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

these agencies are perfect. I believe, however, that through existing mechanisms, including the checks and balances of the other parts of the government and citizen participation, that these health and safety regulatory agencies can 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.

The examples of flawed and/or biased research by Judge Breyer which I will discuss are drawn from his recent book, *Closing the Vicious Circle,* originally published in 1993, with the slightly revised edition published several months ago. These are but a few representative examples of a much larger number which Judge Breyer discusses in the book.

THE DELANEY CLAUSE

One of the ways of criticizing federal health and safety regulation is to paint a statute as ridiculous. Judge Breyer, in *Closing the Vicious Circle* does just that with the Delaney Clause. This 30-plus year-old amendment to the Food Drug and Cosmetic Act 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, Breyer states that "Occasionally a statutory provision goes further, itself setting a standard that, if applied literally, seems unreasonably and pointlessly strict. * * * The Delaney Clause, applicable to food [and color] additives * * * seem[s] to instruct the agenc[y] 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, Breyer has either missed or ignored FDA's constituents policy, which makes it clear that his fears of an "unreasonably and pointlessly strict" interpretation of the Delaney Clause is unfounded. This policy—in effect for more than a decade—has been upheld in the face of a federal court challenge. In 1982, the FDA approved a drug and cosmetic dye. Green 5, even though the dye contained trace quantities of a chemical impurity, p-toluidine, itself a carcinogen. Although p-toluidine alone, fed in large quantities, was a carcinogen, large quantities of Green 5, even though containing trace amounts of p-toluidine, *did not* cause cancer in animals. In its 1982 regulation approving of the dye, the FDA argued that p-toluidine itself was not a color additive and that, therefore, the Delaney Clause was inapplicable. This regulation was upheld in *Scott* v. *Food and Drug Administration* 728 F.2d 322 (6th Cir. 1984).

In this case, involving a direct color additive, it is clear that the FDA has the authority and flexil ility to apply the Delaney Clause, in the case of food or color additives, in a way which protects the public health but which, Judge Breyer notwithstanding, is not "unreasonably and pointlessly strict."

UNDERSTANDING OCCUPATIONAL AND ENVIRONMENTAL CANCER DEATHS

On page 6 of the book, Breyer states that the "range of expert estimates" for those cases of cancer which are caused by pollution and industrial products is from 10,000 to 50,000 deaths a year out of the 500,000 cancer deaths each year. In the endnotes, at the back of the book, however, is one expert estimate which has occupational toxic chemicals causing from 10 to 20 percent of all cancers and environmental toxic exposures causing from 5 to 10 percent of all cancers for a sum of 15 percent to 30 percent of all cancers or 75,000 to 150,000 cancer deaths a year. Another expert mentioned in the back of the book—former government occupational health physician Dr. Phillip Landrigan, now Chief of Occupational Medicine at Mount Sinai School of Medicine—estimated that occupational cancer along may account for as many as 75,000 cancers deaths a year. This is also cited in the references but ignored in the text of the book.

Equally striking is the omission, in the first edition of the book, of the importance of preventable occupational cancer. On page 6, it says that "only a relatively small portion of these [chemically-caused cancers] are preventable." In fact, almost all of the 10,000 to 100,000 occupational cancer deaths (the range of the expert estimates cited by Breyer in the book) are preventable and, to his credit, when this serious error was pointed out, the second edition was changed. Most of the evidence for chemical-induced cancer is among workers. Therefore, most chemical-induced cancer—from inexcusably delayed regulation of such substances as benzene, cadmium, chromium, ethylene oxide and many other chemicals—is and has been preventable and "regulatable."

ACCUSATIONS ABOUT OVERSTATING RISKS

On page 47 of the book, and in many other places, Breyer argues that, especially in the area of EPA and OSHA regulation, the magnitude of risk is greatly overstated. On page 47, Breyer says, "OMB argues that the agencies apply these assumptions too conservatively; it concludes that, taken together, they 'often' overstated risks by factors of 1,000 or even a million or more. * * * At the same time, even such assumptions sometimes can overlook special, much greater than average exposures—exposures via multiple pathways, or exposures that pose special risks to those who also smoke or are also exposed to other chemicals."

To illustrate his statement that OMB "concludes" that regulators who use conservative assumptions to estimate risk may overstate risks by 1,000 to one million times, Breyer cites OSHA's basis for setting standards for cancer-causing chemicals (page 46 of *Closing the Vicious Circle*): OSHA assumes factory worker exposure 8 hours a day, 5 days a week, 50 weeks a year for 45 years, that agency's example of this "conservatism".

In fact, OMB's conclusion about overstated risks is from a 1990 OMB report, "Current Regulatory Issues in Risk Assessment and Risk Management", written by OMB economist Richard Belzer. The report was attached by a prestigious group of experts in risk assessment including former National Cancer Institute Director, Dr. Arthur Upton, former *New England Journal of Medicine* epidemiology consultant and current Chair of the Department of Epidemiology, McGill University, Dr. John Bailar, Dr. Clark Health, Vice President for Epidemiology and Statistics, American Cancer Society and Dr. Adam Finkel, of the Center for Risk Management, Resources for the Future.

In a January 30, 1991 letter from these scientists to Dr. D.A. Bromley in the White House Office of Science and Technology Policy, they stated that "The broader allegation that risk assessment is generically 'conservative' is demonstrably suspect—The OMB document (and the references cites therein) fails to provide any evidence that risk assessment is in fact systematically 'conservative'."

In summary, on this point of a 1,000 to one million times overstatement of risk, the evidence to support such a claim is non-existent, in 1991 as well as the present.

TOXIC SUPERFUND DUMP SITE: KINGSTON, NEW HAMPSHIRE

In the first Superfund site case under that law, a toxic dump site, known as *Ottati and Goss* was the subject of litigation by EPA in a Federal District Court and in the First Circuit Court of Appeals in Boston, the court where Judge Breyer is the Chief Judge. The purpose of this example is not to challenge the First Circuit's upholding of the District Court's ruling that there was a need for abatement/remediation of the contaminated groundwater. Instead, the dispute is with the misleading way Judge Breyer characterizes this case in the book. On page 11 and 12, he says: "The site was mostly cleaned up." Referring to the concerns of children eating contaminated dirt on the site, he said "But there were no dirt-eating children playing in the area, for it was a swamp. Nor were dirt-eating children likely to appear there, for future building seemed unlikely. The parties also agreed that at least half of the volatile organic chemicals would likely evaporate by the year 2000."

What follows is drawn from the District Decision, the First Circuit's decision, and the government's (EPA's) brief (GB) and reply brief (RB) in the First Circuit Court of Appeals.

*A. "The site was mostly cleaned up."*

The site was *not* mostly cleaned up, and Judge Breyer knows this. Judge Breyer states, "We have examined those portions of the record that the parties have cited in their briefs." 900 F.2d 429, 432 (1st Cir. 1990). (a) IMC's (the remaining defendant's) own expert admitted that the average concentration of PCBs left on the site after cleanup was 87 ppm, "The contractor * * * seems to have accepted a characterization of an 'average' level of 87 [ppm] as reasonable." 900 F.2d 440, (b) A post cleanup study of 62 randomly selected test sites amounting to less than 1 percent of the site's total area, "uncovered 4 drums in that small area alone." Government Brief p. 40, (c) the PCB concentrations in the soil at the site are well above 50 ppm, and at least as high as 143 ppm. Three of five "samples exceeded 50 ppm (56, 134, and 143 ppm, respectively)," 900 F.2d 441, (d) "[t]he government's eight laboratory samples for VOCs at the IMC site post cleanup showed VOCs as high as 870 ppm," GB p. 46, (e) "[w]ithout VOC soil cleanup, the source of groundwater contamination will persist for decades," GB p. 47, and (f) IMC's own witness's statement that he "would be amazed if there were not some PCBs on the surface." Reply Brief, note 6. IMC also admitted using soil with PCBs up to 50 ppm as backfill, 694 Fed Supp 977, 982 (D.N.H. 1988).

*B. "The remaining private party litigated the cost of cleaning up the last little bit, a cost of about $9.3 million to remove a small amount of highly diluted PCBs and 'volatile organic compounds' (benzene and gasoline components) by incinerating the dirt."*

Not a "last little bit" (VOCs 870 ppm, average 87 according to IMC; 3/5 samples were greater than 50 PCBs, 900 F.2d 441).

The PCB left was not a small amount and was not highly diluted.

The VOCs left consisted of more than benezene and gasoline: acetone, arsenic, chloroform, creosol, toluene, trichloroethylene (which was found to be 3,000 times higher than the acceptable concentration in some of the wells), to name a few (comprehensive list at 630 Fed Supp 1361, 1383–90 (D.N.H. 1985)).

*C. "But there were no dirt-eating children playing in the area there, for it was a swamp. Nor were dirt-eating children likely to appear there, for future building seemed unlikely."*

A description of the site is found at 630 Fed Supp 1366. "The site is zoned rural residential according to the Kingston Zoning Ordinance," meaning "you can build a single family or a two story dwelling." Fed Supp 1000. "But the undisputed fact is that the site is zoned residential, which means that it may be developed for virtually any purpose." RB at 6.

There is no building there, but not because it is a swamp. "* * * IMBC's real estate witness stated that the site could have developed residentially but for the contaminate remaining on site, and explained that his conclusion concerning current development of the site was based on a view of the property during which he saw 'horrible looking water' and on the statement by IMC's counsel, after IMC's cleanup attempt, that the site was 'severely contaminated.'" RB at 7.

*D. "The parties also agreed that at least half of the volatile organic chemicals would likely evaporate by the year 2000."*

An IMC expert testified to this theory, 900 F.2d 440, but the Government disputed it in detail, "Allowing mere diffusion of VOCs in the soil rather than remediation would result in effectively condemning the site for use the foreseeable future, a 'remedy' plainly not permissible under Section 121 of CERCLA." See 42 U.S.C. 9621(b)(1) (strong preference for remedial action which "permanently and significantly reduces the volume, toxicity or mobility of the hazardous substance)." RB p. 7.

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 ad, to use his terms, become more influenced by the humanity of John Donne than by the corporate hand of Adam Smith, as appears to be the case at this time.

The CHAIRMAN. Thank you, Dr. Wolfe.

Mr. Constantine.

## STATEMENT OF LLOYD CONSTANTINE

Mr. CONSTANTINE. Thank you, Senator. It is a pleasure to be back here again.

I oppose the nomination of Judge Breyer principally on the basis of his antitrust jurisprudence. One might ask why Judge Breyer's record in this area should be of substantial concern for the Senate. I think it should for several reasons.

Judge Breyer is a leading antitrust scholar and jurist who has written many important decisions interpreting our competition laws. I believe an understanding of the way Judge Breyer approaches his role as a judge in antitrust cases is crucial to under-