Comments by Public Citizen's Health Research Group
FDA Hearing on
Current Status of Useful Written Prescription Drug Information for Consumers
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Twenty-two years ago, in 1981, the carefully researched regulation requiring FDA-approved patient information leaflets to be dispensed with prescriptions was cancelled by the Reagan administration just before it was to have gone into effect. This abrupt reversal was at the behest of drug companies, pharmacy organizations and some physician groups, and private sector-designed leaflets, not approved by the FDA, thereby continued to be the norm.

This meeting marks the start of the process that must culminate in the restoration of FDA-approved patient information leaflets as a safer alternative to the dangerously-failed voluntary private sector labels. The fact that Public Citizen had to file suit in Federal District Court in February of this year to compel the Food and Drug Administration (FDA) to hold this public meeting on the failure of voluntary private sector programs to provide consumers with useful, scientifically accurate written drug information escapes all reason. The law is clear. If private sector initiatives fail to achieve the information quality and distribution goals defined in Public Law 104-180 of 1996, the Secretary of Health and Human Services "shall seek public comment on other initiatives that may be carried out to meet such goals."

In June 2002, the FDA announced the results of a University of Wisconsin assessment of the quality of drug information being distributed by pharmacists as required by Public Law 104-180. None of the approximately 1,300 leaflets studied for four common drugs achieved the minimum goals for useful, scientifically accurate drug information. This failure was not at all surprising and is consistent with the private sector's performance since (and before) the creation of the National Council on Patient Information and Education (NCPIE) in 1982, with significant support of the pharmaceutical industry.

This FDA announcement last year of the findings of the University of Wisconsin study was remarkable in two respects. First, the FDA said "... the overall usefulness of information provided, as measured by 8 objective consensus-based criteria, was about 50 percent." The notion that consumer drug information can be 50 percent useful is

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unfathomable. Drug information that communicates only half of what it should is misleading, and misleading drug information is potentially dangerous.

Second, the FDA's conclusion and recommended course of action was extraordinary: "Because the agency sees progress in meeting the goals set under Public Law 104-180, FDA will continue to work with private sector partners to improve the usefulness of patient information, and meet the goal for the year 2006, ..." Amazingly, the FDA determined that the failure of all 1,300 leaflets to comply with the Action Plan guidelines was "progress."

Public Citizen had no option but to file suit since the FDA seemed content with the "progress" thus far and was not planning to challenge the well-documented failure by convening a public meeting as required by the law.

Underscoring the lack of public access to useful, scientifically accurate drug information are the results of a survey Public Citizen assessing the content quality of black box warning information intended for consumers The survey involved 23 top-selling drugs in the U.S. in 2002 that are required to include a black box warning in their professional labeling. (It should be noted that the above-mentioned Wisconsin study commissioned by the FDA did not include any drugs with black box warnings.) Using the guidelines of Public Law 104-180[1] the major results of this survey are:

1. None of the patient drug information leaflets (0/23) being distributed in a Washington, DC CVS Pharmacy or available on the web site of CVS Pharmacy for the top-selling drugs with black box warnings complied fully with the guidelines. This information was produced by First DataBank, Inc of San Bruno, CA.

2. None of the information (0/23) from the United States Pharmacopeia Drug Information (USP-DI) Advice for the Patient used under license to Micromedex, a business of Thomson Healthcare Inc., for these drugs meets the quality goals for communicating black box warning information to consumers.

3. Information for only four drugs (4/22) from MedMaster, a product of the American Society of Health-System Pharmacists (ASHP), fully complied with the quality

[1] Action Plan for the Provision of Useful Prescription Medicine Information, December, 1996, adopted by HHS Secretary Shalala in January, 1997. The recommendation concerning placement and content of black box warning information was that it should be placed immediately after the name of the drug in the patient information leaflet (the first item) and should be "a prominently displayed statement that is consistent with or derived from any "black box" warnings (as required by FDA on the professional labeling) that are relevant to the consumer."

guidelines concerning black box warning information as defined in Public Law 104-180.

These results are extremely troubling. First, the information contained in black box warnings is the most serious type of warning the FDA can require and is the most important to the health and safety of prescription drug consumers. Second, the information form Micromedex-Thomson Healtcare Inc. and the American Society of Health-System Pharmacists was downloaded from the web site of the National Library of Medicine's MEDLINEplus web site. This is a site that proclaims that both health professionals and consumers can "... depend on it for information that is authoritative and up to date."

We find it irresponsible that the management of the National Library of Medicine, a part of the prestigious National Institutes of Health, uncritically features on its web site drug information that is unregulated and fails to meet minimum quality standards. By allowing this information on its web site, the National Library of Medicine gives credibility to drug information that misleads the American public. We strongly urge the Director of National Library of the Medicine, Donald A. B. Lindberg, M.D., to eliminate this information from the library's web site and to replace it with more accurate and complete information.

Consumer access to useful drug information through FDA regulation or by voluntary private sector programs has been at the center of a contentious debate for more than 25 years. The divisions have been along ideological lines, with industry, professional trade groups, and industry-supported organizations favoring a "marketplace for information" and consumers preferring a government-regulated program with quality standards and oversight.

The research has been done and the history is clear. There is no longer any legitimate argument in continuing to consider voluntary private sector programs as a solution for providing consumers with useful, scientifically accurate, written drug information. This is a failed paradigm.

The fact that manufacturers are required to write professional product labels that must be approved by the FDA before they are distributed, but that consumer drug information has been left in the hands of unregulated commercial information vendors who have consistently failed to follow voluntary quality guidelines, is irrational for the following reasons:

1. The FDA has the authority to require agency-approved, written consumer drug information to be distributed with each new and refill prescription for a limited number of drugs under a rule that took effect on June 1, 1999. Only a minor

modification of this rule would be needed to cover consumer information for all prescription drugs.

2. Multinational pharmaceutical companies operating in the European Union have been required for a decade to produce and distribute written consumer drug information based on a drug's professional product labeling that is approved by member states' drug regulatory authorities. Why does government-regulated consumer information exist for all drugs in Europe and not in the U.S?

3. The infrastructure already exists in the U.S. for distributing written information to the majority of prescription drug consumers. The University of Wisconsin study found that 89 percent of consumers were receiving some sort of information even though it was clearly substandard. Obviously the cost of distributing this information has already been passed on to consumers and it would be no more expensive to distribute useful, scientifically accurate information than inferior information.

Dr. Mark B. McClellan, the new FDA commissioner, has listed, as one of his top five priorities, helping consumers to get truthful information about products they use so they can make informed decisions. The commissioner can go a long way in achieving this priority by immediately moving forward with a long-overdue initiative to require the mandatory distribution of FDA approved written drug information with each new and refill prescription. It is time to end the double standard wherein doctors and other health professionals use and are informed by FDA-approved labeling but patients, like second-class citizens, get whatever the out-of-control purveyors of patient information leaflets choose to have dispensed to them with their prescription drugs.