad-X	Ad-Y	Ad-Z
Average Positive	69.8	72.6	74.0
(-)Average Negative	16.8	14.6	18.2
Net Positive Margin	53.0	58.0	55.8

Seniors

	Ad-X	Ad-Y	Ad-Z
Average Positive Statement	65.0	76.0	60.8
(-)Average Negative	19.8	19.8	21.6
Net Positive Margin	45.2	56.2	39.2

The following table shows the cumulative average net agreement percentage for the positive and non-positive questions.

	GENERAL POPULATION	SENIORS	VARIANCE
positive statements			
was extremely useful in teaching me about the medicine	71	61	-10
was easy to understand	77	74	-3
seemed to be complete	68	58	-10
seemed to be trustworthy	75	69	-6
frankly discussed the side effects	70	75	+5
AVERAGE POSITIVE PERCENTAGES	72.2	67.4	-4.8
non-positive statements			
did not really tell me much about the medicine	23	31	+8
was too technical	18	22	+4
did not honestly present the facts about the drug	19	27	+8
was too scary	10	9	-1
made me not want to take the drug	13	12	-1
AVERAGE NON-POSITIVE PERCENTAGES	16.6	20.2	+3.6

The following table shows the net agreement numbers for each type of material grouped by positive and non-positive statements.

	GENERAL POPULATION			SENIORS		
	AD-X	AD-Y	AD-Z	AD-X	AD-Y	AD-Z
positive statements						
was extremely useful in teaching me about the medicine	68	69	76	60	69	54
was easy to understand	82	77	73	78	76	68
seemed to be complete	60	72	71	56	66	51
seemed to be trustworthy	74	77	73	57	81	69
frankly discussed the side effects	65	68	77	74	88	62
AVERAGE POSITIVE PERCENTAGES	69.8	72.6	74.0	65.0	76.0	60.8
non-positive statements						
did not really tell me much about the medicine	29	18	21	28	32	32
was too technical	13	17	24	21	16	30
did not honestly present the facts about the drug	22	17	18	30	27	26
was too scary	9	8	13	8	10	10
made me not want to take the drug	11	13	15	12	14	10
AVERAGE NEGATIVE PERCENTAGES	16.8	14.6	18.2	19.8	19.8	21.6
NET POSITIVE MARGIN	53.0	**58.0**	55.8	45.2	**56.2**	39.2

The general population gave a net agreement average of 72.2 percent to the positive questions while only giving a 16.6 percent average net agreement to the non-positive questions.

The seniors, while still overwhelmingly positive, were measurably more skeptical of the material than the general population. On average the seniors were 4.8 percent less in agreement on the positive statements than the general population, and 3.6 more in agreement on the non-positive statements.

The seniors had an average net agreement percentage ten (10) percent lower for the statements *was extremely useful in teaching me about the medicine* and *seemed to be complete*, and their net agreement was eight (8) percent higher for the statements *did not really tell me much about the medicine* and *did not honestly present the facts about the drugs*.

AD-Y has the highest net positive margin for both the general population and senior citizens.

Analytical Note: Overall reactions are positive to all of the ads with low levels of dissatisfaction.

Appendix A

LEVEL OF AGREEMENT TO STATEMENTS CONCERNING THE THREE TYPES OF MATERIAL

was extremely useful in teaching me about the medicine

General Population/Mean Score

	AD X	AD Y	AD Z	AVG
Drug A	3.92	3.93	4.02	3.95
Drug B	3.86	4.00	4.04	3.96
Drug C	3.89	3.91	4.09	3.96
AVG	3.89	3.95	4.05	3.96

(RANK = 3)

Senior Citizens/Mean Score

	AD X	AD Y	AD Z	AVG
Drug A	3.72	3.95	3.86	3.84
Drug B	3.68	3.44	2.81	3.31
Drug C	4.08	4.00	3.83	3.97
AVG	3.83	3.79	3.50	3.71

(RANK = 4)

General Population/Net Agreement

	AD X	AD Y	AD Z	AVG
Drug A	63	70	78	70
Drug B	68	69	76	71
Drug C	74	69	74	72
AVG	68	69	76	71

(RANK = 3)

Senior Citizens/Net Agreement

	AD X	AD Y	AD Z	AVG
Drug A	61	74	64	66
Drug B	58	63	32	51
Drug C	61	69	67	66
AVG	60	69	54	61

(RANK = 4)

was easy to understand

General Population/Mean Score

	AD X	AD Y	AD Z	AVG
Drug A	4.08	4.00	4.31	4.13
Drug B	4.22	4.17	3.97	4.12
Drug C	4.30	4.09	3.98	4.12
AVG	4.20	4.09	4.09	4.12

(RANK = 1)

Senior Citizens/Mean Score

	AD X	AD Y	AD Z	AVG
Drug A	4.00	3.89	4.00	3.96
Drug B	3.79	3.94	3.13	3.62
Drug C	4.77	4.50	3.92	4.40
AVG	4.19	4.11	3.68	3.99

(RANK = 1)

General Population/Net Agreement

	AD X	AD Y	AD Z	AVG
Drug A	77	68	83	76
Drug B	82	80	73	78
Drug C	86	82	64	77
AVG	82	77	73	77

(RANK = 1)

Senior Citizens/Net Agreement

	AD X	AD Y	AD Z	AVG
Drug A	72	74	77	74
Drug B	63	69	51	61
Drug C	100	85	75	87
AVG	78	76	68	74

(RANK = 1)

left me wondering if there was more I needed to know about the medicine

General Population/Mean Score

	AD X	AD Y	AD Z	AVG
Drug A	2.95	3.12	2.61	2.89
Drug B	2.85	2.61	2.95	2.81
Drug C	3.13	2.74	2.73	2.86
AVG	2.98	2.82	2.76	2.85

(RANK = 6)

Senior Citizens/Mean Score

	AD X	AD Y	AD Z	AVG
Drug A	3.06	2.47	3.09	2.87
Drug B	2.47	3.25	3.31	3.01
Drug C	2.77	3.13	4.00	3.30
AVG	2.77	2.95	3.47	3.06

(RANK = 6)

General Population/Net Agreement

	AD X	AD Y	AD Z	AVG
Drug A	42	38	40	40
Drug B	36	26	42	35
Drug C	53	30	32	38
AVG	44	31	38	38

(RANK = 6)

Senior Citizens/Net Agreement

	AD X	AD Y	AD Z	AVG
Drug A	45	16	27	29
Drug B	11	44	51	35
Drug C	31	44	75	50
AVG	29	35	51	38

(RANK = 6)

seemed to be complete

General Population/Mean Score

	AD X	AD Y	AD Z	AVG
Drug A	3.66	3.93	3.95	3.84
Drug B	3.73	4.02	3.99	3.91
Drug C	3.59	3.93	3.87	3.80
AVG	3.66	3.96	3.94	3.85

(RANK = 5)

Senior Citizens/Mean Score

	AD X	AD Y	AD Z	AVG
Drug A	3.56	3.89	3.55	3.67
Drug B	3.58	3.63	3.00	3.40
Drug C	4.00	4.07	3.67	3.91
AVG	3.71	3.86	3.40	3.66

(RANK = 5)

General Population/Net Agreement

	AD X	AD Y	AD Z	AVG
Drug A	57	69	74	67
Drug B	65	73	74	71
Drug C	57	73	66	65
AVG	60	72	71	68

(RANK = 5)

Senior Citizens/Net Agreement

	AD X	AD Y	AD Z	AVG
Drug A	61	63	50	58
Drug B	47	56	38	47
Drug C	61	80	66	69
AVG	56	66	51	58

(RANK = 5)

seemed to be trustworthy

General Population/Mean Score

	AD X	AD Y	AD Z	AVG
Drug A	3.88	4.15	4.02	4.02
Drug B	4.16	3.96	4.05	4.06
Drug C	4.02	3.96	4.22	4.07
AVG	4.02	4.03	4.09	4.05

(RANK = 2)

Senior Citizens/Mean Score

	AD X	AD Y	AD Z	AVG
Drug A	4.00	4.06	3.82	3.96
Drug B	3.63	3.94	3.38	3.65
Drug C	3.77	4.36	4.08	4.07
AVG	3.80	4.12	3.76	3.89

(RANK = 3)

General Population/Net Agreement

	AD X	AD Y	AD Z	AVG
Drug A	66	93	74	78
Drug B	80	68	78	75
Drug C	77	71	68	72
AVG	74	77	73	75

(RANK = 2)

Senior Citizens/Net Agreement

	AD X	AD Y	AD Z	AVG
Drug A	72	74	64	70
Drug B	52	75	50	59
Drug C	46	93	92	77
AVG	57	81	69	69

(RANK = 3)

frankly discussed the side effects

General Population/Mean Score

	AD X	AD Y	AD Z	AVG
Drug A	3.46	3.77	3.75	3.66
Drug B	4.13	3.80	4.14	4.02
Drug C	3.78	4.05	4.02	3.95
AVG	3.79	3.87	3.97	3.88

(RANK = 4)

Senior Citizens/Mean Score

	AD X	AD Y	AD Z	AVG
Drug A	3.78	4.42	3.68	3.96
Drug B	3.84	4.00	3.19	3.68
Drug C	4.38	4.27	3.92	4.19
AVG	4.00	4.23	3.60	3.94

(RANK = 2)

General Population/Net Agreement

	AD X	AD Y	AD Z	AVG
Drug A	50	66	80	65
Drug B	80	60	80	73
Drug C	64	78	71	71
AVG	65	68	77	70

(RANK = 4)

Senior Citizens/Net Agreement

	AD X	AD Y	AD Z	AVG
Drug A	67	94	55	72
Drug B	64	75	56	65
Drug C	92	94	75	87
AVG	74	88	62	75

(RANK = 1)

did not really tell me much about the medicine

General Population/Mean Score

	AD X	AD Y	AD Z	AVG
Drug A	2.53	2.21	2.19	2.31
Drug B	2.69	2.37	2.31	2.46
Drug C	2.36	2.46	2.69	2.50
AVG	2.52	2.35	2.40	2.42

(RANK = 7)

Senior Citizens/Mean Score

	AD X	AD Y	AD Z	AVG
Drug A	2.28	2.89	2.73	2.63
Drug B	3.32	2.25	2.69	2.75
Drug C	2.92	3.07	3.00	3.00
AVG	2.84	2.74	2.80	2.79

(RANK = 7)

General Population/Net Agreement

	AD X	AD Y	AD Z	AVG
Drug A	25	16	19	20
Drug B	34	12	24	23
Drug C	27	26	21	25
AVG	29	18	21	23

(RANK = 7)

Senior Citizens/Net Agreement

	AD X	AD Y	AD Z	AVG
Drug A	17	37	37	30
Drug B	37	19	19	25
Drug C	31	40	41	37
AVG	28	32	32	31

(RANK = 7)

was too technical

General Population/Mean Score

	AD X	AD Y	AD Z	AVG
Drug A	2.02	2.45	1.98	2.15
Drug B	2.11	2.32	2.40	2.27
Drug C	2.05	2.35	2.89	2.43
AVG	2.06	2.37	2.42	2.29

(RANK = 9)

Senior Citizens/Mean Score

	AD X	AD Y	AD Z	AVG
Drug A	2.22	2.26	2.00	2.16
Drug B	2.58	2.38	2.88	2.61
Drug C	1.69	2.40	3.18	2.42
AVG	2.16	2.35	2.69	2.40

(RANK = 9)

General Population/Net Agreement

	AD X	AD Y	AD Z	AVG
Drug A	14	20	11	15
Drug B	14	16	24	18
Drug C	11	15	37	21
AVG	13	17	24	18

(RANK = 9)

Senior Citizens/Net Agreement

	AD X	AD Y	AD Z	AVG
Drug A	22	16	9	16
Drug B	32	13	38	28
Drug C	8	20	42	23
AVG	21	16	30	22

(RANK = 9)

did not honestly present the facts about the drug

General Population/Mean Score

	AD X	AD Y	AD Z	AVG
Drug A	2.32	2.11	2.32	2.25
Drug B	2.31	2.41	2.09	2.27
Drug C	2.51	2.31	2.36	2.40
AVG	2.38	2.28	2.25	2.30

(RANK = 8)

Senior Citizens/Mean Score

	AD X	AD Y	AD Z	AVG
Drug A	2.67	2.68	2.55	2.63
Drug B	3.16	2.31	2.19	2.55
Drug C	2.08	2.93	2.83	2.61
AVG	2.63	2.64	2.52	2.60

(RANK = 8)

General Population/Net Agreement

	AD X	AD Y	AD Z	AVG
Drug A	20	11	23	18
Drug B	20	20	14	18
Drug C	27	20	17	21
AVG	22	17	18	19

(RANK = 8)

Senior Citizens/Net Agreement

	AD X	AD Y	AD Z	AVG
Drug A	34	27	32	31
Drug B	32	13	13	19
Drug C	23	40	33	32
AVG	30	27	26	27

(RANK = 8)

was too scary

General Population/Mean Score

	AD X	AD Y	AD Z	AVG
Drug A	1.72	1.78	1.75	1.75
Drug B	1.59	1.98	1.83	1.80
Drug C	1.91	1.81	2.64	2.12
AVG	1.74	1.86	2.07	1.89

(RANK = 11)

Senior Citizens/Mean Score

	AD X	AD Y	AD Z	AVG
Drug A	1.72	1.79	1.86	1.79
Drug B	1.84	1.63	2.13	1.86
Drug C	1.62	1.93	1.67	1.74
AVG	1.73	1.78	1.89	1.80

(RANK = 11)

General Population/Net Agreement

	AD X	AD Y	AD Z	AVG
Drug A	6	6	9	7
Drug B	6	13	11	10
Drug C	14	6	20	13
AVG	9	8	13	10

(RANK = 11)

Senior Citizens/Net Agreement

	AD X	AD Y	AD Z	AVG
Drug A	12	5	9	9
Drug B	5	6	12	8
Drug C	8	20	8	12
AVG	8	10	10	9

(RANK = 11)

made me not want to take the drug

General Population/Mean Score

	AD X	AD Y	AD Z	AVG
Drug A	1.89	1.81	1.88	1.86
Drug B	1.67	2.23	2.28	2.06
Drug C	2.06	2.04	2.42	2.17
AVG	1.87	2.02	2.19	2.03

(RANK = 10)

Senior Citizens/Mean Score

	AD X	AD Y	AD Z	AVG
Drug A	1.78	1.84	2.09	1.90
Drug B	2.32	2.06	2.31	2.23
Drug C	1.62	2.27	2.08	1.99
AVG	1.90	2.06	2.16	2.04

(RANK = 10)

General Population/Net Agreement

	AD X	AD Y	AD Z	AVG
Drug A	13	4	7	8
Drug B	6	20	21	16
Drug C	15	14	17	15
AVG	11	13	15	13

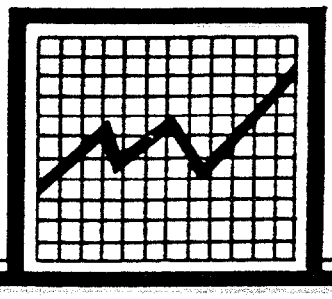
(RANK = 10)

Senior Citizens/Net Agreement

	AD X	AD Y	AD Z	AVG
Drug A	12	11	9	11
Drug B	16	12	12	13
Drug C	8	20	8	12
AVG	12	14	10	12

(RANK = 10)

FINGERHUT OPINION



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Level of Respondents' Mis-Readings and Mis-Perception of the Drug Advertisements

VIC FINGERHUT • JAMES C. ROSAPEPE

I. For Whom and In What Situations Should the Drug Not Be Used

In this section, we looked at the degree of accuracy in respondent's answers when it came to who should not use the drug.

A. Comparison of Ads

First, we compare the ads of one drug against the different types of ads to see if there is a pattern among different types of ads.

Responses to Ad Z were the most accurate, when looking at who or in what situations the medicine should not be used.

In Drug B (Zithromax), Ad Z, nearly three-fourths(73%) of respondents correctly identified the drug as one that should not be used by those allergic to erythromycins. All ads mentioned this, however, a somewhat smaller percentage of people picked this up from Ad X (Drug B) -- 67%, and an especially low (less than half) percentage of people picked this up from Ad Y (Drug B) -- only 36%.

In Drug C (Claritin), Ad Z got the most accurate responses in regard to this as well.

Over three-fourths (83%) said the drug should not be used if pregnant (it did say consult a physician if pregnant).

Ad Y had fairly accurate responses as well.

Nearly three-fourths (72%) of respondents said do not use if pregnant (72%) while the ad did say consult a physician if pregnant. This is compared to Ad X, where only half (50%)said the drug should not be used if pregnant. However, in Ad X, this was actually not mentioned. However, if taken into account that 50% of respondents may be incorrectly reading into the ads, it still leaves a 20 to 25% margin of accuracy in the Drug C, X and Y ads.

However, while the responses to Ad Z were the most accurate, regarding who and when the drug should not be used, it must be pointed out that for Drug A, Ad Z, as high as 57% of respondents said the drug should not be used if pregnant, when, in fact, the ad did not say this. Thus, there is high degree of inaccuracy, overall, when it comes to respondent's answers.

B. Comparison of Drugs

Secondly, we will see if there is a difference in accuracy of responses between different drugs, within the same ad group.

Clearly, Drugs B and C got much more accurate responses than Drug A. It is unclear as to why.

C. Senior Population vs. General Population

Next, we will see how the accuracy of the responses of the senior population, within each individual drug and ad category, compares to that of the general population.

Drug A - Ad X

Responses for seniors were slightly more accurate here than for the general population. The drug did not say it should not be used for any of the ten categories listed. However, those of the general population that incorrectly said the drug should not be used in certain situations ranged between 17% and 55%. Seniors were slightly more accurate. Those of the senior population that incorrectly said the drug should not be used in certain situations ranged from an error between 3% and 50%, less of an error than for the general population.

Drug A - Ad Y

When comparing seniors' responses to the general population's responses in Drug A, Ad Y, the results were mixed.

A lesser amount of the general population responded, more correctly, as to when the drug should not be used. Seven times out of eight times, they responded, correctly, with less than 50% saying the drug should not be used in certain situations, as compared with only three out of eight times in which the senior population responded, correctly, with less than 50% saying the drug should not be used in certain situations.

In addition, the seniors were more accurate in knowing that the drug should not be used if pregnant (a high 79%) as opposed to less than half (43%) of the general population.

However, the general population was more accurate when it came to the usage of the drug if one suffers from heart disease – half (50%) saying, correctly, that the drug should not be used, as opposed to only 21% of seniors saying that the drug should not be used.

Drug A - Ad Z

Results in this category were roughly the same between the senior and the general populations.

Drug B - Ad X

Both groups were relatively accurate on this drug and ad, with the largest percentage of

the general population in the "should not use" category saying correctly that the drug should not be used if allergic to erythromycins - 67%, and the largest percentage of seniors saying correctly that the drug should not be used if allergic to erythromychins - 47%.

However, when it came to the inaccuracy of respondents saying the drug should not be used (when, in fact, the ad does not specify), the seniors were overwhelmingly more accurate (or unsure) than the general population. In each of the nine leftover categories where the ad did not say the medicine could not be used, less than 50% of seniors said, correctly, the drug "should not be used". And, of these, a significantly higher percentage said "they couldn't recall," as opposed to those actually saying incorrectly the drug could be used (only as high as 26% said the drug could be used).

Contrariwise, in six of nine categories, over 50% of the general population said the drug "could not be used" when the ad did not specify this.

Also, a significantly lesser percentage of the general population responded with "can't recall" than the seniors.

However, a larger percentage of general population did say the drug was "alright to use", as opposed to the senior population.

Drug B - Ad Y

In this drug and ad category, results for the general population and the senior population were fairly close. 59% of the general population answered correctly that the drug "should not be used" if pregnant (ad does say "only use if clearly needed") as compared to 50% of the senior population.

However, a somewhat lesser percentage of seniors and the general population said correctly that the drug should not be used by someone allergic to erythromycins, 38% of seniors and 36% of the general population.

Understanding of both groups, for this drug's usage, seems to be fairly good. For the remaining nine categories, not more than 50% of any of them, for seniors and the general population, said the drug "should not be used".

Again, in this category, as in Drug B- Ad X: 1) more seniors answered "can't recall" than in the general population, and 2) a larger percentage of the general population correctly identified when and for whom the drugs could be used.

Drug B - Ad Z

Here, the correct responses, that one "should not use the drug" if pregnant or allergic to

erthromycins, were also among the highest overall responses in this category. A high 72% of the general population and 81% of the senior population correctly identified pregnancy as a situation in which one should not use the medicine.[1] And as many as 73% of the general population and 75% of the senior population recognized being allergic to erthromycins as a situation in which the drug may not be used.

However, an also high percentage of respondents in the general population mistakenly answered that the drugs should not be used if under 18 - 72%, or if taking other medication for asthma - 65%.

And, a high percentage of seniors mistakenly answered that the drugs should not be used if one has high blood pressure -- 75% saying the drug should not be used -- or if one suffers from heart disease - 69% saying the drug should not be used.

Drug C - Ad X

In this drug and ad category, seniors were less accurate than the general population in identifying that the drug should not be used (ad says consult physician) if one is taking other medication for asthma - with 66% of the general population saying the drug should not be used and only 38% of the senior population saying the drug should not be used.

Drug C - Ad Y

Here, a slightly larger percentage of seniors identified correctly that this drug should not be used by those who have difficulty swallowing tablets, with 73% of seniors saying it should not be used, and 67% of the general population saying it should not be used.

In addition, a larger percentage of the general population also erred higher than the seniors when it came to whether the drug could be used for those taking other medication for asthma - as many as 64% of the general population saying it could not be used, as opposed to 27% of seniors - or whether or not the drug could be used by those allergic to erthromycins - 58% of the general population saying it couldn't while a slightly lesser 47% of the seniors saying it couldn't.

If the category of "consult physician" is considered part of the "should not use" category, the seniors were much more accurate than the general population in identifying when the drug should not be used when it came to pregnancy, heart disease, diabetes, and glaucoma, and slightly more accurate when it came to high blood pressure.

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[1] Actually, the ad says to "consult physician" if pregnant or allergic to erthromycins.Since there was no category which specified "the ad said consult physician", we will put this in the category of "should not use".

Drug C - Ad Z

Here, however, if "consult physician" is placed in the "should not use" category, the general population is more correct in identifying pregnancy as a "should not use" condition – 83% saying ad said should not use – than the senior population – 67% saying the ad said should not use.

D. Overall Accuracy of "Should Not Use" Response

Finally, we calculated the average of respondents who said the drug should not be used (under certain conditions, such as pregnancy, age, etc.) when, in fact, the ad did not specify that the drug should not be used under these conditions.

We found a marked misconception in this area.

Over a third (to a half) of all respondents in every category except one gave the wrong answer when asked if the ad said the drug should or should not be used under certain circumstances or conditions.

The respondents were overwhelmingly biased toward thinking that the drug should not be used (in certain situations) when, in fact, the ad did not say this.

Respondents erred in the thirty-percentage range when they were asked whether one could use the drug if one is under 18, has difficulty swallowing tablets, has diabetes, or has been diagnosed with glaucoma.

Nearly half of respondents answered incorrectly when asked if the drug could be used if one is pregnant, is taking other medication for asthma, has high blood pressure, is allergic to erythromycins, or suffers from heart disease.

A lesser, though still high, 20% error rate was found when asked about the condition of obesity – where an average of 20% of respondents said the drug should not be used when the ad did not specify this.

Results For Senior Population to "Should Not Use" Category

Drug A - Ad X

Ad Does *Not* Say Should Not Use If ...	*Respondents* Say Should Not Use If...
✔ Pregnant	44%
✔ Under 18	11%
✔ Have difficulty swallowing tablets	3%
✔ Taking other medication for asthma	39%
✔ Have high blood pressure	39%
✔ Allergic to erythromycins	50%
✔ Suffer from heart disease	50%
✔ Obese	11%
✔ Have diabetes[1]	22%
✔ Have glaucoma	17%

Drug A - Ad Y

Ad Does *Not* Say Should Not Use If...	*Respondents* Say Should Not Use If...
✔ Under 18	32%
✔ Have difficulty swallowing tablets	58%
✔ Taking other medication for asthma	58%
✔ Have high blood pressure	68%
✔ Allergic to erythromycins	58%
✔ Obese	26%
✔ Have diabetes[2]	47%
✔ Have glaucoma	53%

Ad Does Say Should Not Use If...	*Respondents* Say Should Not Use If...
✘ Pregnant	79%
✘ Suffer from heart disease	21%

[1] The ad specifies that diabetes is what the drug is used for; however, it also says that the drug *should not* be used for Type 1 Diabetes.

[2] The ad specifies that diabetes is what the drug is used for; however, it also says that the drug *should not* be used for Type 1 Diabetes.

Drug A - Ad Z

Ad Does *Not* Say Should Not Use If ...	*Respondents* Say Should Not Use If...
✔ Pregnant	68%
✔ Under 18	41%
✔ Have difficulty swallowing tablets	27%
✔ Taking other medication for asthma	41%
✔ Have high blood pressure	45%
✔ Allergic to erythromycins	36%
✔ Suffer from heart disease	55%
✔ Obese	32%
✔ Have diabetes[3]	27%
✔ Have glaucoma	36%

[3] The ad specifies that diabetes is what the drug is used for; however, it also says that the drug *should not* be used for Type 1 Diabetes.

Drug B - Ad X

Ad Does *Not* Say Should Not Use If ...	*Respondents* Say Should Not Use If...
✔ Pregnant	42%
✔ Under 18	17%
✔ Have difficulty swallowing tablets	37%
✔ Taking other medication for asthma	37%
✔ Have high blood pressure	32%
✔ Suffer from heart disease	22%
✔ Obese	6%
✔ Have diabetes	16%
✔ Have glaucoma	11%

Ad Does Say Should Not Use If...	*Respondents* Say Should Not Use If...
✘ Allergic to erythromycins	47%

Drug B - Ad Y

Ad Does *Not* Say Should Not Use If...	*Respondents* Say Should Not Use If...
✔ Under 18	19%
✔ Have difficulty swallowing tablets	31%
✔ Taking other medication for asthma	44%
✔ Have high blood pressure	31%
✔ Suffer from heart disease	38%
✔ Obese	19%
✔ Have diabetes	31%
✔ Have glaucoma	25%

Ad Does Say Should Not Use If...	*Respondents* Say Should Not Use If...
✘ Pregnant[4]	50%
✘ Allergic to erythromycins[5]	38%

[4] In Fine Print Only – "only use if clearly needed".

[5] In Fine Print Only – "Do not use"

Drug B - Ad Z

Ad Does *Not* Say Should Not Use If ...	*Respondents* Say Should Not Use If...
✔ Under 18	31%
✔ Have difficulty swallowing tablets	27%
✔ Taking other medication for asthma	50%
✔ Have high blood pressure	75%
✔ Suffer from heart disease	69%
✔ Obese	13%
✔ Have diabetes	38%
✔ Have glaucoma	31%

Ad Does Say Should Not Use If...	*Respondents* Say Should Not Use If...
✘ Pregnant[6]	81%
✘ Allergic to erythromycins[7]	75%

[6] Ad says consult physician.

[7] Ad says consult physician.

Drug C - Ad X

Ad Does *Not* Say Should Not Use If ...	*Respondents* Say Should Not Use If...
✔ Pregnant	38%
✔ Under 18	8%
✔ Have difficulty swallowing tablets	8%
✔ Have high blood pressure	46%
✔ Allergic to erythromycins	46%
✔ Suffer from heart disease	54%
✔ Obese	23%
✔ Have diabetes	46%
✔ Have glaucoma	38%

Ad Does Say Should Not Use If...	*Respondents* Say Should Not Use If...
✘ Taking other medication for asthma[8]	38%

[8] Ad says consult physician.

Drug C - Ad Y

Ad Does *Not* Say Should Not Use If...	*Respondents* Say Should Not Use If...
✔ Under 18	31%
✔ Taking other medication for asthma	27%
✔ Allergic to erythromycins	47%
✔ Obese	20%

Ad Does Say Should Not Use If...	*Respondents* Say Should Not Use If...
✘ Pregnant[9]	40%
✘ Have difficulty swallowing tablets	67%
✘ Have high blood pressure[10]	73%
✘ Suffer from heart disease[11]	67%
✘ Have diabetes[12]	53%
✘ Have glaucoma[13]	53%

[9] Ad says consult physician.

[10] Ad says consult physician.

[11] Ad says consult physician.

[12] Ad says consult physician.

[13] Ad says consult physician.

Drug C - Ad Z

Ad Does *Not* Say Should Not Use If ...	*Respondents* Say Should Not Use If...
✔ Under 18	67%
✔ Have difficulty swallowing tablets	8%
✔ Taking other medication for asthma	33%
✔ Have high blood pressure	50%
✔ Allergic to erythromycins	42%
✔ Suffer from heart disease	36%
✔ Obese	0%
✔ Have diabetes	8%
✔ Have glaucoma	--%

Ad Does Say Should Not Use If...	*Respondents* Say Should Not Use If...
✘ Pregnant[14]	67%

[14] Ad says consult physician.

Results For General Population to "Should Not Use" Category

Drug A - Ad X

Ad Does *Not* Say Should Not Use If ...	*Respondents* Say Should Not Use If...
✔ Pregnant	51%
✔ Under 18	32%
✔ Have difficulty swallowing tablets	36%
✔ Taking other medication for asthma	43%
✔ Have high blood pressure	55%
✔ Allergic to erythromycins	40%
✔ Suffer from heart disease	49%
✔ Obese	17%
✔ Have diabetes[1]	27%
✔ Have glaucoma	25%

Drug A - Ad Y

Ad Does *Not* Say Should Not Use If...	*Respondents* Say Should Not Use If...
✔ Under 18	28%
✔ Have difficulty swallowing tablets	35%
✔ Taking other medication for asthma	46%
✔ Have high blood pressure	60%
✔ Allergic to erythromycins	37%
✔ Obese	20%
✔ Have diabetes[2]	19%
✔ Have glaucoma	30%

Ad Does Say Should Not Use If...	*Respondents* Say Should Not Use If...
✘ Pregnant	43%
✘ Suffer from heart disease	50%

[1] The ad specifies that diabetes is what the drug is used for; however, it also says that the drug *should not* be used for Type 1 Diabetes.

[2] The ad specifies that diabetes is what the drug is used for; however, it also says that the drug *should not* be used for Type 1 Diabetes.

Drug A - Ad Z

Ad Does *Not* Say Should Not Use If ...	*Respondents* Say Should Not Use If...
✔ Pregnant	57%
✔ Under 18	33%
✔ Have difficulty swallowing tablets	39%
✔ Taking other medication for asthma	38%
✔ Have high blood pressure	43%
✔ Allergic to erythromycins	33%
✔ Suffer from heart disease	46%
✔ Obese	24%
✔ Have diabetes[3]	14%
✔ Have glaucoma	29%

[3] The ad specifies that diabetes is what the drug is used for; however, it also says that the drug *should not* be used for Type 1 Diabetes.

Drug B - Ad X

Ad Does *Not* Say Should Not Use If ...	*Respondents* Say Should Not Use If...
✔ Pregnant	56%
✔ Under 18	27%
✔ Have difficulty swallowing tablets	54%
✔ Taking other medication for asthma	61%
✔ Have high blood pressure	61%
✔ Suffer from heart disease	59%
✔ Obese	30%
✔ Have diabetes	53%
✔ Have glaucoma	39%

Ad Does Say Should Not Use If...	*Respondents* Say Should Not Use If...
✘ Allergic to erythromycins	67%

Drug B - Ad Y

Ad Does *Not* Say Should Not Use If...	*Respondents* Say Should Not Use If...
✔ Under 18	9%
✔ Have difficulty swallowing tablets	24%
✔ Taking other medication for asthma	28%
✔ Have high blood pressure	28%
✔ Suffer from heart disease	40%
✔ Obese	16%
✔ Have diabetes	42%
✔ Have glaucoma	25%

Ad Does Say Should Not Use If...	*Respondents* Say Should Not Use If...
✘ Pregnant[4]	59%
✘ Allergic to erythromycins[5]	36%

[4] In Fine Print Only – "only use if clearly needed".

[5] In Fine Print Only – "Do not use"

Drug B - Ad Z

Ad Does *Not* Say Should Not Use If ...	*Respondents* Say Should Not Use If...
✔ Under 18	72%
✔ Have difficulty swallowing tablets	32%
✔ Taking other medication for asthma	65%
✔ Have high blood pressure	53%
✔ Suffer from heart disease	49%
✔ Obese	16%
✔ Have diabetes	47%
✔ Have glaucoma	38%

Ad Does Say Should Not Use If...	*Respondents* Say Should Not Use If...
✘ Pregnant[6]	72%
✘ Allergic to erythromycins[7]	73%

[6] Ad says consult physician.

[7] Ad says consult physician.

Drug C - Ad X

Ad Does *Not* Say Should Not Use If ...	*Respondents* Say Should Not Use If...
✔ Pregnant	50%
✔ Under 18	18%
✔ Have difficulty swallowing tablets	20%
✔ Have high blood pressure	50%
✔ Allergic to erythromycins	44%
✔ Suffer from heart disease	51%
✔ Obese	28%
✔ Have diabetes	40%
✔ Have glaucoma	30%

Ad Does Say Should Not Use If...	*Respondents* Say Should Not Use If...
✘ Taking other medication for asthma[8]	66%

[8] Ad says consult physician.

Drug C - Ad Y

Ad Does *Not* Say Should Not Use If...	*Respondents* Say Should Not Use If...
✔ Under 18	26%
✔ Taking other medication for asthma	64%
✔ Allergic to erythromycins	58%
✔ Obese	26%

Ad Does Say Should Not Use If...	*Respondents* Say Should Not Use If...
✘ Pregnant[9]	72%
✘ Have difficulty swallowing tablets	73%
✘ Have high blood pressure[10]	78%
✘ Suffer from heart disease[11]	75%
✘ Have diabetes[12]	66%
✘ Have glaucoma[13]	64%

[9] Ad says consult physician.

[10] Ad says consult physician.

[11] Ad says consult physician.

[12] Ad says consult physician.

[13] Ad says consult physician.

Drug C - Ad Z

Ad Does *Not* Say Should Not Use If ...	*Respondents* Say Should Not Use If...
✔ Under 18	33%
✔ Have difficulty swallowing tablets	38%
✔ Taking other medication for asthma	67%
✔ Have high blood pressure	65%
✔ Allergic to erythromycins	49%
✔ Suffer from heart disease	73%
✔ Obese	24%
✔ Have diabetes	52%
✔ Have glaucoma	46%

Ad Does Say Should Not Use If...	*Respondents* Say Should Not Use If...
✘ Pregnant[14]	83%

[14] Ad says consult physician.

APPENDIX G

National Consumers League
Direct To Consumer Promotion of Prescription Drugs

Roundtable II

National Wildlife Federation Conference Center
1400 16th Street, NW
Washington, DC
September 28-29, 1998

September 28

8:30 - 9:00	**Registration and Continental Breakfast**
9:00 - 9:15	**Welcome: Review of Roundtable I** Linda F. Golodner, President, National Consumers League
9:15 - 9:30	**Introductions: Participants**
9:30 - 10:30	**Current State of Affairs** • *FDA overview* -- Nancy Ostrove, Branch Chief, Drug Marketing, Advertising, and Communication Division, Food and Drug Administration • *Montage of TV, print ads* -- John Kamp, Senior Vice President--American Association of Advertising Agencies; Paul Boyle, Director, Government Affairs--Newspaper Association of America • *Scope/extent of DTC Ads* -- John Kamp
10:30 - 10:45	**Break**
10:45 - 11:30	**Open discussion --Roundtable participants**
11:30 - 12:30	**Research Review** • *Summary of current research and studies* Lou Morris, Senior Vice President--PRR, Inc. • *Consumer Research* -- National Consumers League
12:30 - 1:45	**Lunch** • Janet Woodcock, Director--Center for Drug Evaluation and Research, Food and Drug Administration

1:45 - 2:45	**Break-Out Sessions** -- Roundtable participants
2:45 - 3:00	**Break**
3:00 - 4:30	**Break-Out Sessions** (continued)
4:30 - 5:30	**Reports from the Groups**
5:30 - 6:30	**Reception**

<u>September 29</u>

8:30 - 9:00	**Continental Breakfast**
9:00 - 9:45	**Summary of Day One**: (Group Leaders will have consolidated reports from previous day into one document)
9:45 - 10:15	**Anne Maher**, Deputy Director--Bureau of Consumer Protection, Federal Trade Commission
10:15 - 10:30	**Break**
10:30 - 10:45	**Roundtable discussion**
10:45 -- 12:30	**Recommendations / Consensus Report from Roundtable**

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APPENDIX H

National Consumers League

Direct-To-Consumer Promotion of Prescription Drugs Roundtable II

September 28-29, 1998
Washington, DC

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