



Medical Monitors

Public Health Advocacy Exposes Threats, Educates Consumers

By Sidney Wolfe, M.D.

For almost 30 years, the Public Citizen Health Research Group has been fighting to improve the public health by using research-based advocacy. The areas on which we have focused most of our attention are products such as prescription drugs and other FDA-regulated products, worker health issues and the health care delivery system. Using the traditional tools of health research, aided by access to unpublished data that we obtain from the government under the Freedom of Information Act, we have been able to effect change through two different but complementary means.

The first method involves petitioning and, if necessary, suing the government — especially the Food and Drug Administration (FDA) and the Occupational Safety and Health Administration (OSHA) — to enforce the health protection laws they are charged with upholding. In the case of the FDA, this means gathering enough scientific evidence to force the FDA to put a warning label on a drug or medical device, or, if necessary, to ban the product or other FDA-regulated substances such as food additives. In the case of OSHA, the process similarly involves accumulating and analyzing data that support getting the agency to set a safer health standard for chemicals to which workers are exposed.

The second means of change concerns providing information to the public so that even before the government takes the actions, we are requesting the public be informed about the problem, so they may use that information to protect themselves and their families. This information dissemination takes several forms, including the media, books, newsletters and reports.

With the exception of issues concerning worker health, which the news media ignore most of the time, our research is usually widely reported by newspapers, radio and TV. Three of our books, all concerning pharmaceuticals, have been national best-sellers. They include *Pills That Don't Work* (1981), *Over-the-Counter Pills That*

Don't Work (1983) and *Worst Pills, Best Pills* (1999). *20,125 Questionable Doctors* is the latest version of our national database of doctors disciplined by the federal government or state medical boards. It is the only publicly available book (and now available on CD-Rom) listing such doctors. In addition, we publish two monthly newsletters. *Health Letter*, now in its 17th year of publication, has a circulation of 50,000 and contains summaries of projects we have done and other information concerning the health care system. *Worst Pills, Best Pills News*, the monthly update of the information in the book, *Worst Pills, Best Pills*, has a circulation of 130,000. In many instances, we have warned people not to use dangerous drugs sometimes years before they were eventually banned, and this has saved lives and prevented unnecessary health problems.

We have also published many reports of our work in the health care delivery area, including a ranking of state Medicaid programs, state medical board disciplinary actions, several rankings of state programs for the seriously mentally ill, listings of hospital Cesarean section rates, and the names of hospitals that have illegally dumped seriously ill patients from their emergency rooms.

In addition to the direct dissemination of health information, we have, in conjunction with the Public Citizen Litigation Group, continually pushed, often through litigation against the FDA, OSHA or the Department of Health and Human Services, for more public access to information on prescription drugs, medical devices, workplace health conditions and a variety of health care issues.

For us to assess our effectiveness, it is useful to examine the results and impact of our work. A quantitative measurement is found in the outcome of our petitions and lawsuits filed against the FDA and OSHA. From the time we began our work in 1971 through the end of the year 2000, we filed 22 petitions with the FDA to ban prescription drugs, in each case because there was clear evidence that the drugs' risks outweighed their benefits. Thirteen of these drugs (59 percent) have been banned and another eight (36 percent) have had their use severely restricted. The banned drugs include Rezulin for diabetes,

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Redux for weight reduction, Oraflex and Suprol for arthritis and pain, and Lotronex for irritable bowel syndrome. Other examples of FDA regulation forced by Public Citizen include the currently required warnings on aspirin against use by children with chicken pox or flu-like illnesses because of the risk of often-fatal or brain-damaging Reye's Syndrome, and the requirement for warnings on all tampons concerning their amount of absorbency because of the well-documented link between higher absorbency and increased risk of toxic shock syndrome.

In the worker health area, we have filed 17 OSHA petitions to force the agency to set safer workplace health standards. Thirteen of the petitions (77 percent) have been granted. They resulted in newer, safer standards for workplace exposure to carcinogens such as benzene, ethylene oxide and cadmium. In each case, working in conjunction with the Public Citizen Litigation Group, we had to file a lawsuit against OSHA because the agency did not respond favorably to our petitions.

More difficult to measure are the results of our ranking reports. The main feedback we continue to get on this kind of research is that it sparks institutional reforms. Typically, the state programs or hospitals and patients who are treated by them did not know how they compared to other such institutions until our rankings were published. In a number of instances, especially because we provide evidence of the best models as well as criticism of the worst, our reports have led to important improvements in the performance of these institutions.

The impact of our books and newsletters is the most difficult to measure because it depends on how patients and their families use the information we provide. However, we get an enormous amount of positive feedback from readers of these publications. They tell us, for example, about how they discovered that the "illnesses" that they had developed — be it Parkinsonism, depression, delirium, memory loss or heart or liver problems — were actually adverse drug reactions or interactions that they had not previously connected to the drugs they were taking until they read *Worst Pills, Best Pills* or *Worst Pills, Best Pills News*. In the most ideal circumstances, their physi-

cians welcome this information and work with the patients to lower the dose of the drug or, if necessary, to switch to an alternative drug that does not cause the adverse reaction.

This 30th anniversary of our work also affords an opportunity to look at recent events such as the performance of the FDA and OSHA. From the data we have accumulated, it is clear that the performance of these agencies is as bad or worse than at any time in the many years we have been monitoring them — worse than under Presidents Nixon, Ford, Carter, Reagan or Bush.

The election of a Republican president, after eight years of a Democrat leading the country, might seem to be good news for the pharmaceutical industry. However, the last several years of the Clinton regime brought little but praise from the industry, which currently gives the FDA the highest marks I have ever witnessed. There are several reasons for this, including the relative silence and lack of criticism of the industry in the media, especially TV, by the current commissioner, Dr. Jane Henney, and her predecessor, Acting Commissioner Dr. Michael Friedman. As a result, the pharmaceutical industry supports retaining Henney in the Bush administration. In addition, the 92 new drugs approved in 1996 and 1997 are the largest number ever approved in a two-year period, clearly the result of a lowering of the standards for approval. Third, the enactment of the 1997 Food and Drug Modernization Act, whose provisions concerning prescription drugs were largely crafted by the pharmaceutical industry, has made the FDA legally more friendly to the industry in a variety of ways. Fourth, the new law also relaxed requirements for prescription drug TV ads, creating a windfall for manufacturers of the most heavily advertised products, whose sales have skyrocketed with this massive, frequently misleading TV exposure.

What is good news for the pharmaceutical industry, however, is not good news for patients. It is hard to imagine how the FDA's drug safety record can get worse. I am hopeful that it will actually improve, in part because

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Dr. Sidney Wolfe appears on Phil Donahue's long-running talk show in 1993 to promote *Worst Pills, Best Pills II*, a book that warned consumers about dangerous drugs and provided information about safer alternatives.

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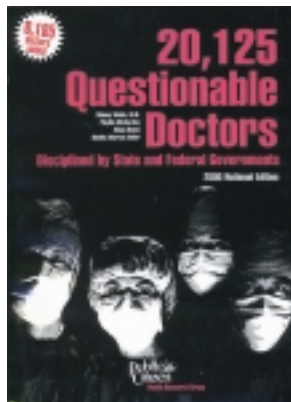
of the publicity surrounding the extraordinary spate of drug safety withdrawals in the past several years. And while Congress has largely relinquished its role in oversight of the FDA, there may be some effort to modify the patient-endangering Dietary Supplement Health and Education Act, which has crippled the FDA's ability to regulate herbs and food supplements. In addition, we will make sure that negotiated prices or price controls on prescription drugs, at least for Medicare beneficiaries, will be forced onto the table as part of the consideration of a Medicare drug benefit.

American workers also have been seriously underserved because of OSHA's dreadful performance. In the eight

years of the Clinton administration, not one new occupational chemical hazard standard has been proposed. This is the longest stretch of dangerous inactivity since the law went into effect in 1971. In a report we issued in 1999, we showed that OSHA's enforcement record on existing regulations and other OSHA policing activities was as bad or worse than during any previous administration.

For the future, we will continue using petitions and lawsuits against the FDA and OSHA to push for better government/industry oversight functions. At the same time, we will keep providing the public, through the media, books, newsletters and reports, information that allows consumers to take matters into their own hands until the government is forced to extricate itself from the influence of

the industries it is supposed to regulate. [IPCI](#)



The People's Lawyer

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the current law is flawed.

Fourth, the process of litigation is partially a process of education. Perhaps the most striking example of that is our lawsuit challenging the efforts by the White House to destroy the e-mail records from the Reagan and Bush administrations. The defendants claimed there was nothing of substance in the e-mails and that the few messages of importance were printed out. Not only did our lawsuit succeed in preventing the destruction of these records and securing their eventual release, it also showed how important the use of electronic mail had become for the White House, leading to a massive change (that is still under way) to alter the system for maintaining electronic records throughout the government.

Fifth, sometimes there is no choice but to litigate. When a case reaches the Supreme Court, the Court is going to decide the issue at hand, and it is vital that the interests of average citizens be represented to the greatest extent possible, particularly since the government and large business entities will surely take the opportunity to present their views to the Justices.

Sixth, litigation is a vital tool, but it is not the only one that we use. Many times the answer to a problem will be legislative, and our lawyers frequently are asked to participate in the analysis of a proposed law (in particular its

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constitutional soundness and its practical implications). We will make suggestions in the drafting and provide testimony to the relevant congressional committees. Similarly, when administrative agencies propose new regulations, we often comment on them and consult with agency officials. When they are not considering an action that Public Citizen considers necessary, the Litigation Group works with others at Public Citizen to file petitions to urge the agency to remedy the problem. We also keep a watchful eye on the rules under which court cases are conducted and often comment on proposed changes and make suggestions of our own. And we take advantage of opportunities to set forth our ideas by writing articles, teaching, appearing on educational programs and being available to the media.

Seventh, persistence and long distance matter. Over the years we have accumulated vast knowledge about the law and the way courts and agencies conduct their business. But perhaps even more important, the fact that we are around for the long-term helps us assure that the victories we win today are not lost tomorrow because no one is there to prevent backsliding. We have seen all too often that if no one remembers what happened before, the past is likely to recur.

Most of the issues on which we have worked continue to need our attention, although perhaps in somewhat different forms than in the past. The advent of the Internet and the increasing globalization of our economy have required us to adapt to a new era. Like the law itself, we will continue to evolve as we meet the legal challenges of the 21st century. [IPCL](#)

Corporate Accountability

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tions that criticize corporate behavior.

The other danger is that injured citizens will not get their day in court because public attitudes and huge campaign contributions facilitate corporate-written legislation that makes legal redress too costly or difficult. Since the outset of this corporate onslaught, Public Citizen has been the leading voice in the public interest community to stop the enactment of federal legislation pushed by hundreds of huge companies to preempt state liability laws. This federal legislation is designed to overturn pro-consumer state laws so that companies won't be held accountable for reckless misconduct that injures consumers or defrauds them.

Public Citizen has played an instrumental role in stop-

ping federal bills limiting liability for faulty products, asbestos, tobacco and Amtrak crashes. We also helped stop bills that would have attacked the ability of consumers to bring class action lawsuits, limited punitive damage awards and instituted a no-fault auto insurance scheme that will harm innocent crash victims.

If such federal legislation had been enacted in the 1990s, we might never have learned about the Firestone/Ford Explorer defects, and hundreds of families who have suffered grievous losses would remain uncompensated. The company documents that reveal the true story would still be buried from view. And the auto and tire companies would not be madly redesigning their vehicles and tires to reduce the likelihood of rollover crashes and tragic injuries. [IPCL](#)