



NATIONAL CONSUMERS LEAGUE

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May 4, 2004

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

Re: Docket No. 2004D-0042

Comments of the National Consumers League On FDA Draft Guidances To Improve Health Communication To Consumers

The National Consumers League is pleased to submit these comments to the Food and Drug Administration (FDA) on the Draft Guidances for Industry on Improving Information About Medical Products and Health Conditions, 69 Fed. Reg. 6308 (Feb. 10, 2004). NCL, founded in 1899, is a private, nonprofit advocacy group representing consumers and workers on marketplace and workplace issues. NCL provides government, businesses, and other organizations with the consumer's perspective on concerns including fair labor standards, consumer fraud, privacy, food safety, and medication information. Our mission is to identify, protect, represent, and advance the economic and social interests of consumers and workers.

NCL is a leading consumer advocate for improved healthcare information and education for consumers so they can be more involved in their own healthcare decisions for themselves and their families. NCL monitors rulemaking and legislation involving health issues, provides and participates in patient education on medication and disease awareness, and promotes and researches factors that influence the provision of medical services to patients.

NCL commends FDA for undertaking these much needed reforms of DTC prescription drug promotion. We believe the draft guidances are an excellent step forward in improving the flow of information to consumers. Informed consumers are vested in their own healthcare and providing better healthcare information to which consumers are entitled will mean a healthier and more productive population.

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DTC promotion is a useful tool for initiating and complementing patient/health professional communication. In an October 2002 survey commissioned by NCL, we found that respondents who spoke with their doctor about an advertised prescription drug were very positive about how it impacted their discussion with their doctor. In addition, we found that about one in four consumers who saw an ad that interested them sought more information because they wanted to find out if the medication was right for them or a family member. They sought information from pharmacists, medical or drug reference books or a general health Web site. Based on this data, NCL supports that an ad:

- Should not be false or misleading;
- Should be fairly balanced; and
- Should help consumers seek and easily locate additional information with varying degrees of complexity.

FDA's draft guidance, "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements," is a huge step toward improving the quality of DTC prescription drug print advertising, an area that has been neglected for too long.

NCL agrees that the "brief summary":

- Should be reformatted to provide important risk and benefit information in a consistent, balanced, useful format and in plain language;
- Should not be required to include exhaustive risk information from the full product label;
- Should include:
 - a. a brief statement of the drug's indication
 - b. all contraindications
 - c. all warnings
 - d. the major precautions; and
 - e. the 3-5 most common nonserious adverse reactions most likely to affect the patient's quality of life or compliance with drug therapy.
- Particularly because the brief summary is accompanying an advertisement and a consumer must still obtain a prescription before receiving the drug, NCL believes an adequate brief summary may delete certain information. Sections that may be deleted would include detailed indications information, dosage and administration information, and "how supplied" information.

NCL still believes that the broadcast “adequate provision” model is an alternative for DTC print promotions, so long as the advertisement contains:

- “fair balance”
- a “major statement” of the risks associated with the drug; and
- “adequate provision” for the consumer to obtain information from other sources.

NCL further believes that a standardized information panel, such as an Rx Facts box, that is similar to the formats adopted for other FDA-regulated products – Nutrition Facts, Supplement Facts, Drug Facts (OTC) holds great promise. We are encouraged that FDA seems to consider this type of presentation of risk information as one option. Overall, advertisers need to rise to FDA’s “less is more” challenge and communicate the drug’s serious and most common side effects as well as the effectiveness information. NCL is concerned that development of new, better, more concise brief summary formats will be delayed if manufacturer sponsors must wait for FDA to approve particular formats or Highlights boxes. NCL interprets the sample attached to the draft guidance for the fictional Ocracephalose as model manufacturers may follow in developing their own consumer-friendly brief summaries.

Because consumers receive their health care information from many sources (family, friends, employers, pharmacies, and healthcare professionals), FDA should consider how its regulations and policies can foster, rather than hinder, the flow of high quality information via these alternative channels. Restrictions and disclosure requirements that are necessary for drug sponsors’ DTC advertising may not be useful for communications from health care professionals, pharmacies, and health plans, and may even interfere with consumer comprehension. NCL urges FDA to look especially at the special challenges of in-pharmacy communications.

- FDA should consider following the requirements of the Department of Health and Human Services’ final privacy rule, Standards for Privacy of Individually-Identifiable Health Information, 67 Fed. Reg. 53,182 (Aug. 14, 2002).
- Specifically, the privacy rule deems refill reminder and similar pharmacy-initiated communications programs to be part of a health care professional’s treatment of a patient, not marketing to the patient. These communications should be outside of FDA’s DTC prescription drug promotion requirements altogether.

Messages urging consumers to comply with and adhere to the medication regimes their physicians have prescribed should not be subject to the same requirements FDA would apply to conventional DTC prescription drug promotion. These types of messages do not raise the same concerns that

conventional DTC promotions do and FDA regulatory policies should be encouraging, not burdening, these communications.

In addition, the draft guidance does not address a persistent problem that must be remedied – the technical requirement the full prescribing information must accompany promotional labeling – promotional messages that accompany the drug – even when that promotional labeling is directed to consumers, not the healthcare professional. FDA’s approach to DTC reform should follow a more holistic and realistic approach. Data show consumers don’t obtain their health care information through a single document, but from a variety of sources, in a variety of ways. Consequently, information about drugs should be available in a variety of different formats, in easy to obtain ways. The consumer should be able to easily obtain information of varying degrees of complexity. By trying to do it all in one document, FDA encourages creation of documents like the brief summary that no one reads or understands.

NCL continues to support FDA’s broadcast policy. However, NCL believes that advertisers need to do as good a job of providing risk information as they do on building brand awareness.

NCL supports the “Help-Seeking” and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms.” Data plainly show that help-seeking and disease awareness communications are conversation starters between patients and consumers. These messages raise awareness about untreated conditions and inform patients about treatment options. NCL welcomes a guidance that encourages these communications and clarifies when these useful communications may cross the line from awareness messages to product specific messages that trigger other FDA promotional requirements.

NCL further supports the “Consumer-Directed Broadcast Advertising of Restricted Devices.” The guidance provides clarity to restricted device manufacturers to assure that their broadcast advertising is not misleading. Also, NCL supports a consistent approach that treats broadcast advertising for medical devices in a way that is similar to that for prescription drugs.

We appreciate the opportunity to comment on these guidances.

Respectfully submitted,



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