DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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Sidney M. Wolfe, M.D.
Allison Zieve
Patricia Christen
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Public Citizen's Health Research Group
1600 20th Street, N.W.
Washington, DC 20009-1001

Re: Docket No. 98P-0446/CP1

Dear Mr. Sasich, Dr. Wolfe, Ms. Zieve, Mrs. Christen, and Mr. Christen:

This letter responds to your citizen petition dated June 9, 1998, filed on behalf of Public Citizen's Health Research Group. You request that the Food and Drug Administration (FDA) recall or seize written information voluntarily distributed to patients with prescription drugs that, in your opinion, is not consistent with or derived from a drug's FDA-approved product labeling. You state that a large proportion of these patient information leaflets (PILs), produced by commercial information vendors and voluntarily distributed by pharmacists to consumers, fail to warn about adverse reactions or proper use. You request that FDA immediately recall PILs whose inaccurate information is most likely to cause substantial harm if not corrected.

FDA has considered the information submitted in your petition and addresses your request in this response. For the reasons explained below, your petition is denied.

I. FDA REGULATION OF WRITTEN PRESCRIPTION DRUG INFORMATION FOR CONSUMERS

You state that FDA has clear legal authority and mandate to regulate all written information distributed with a prescription drug, including commercially produced and voluntarily distributed PILs (Petition at 2). While you acknowledge that there are no regulations on PIL content, you state that the PILs with the most flagrant violations could be recalled or seized by FDA because they violate the misbranding provisions of the Federal Food, Drug, and Cosmetic Act (the Act) (Petition at 3-4). A review of FDA's past efforts to regulate written information voluntarily distributed to consumers with prescription drugs, set forth below, clarifies FDA's legal authority to regulate such information. FDA's announced public meeting, to be held in July 2003, to discuss the status of written prescription drug information and request public input on the next steps to improve the quality of this information reflects the Agency's commitment to addressing the issue (68 FR 33724, June 5, 2003).

98P-0446

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A. FDA's Past Efforts to Regulate Patient Information Voluntarily Distributed to Consumers

As you know, since 1968, FDA has occasionally required that prescription drug labeling written specifically for patients in nontechnical language be distributed to patients whenever certain prescription drugs, or classes of prescription drugs, are dispensed. In the 1970s, FDA began evaluating the usefulness of patient labeling for prescription drug products generally and, in 1979, published a proposed rule to require written patient information for prescription drugs (44 FR 40016, July 6, 1979). In 1980, FDA published a final rule establishing requirements and procedures for the preparation and distribution of FDA-approved patient labeling for a large number of prescription drugs (45 FR 60754, Sept. 12, 1980). FDA revoked those regulations in 1982 based, in part, on assurances by the private sector that the goals of the 1980 final rule would be met (47 FR 39147, Sept. 7, 1982). A decision was made to allow voluntary private sector initiatives to proceed before a determination was made whether to impose a mandatory program.

In 1995, FDA published a proposed rule entitled "Prescription Drug Product Labeling; Medication Guide Requirements" (60 FR 44182 , Aug. 24, 1995), which provided that the Agency would encourage development and distribution of written patient medication information by the private sector. This information was intended to supplement oral counseling from health care professionals. Distribution goals and performance standards for this information were proposed by FDA. The Agency proposed to survey the marketplace in the years 2000 and 2006 to determine how much patient medication information is being distributed and whether it is useful. The Agency also proposed to require manufacturers to prepare FDA-approved written patient information (Medication Guides) for distribution with prescription drugs that pose a "serious and significant public health concern requiring immediate distribution of FDA-approved patient medication information." The Agency indicated that it would use this authority only on limited occasions.

In the proposal, FDA reaffirmed its position that patient information about the risks and benefits of prescription drugs is important so that patients use these products safely and effectively. The overall patient medication information program was proposed to provide patients with the information needed to improve their use of prescription drugs. Furthermore, FDA demonstrated in the preamble to the proposed rule that the program could result in substantial health care savings by reducing the harm caused by inappropriate prescription drug use and enhancing the benefits of prescription drugs by facilitating their proper use.

In August 1996, while FDA was reviewing comments on the proposed rule, Congress enacted legislation regarding the distribution of written patient information with prescription drugs.[1] Section 601 of Public Law 104-180 established a voluntary private-sector process under which national

[1] The Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 1997 (Pub. L. 104-180, Title VI, § 601, August 6, 1996).

organizations representing health care providers, consumers, pharmaceutical companies, and other interested parties were to collaborate in the development of a long-range comprehensive action plan to achieve the goals of FDA's proposed rule. In Public Law 104-180, Congress adopted these goals – that useful written information would be distributed to 75 percent of individuals receiving new prescriptions by the year of 2000, and that 95 percent of individuals receiving new prescriptions would receive useful written information by the year 2006. Under Public Law 104-180, FDA could not implement the portion of the proposed rule, or any regulation or guideline, that specified a uniform content or format for written information voluntarily provided to consumers about prescription drugs if private-sector organizations met the requirements of the action plan within the specified time-frame. Therefore, your statement that the Agency has clear legal authority and mandate over voluntarily distributed written information on prescription drugs provided to consumers (Petition at 2) is not entirely accurate.

Although Public Law 104-180 limited the Agency's authority to implement its proposed rule regarding written information voluntarily provided to consumers about prescription drugs, the legislation did not prevent FDA from implementing a mandatory program for the small number of prescription drug products that pose a serious and significant public health concern. FDA adopted its final rule on Medication Guides in 1998 for those prescription drugs, and the final rule became effective on June 1, 1999 (63 FR 66378). Under the final rule, Medication Guides are required for prescription drug products that FDA determines pose a serious and significant public heath concern requiring distribution of FDA-approved patient information necessary for the products' safe and effective use. To date, approximately 13 Medication Guides have been approved by FDA.

In addition, the agency maintains its authority to review specific PILs, on a case-by-case basis, to evaluate whether a particular PIL is false, misleading, or otherwise inconsistent with the approved product labeling. Since PILs are labeling under section 201(m) of the Act (21 U.S.C. 321(m)), PILs that are considered by FDA to be false, misleading, or otherwise inconsistent with the approved product labeling can cause a drug to be misbranded under section 502 of the Act (21 U.S.C. 352).

B. Status of Written Prescription Drug Information for Consumers

You state that the majority of PILs now being distributed contain incomplete safety information. An FDA-commissioned study of written information disseminated during 2001 with four widely-prescribed drugs found that, on average, 89 percent of patients received some form of written medication information and that the average usefulness of the information (evaluated according to scientific accuracy, nonpromotional tone and content, specificity, comprehensiveness, understandable language, and legibility) was about 50 percent.[2]

In 2002, FDA's Drug Safety and Risk Management Advisory Committee met and recommended that FDA take a more active role in advising and encouraging the private sector to meet the 2006

[2] The report of this study is available at http://www.fda.gov/cder/reports/prescriptioninfo/default.htm.

goals for written patient prescription drug information. While FDA accords the recommendations of advisory committees significant weight, their recommendations are not binding on the Agency.

C. Public Meeting on Status of Written Prescription Drug Information for Consumers

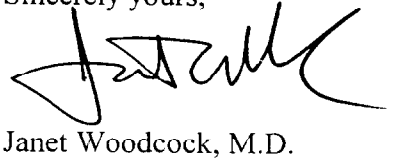
In February 2003, Public Citizen filed suit against FDA, to require the agency to seek public comment on initiatives for PILs. In April 2003, FDA and Public Citizen settled the suit after FDA agreed to schedule a public meeting in July 2003. FDA has announced in a *Federal Register* notice (68 FR 33724, June 5, 2003) that the Agency is soliciting comments on and convening a public meeting to discuss the current status of the private sector's efforts to provide useful written prescription drug information to consumers and what steps can be taken to improve the usefulness of such information. Interested persons are invited to submit comments to the docket and/or to attend the public meeting and present their views.

II. CONCLUSION

You ask the Agency to recall or seize PILs with inaccurate information most likely to cause substantial harm if not corrected. With the implementation of FDA's final rule on Medication Guides for drug products that pose a serious and significant concern to the public health, the Agency is working to provide consumers with accurate written information, based on FDA-approved product labeling, for drug products of the greatest concern. For all other prescription drugs, FDA is seeking public input on steps that can be taken to improve the usefulness of written information voluntarily provided to consumers with the drugs. At this time, the Agency believes that the best use of its limited resources is to require Medication Guides for drug products of serious and significant public health concern and to help the private sector achieve the goal that by the year 2006, 95 percent of individuals receiving new prescriptions receive useful written information.

Therefore, for the reasons discussed above, your petition to recall or seize patient information produced by commercial vendors and voluntarily distributed by pharmacists to consumers is denied. You are invited to present your concerns regarding written prescription drug information provided to consumers in comments and/or in a presentation at the public meeting on the status of such information as detailed in the June 5, 2003, *Federal Register* notice.

Sincerely yours,



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