

The CHAIRMAN. Thank you very much.
Dr. Wolfe.

STATEMENT OF DR. SIDNEY M. WOLFE

Dr. WOLFE. According to Judge Breyer, because the existing system fails to rationally cope with risk assessment management, a new entity, a priesthood of people outside of the regulatory agencies, the courts and the Congress, should be created, according to what he states in his book "Closing the Vicious Circle."

As a frequent critic of and litigant against FDA and OSHA, I am not here to say that these agencies are perfect, but I believe that through existing mechanisms, including the checks and balances of the other parts of the Government and citizen participation, that these agencies could be made to function better.

If there is one reason why they do not currently function better, it is not because of the absence of a Judge Breyer "risk superbody," but because of relentless interference with their function by corporations which withhold information, submit false information and otherwise obstruct the activities of these agencies.

I am just going to go through several examples, all of which are taken from his book "Closing the Vicious Circle." They are just representative examples of a much larger number of instances in which Judge Breyer has done I believe sloppy and often in many cases biased research.

The first has to do with the Delaney clause. Yesterday, when he testified here, he talked about we can't count molecules, what number of molecules, and the implication was that there is government regulatory activity being taken on the basis of a few molecules.

One of the ways of criticizing Federal health and safety regulations is to paint a statute as ridiculous. In his book, Judge Breyer paints the 30-year-old amendment to the Food, Drug and Cosmetic Act, the Delaney clause as ridiculous. The Delaney clause prohibits the addition of any food or color additive which, in well-done studies in animals or humans, has been shown to cause cancer.

On page 41 of the book, he states that:

Occasionally, a statutory provision goes further itself, setting a standard that, if applied literally, seems unreasonably and pointlessly strict. The Delaney Clause seems to instruct the agency not to permit addition or packaging of or by any substance that contains even a single molecule of an offending chemical, however large the cost or small the risk.

In making this faulty assertion, Judge Breyer has either missed or ignored FDA's constituents policy, which was set over 10 years ago, which makes it clear that his fears of unreasonably and pointlessly strict interpretation of the Delaney clause are unfounded. This policy was upheld in the face of a Federal court challenge, and it arose over FDA's decision to approve a drug and cosmetic dye, Green 5, even though the dye contained trace amounts of a chemical impurity, p-toluidine, which itself was a carcinogen.

The FDA found that, although the contaminant carcinogen, when it was fed itself in large quantities, caused cancer, that it was there in such a small amount in the dye, that when the dye was fed to animals, they did not get cancer. It concluded this was not a food additive or a color additive, and in this case it showed that the

Delaney clause is a good law, that it has some reason and it is not "unreasonably and pointlessly strict."

Other errors in the book include his gross understatement of the number of workers who are injured or in this case killed every year from occupational cancer. He says that all people killed by cancer from pollution and industrial products amount to only 10,000 to 50,000 deaths a year. But in the footnotes, not in the text of the book, buried in the footnotes he has estimates ranging from 75,000 to 150,000 cancer deaths a year, and for occupational cancer alone one estimate is as high as 75,000.

But worse is the omission of the importance of preventing occupational cancer. He says that:

Only a relatively small portion of these chemical induced cancers are preventable. In fact, almost all of the 10,000 to 100,000 occupational cancer deaths (the range in the book) are preventable.

To his credit, when I pointed this out to him, in the second edition of the book he changed it.

Most of the evidence for chemical induced cancer is among workers. Therefore, most chemical induced cancer from inexcusably delayed regulation of various substances, including benzene, cadmium, and chromium, is and has been preventable and regulatable. He also denigrates the ability to regulate cigarettes and tobacco, claiming that only 30 percent of those cancer deaths could be prevented. I think there is lots of evidence that that is not the case.

Another error in the book is that he seems to go with the OMB conclusion, as he calls it, that there is an overestimation of risk of a thousand or a million times, particularly in the area of environmental hazards. The conclusion that he cites is actually from an OMB economist, and this conclusion was attacked by a large group of prestigious risk-assessment experts, including the former Director of the National Cancer Institute.

In the letter they wrote to the White House, refuting this notion that there is a systematic 1,000 to 1,000,000 overstatement of risk, they said:

The broader allegation that risk assessment is generically "conservative" is demonstrably suspect. * * * The OMB document (and the references cited therein) fails to provide any evidence that risk assessment is, in fact, systematically "conservative."

Finally, an example that you have discussed a number of times during this hearing, the toxic dump site in Kingston, NH, known because of its name in the litigation as *Ottati and Goss*. In the book, there are a number of statements that Judge Breyer makes referring to this case, including the idea that the site was mostly cleaned up, that it was a swamp and, therefore, children would not play there, and that the parties had agreed that half of the volatile organic toxic chemicals would evaporate by the year 2000.

In the actual opinions that he wrote on this case, and in other documents we have obtained, these statements are demonstrably false. The statement that the site was mostly cleaned up is refuted in his own opinion in the first circuit, in which he said:

We remand this aspect of the case to the district court so that it can devise a further volatile organic chemical cleanup which, in light of its findings about danger to the public health, will adequately satisfy the public interest.

He also said in the opinion that:

The studies and related testimony indicate that such overstandard concentrations, too high concentrations of these toxic chemicals, are widespread and in significant amounts within the total test area.

Elsewhere in the opinions in his court and in the district court and in briefs filed in the case is other evidence that these statements about this case, which he uses repeatedly in the book to cite the example of ridiculous government regulation, are wrong. In the Government's brief, the site, this toxic dump site was referred to by one of the defendants' own counsel as "severely contaminated."

Other evidence concerning it has to do with levels of ground water contamination which, according to a State official I spoke to yesterday, are thousands of—are more than a thousand times higher than the allowable amount of contamination in ground water. And right now, despite the fact that Judge Breyer characterized this site as mostly clean several years ago, there is a massive cleanup effort beginning to try and do something about the ground water so that it does not migrate to adjacent sites where people are likely to live. He also characterizes it as a swamp, which it is not. It is actually zoned for rural residential use.

Finally, he claims again in the book that half of the volatile organic chemicals will evaporate by the year 2000, and the planned cleanup of the site belies that. In fact, that statement was made by the counsel for the defendant. The parties did not agree on that.

In conclusion, for me and for many others concerned about occupational and environmental health and food safety, it is extremely disappointing that President Clinton was unable or unwilling to nominate someone with a more enlightened attitude toward the solution of these serious problems. Although stating that economic considerations are not as decisive in health, safety, and environmental regulation, Judge Breyer's views as expressed in this book amount to an unfair and unwarranted bashing of the very Federal agencies who are trying to prevent toxic chemical-induced deaths and illnesses. I can only hope that, good listener that he is, Judge Breyer will listen to these concerns and, to use his terms, become more influenced by the humanity of John Donne than by the corporate hand of Adam Smith, as he appears to be at this time.

Thank you.

[The prepared statement of Dr. Wolfe follows:]

PREPARED STATEMENT OF SIDNEY M. WOLFE, M.D.

In statements made at these hearing on Tuesday, July 12, Judge Breyer said that he distinguished between classic economic regulation (airlines and trucks) and health, safety and environmental regulation. He said: "When you start talking about health, safety and the environment, the role [of economics] is much more limited, because there no one would think that economics is going to tell you how much you want to spend helping the life of another person. If in fact people want to spend a lot of money to help save earthquake victims in California, who could say that was wrong? * * * That's a decision for Congress to make reflecting the values of people." Whereas there is no reason to question Judge Breyer's attitudes about the victims of natural disasters, his recent book, *Closing the Vicious Circle* deals exclusively with industry-caused disasters. Throughout the book are examples wherein he minimizes the risks of exposure to various chemicals and questions and deprecates health and safety laws or the efforts which the federal health and safety agencies make to protect the lives he professes to cherish.

According to Judge Breyer, because the existing system fails to rationally cope with risk assessment and its management, a new entity, a priesthood of people outside of the regulatory agencies, the courts and the Congress, should be created. As a frequent critic of, and litigant against the FDA and OSHA, I am not here to say