HEALTH RESOURCE™
PUBLISHING COMPANY

July 20, 2001

BY HAND DELIVERY

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Re: Docket No. 01D-0162; Draft Guidance for Industry on Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements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

Health Resour$_x$ce® Publishing Co. (HRPC) is pleased to submit comments to the Food and Drug Administration (FDA) concerning the Draft Guidance for Industry on Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements (hereinafter "Draft Guidance"), 66 Fed. Reg. 20468 (April 23, 2001). The Draft Guidance describes how sponsors can use certain FDA-approved patient labeling to fulfill the requirement that prescription drug and biological product advertisements directed to consumers (DTC) in print media contain adequate risk information. If finalized, the Draft Guidance would permit sponsors to satisfy the so-called "brief summary" requirement by disseminating FDA-approved patient labeling with DTC print advertising.

The Draft Guidance is one of many steps FDA has taken to improve the quality of the information about prescription drugs communicated to consumers. HRPC recognizes and supports FDA's efforts to make the information that accompanies prescription drug advertising and promotional labeling more useful and comprehensible to consumers.

HRPC supports the adoption of the Draft Guidance as an important and much-needed reform of DTC advertising. However, FDA should expand its reform efforts with the issuance of a Final Guidance that goes further. Much more work needs to be done -- FDA's utilization of the Guidance process demonstrates how reform can be attained without the need for often burdensome formal and/or informal rulemaking.

01D-0162

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INTRODUCTION

HRPC assists retail pharmacies nationwide by providing their patients with a customized educational newsletter printed at the pharmacy and given to the patient with his or her prescription. The HRPC prepared newsletter includes several components. The first section is the Patient Information Leaflet (PIL), which includes information about the proper use of the drug dispensed to the patient, including the name of the drug, indications for use, drug interaction precautions, adverse reactions, and possible side effects. Other sections of the newsletter present related health information. For example, when a consumer fills a prescription for a diabetes medication, the newsletter might include an article describing the preventative steps a person with diabetes should take to protect his or her feet, since foot infections are a common complication of diabetes. The newsletter also may include an "FYI" section through which patients can request information on a variety of health related topics from their pharmacist. Finally, the newsletter contains, in a separate and distinguishable section, advertising and coupons for health and non-health related items.

The PIL section of the HRPC is intended to satisfy the "useful patient information" criteria of Public Law 104-180 and the "Action Plan for the Provision of Useful Prescription Medicine Information" (Action Plan). The HRPC PIL is scientifically accurate, useful, neutral in tone, and presented in a format that is easily understandable to consumers. As of today, HRPC is printing PILs in over 10,000 pharmacies nationwide.

An expert, independent company, MedEduSource, prepares the PILs for HRPC. MedEduSource relies upon authoritative references, including FDA-approved product labeling, U.S. Pharmacopeia entries and dispensing information, manufacturer-supplied materials, and research through MedLine, International Pharmaceutical Abstracts, and other similar information services.

The MedEduSource PILs are further reviewed by the HRPC Advisory Board. The Advisory Board includes pharmacists, physicians, and a consumer representative.

In each participating pharmacy, HRPC installs a laser printer, a personal computer, and a modem hook-up. On a bi-weekly basis, HRPC transmits by modem to the computer in each participating pharmacy the content of different PILs and newsletters that accompany the dispensed prescription drugs. Based upon this up-to-date information, the pharmacy is able to print a customized newsletter with useful prescription information for each individual patient.

BACKGROUND TO DTC PROMOTION -- THE "HOLY ROMAN EMPIRE"

Print advertisements for prescription drugs must include a "brief summary" of the advertised drug's side effects, contraindications, and effectiveness. 21 U.S.C. § 352(n). FDA's implementing regulations specify that the information about risks in the brief summary should include each

specific side effect and contraindication from the advertised drug's approved labeling. 21 C.F.R. § 202.1(e)(3)(iii). Draft Guidance at 1. In contrast, promotional labeling for prescription drugs (written, printed, or graphic matter on the drug, or accompanying the drug) must include adequate directions for use. 21 U.S.C. § 352(f)(1); 21 U.S.C. § 321(m). "Adequate directions for use" are defined by regulation as the "full package labeling" or "package insert." 21 C.F.R. § 201.5. Thus, any promotional labeling distributed must be accompanied by the drug's full package labeling.

For many years, FDA, consumer groups, and the pharmaceutical industry have expressed concern regarding the usefulness of the information that must accompany DTC promotions, whether in the form of a brief summary or full package labeling. Almost six years ago, in the Federal Register notice announcing a public hearing on DTC promotion, FDA summarized the disclosure requirements for print promotion and noted that the full package insert and the brief summary are usually written in technical language, are "relatively inaccessible to consumers," are of "questionable" value, and may not be effective or informative. 60 Fed. Reg. 42,851, 42,583 (Aug. 16, 1995).

At the public hearing that followed, Dr. Robert Temple, then FDA Associate Director for Medical Policy bluntly acknowledged that the brief summary was an oxymoron:

> Let's say we all agree for the sake of argument that the current brief summary, which is neither brief nor a summary -- like the Holy Roman Empire was neither holy nor an empire -- isn't very helpful. I think you won't find a great deal of disagreement about that among FDA staff either.

DTC Public Hearing, Statement of Robert Temple, October 18, 1995 (Panel 5). The same sentiment was echoed again and again at the hearing in a near unanimous chorus -- the disclosure requirements accompanying DTC promotions were too lengthy and too technical to be of any use to consumers. For example, one commentator stated:

> Senior FDA personnel have repeatedly conceded that brief summaries are so lengthy that consumers virtually never read them. Moreover, it would make no difference even if they did read the comments. Commissioner David Kessler has stated that very few consumers can understand them.

DTC Public Hearing, Statement of Richard A. Samp, October 18, 1995 (Panel 1).

In 1996, FDA again acknowledged the "Holy Roman Empire" its regulations and guidances had built:

> FDA recognizes that many consumers do not have the technical background to understand fully the information typically included in prescription drug and biological advertisements to fulfill the "brief summary" requirement. To meet the "brief summary" requirement, sponsors typically reprint, in small type, whole sections of the professional labeling, which is generally written in terms that are not easily understood by the average consumer.

61 Fed. Reg. 24314, 24315 (May 14, 1996).

In that same 1996 Federal Register notice, FDA solicited comment on other issues related to the information to be disseminated to consumers in DTC promotions. FDA specifically recognized the shortcomings of existing disclosures and sought comments on how to make risk information conveyed to consumers more useful and understandable:

> Much testimony, petitions, and comments questioned the usefulness, for the consumer of the existing "brief summary" of risk information that results from the application of these requirements. Many comments contended that, for consumer advertising, a shorter, more focused presentation of user-friendly information could meet the statutory requirement and also provide appropriate risk-related information. Some comments suggested that a consumer brief summary should include 'information relating to the major side effects and contraindications" of the product, as currently required in prescription drug and biological product broadcast advertising. . . . If FDA required or permitted more limited risk information in place of the current brief summary, what specific information should be included?

61 Fed. Reg. at 24315-16. The comment period on these issues closed on August 12, 1996.

Seven months later, FDA called for comments on its program for the development of guidance documents regarding prescription drug advertising and promotional labeling. 62 Fed. Reg. 14912 (March 28, 1997). In that notice, FDA announced its intent to develop a guidance for industry on DTC promotion. Five months after that announcement, FDA issued a new guidance on broadcast advertising (the Broadcast Guidance) and stated that this long-awaited, much needed guidance was "the first step in a comprehensive review of all policies on direct to consumer promotion for prescription medicines." FDA Press Release, August 8, 1997, P97-26. FDA stated:

> In response to recent agency requests for input, many comments have expressed concerns about the value for consumers of the complex, detailed information in the brief summary for print advertisements and approved package labeling for broadcast advertisements. FDA will initiate any rulemaking necessary to address these concerns.

62 Fed. Reg. at 43,172.

If the brief summary is an amusing oxymoron, the requirement that patients receive the full package labeling with promotional labeling and broadcast advertising is an absurd anachronism. Full package labeling is intended for the health care profession. It includes detailed pharmacology information, recitation of how the drug is metabolized, distributed, and eliminated, chemical structure, carcinogenicity and mutagenicity, and full disclosure of every adverse event observed. Full package labeling is printed in tiny typesize to squeeze as much information as possible onto the front and back of a flimsy sheet of paper. It is dense, scientific, detailed, and likely beyond the comprehension of all but the most educated. It is likely to be unreadable to anyone with poor eyesight or limited proficiency in English.

Years have passed since FDA first recognized the desperate need for reform of the information disclosure requirements for DTC promotion. Change has been very slow. Industry must still disclose to consumers information that is not brief, is not a summary and requires medical training and a magnifying glass to read and comprehend. Some important progress has been made with respect to broadcast ads and in the area of information pharmacists disseminate with dispensed prescriptions (PILs). Thus, it can be said that the "Holy Roman Empire" of brief summary and full package labeling requirements has begun to crumble.

A NEW STANDARD -- "USEFUL WRITTEN INFORMATION"

On August 24, 1995, FDA published a proposed rule in the Federal Register that would have mandated standards for the type and format of information that would accompany dispensed prescription drugs -- the "Med Guide" proposal. 60 Fed. Reg. Page 4418 (Aug. 24, 1995). A year later, Congress enacted Public Law No. 104-180 that limited the authority of the Secretary, Department of Health and Human Services, to enact the Med Guide rule. In the alternative, Congress mandated that the Secretary request that health care professionals, consumer organizations, and other entities develop an "Action Plan" to achieve the goals of the proposed rule.

Drawing from the Med Guide proposal, Congress stated that the goal of Public L. No. 104-180 and its implementation through the Action Plan was the distribution to consumers of "useful written information" about the prescription drugs they receive. Congress mandated that the useful information to be transmitted to the public must be:

> scientifically accurate, non-promotional in tone and content, sufficiently specific and comprehensive as to adequately inform consumers about the use of the product, and in an understandable, legible format that is readily comprehensible and not confusing to consumers expected to use the product.

Pub. L. No. 104-180, 110 Stat. 1593, Section (c)(4).

A coalition of stakeholders convened at the Keystone Center in Washington, D.C. to implement the goals of Pub. L. No. 104-180. The result was the "Action Plan for the Provision of Useful Prescription Medicine Information" (Action Plan). The Secretary of the Department of Health and Human Services accepted the Action Plan in January 1996.

Under the Action Plan, written prescription drug information must be scientifically accurate and unbiased, should identify the drug and its benefits, should identify contraindications, should include specific directions, storage instructions, and precautions in sufficient detail for proper adverse event reporting, and should be legible and timely. Written prescription information that included eleven components -- 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, and disclaimers -- could meet the standard for "useful."

FDA has recognized "usefulness" as a sound standard, but has been slow to adopt it in contexts other than the dissemination of Med-Guide type information or PILs with dispensed prescriptions. In the Federal Register notice accompanying the release of the Broadcast Guidance, FDA stated that it intended to initiate a rulemaking to address the shortcomings of the brief summary and full package insert dissemination requirements.

> In the interim, FDA encourages product sponsors to provide consumers with nonpromotional, consumer-friendly information that is consistent with approved product labeling, in addition to the information currently required by the regulations (package insert for broadcast advertisements or brief summary for print advertisements). FDA suggests that this information follow the guidelines outlined in the "Action Plan for the Provision of Useful Prescription Medicine Information" coordinated by The Keystone Center, as accepted by the Secretary of the Department of Health and Human Services in January 1996.

62 Fed. Reg. at 43,172.

Congress, the health care community, consumer advocates, industry, and FDA all have settled upon "usefulness" as the touchstone for effective communication to patients. "Usefulness" is a multi-faceted concept, including completeness and accuracy, balanced with legibility and clarity. Unlike the full package labeling or the oxymoronic "brief summary," the information disseminated with new prescriptions must be clear enough, accurate enough, and succinct enough, that it can actually be read and understood by the patients who will be taking the medication.

TO THE CONSUMER, IT'S ALL THE SAME

A patchwork of requirements dictates different disclosures depending on the regulatory definition (advertising versus labeling), media (broadcast versus print) and the disseminating party (pharmacy versus drug sponsor). To the consumer bombarded with these different messages, the result is confusion. The brief summary is useless, and the full package labeling incomprehensible, even to a well-educated consumer. FDA-approved patient labeling suffers the same flaws – it is typically very long, detailed, and technical. None meet the criteria for "usefulness" set out in the Public Law and the Action Plan.

HRPC urges FDA to follow the path charted by Congress in the Public Law and navigated by stakeholders in the Action Plan. Whether important prescription information is delivered to a patient on the television, in a magazine, from a website, or at the pharmacy attached to the drug itself, the standard for measuring the effectiveness of that communication should be the same -- whether the information conveyed is useful and understandable to the patient.

The communications flowing to patients and consumers about their prescription drugs should not be sliced into pieces depending upon the nuances of drug law. "Usefulness" should be the standard. That yardstick should measure all communications to patients and consumers, whether they are a patient package insert, brief summary, or Med Guide-type PIL.

WITH "USEFULNESS" AS THE TOUCHTSTONE, THE DRAFT GUIDANCE IS ONLY THE BEGINNING OF MUCH NEEDED REFORM

FDA first proposed that patient labeling could satisfy the brief summary requirement in May 1996. 61 Fed. Reg. at 24314. It would seem to be an uncontroversial proposition. FDA pre-approves patient labeling during the drug review process. While still long and detailed, patient labeling is, in theory, written for patients. HRPC urges FDA to adopt and implement the Draft Guidance swiftly.

FDA should go further. The need is clear; FDA's authority to address that need is also clear.

In the Draft Guidance, FDA takes a flexible approach to the brief summary requirements of 21 U.S.C. § 352(n). Patient-approved labeling is an adequate disclosure to consumers, even if the labeling does not include "'each specific' risk." Draft Guidance at 2. As FDA states, patient labeling can satisfy the brief summary requirement because "[s] uch labeling generally addresses the rationale behind the law's brief summary requirements by providing benefit and risk information in a form understandable to consumers." Draft Guidance at 2. "Patients desiring more complete information can obtain it from their health care provider or by referring to labeling that is written for health care providers." Draft Guidance at 2.

Thus, the Draft Guidance implicitly recognizes that the general purpose of the brief summary requirement is to inform patients and consumers. Further, that vital communicative purpose is not served, and is even undermined, by lengthy recitations of each and every possible risk of a prescription drug.

HRPC urges FDA to take the next, sorely needed step and issue an expanded Final Guidance on brief summary requirements that continues what the agency has begun in the Draft Guidance. In the Draft Guidance, the agency has abandoned the rigid, formulaic approach -- brief summary requirements can be satisfied by communications that provide risk and benefit information that is understandable to consumers. An expanded Final Guidance document, in the same spirit as the Draft Guidance and stemming from the same authority, could achieve long looked-for reform of the brief summary requirement.

Further, FDA has the legal authority to address the incongruous "requirement" that even promotional labeling directed to consumers include the full product labeling. This requirement derives from regulations intended to address only promotions to health care professionals. The regulations never contemplated promotional labeling directed to consumers. FDA should address this peculiar vacuum in an expanded Guidance document.

HRPC posits that FDA need not "reinvent the wheel" as these reforms to DTC promotion proceed. FDA can look to Public L. No. 104-180 and the Action Plan. Useful written information that adequately informs consumers in an understandable format should be the standard for all communications directed to patients and consumers, whether in advertising, labeling, or accompanying a dispensed prescription. The adoption of a consistent format for presentation of prescription drug risk, benefit, and usage information would aid comprehension. For example, uniform "Nutrition Facts" for food and "Drug Facts" for over-the-counter drug labeling have been very successful. Consumers like this presentation of important information in a simple, easy-to-read format that becomes very familiar to them; they use it and understand it.

Further, the Broadcast Guidance provides an additional model for success. Under the Broadcast Guidance, an advertisement must contain a major statement of a prescription drug's risks and benefits, be otherwise fairly balanced, and make adequate provision for a consumer to obtain the drug's full package labeling. Leaving aside the futility of providing full package labeling to consumers as opposed to useful, consumer-friendly information (see discussion above), broadcast advertisers can satisfy this "adequate provision" requirement through a variety of means that allow for the different information-seeking habits of the consumers. The broadcast advertisement makes "adequate provision" if it directs a consumer to a company's website, an 800 number, and to a doctor or pharmacist for further information about the drug.

In contrast to this streamlined approach for broadcast advertising, print promotions must, in most circumstances, continue to provide the brief summary or full package labeling. FDA should reconcile these two different regimes. It is nonsensical to continue to hold print advertisers to standards far more onerous than those to which broadcast advertisers must comply.

* * *

HRPC has many years of experience in providing useful written information to consumers. A patient's health may depend on the accuracy and completeness of the HRPC PIL received with a dispensed prescription drug. We take very seriously the issue of how to make a PIL useful to patients; if a patient does not read the PIL because it is too long, too technical, or too complex, he or she may miss important adverse events or drug interactions. The patient may take the drug incorrectly, store it improperly, or stop taking it too soon. Moreover, millions of prescription drugs are dispensed to patients who are elderly or have poor English proficiency. In the call to "inform," HRPC is ever mindful that above all, prescription drug information must be "understood" by those who will be taking the medication or their caregiver.

In HRPC's experience, consumers are best served by succinct, easy to understand information. The written information must also make allowance for the more motivated or curious patient -- thus, including toll free numbers and websites addresses for obtaining more complete information are an important part of any patient-directed communication. Above all else, no single piece of information, whether it is a PIL, a brief summary, a full package label, or an FDA-approved patient label, substitutes for the best provider of all -- the patient's own physician or pharmacist.

One goal of the newsletter is to provide patients with sufficient information to have a meaningful dialogue with these professionals. Prescription drug promotions in whatever format can provide valuable information for patients and consumers, but they cannot and should not replace the health care professional.[1]

HRPC supports the first steps FDA has taken that would permit drug sponsors to satisfy the brief summary requirements by using FDA-approved patient labeling. HRPC urges FDA to go further, and initiate, by expanded or new guidance, other much needed reforms, including revision of the brief summary requirement as a whole, harmonization of DTC print promotion with broadcast, and reinterpretation of the requirements that have consumers receiving product labeling intended for health care professionals. Above all, HRPC encourages FDA to look to the admirable and important work already done in implementing Public L. No. 104-180 and adopt a consistent standard that measures DTC promotions by the yardstick of usefulness to the consumer.

Sincerely,

Michael T. McClorey
President and CEO

[1] In the interest of better educating the patient, the newsletter now frequently contains an editorial explaining what DTC advertising is and how it differs from other health/medical information directed at consumers.