



# NATIONAL CONSUMERS LEAGUE

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September 9, 2002

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

Re: Docket No. 02N-0209; Request for Comment on  
First Amendment Issues – Comments on Questions  
2/8 and 6

Dear Sir or Madam:

The National Consumers League (NCL) appreciates this opportunity to comment on the Food and Drug Administration's (FDA) Request for Comment on First Amendment Issues (First Amendment Notice), 67 Fed. Reg. 34,942 (May 16, 2002). NCL is a national nonprofit consumer advocacy organization founded in 1899 to represent consumers in the marketplace and the workplace. NCL supports strong enforcement of regulations on direct-to-consumer advertising of prescription drugs and continuous oversight by FDA. We welcome 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 meetings as an observer. We distributed reports on the discussions to FDA and others. Copies of the reports of NCL Roundtables I and II are available from the National Consumers League if you wish copies.

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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.
- 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, and may refer consumers to other sources for further information.

With little movement on the implementation of these recommendations, NCL commented on FDA's Draft Guidance for Industry on Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements, 66 Fed. Reg. 20468 (April 23, 2001). NCL commended FDA for its efforts to improve the flow of quality information to consumers. However NCL urged FDA to go further, for the Draft Guidance was only an incremental step toward badly needed reform of FDA's DTC regulations and policies. Today, NCL repeats its call for reform.

NCL addresses two points from FDA's First Amendment Notice. First, Questions 2 and 8 pose a series of questions that turn on what effects, if any, DTC promotion of drugs has on patients and their health and whether FDA policies and regulations advance or hinder patient well-being. The question is an important one for if FDA's restrictions on DTC promotion do not further patient well-being, they will likely fail scrutiny under the U.S. Supreme Court decision in Central Hudson Gas & Elec. Corp. v. Public Service Commission, 447 U.S. 557 (1980). A more

specific issue is raised by Question 6 in which FDA asks, among other things, what arguments can support the agency's distinction between claims made in advertising and those made in labeling. NCL's views on these questions follow.

**QUESTIONS 2 AND 8 – DTC PROMOTION – A SUMMARY OF DATA ON THE EFFECTS OF DTC PROMOTION AND HOW FDA'S REGULATIONS AND POLICIES DO NOT ADVANCE THE FLOW OF QUALITY HEALTH CARE INFORMATION TO CONSUMERS**

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In NCL's view, DTC promotion is an important component to empower 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, non-compliance, and adverse effects. Armed with balanced, clear information, consumers can initiate a discussion with their doctors about the risks and benefits of, and alternatives to, prescription drugs.

Question 2 asks, among other things, what are the positive and negative effects of DTC promotion? NCL addresses below the data on what DTC promotion does, and does not, do. NCL then addresses how FDA's DTC regulations and policies do not advance the government interest in assuring a flow of quality of healthcare information to consumers. Last, in response to Questions 2 and 8, NCL proposes alternative models for the disclosure of product and risk information that would better advance consumer interests.

**Critics Overstate The Influence of DTC Promotion**

Much attention has been devoted to the concern that consumers are obtaining biased health information from advertising and that DTC promotion unfairly raises patient expectations. NCL believes such criticisms overstate the impact and effects of DTC promotion. Consumers intuitively recognize something perhaps lost upon other observers. Health information is not a single, unitary item spoon-fed to consumers in advertising by economically motivated companies. Rather, data show that consumers inform themselves in a variety of ways and avail themselves of a myriad of resources -- face-to-face interaction with professionals and lay persons, advertising, government agencies, health plans, news reporting, and the Internet. Advertising is but one source to which an information-seeking consumer turns.

A survey conducted in 2000 by the Kaiser Family Foundation and the United States Agency for Healthcare Research and Quality (AHRQ) revealed<sup>1</sup> when asked how they would research for “quality” health information, respondents answered the following:

Ask friends, family members, or co-workers	70%
Ask a doctor, nurse, or other health professional	65%
Contact someone or refer to materials from your health plan	37%
Go online	28%
Order a printed booklet	21%
Contact a state agency	20%
Call a toll-free number	18%
Refer to a newspaper or magazine	17% <sup>2</sup>

Consumers receive significant information from their pharmacists. The quality of this information is particularly important because it is frequently targeted to a specific patient based upon a drug the physician has already prescribed for that patient. In growing numbers, consumers receive leaflets from their pharmacist that include useful information on the drug, how to take it, and potential side effects and contraindications.<sup>3</sup> Pharmacies may also distribute newsletters that provide health tips, compliance tips, and information about the availability of complementary and alternative therapies and drugs.<sup>4</sup>

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<sup>1</sup> National Survey on American as Health Care Consumers: An Update on the Role of Quality Information. The Kaiser Family Foundation/Agency for Health Care Research and Quality, December 2000 (hereinafter “AHRQ Survey”).

<sup>2</sup> AHRQ Survey, Chart 13.

<sup>3</sup> On August 24, 1995, FDA published a proposed “Med Guide” rule that would have mandated standards for the type and format of information that would accompany dispensed prescription drugs. A year later, Congress enacted Public Law No. 104-180 that limited FDA’s authority to enact the Med Guide rule and set the goal of distribution to consumers of “useful written information” about the prescription drugs that they receive. The Secretary of Health and Human Services convened stakeholders to develop an “Action Plan” to achieve the goals of the proposed rule and the Public Law. NCL was one stakeholder that participated in the creation of this Action Plan. The Action Plan set out eleven components of “useful written prescription information,” including drug name, warnings, indication for use, contraindications, precautions, possible adverse reactions, risks of tolerance to and dependence on the drug, proper use, storage, general information, disclaimers.

<sup>4</sup> According to a January 24, 2002 presentation at the NCL Symposium on Risk and the Media by Mike McClorey, President of Health Recour,ce Publishing Co., in 2002 that company alone will

Furthermore, many pharmacies, in conjunction with manufacturers and other providers, send compliance notices to patients, reminding users of the importance of refilling prescriptions for chronic medical conditions. While some critics argue that these communications are merely promotional vehicles driving consumption of expensive pharmaceuticals, such compliance communications are also invaluable reminders for patients. The costs of patient noncompliance are enormous. Patients who do not adhere to their prescriptions cost the U.S. health care system an additional \$100 billion each year.<sup>5</sup> According to FDA, about one-third of patients fail to take their prescribed medications, parental noncompliance with the drug therapies prescribed for their children exceeds 50%, and noncompliance in the elderly ranges from 26 to 59%. 60 Fed. Reg. 44,182, 44,286 (Aug. 24, 1995) The American Heart Association has stated “the cost of noncompliance, in terms of human lives and money, is shocking” and has made prescription drug compliance management one of the Association’s key issues. American Heart Association Press Release, April 21, 1999.

With consumers receiving information from so many sources, it is important to query the degree of trust consumers place in these sources. Some sources of information are obviously of greater reliability than others. The data seem to show that although consumers have broad information-seeking habits, in the end, they trust very few with their own health. According to the AHRQ Survey, consumers trust the following sources “a lot” to provide accurate information about prescription drugs:

Your doctor	76%
Your pharmacist	70%
The printed information included in packages of prescription medicine	48%
Government agencies	37%
Health websites on the Internet	9%
Advertisements for prescription drugs	6% <sup>6</sup>

The 2000 National Survey of Consumer Reactions to Direct-to-Consumer Advertising conducted by *Prevention Magazine* (“the *Prevention* survey”)<sup>7</sup> reported similar skepticism for

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publish between 750 million and 1 billion information leaflets for consumers to receive from their pharmacists.

<sup>5</sup> Berg, JS , et al., Medication Compliance: a Healthcare Problem, *The Annals of Pharmacotherapy*, 27 (9): S1-S24 (1993).

<sup>6</sup> AHRQ Survey, Chart 25.

everyone and everything save a consumer's own physician and pharmacist. Approximately two-thirds of all adults trust doctors and pharmacists "a lot" for accurate information about prescription drugs.<sup>8</sup> Only 5% of respondents reported trusting print or broadcast advertising of prescription drugs "a lot."<sup>9</sup> Over 55% reported having no trust or "only a little" trust in print and broadcast DTC advertising.<sup>10</sup>

The November 2001 report and analyses by the Kaiser Family Foundation and the Sonderegger Research Center at the University of Wisconsin-Madison School of Pharmacy, "Understanding the Effects of Direct-to-Consumer Prescription Drug Advertising," ("Kaiser 2001 DTC Report") also looked at levels of consumer trust.<sup>11</sup> Among those who had just seen a DTC advertisement, 64% said they trusted the information about the health condition described in the advertisement and 62% said they trusted the information about the medicine advertised.<sup>12</sup> In contrast, those who had not just reviewed DTC advertising reported much lower levels of trust -- 33% of nonviewers trusted information about the health condition and 46% of non-viewers trusted the information about the drug.<sup>13</sup>

The Kaiser 2001 DTC Report did not assess whether consumers continue to believe that DTC advertising is reliable over time or the degree of trust they place in advertising as compared to other sources of information. Data such as that presented in the *Prevention* and AHRQ surveys discussed above suggest that, over all, consumers are skeptical of DTC advertising.<sup>14</sup>

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<sup>7</sup> National Survey of Consumer Reactions to Direct-to-Consumer Advertising, *Prevention Magazine*, 2000 (hereinafter "*Prevention survey*").

<sup>8</sup> *Prevention survey*, Chart U.

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> Understanding the effects of direct-to-consumer prescription drug advertising. The Henry J. Kaiser Family Foundation, November 2001 (hereinafter "Kaiser 2001 DTC Report").

<sup>12</sup> Kaiser 2001 DTC Report, Chart U; AHRQ Survey, Chart 25.

<sup>13</sup> *Id.*

<sup>14</sup> *Prevention survey*, Chart U.

In short, consumers seek and obtain information from a variety of sources. Yet, they approach this information cautiously and are likely skeptical of the claims in DTC promotion. Consumers are most likely to place the greatest trust in their own health care professionals.

### **DTC Promotion Is Promoting Patient/Physician Communication**

Recent commentary has argued that DTC promotion intrudes upon the patient/physician relationship and is likely resulting in inappropriate utilization of prescription drugs and higher health care costs. NCL believes, on the contrary, that the data show that DTC promotion is stimulating consumers to communicate with their doctors.

Generally, DTC advertising is prompting discussion and information seeking behavior more than requests for the particular drug advertised. 70% of respondents to the *Prevention* survey stated that they asked their doctors for more information; only 28% asked for the advertised drug specifically.<sup>15</sup> The *Prevention* survey estimates that as a direct consequence of a DTC advertisement, as many as 21 million Americans discussed a medical condition of illness with their doctor that they had never discussed before.<sup>16</sup>

The Kaiser Family Foundation reported smaller, but still significant, percentages in 2001. As with the *Prevention* survey, consumers are more likely to seek information about the health condition for which the advertised drug is indicated, rather than information about the drug itself. In response to a DTC advertisement, respondents to the Kaiser 2001 DTC Report were “very” or “somewhat likely” to:

Talk to doctor about the health condition	42%
Talk to doctor about the medicine advertised	37%
Look for more information about the health condition	36%
Look for more information about the medicine	34% <sup>17</sup>

Data show that once patients initiate the subject, physicians are talking to them about advertised drugs. Patients in the *Prevention* survey reported that 80% of their doctors were “very

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<sup>15</sup> *Prevention* survey, Table O.

<sup>16</sup> *Prevention* survey, Table J.

<sup>17</sup> Kaiser 2001 DTC Report, Chart 3.

willing” to talk about advertised medicines; another 15% were “somewhat willing.”<sup>18</sup> Similarly, 85% of the respondents to FDA’s own recent DTC survey reported being “satisfied” or “very satisfied” with their doctor’s reaction when he or she asked the doctor about an advertised prescription drug.<sup>19</sup>

Overall the data show that physicians are prescribing the advertised medications when consumers ask for them. The Kaiser 2001 DTC Report reported that of those consumers who talked to their doctor about medicine they saw advertised, the doctor:

Gave the prescription asked for	44%
Recommended changes in behavior or lifestyle	35%
Recommended a different prescription drug	25%
Recommended no drug	19%
Recommended an over-the-counter drug	15%
Something else	14% <sup>20</sup>

The *Prevention* survey reported a much higher result. Of the consumers who saw a DTC advertisement, and asked their doctor for the advertised medication, 80% reported receiving the prescription they sought.<sup>21</sup>

Doctors are writing more prescriptions for their patients. The Kaiser Family Foundation found that the number of prescriptions dispensed in retail pharmacies has grown at an average annual rate of 6% since 1992, as compared to only a 1.4% growth in the general population over the same time period.<sup>22</sup> The Kaiser Family Foundation posits that DTC promotion is but one reason for the increased utilization. Other factors influencing this growth include increased availability of and dependence on medications for treatments, improved access to drugs through insurance coverage, and an aging population.<sup>23</sup>

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<sup>18</sup> *Prevention* survey, Chart 5.

<sup>19</sup> FDA Direct-to-Consumer Advertising of Prescription Drugs: Preliminary Patient Survey Results, available at [www.fda.gov/cder/ddmac/ddmacpresentations.htm](http://www.fda.gov/cder/ddmac/ddmacpresentations.htm) (hereinafter “DTC Advertising: FDA 2002 Preliminary Survey Results”).

<sup>20</sup> Kaiser 2001 DTC Report, Chart 2.

<sup>21</sup> *Prevention* survey, Table P.

<sup>22</sup> Kaiser Chartbook Update, p. 8.

<sup>23</sup> *Id.*

It is difficult to draw conclusions about DTC advertising based upon increased utilization alone. As the Kaiser Foundation report states, more drugs are being prescribed for many reasons. In some instances, there is drug therapy for previously untreated conditions. Newer generations of drugs may also have better risk profiles that make their use more effective and safer for broader classes of consumers. Managed care may push patients on to drugs as an alternative to other, more costly, alternative therapies. In NCL's view, the *appropriate* prescribing of medications means a healthier, more productive population.

Increased utilization *is* very worrisome if due to *unnecessary, improperly prescribed* prescription drugs. Yet, there is no evidence at all that DTC promotion has led to physicians abandoning their responsibilities to their patients and prescribing medications simply because their patients ask for them. Indeed, the data discussed above indicate the contrary. Physicians may recommend a different course of treatment and overall patients report being satisfied with these interactions with their doctors, regardless of whether they receive a prescription for the drug advertised.

DTC promotion has done much to educate and inform consumers about basic information in how prescriptions drug can improve health. As discussed below, DTC promotion could do much better. Despite the onerous disclosure requirements FDA regulations and policies mandate, data show that consumers do not retrain much of the information DTC promotion conveys.

### **FDA's DTC Regulations And Policies Are Not Advancing The Flow Of Quality Health Care Information To Consumers**

The current scheme of DTC rules and guidances are ill-suited to communicating important risk information to consumers. While DTC promotion has been able to raise basic awareness of certain prescription drugs, it has been less effective in communicating specific information about the drug and their risks. NCL believes the fault does not rest exclusively with sponsors who may gloss over a product's risk information in DTC promotion. Rather, given the sheer volume of risk disclosures that current regulations require an advertiser to cram into an advertisement, the data seem to indicate that consumers cannot absorb more than the most basic of information.

Under current FDA regulation and guidances, prescription drug promotion must fairly balance the positive information about a drug's safety and effectiveness against the negative information about the drug's side effects and contraindications. Print advertising must include, in brief summary, information regarding each of a drug's side effects, contraindications, and warnings. Broadcast advertising must include a "major statement" of the drug product's risks

and make “adequate provision” for a consumer viewer to obtain a copy of the drug product’s full, FDA-approved labeling for health care professionals.<sup>24</sup>

To the extent DTC promotion seeks to increase basic knowledge, it is succeeding. Over two-thirds of respondents to a 1998 NCL survey reported that DTC advertising “always” or “sometimes” increased their knowledge of medicine and disease.<sup>25</sup> The *Prevention* survey reported that over 40% and as many as 60% of respondents were able to correctly identify the condition that five heavily promoted, commonly prescribed drugs were indicated to treat.<sup>26</sup> The Kaiser 2001 DTC Report concluded that three representative prescription drug advertisements shown to consumers were effective in communicating very basic information -- the name of the drug and what the drug treats.<sup>27</sup>

Other data is not so encouraging. The Kaiser 2001 DTC Report found that even after seeing a DTC advertisement, 70% of consumers reported that they knew little or nothing more about the health condition for which the drug was indicated; 59% responded that they knew little or nothing more about the medicine after seeing the advertisement.<sup>28</sup> The *Prevention* survey similarly reported that prescription drug advertisements were only moderately effective in disseminating benefit information. Only 57% of consumers who had seen DTC advertisements in magazines and 55% of consumers who have seen them on television thought the advertisements did an “excellent” or “good” job of informing consumers about the benefits of taking the prescription drug.<sup>29</sup>

Moreover, consumers rating DTC advertising they had seen as “very clear” or “somewhat clear” dropped by several percentage points between 1997 and 1998. Among seniors, a population likely to be chronic users of prescription drugs, the *Prevention* survey results were

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<sup>24</sup> 21 U.S.C. § 352(n); 21 C.F.R. § 202.1.

<sup>25</sup> 1998 NCL Survey, \_\_\_\_.

<sup>26</sup> *Prevention* survey, Table E (percentage of respondents correctly identifying the drug’s indication: Prozac/61%; Claritin/51%; Allegra/47%; Premarin/42%; Glucophage/43%).

<sup>27</sup> Kaiser 2001 DTC Report, p. 12.

<sup>28</sup> Brodie, M. Understanding the Effects of Direct-to-Consumer Prescription Drug Advertising. The Henry J. Kaiser Family Foundation, November 2001, Chart 5.

<sup>29</sup> *Id.* at Table H.

more disturbing still. Seniors who thought DTC advertisements were “clear” dropped by half between 1997 and 1998, from 32% to 16%.<sup>30</sup>

As to conveying important risk information, DTC advertising is especially lacking. The Kaiser 2001 DTC Report noted that FDA guidelines require that television prescription drug advertising include a “major statement” prominently disclosing all of the major risks associated with the drug. Yet, as the Report states,

just because the ads include this information, it is not necessarily successfully communicated to viewers. With the exception of one of the side effects mentioned in [one] ad, about half or more of respondents could not correctly identify the potential side effects after having just viewed an ad.<sup>31</sup>

The *Prevention* survey reported similar problems. Over 50% of respondents thought print advertising did a “fair” or “poor” job of communicating annoying, but not serious side effects, and serious warnings about the product.<sup>32</sup> The misgivings were even higher for television advertising -- over 60% of respondents thought DTC television commercials did a “fair” or “poor” job of communicating not serious, but annoying side effects and serious warnings about the drug advertised.<sup>33</sup>

The Kaiser 2001 DTC Report further found that, even after viewing a broadcast ad, consumers were only able to identify 49% of the time that they could obtain additional information about the drug from their physician or pharmacist.<sup>34</sup> Only 12% could name any of the other sources mentioned in the advertisements, such as a toll-free number, magazine advertisement, or website.<sup>35</sup>

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<sup>30</sup> Id. at Table G.

<sup>31</sup> Kaiser 2001 DTC Report, p. 8.

<sup>32</sup> *Prevention* survey, Table H.

<sup>33</sup> Id.

<sup>34</sup> Brodie, M.. Understanding the Efficacy of Direct-to-Consumer Prescription Drug Advertising, Chart 10.

<sup>35</sup> *Prevention* survey, Table L.

This particular finding is at odds with *Prevention* survey and FDA's own data. According to the *Prevention* survey, high percentages of consumers are remembering that they can go to their pharmacist, physician, or a toll-free number for more information about the drug advertised.<sup>36</sup> Eighty-six percent of respondents to FDA's 2002 DTC survey reported recalling how they could obtain more information on the drug advertised.<sup>37</sup> Gauging whether consumers are recalling where they can go for additional information about the advertised drug is especially important because a prescription drug's full risk information cannot be communicated in a short broadcast.

The FDA 2002 survey, the NCL survey which was reported in the Roundtable discussions, and the *Prevention* survey all reported on the failure of the so-called "brief summary" to communicate useful risk information to consumers. The "brief summary" is required to accompany all print advertisements. It is frequently nothing more than a reprinting of the warnings, indications, contraindications, and side effects from the drug product's full package labeling. A drug's full product labeling is used by, and written for, physicians and pharmacists. It is dense, printed in minute type, highly technical, and contains every single side effect ever, potentially, associated with use of the drug. It is typically neither legible nor comprehensible. Not surprisingly, the data consistently show that at least 30% of consumers (and likely far more) read little or none of the brief summary that accompanies the print advertising.<sup>38</sup> Among those who responded that they had been interested in a drug advertised in a print media, 54% reported that they read "about half," "little," or "none" of the accompanying brief summary.<sup>39</sup> An equally high percentage, 55%, reported finding the brief summary "somewhat hard" or "very hard" to understand.<sup>40</sup>

In sum, DTC promotion is likely succeeding in several important areas. It is, at least, communicating the name of important medications and that prescription drugs can treat certain medical conditions. Despite detailed risk disclosures and accompanying information requirements, DTC promotion still falls short in other important areas. Consumers are not recalling important risk information from broadcast advertisements. In the case of print advertisement, a large percentage of consumers fail to read or comprehend the "brief summary" of risk information about the drug.

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<sup>36</sup> *Prevention* survey, Table I.

<sup>37</sup> DTC Advertising: FDA 2002 Preliminary Survey Results.

<sup>38</sup> *Prevention* survey, Table L.

<sup>39</sup> DTC Advertising: FDA 2002 Preliminary Survey Results.

<sup>40</sup> Id.

NCL submits that the best DTC promotion is not necessarily the one that is the most exhaustive in its recitation of risk information. Below, NCL discusses alternative models for the disclosure of risk and benefit information in DTC promotion that will better advance consumer welfare and public health.

#### **Alternatives To Disclosure of Risk Information In DTC Promotion**

NCL welcomes the opportunity for examination of FDA policies and regulations regarding DTC promotion. In the view of NCL, if FDA regulates speech, it must do so in such a way that plainly and clearly advances consumer interests. Sadly, the data show that the existing DTC regulatory scheme, despite its many restrictions and required disclosures, is not informing and educating consumers.

Most especially, FDA must either amend the old 21 C.F.R. § 202.1 regulation or promulgate a new regulation or guidance specific to DTC promotion. Section 202.1 was written to advise sponsors on how to promote their drugs to the medical profession. FDA must adopt new regulations or guidances that address DTC advertising specifically. A new guidance or regulation specific to DTC advertising should incorporate lay consumer comprehension into its evaluative criteria.

Much of Roundtable I and Roundtable II addressed the inadequacy of the brief summary in DTC print advertising. The “brief summary” must be reformatted to provide important risk and benefit information in a consistent, balanced, format and be written in plain language a lay consumer can and will understand. The brief summary should include important use and safety information, it should clearly identify who should and should not use the product, should state what the drug does and does not do, and what the drug is intended to treat. The brief summary further, should not include, as it must now, every single risk in the full product labeling, but should emphasize the most serious and the most frequent side effects. The useful written information accompanying dispensed prescriptions (i.e., “MedGuide-type information”) is an example of one format that might be adopted in lieu of the current brief summary.

In NCL’s view, the format for presenting risk and benefit information for prescription drugs should be standardized, as it was for over-the-counter drugs, dietary supplements, and foods. In this way, consumers can become familiar with a single format and learn how to use it to obtain important health information. The “Drug Facts,” “Supplement Facts” and “Nutrition Facts” formats provide excellent models for a standardized presentation of important risk and usage information for prescription drugs.

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, through such means as pharmacists and physicians, calling a toll-free number, and visiting a Web site.

The data show that more work needs to be done to improve consumer "take-away" from DTC broadcast advertising. Nevertheless, FDA's DTC Advertising Broadcast Guidance was a significant step in the right direction. FDA recognized that consumers can be informed without burying them in detailed, technical information they could not hope to absorb in a 60-second broadcast. The Broadcast Guidance requires that consumers receive the most important risk information in a 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 will increase the likelihood that consumers will actually understand the most important risk information, and remember it.

Moreover, simplifying and clarifying risk information and making adequate provision for consumers to obtain additional, useful information recognizes how consumers actually perceive and act upon advertising messages. Data consistently show that consumers look to DTC advertising only for basic information and treat its messages skeptically. DTC advertising may

spur consumers to act but that action is merely a first step in a long process of information seeking and dialogue with family, friends and health care professionals.

**QUESTION 6 – THERE IS NO BASIS FOR DIFFERENT ACCOMPANYING INFORMATION REQUIREMENTS FOR DTC ADVERTISING AND DTC LABELING**

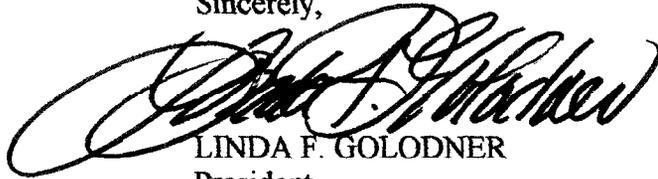
NCL continues to be troubled by FDA's requirement that drug sponsors provide full product labeling to consumers if a DTC drug promotion is disseminated as either "labeling" or through broadcast media. Although brief summaries and FDA-approved patient labeling are detailed and difficult to understand, full product labeling is far 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 full product labeling be disseminated to consumers and actual harm may come from its distribution. The arcane FDA distinction between "advertising" and "labeling" is irrelevant to a consumer who sees the message as "promotion." Most consumers will not attempt to read a document that is so lengthy and technical and therefore 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, for all DTC promotions, whether "advertising" or "labeling."

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NCL thanks FDA for this opportunity to comment upon an important step in improving the flow of information to consumers about prescription drugs.

Sincerely,



LINDA F. GOLODNER  
President