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	)	District Court No. 03-00196 (RJL)
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.	)	

STIPULATION FOR SETTLEMENT

This Stipulation for Settlement ("Stipulation") is entered into between defendant Department of Health and Human Services ("DHHS") and plaintiffs Public Citizen, Inc. ("Public Citizen"), Eric Bradbery, Tobi Palmer, Brian Wolfman, the parties in the above-captioned lawsuit, who agree to resolve this case, solely for purposes of settlement, and without admission of liability, as follows:

1. DHHS will schedule a meeting to be held in July 2003 to discuss the fact that P.L. 104-180, Title VI, § 601, Aug. 6, 1996, 110 Stat. 1593, requires the distribution of useful written information to 75 percent of individuals receiving new prescriptions by the year 2000, and that an FDA-commissioned study of four widely-used prescription drugs reported the average "usefulness" of the information in the written information provided with these prescriptions during the calendar year 2001 was only about 50 percent;

2. The meeting will be announced in a Federal Register notice that also solicits comments to the docket about alternative methods of providing patients with useful written information about prescription drugs, including the possibility that FDA would require manufacturers to provide authorized dispensers with the means to distribute useful written patient information approved by FDA;

3. The Federal Register notice will also contain background information on the patient prescription drug information issue. At a minimum, the Federal Register notice will state that:

   a) Since 1968, FDA has on occasion required that prescription drug labeling written specifically for patients in non-technical language be distributed to patients whenever certain prescription drugs, or classes of prescription drugs, are dispensed.

   b) 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. FDA revoked those

regulations in 1982 based, in part, on assurances by the private sector that the goals of the final rule would be met. A decision was made to allow voluntary private sector initiatives to proceed before a determination was made to impose a mandatory program.

c) In 1995, FDA published a proposed rule that would have required manufacturers to prepare and distribute "Medication Guides" to accompany a limited number of prescription drug products that posed a serious or significant public health concern, and set forth the requirements for the Medication Guide program. FDA's proposed goal for all other prescription drug products was that, by the year 2000, at least 75 percent of people receiving new prescriptions would be given useful written patient information, and that by 2006, 95 percent of people who receive new prescriptions would also receive useful written patient information. FDA defined "useful" as written in nontechnical language and containing a summary of the most important information about the drug. FDA also specified that the usefulness of written patient information would be evaluated according to its scientific accuracy, consistency with a standard format, nonpromotional tone and content, specificity, comprehensiveness, understandable language, and legibility.

d) On August 6, 1996, as FDA was reviewing the public comments on its proposed rule, Public Law 104-180 was enacted, which adopted goals consistent with the 1995 proposed rule for the distribution of useful

written information by the private sector. The legislation also required that, no later than 30 days after its enactment, the Secretary of DHHS 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. Required elements of the plan included: an assessment of the effectiveness of the current private-sector approaches to providing consumer medication information; the development of guidelines for providing effective consumer medication information consistent with the findings of such assessment; the identification of components necessary to ensure the transmittal of useful information to the public expected to use the product, including the criteria identified in the proposed rule; and the development of a mechanism to periodically assess the quality of prescription information and the frequency with which it is provided to consumers.

e) Under subsection (d) of § 601, P.L. 104-180, FDA could not implement the portion of the proposed rule, or any other regulation or guideline, that specified a uniform, FDA-approved content or format for written information voluntarily provided to consumers about prescription drugs, if private sector organizations met the requirements of the long-range action

plan within the time-frame provided in the law.

f) The law also required DHHS to review the private sector initiatives designed to achieve the goals of the action plan by January 1, 2001. If the goals were not achieved, the Secretary of DHHS was required to seek public comment on other initiatives that could meet the goals.

g) P.L. 104-180 requires the distribution of useful written information to 75 percent of individuals receiving new prescriptions by the year 2000. FDA commissioned a study to assess the usefulness of written prescription information, and the results were announced in 2002. This study reported that for four widely-used prescription drugs, the average "usefulness" of the information in the written information provided with these prescriptions during the calendar year 2001 was only about 50 percent.

4. In light of the fact that P.L. 104-180 requires the distribution of useful written information to 75 percent of individuals receiving new prescriptions by the year 2000, and that the FDA-commissioned study of four wide-used prescription drugs reported the average "usefulness" of the information in the written information provided during the calendar year 2001 with these prescriptions was about 50 percent, the participants in the meeting and invited comments to the docket will consider the distribution of FDA approved information or other initiatives to provide patients with useful drug information as endorsed by P.L. 104-180.

5. A Stipulation of Dismissal With Prejudice of all claims by Public Citizen against DHHS will be signed and entered at the same time as this Stipulation for

Settlement.

DATED: April 4, 2003

For Plaintiffs:

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202-588-1000

For Government Defendant:

Drake Cutini
U.S. DEPARTMENT OF JUSTICE
P.O. Box 386
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202-307-0044

APPROVED AND SO ORDERED

_____ Date: _____
United States District Judge