UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PUBLIC CITIZEN, INC.
1600 20th Street, NW
Washington, DC 20009

ERIC BRADBERY
22305 SW 63d Ave.
Boca Raton, Florida 33428

TOBI PALMER
1833 New Hampshire Ave., NW
Washington, DC 20009, and

BRIAN WOLFMAN
100 Grant Avenue
Takoma Park, Maryland 20192

Plaintiffs,

v.

DEPARTMENT OF HEALTH
AND HUMAN SERVICES,
200 Independence Ave., SW
Washington, DC 20201,

Defendant.

Case No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. This action challenges the failure of the Food and Drug Administration ("FDA") to seek public comment on initiatives to convey information to consumers about prescription drugs as required by Public Law 104-180, § 601, 110 Stat. 1593-94 (1996).

Jurisdiction

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 and

§ 1361.

Parties

3. Plaintiff Public Citizen, Inc. ("Public Citizen") is a non-profit public interest organization organized under the laws of the District of Columbia, with its principal office in the District of Columbia and more than 125,000 members nationwide. Founded in 1971, Public Citizen's objectives include fighting for safe and effective drugs and medical devices, responsible controls over the delivery of health care, and informed consent and public access to health care information. Public Citizen's Health Research Group conducts research and is active before Congress and the FDA in many areas involving consumer health and safety. The Health Research Group also provides consumer education through its publications. In 1988, the Health Research Group published the first edition of *Worst Pills, Best Pills: A Consumer's Guide to Avoiding Drug-Induced Death or Illness*. More than two million copies have been sold and a fourth edition is now being planned. A monthly newsletter on the same topic now has a circulation of approximately 140,000. Disseminating accurate information about prescription drugs through the *Worst Pills, Best Pills* publications is an essential part of the Health Research Group's efforts to remedy the pharmaceutical industry's failure to inform the public about its products. The nature of the Health Research Group's advocacy gives Public Citizen a particular interest in making sure that consumers receive clear, useful, and thorough written information with their prescription medications. Public Citizen brings this action on behalf of itself and its members who purchase prescription drugs and, as Congress has determined, would benefit from useful written information about prescription drugs.

4. Plaintiff Eric Bradbery, a Public Citizen member since 1997, regularly fills five

prescriptions at a pharmacy in Boca Raton, Florida. He receives only unregulated patient medication leaflets when he has a prescription filled for the first time; he does not receive any information with refills.

5. Plaintiff Tobi Palmer regularly fills several prescriptions at pharmacies in Washington, DC, and receives unregulated patient medication leaflets when she does so.

6. Plaintiff Brian Wolfman has regularly filled prescriptions at pharmacies since 1995, and receives unregulated patient medication leaflets when he does so. In addition, he would like to comment on FDA's plans for medication guides.

7. The Department of Health and Human Services ("HHS") is the federal agency responsible for protecting the health of American citizens. Food and Drug Administration ("FDA") is a federal agency within HHS. By delegation from HHS, FDA is the federal agency responsible for the proper labeling of prescription drug and biological products and for implementing the requirements of Public Law 104-180 at issue in this lawsuit.

FDA's Involvement in Consumer Drug Labeling and Overview of Public Law 104-180

8. On August 24, 1995, prior to the passage of Public Law 104-180, FDA published a proposed rule that would "require manufacturers to prepare and distribute, or provide the means for distributing, a Medication Guide that would accompany prescription drug products that patients receive and use on an outpatient basis without the direct supervision of a health care professional." 60 Fed. Reg. 44182, 44203 (1995). At the same time, FDA proposed two alternative approaches for implementation of the Medication Guide program. *Id.* at 44198. Under the first approach, implementation of the program would be deferred if the private sector voluntarily met predetermined standards for quality and distribution of useful patient information

within specified time frames; and under the second approach, FDA would finalize the Medication Guide program only for products posing a serious and significant public health concern and a more comprehensive program covering all prescription drugs would be developed later as part of a long-range plan. *Id.* at 44199. Either approach would entail notice-and-comment rulemaking. *Id.* at 44204.

9. FDA also set forth its goal for the Medication Guide program, namely, that by the year 2000, at least 75 percent of people receiving new prescriptions should be given useful written patient information. *Id.* at 44198. In addition, FDA proposed that by 2006 the distribution standard should "be increased such that 95 percent of people who receive new prescriptions also receive useful written patient information." *Id.* at 44199. FDA also specified that the "usefulness" of written patient information would be judged according to its "scientific accuracy, consistency with a standard format, nonpromotional tone and content, specificity, comprehensiveness, understandable language, and legibility." *Id.* at 44200. In short, the proposed rule required that Medication Guides "be written in nontechnical language" and "contain a summary of the most important information about a drug product, including the approved uses for the product, circumstances under which the drug product should not be used, serious adverse reactions, proper use of the product, cautions related to proper use, and other general information." *Id.* at 44204.

10. On August 6, 1996, as FDA was reviewing the public comments on its proposal, Congress enacted Public Law 104-180. Section 601 of that law adopted the distribution and information quality goals of FDA's proposed rule, namely, "the distribution of useful written information to 75 percent of individuals receiving new prescriptions by the year 2000 and to 95

percent by the year 2006." Public Law 104-180, § 601(b). The legislation also required that, no later than 30 days after its enactment, HHS would request that national organizations representing "health care professionals, consumer organizations, voluntary health agencies, the pharmaceutical industry, drug wholesalers, patient drug information database companies, and other relevant parties" collaborate to develop a "long-range comprehensive action plan to achieve goals consistent with the goals of the proposed rule." The action plan would 1) assess the effectiveness of private sector approaches used to provide prescription information to consumers; 2) develop guidelines for providing effective prescription information consistent with the findings of any such assessment; 3) provide for the transmission of useful information to the consuming public; 4) develop a mechanism to assess periodically the quality of prescription information and the frequency with which the information is provided to consumers; and 5) provide for compliance with relevant state regulations. Public Law 104-180, § 601(d). In short, Congress adopted the first of the two approaches FDA had developed for implementing the proposed rule.

11. Public Citizen's Health Research Group participated in drafting the action plan required by Public Law 104-180 as a member of The Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information (the "Steering Committee"). The Committee met for the first time on September 18, 1996, and met several times thereafter before presenting the action plan to HHS for consideration in December 1996.

12. Under subsection (d), FDA could not implement its original proposed rule, or any other regulation or guideline developing a Medication Guide program, if private sector

organizations met the requirements of the long-range action plan within the time-frame provided in the law. Public Law 104-180, § 601(d).

13. The law also required HHS to review the status of private sector initiatives designed to achieve the goals of the action plan by January 1, 2001. Public Law 104-180, § 601(e). If the goals were not achieved by that date, the Secretary was required to "seek public comment on other initiatives that may be carried out to meet such goals," and the "limitation in subsection (d) shall not apply." *Id.*

Facts Concerning FDA's Non-Compliance With Public Law 104-180

14. In accordance with Public Law 104-180, § 601, in 2001 FDA conducted a study "designed to assess the extent and usefulness of private sector prescription information patients receive when filling their prescriptions." *See* FDA Talk Paper, *Success of Private Sector Patient Information With Prescription Medicines Assessed*, *available at* http://www.fda.gov/bbs/topics/ANSWERS/2002/ANS01153.html (last visited February 3, 2003).

15. On June 18, 2002, FDA announced the results of the study. The researchers found that 89 percent of patients received written drug information, which surpassed the quantity goal of 75 percent contained in § 601. Dr. Bonnie L. Svarstad & Dr. Jeanine K. Mount, *Evaluation of Written Prescription Information Provided in Community Pharmacies, 2001*, available at www.fda.gov/cder/reports/prescriptioninfo.default.htm (last visited February 3, 2003). However, the quality of the written drug information did not meet § 601's goals. None of the patient information leaflets satisfied the seven criteria set forth in the proposed law and, therefore, none of them met the quality standard. According to FDA, the average "usefulness" of the information contained in the medication guides was 50 percent. In addition, the study

reported that consumers found the written drug information extremely difficult to read. *See id.*

16. Despite the acknowledged failure to reach the goal set forth in the law, FDA did not seek public comment on other initiatives to reach its stated goals as required by § 601(e). Instead, FDA stated that it would "continue to work with private sector partners to improve the usefulness of patient information, and meet the goal for the year 2006." *See* FDA Talk Paper.

17. FDA's ongoing efforts with its private sector partners violate § 601(e), which establishes that notice-and-comment must occur.

18. Plaintiff Public Citizen would have submitted comments on other initiatives had the notice-and-comment period required by § 601(e) been scheduled. In addition, FDA's failure to comply with § 601(e) presents an obstacle to Public Citizen's ongoing efforts to inform its members and the general public about the safe use of prescription drugs.

19. Plaintiffs Bradbery, Palmer, and Wolfman and many Public Citizen members are harmed by FDA's violation of § 601(e)'s notice and comment requirement. Congress has determined that providing consumers with useful and readable information about prescription drugs would benefit their health, and Congress has set forth a procedure for ensuring that its goal was met in a timely manner. As purchasers of prescription drugs, these plaintiffs are harmed by the lack of quality information about their medications, and thus by FDA's failure to follow the procedure that Congress determined should be used to ensure that effective initiatives were explored and used to meet the Congressional timetable.

20. The private sector initiatives have demonstrably failed to meet the standards for useful written patient information criteria set forth in the proposed law. FDA's failure to schedule a comment period as required by Public Law 104-180 is preventing users of

prescription drugs, including the many members of Public Citizen who use prescription drugs, from receiving the most useful and safe patient medication guides possible. FDA's failure is also denying Public Citizen, its members, and plaintiffs Palmer and Wolfman their statutory right to participate in the notice-and-comment process.

Claim for Relief

21. FDA's failure to seek public comment on initiatives that could meet the standards for the provision of useful prescription drug information to patients, as required by Public Law 104-180, § 601(e), constitutes agency action unlawfully withheld and not in accordance with law in violation of the Administrative Procedure Act, 5 U.S.C. § 706(1) and (2)(A).

WHEREFORE, plaintiffs request an order:

(A) Declaring unlawful FDA's failure to seek public comment on initiatives that could achieve the goals set forth in Public Law 104-180 § 601, as required by § 601(e);

(B) Ordering FDA to seek public comment on initiatives that could achieve the goals set forth in Public Law 104-180, § 601, as required by § 601(e);

(C) Awarding plaintiffs their costs and reasonable attorney fees pursuant to 28 U.S.C. § 2412(d); and

(D) Granting all other appropriate relief.

Dated: February 6, 2003

Respectfully submitted,

_____

Amanda Frost (DC Bar No. 467425)
Michele Host
Member of the NY Bar (DC Admission Pending)
Public Citizen Litigation Group
1600 20th Street, NW
Washington, DC 20009
(202) 588-1000

Counsel for Public Citizen, Inc.