

September 13, 2002

**BY HAND DELIVERY**

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 – Questions 8 and 9

Dear Sir or Madam:

Health Resource® Publishing Co. (HRPC) is pleased to submit comments to the Food and Drug Administration (FDA) concerning the agency's Request for Comment on First Amendment Issues (hereinafter "Comment Request"), 67 Fed. Reg. 34,942 (May 16, 2002). The Comment Request is an excellent step toward evaluating how FDA regulations and practices may impede the flow of quality information to consumers. HRPC hopes that the Comment Request signals FDA's decision to consider carefully and rescind or modify the regulations, guidances, and policies that infringe on First Amendment rights of commercial entities to communicate truthful, non-misleading information.

HRPC's comments are limited to two questions the Comment Request poses:

8. Do FDA's speech-related regulations advance the public health concerns they are designed to address? Are there other alternative approaches that FDA could pursue to accomplish those objectives with fewer restrictions on speech?

9. Are there any regulations, guidance, policies, and practices FDA should change, in light of governing First Amendment authority?

67 Fed. Reg. at 34,943-34,944. HRPC specifically comments below on how FDA regulation of direct-to-consumer (DTC) promotion of prescription drugs violates the First Amendment.

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## I. INTRODUCTION

HRPC is well-positioned to address how current FDA regulation of DTC promotion impedes the flow of useful, accurate information about prescription drugs to consumers. HRPC is in the business of providing prescription drug information to consumers. HRPC assists retail pharmacies nationwide by providing each patient with a customized educational newsletter printed at the pharmacy and given to the patient with his or her prescription.

The HRPC-prepared newsletter typically includes several components. The first section of the newsletter contains 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 compliance advice, information on alternative therapies, and other 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 pharmacists. Finally, the newsletter contains, in a separate and distinguishable section, advertising and coupons for health and non-health related items.<sup>1</sup>

Because pharmaceutical companies pay for advertising in the newsletter, the newsletter is an attractive option for pharmacies. Thus, the costs to provide the newsletter and the information within it shift from the pharmacy and the consumer to the pharmaceutical company. As of today, HRPC is printing newsletters in over 17,000 pharmacies nationwide.

The section of the newsletter providing prescription drug information is intended to satisfy the "useful patient information" criteria of Pub. L. No. 104-180 and the "Action Plan for the Provision of Useful Prescription Medicine Information" ("Action Plan"). The useful patient information within the HRPC newsletter is scientifically accurate, useful, neutral in tone, and presented in a format that is easily understandable to consumers.

An expert, independent company, MedEduSource, prepares the useful patient information for HRPC. The useful patient information is derived from 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 HRPC Advisory Board reviews the useful patient information. The Advisory Board includes pharmacists, physicians, and a consumer representative.

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<sup>1</sup> The newsletter is printed and disseminated for all prescriptions the pharmacy fills and dispenses, irrespective of whether there is a paid advertisement for the particular drug dispensed.

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Each participating pharmacy prints the HRPC newsletter via a computer and laser printer. Periodically, HRPC transmits by modem to the computer in each participating pharmacy the content of different newsletters that will 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.

HRPC is, thus, in the business of providing important, useful, written prescription drug information to consumers. HRPC is motivated to comment because, as explained below, current FDA regulations and policies impose unnecessary and costly burdens upon how information about prescription drugs must be disseminated in print media. These burdens, requiring detailed disclosures and accompanying information, encumber communications and confound consumers. The requirements are widely derided, even within FDA, and so inimical to the constitutional free flow of information that they most certainly violate the First Amendment.

## **II. THE BACKGROUND OF “ACCOMPANYING INFORMATION” IN DTC PROMOTION**

Under the Federal Food, Drug and Cosmetic Act (“FDC Act”) and the FDA’s implementing regulations, promotion of prescription drugs is divided into two categories – “labeling” and “advertising.” A prescription drug’s full product labeling contains the essential information necessary for a physician to prescribe the drug safely and effectively. A prescription drug’s full product labeling is created during a drug’s lengthy FDA review and approval process. It is modified over time as new information about safety and effectiveness develops for the drug. It is a lengthy, detailed, highly technical document that includes, among other things, information about the drug’s clinical pharmacology, a summary of clinical data supporting the drug’s approval, indications and usage, contraindications, warnings, precautions, and adverse reactions, including virtually every adverse event recorded during clinical testing. See 21 C.F.R. § 201.57. A copy of the full product labeling for Altace® is attached as Exhibit A.

Apart from the full, FDA-approved product labeling, “labeling” also encompasses written, printed, or graphic material that accompanies the drug. 21 U.S.C. § 321(m); Kordel v. U.S., 335 U.S. 345 (1948). Labeling includes brochures, booklets, mailers, detailing materials, letters, and any other similar pieces of printed, audio, or visual matter descriptive of the drug. 21 C.F.R. § 202.1(l). In contrast, advertising is defined much more narrowly and encompasses material published in journals, magazines, other periodicals, and newspapers, and material advertisements broadcast through media such as radio, television, and telephone communication systems. Id.

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In sum, if the material is printed in a periodical or broadcast, it is “advertising.” Otherwise, FDA is likely to deem the communication to be labeling that accompanies the drug product. This distinction is important, for the promotion must comply with different legal requirements, depending upon whether it is “advertising” or “labeling.”<sup>2</sup>

### III. ACCOMPANYING INFORMATION REQUIREMENTS: INCONSISTENT, CONTRADICTIONARY, AND TOO SLOW TO CHANGE

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 (which include side effects, warnings, precautions, and contraindications)*” contained in the advertised drug’s FDA-approved labeling. 21 C.F.R. § 202.1(e)(3)(iii) (emphasis supplied).

These extensive disclosure requirements mean that the “brief summary” that accompanies a print advertisement is typically highly technical and very difficult to read. A copy of the brief summary for Altace® obtained from U.S. News and World Report is attached as Exhibit B. Exhibit B is, essentially, the full FDA-approved labeling for Altace®, with certain categories of information, such as clinical pharmacology, omitted. The illogic of the disclosure requirement is immediately apparent – full drug labeling is intended for health care professionals, yet to comply with the requirements of 21 C.F.R. § 202.1(e)(3)(iii), advertisers are compelled to reprint the dense medical jargon of the full drug labeling when they advertise their prescription drugs in consumer publications or as part of newsletters that are communicating useful information for patients.

Accompanying information requirements for print promotional labeling can be even more onerous and irrational. Any promotional labeling, such as booklets, brochures, mailers, and letters, (21 C.F.R. § 202.1(e)) must include “adequate directions for use.” 21 U.S.C. § 352(f)(1). “Adequate directions for use” are interpreted by FDA to mean the full product labeling. Thus, any promotional labeling, even when distributed to consumers, must be accompanied by the drug’s full product labeling for health care professionals.

FDA’s implementing regulations, 21 C.F.R. § 201.100 for labeling and 21 C.F.R. § 202.1 for advertising, assume promotion to medical professionals, not to consumers. Burdensome as they may be, there is at least defensible logic to providing such detailed information with any promotion directed to a health care professional. Such justification is wholly absent when those promotions are directed to the lay consumer. For many years, FDA, consumer groups, and the pharmaceutical

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<sup>2</sup> HRPC newsletters may be either advertising or promotional labeling. If the newsletter contains a promotion for the drug dispensed, it is labeling. If the newsletter contains a promotion for a different prescription drug, it is advertising.

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industry have expressed concern regarding the utility of these accompanying information requirements for DTC promotions.

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 “brief summary” is 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 irrationality within its regulations and guidances:

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.

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61 Fed. Reg. 24,314, 24,315 (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 consumers of the existing “brief summary” of risk information that results from 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 24,315-16. 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 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. 43, 171, 43,172 (emphasis supplied).

Even ardent critics have come to see the benefits of DTC promotion. Former FDA Commissioner David Kessler had long opposed DTC promotion as potentially confusing to consumers. In April 2002, Dr. Kessler conceded he may have been wrong to resist DTC promotion:

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“On the whole, I think there is a lot of educational benefit” to DTC promotion. Mishra, R. “Ex-FDA Chief Recants on Drug Advertising,” The Boston Globe, p. A2 (April 17, 2002).

If the brief summary is a confounding oxymoron, the requirement that patients receive the full product labeling with consumer-directed promotional labeling is an absurd anachronism. As discussed above, full product labeling is intended for the health care profession. It includes detailed pharmacology information; a recitation of how the drug is metabolized, distributed, and eliminated; chemical structure, carcinogenicity and mutagenicity; and full disclosure of every adverse event observed. Full product 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, and detailed. It is likely to be unreadable to anyone with poor eyesight. It likely will be incomprehensible to anyone who is not highly educated.

Some prescription drugs have labeling information that FDA has approved specifically for dissemination to patients. This “patient information leaflet” (PIL) is somewhat simpler and more consumer-friendly than the full product labeling. Even FDA-approved PILs, however, are lengthy, technical documents. See, e.g., Exhibit C. A consumer likely would have to be highly educated and familiar with medical terminology to understand the information within a PIL. While better than the full product labeling, a PIL scarcely improves upon the typical brief summary.

Common sense and logic would conclude that consumers are not reading the detailed, technical, fine print disclosures within DTC promotions. Empirical research on consumer comprehension of the information accompanying DTC promotion is discussed below.

#### **IV. THE DATA ARE CLEAR – CONSUMERS DON’T READ IT, DON’T UNDERSTAND IT, AND DON’T REMEMBER IT**

The FDA Comment Request sought information on whether FDA DTC regulations were consistent with empirical research. The data show, not surprisingly, that consumers are not reading and do not understand the brief summary that accompanies prescription drug print advertising. A survey from 1999 revealed that at least 30% of consumers read little or none of the brief summary that accompanies the print advertising.<sup>3</sup>

FDA’s own data is even more revealing. FDA’s Division of Drug Marketing, Advertising and Communications (DDMAC) recently disclosed the preliminary results of its survey of DTC advertising of prescription drugs. See Preliminary Patient Survey Results Direct-to-Consumer Advertising of Prescription Drugs (<http://www.fda.gov/cder/ddmac/DTCnational2002a/index.htm>) May 10, 2002. That survey reveals that over 70% of respondents read little or none of the brief

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<sup>3</sup> National Survey of Consumer Reactions to Direct-to-Consumer Advertising, *Prevention Magazine*, 2000 Table L, Exhibit D.

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summary. Fewer people are reading the brief summary now than they did three years ago – “only” 56% reported that they read little or none of the brief summary in 1999. In 2002, over 50% reported that the brief summary was “somewhat hard” or “very hard” to understand.

Thus, by FDA’s own repeated admissions, and as established by FDA’s own data, the disclosure requirements for DTC promotion do not further consumer comprehension of the promoted drugs. Consumers do not read the accompanying information and most do not understand it if they do read it.

The societal costs of FDA’s accompanying information requirements extend beyond merely confusing the audience they are intended to inform. To include a “brief summary” in a print advertisement, the sponsor must pay for an additional page in a newspaper or magazine. For promotional labeling, such as letters, brochures, or newsletters, the sponsor must also include several additional pages to accommodate the drug’s full product labeling. These requirements impose enormous costs upon drug sponsors and advertisers, while providing no benefit to consumers. The accompanying information requirements, it may be concluded, violate the First Amendment to the U.S. Constitution.

## **V. THE ACCOMPANYING INFORMATION REQUIREMENTS ARE UNCONSTITUTIONAL**

The Comment Request specifically seeks comment on any FDA requirements that are contrary to the First Amendment to the Constitution. When held to the standards of Central Hudson Gas & Elec. Corp. v. Public Serv. Comm’n of N.Y., 447 U.S. 557, 566 (1980), as recently elucidated in Thompson v. Western States Med. Ctr., 122 S. Ct. 1497 (2002), it is clear that FDA’s accompanying information requirements are constitutionally infirm.

The promotion of prescription drugs is, it may be agreed without controversy, “commercial speech” that is entitled to protection under the First Amendment to the U.S. Constitution. See Western States, 122 S. Ct. at 1503; Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976). “It is a matter of public interest that [economic] decisions, in the aggregate, be intelligent and well-informed. To this end, the free flow of commercial information is indispensable.” Western States, 122 S. Ct. at 1503, quoting Virginia Bd. of Pharmacy, 425 U.S. at 765. “[E]ven a communication that does no more than propose a commercial transaction is entitled to the coverage of the First Amendment.” Western States, 122 S. Ct. at 1503, quoting Edenfield v. Fane, 507 U.S. 761, 767 (1993).

Under a test first enunciated in Central Hudson and applied in Western States, a government restriction upon commercial speech is constitutional if, as a threshold matter, the commercial speech concerns unlawful activity or is misleading. Western States, 122 S. Ct. at 1504; Central Hudson, 447 U.S. at 566. Such speech is not protected by the First Amendment. However, if the speech concerns

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lawful activity and is not misleading, a court must then evaluate whether the asserted governmental interest in the restriction is substantial. Western States, 122 S. Ct. at 1504; Central Hudson, 447 U.S. at 566. If the government's interest is substantial, a court next determines "whether the regulation directly advances the governmental interest asserted." Ibid. Finally, the court determines whether the government restriction is "more extensive than is necessary to serve that interest." Ibid. In order for the restriction on speech to be constitutional, each of these three questions must be answered in the affirmative.

Certainly, prescription drug print promotion meets the first prong of the Central Hudson test. It is not inherently misleading or concerning any unlawful activity. With regard to the second prong, it also may be assumed that assuring consumers receive accurate information about the prescription drug promoted is a legitimate and substantial government interest. Where FDA's accompanying information requirements plainly stumble is in the third and fourth prongs of the Central Hudson test.

As FDA has conceded, publicly and repeatedly, the requirement that the brief summary or full package labeling accompany DTC promotions is not directly advancing any government interest in promoting consumer health and welfare. Section III above recounts FDA's many admissions over the years that the accompanying information requirements are not useful to consumers, that consumers are not reading the accompanying information, and that they are not understanding it when they do. FDA's own data from April 2002 underscores the futility of the accompanying information requirements for print media. See Section IV above. By FDA's own admission, the requirements that sponsors include a brief summary of each specific side effect and contraindication with every print advertisement and the full product labeling with every piece of promotional labeling plainly fail the third prong of the Central Hudson test.

Additionally, the accompanying information requirements are "more extensive than is necessary" to serve the interest of consumer health and welfare. See Western States, 122 S. Ct. at 1504; Central Hudson, 447 U.S. at 566. There are other less burdensome and less costly methods of communicating important information about prescription drugs to consumers – vehicles that provide useful, valuable information, in easy-to-understand formats. These information vehicles have been subject to Congressional scrutiny and consensus decision-making by interested stakeholders. Consumers like them and are familiar with them. Alternative, less burdensome means of adequately informing consumers about promoted prescription drugs are discussed below.

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## VI. THE NEW DISCLOSURES – “ADEQUATE PROVISION” AND “USEFUL WRITTEN INFORMATION”

FDA need look no further than its own Guidance for Industry – Consumer-Directed Broadcast Advertisements (August 1999) (“Broadcast Guidance”) for a new, successful paradigm for print promotion. Under the Broadcast Guidance, which interprets 21 C.F.R. § 202.1(e)(1), a consumer-directed broadcast advertisement for a prescription drug is lawful if it:

- Is not false or misleading in any respect, including communicating that the drug is available only by prescription and that only a prescribing healthcare professional can decide whether the product is appropriate for a patient.
- Presents a fair balance between information about effectiveness and information about risk.
- Includes a *major statement* conveying all of the product's most important risk information in consumer-friendly language.
- Communicates all information relevant to the product's indication (including limitations to use) in consumer-friendly language.
- Makes *adequate provision* for the dissemination of the drug's full product labeling.

Broadcast Guidance at 2.

The Broadcast Guidance discusses the “adequate provision” requirement in detail. Leaving aside the counter-intuitive futility of requiring the advertiser to provide full product labeling to a consumer, the overall concept of “adequate provision” is a very sound one. Under the Broadcast Guidance, the adequate provision requirement is satisfied with some or all of the following:

- Disclosure in the advertisement of a toll-free telephone number for consumers to obtain the product package labeling by mail, fax, email, or by having it read to them over the phone;
- Reference in the advertisement to additional product information in concurrently running print advertisements;

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- Making package labeling available in a variety of publicly accessible sites (e.g., pharmacies, doctors' offices, grocery stores, public libraries);<sup>4</sup>
- Disclosing an Internet web page (URL) address in the advertisement that provides access to the full product labeling;
- Disclosing in the advertisement that pharmacists, physicians, and other healthcare providers may provide additional product information.

Broadcast Guidance at 2-3.<sup>5</sup>

In short, unlike a print promotion, a broadcast advertisement does not need to include every single piece of risk, usage, and safety information. A broadcast advertisement is lawful so long as it is fairly balanced, contains a major statement of the most important risk information, and makes adequate provision for the consumer to receive fuller, more complete information about the drug. In contrast, a print promotion – even if it contains claims verbiage identical to a broadcast advertisement, is fairly balanced, and contains a major statement of important risk information – must be accompanied by the brief summary or full product labeling. It is nonsensical and – we contend – unconstitutional to hold print advertisers to standards that are far more onerous than those with which broadcast advertisers must comply. There is no reason why FDA cannot reconcile these two different regimes.

There is a second excellent model for the communication of important information about prescription drugs to consumers – the “useful written information” that must accompany all new prescription drugs dispensed. This “useful written information” stems from the so-called “Med Guide” rulemaking. 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. 4,418 (Aug. 24,

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<sup>4</sup> HRPC intends to offer an Internet website where a consumer can download the full product labeling for any prescription drug.

<sup>5</sup> In a July 17, 1995, letter from Kenneth R. Feather, FDA Senior Advisor, FDA concluded that communications made by telephone, such as over a modem, could comply with the adequate provision requirements by providing a toll-free number and the page of the Physician's Desk Reference where the promoted drug product's full product labeling could be obtained.

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1995). A year later, Congress enacted Pub. L. No. 104-180 that limited the authority of the Secretary of the Department of Health and Human Services to enact the Med Guide rule.

The goal of Pub. L. No. 104-180 was the distribution to consumers of “useful written information” about the prescription drugs they receive. According to the law, useful information 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. 1569, 1593.

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 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 product labeling 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

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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. 43,171, 43,172.

Like the Broadcast Guidance, this “useful written information” is a superb model for reform of the brief summary and full product labeling accompanying information requirements. 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 brief summary, the information disseminated to consumers with new prescriptions must be clear, accurate, and succinct enough that it actually can be read and understood by the patients who will be taking the medication.<sup>6</sup>

## VII. RECOMMENDATIONS AND CONCLUSIONS

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 newsletter received with a dispensed prescription drug. We take very seriously the issue of how to make a newsletter useful to patients; if a patient does not read the newsletter 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 by their caregivers.

In HRPC’s experience, consumers are best served by succinct, easy-to-understand information. The written information also must make allowances for the more motivated or curious patient – thus, including toll-free numbers and website addresses for obtaining more complete information is an important part of any patient-directed communication. Above all else, no single piece of information, whether it is a newsletter, a brief summary, full product labeling, or FDA-

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<sup>6</sup> FDA has proposed one reform – allowing FDA-approved patient labeling to be used in lieu of the brief summary for print advertising. See Draft Guidance for Industry – Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements, 66 Fed. Reg. 20,468 (April 23, 2001). While a positive step, use of the FDA-approved patient labeling is at most a half-measure that continues to preserve without justification the disparity between print and broadcast media. The FDA-approved patient labeling also is very lengthy and highly technical. See Exhibit C. In many cases, it would still require placement of an additional page of advertising in a periodical.

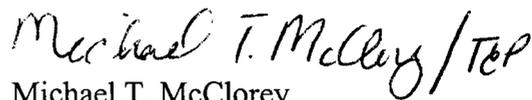
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approved patient labeling, substitutes for the best information source of all – the patient's own physician or pharmacist.

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.<sup>7</sup>

HRPC urges FDA to initiate, by guidance, 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 the Broadcast Guidance and Pub. 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  
Chief Executive Officer

cc: Daniel Troy, Esq.  
Chief Counsel  
Food and Drug Administration

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<sup>7</sup> 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.