TWO

# The Corrosive Effects of Politicized Regulation of Science and Technology

HENRY I. MILLER

**There is politicization,** and there is politicization. The Random House dictionary defines "political" in a number of ways, including: "pertaining to, or connected with a political party; and exercising or seeking power in the governmental or public affairs of a state, municipality, etc." So when we talk of the politicization of public policy concerned with the oversight of science and technology, we can mean a number of things, not all of them necessarily bad. Not necessarily, but commonly. The term is usually used to imply politicians' undue or inappropriate influence over governmental activities or processes in order to achieve some sort of partisan gain.

When political fortunes change and a new party comes into power in the Executive Branch, one expects a change in overall philosophy of government—and the same is true of the Congress,

which exerts oversight over the activities and actions of executive departments and agencies. Such changes are part and parcel of the political process. However, the imposition of heavy-handed, improper coercion and influence on governmental, science-based activities during the Clinton administrations were outside the usually recognized rules of the game.

## Science Gored

As congressman, senator, and vice president, Al Gore was one of the most ruthless and determined politicians of his generation. As vice president, he exercised unprecedented interference in public policy related to technology. What could be the motivation for what were, in fact, antitechnology actions by this man who extolled the importance of technology, and whose spin doctors presented him as something of a science and policy wonk? Vice President Gore's attitudes, ascertained from his extensive writings over many years, provide a clue.

While a congressman and self-styled expert on biotechnology issues, Al Gore praised Jeremy Rifkin's shoddy antibiotechnology diatribe, *Algeny*, as "an important book" and an "insightful critique of the changing way in which mankind views nature."[1] In a 1991 article in the *Harvard Journal of Law and Technology*, then-Senator Gore displayed an astounding lack of appreciation of the historically positive linkage between science and economic development. He disdainfully described investors' eager reception of Genentech's 1980 stock offering as the first sellout of the "tree of knowledge to Wall Street,"[2] ignoring that much of the modern economy is built on physics, chemistry, and geology, and that

1. A. Gore, Jacket quotes for J. Rifkin, *Algeny* (New York: Penguin Books, 1983).

2. A. Gore, "Planning a New Biotechnology Policy," *Harvard Journal of Law and Technology* 5 (1991): 19–30.

biotechnology was a $100 billion industry long before the gene-splicing industry emerged, regularly making impressive contributions to the betterment of human health and the environment, using microorganisms to produce antibiotics, enzymes, vaccines, beverages and other products, and genetics to breed more nutritious crops requiring less cultivated land.

In the same article, Gore coined a "principle that applies to regulating new and strange technologies such as biotechnology": "If *you* don't [regulate], you know somebody else will" (emphasis in original).

Gore was not entirely pessimistic about biotechnology's possible contributions to better processes and products, but, in an original but bizarre twist, he worried about biotechnology's possible success:

> The most lasting impact of biotechnology on the food supply may come not from something going wrong, but from all going right. My biggest fear is not that by accident we will set loose some genetically defective Andromeda strain. Given our past record in dealing with agriculture, we're far more likely to accidentally drown ourselves in a sea of excess grain.

It is doubtful that that apprehension is shared by developing countries, confronted by the prediction that over the next century the world's population is expected to more than double, from 5.5 billion to about 11.3 billion people, with more than 80 percent of the additions expected to reside in their regions.

Gore's attitudes toward biotechnology are consistent with his views of science generally, which he presents in *Earth in the Balance*.[3] Throughout the book, he employs the damning comparison that those who believe in technological advances are as sinister, and polluters are as evil, as the perpetrators of the World

3. A. Gore, *Earth in the Balance* (New York: Plume, 1992).

War II Holocaust. He decries the separation of science and religion. He accuses Americans of being dysfunctional because we've developed "an apparent obsession with inauthentic substitutes for direct experience with real life," such as "Astroturf, air conditioning and fluorescent lights . . . Walkman and Watchman, entertainment cocoons, frozen food for the microwave oven," and so on. Should we assume, then, that Mr. Gore has returned to an air-conditioning-, microwave-, TV-, VCR-, and DVD-free existence in Tennessee?

## The Gore Appointments

As the Clinton administrations' science and technology czar, Gore chose many high-level appointees to regulatory agencies—and, thereby, politicized agency policies and decisions. And what a collection of yes-men and antiscience, antitechnology ideologues they were:

- *Presidential science adviser Jack Gibbons,* one of the less distinguished people to occupy that important post;
- *Environmental Protection Agency Administrator and Gore acolyte Carol Browner,* whose agency was condemned repeatedly by the scientific community and admonished by the courts for flawed policies and decisions;
- *Food and Drug Administration Commissioner Jane Henney,* rewarded with that position after politicizing the agency's critical oversight of food and drugs while she was its deputy head;
- *Jerrold Mande,* an untalented nonentity whom FDA officials regarded as Vice President Gore's "political commissar" at the agency;
- *State Department Under Secretary Tim Wirth,* who worked tirelessly to circumvent Congress's explicit refusal to ratify

radical, wrong-headed treaties signed by the Clinton administration;

- *Agriculture Under Secretary Ellen Haas,* former director of an antitechnology advocacy group, who reconstructed science thusly, "You can have 'your' science or 'my' science or 'somebody else's' science. By nature, there is going to be a difference."[4]

## Public Policy Gored

Gregory Simon, Vice President Al Gore's senior domestic policy adviser, represented a low point of the Clinton administration appointments that politicized science. A lawyer without scientific training or experience (and, therefore, a typical Gore choice for directing science policy), Simon had been a nemesis of the new biotechnology even before his tenure in the White House. While a staffer on the House Science, Space, and Technology Committee, Simon had authored the Biotechnology Omnibus Act of 1990, HR 5232, which was science-averse, would have created potent regulatory *dis*incentives to the use of the most precise and predictable genetic technology, and had no pretense of protecting consumers from genuine risks. The bill, had it become law, could have initiated the devastation of the biotech industry several years before the Clinton administration's health care reform and regulatory policies actually began it in the mid-1990s.

After becoming the vice president's aide, Simon in his public utterances revealed no diminution of his troglodytism. Simon said that the actual degree of biotech's risks is irrelevant, that the new biotechnology must be subjected to a high degree of governmental

4. E. Haas, "Diet Risk Communication: A Consumer Advocate Perspective," in G. E. Gaull and R. A. Goldberg, eds., *The Emerging Global Food System* (New York: Wiley & Sons, 1993), pp. 133–46, esp. p. 134.

control and regulation in order to calm a "hysterical" public. He went on to opine that, for regulatory purposes, biotech products simply cannot be compared to traditional products and that "consumers will have to change their concept of how food is made" before they will accept the technology.[5] His statements cannot be reconciled with consumers' actual attitudes and behaviors or with scientific consensus about the safety of the new technology.

## Eliminating Opponents

The intolerant nature of their practices was as troubling as the substance of the Clinton-Gore policies. Gore, Simon, et al. brooked no dissension or challenge to their views and acted to purge those whom they considered to be their "enemies." In order to slant—that is, to "politicize"—federal science and technology policy and to rid the civil service of dissenting views, Gore and Simon interfered in federal personnel matters to an unusual degree.

For example, Simon threatened a high-ranking official at the Department of Energy with retaliation if she hired David Kingsbury, the former assistant director of the National Science Foundation. (Simon and Kingsbury had clashed on biotechnology policy in earlier years, and, as a congressional staffer, Simon had hounded Kingsbury from government with unsubstantiated charges of conflict of interest.) Simon also improperly ordered FDA to remove a senior civil servant from his position at FDA. Agency officials admitted that this was retribution for the "transgression" of having implemented Reagan-Bush policies effectively.

William Happer, in his chapter in this volume, describes his

5. B. Davis, Harvard University, personal communication; R. Hoyle, "Comments from the White House's Greg Simon," *Bio/Technology* 11 (1993): 1504–5.

dismissal from a senior scientist position at the Department of Energy because his interpretation of the scientific evidence about ozone depletion and global warming conflicted with those of the vice president's advisers. Similar incidents occurred at the departments of State, Energy, and Interior, and at EPA, where a number of prominent civil servants were moved to less visible positions and a number of others were replaced—for their own "protection"—with more "acceptable" officials during interactions with the White House.

## Green Accounting

In 1994, the Commerce Department's Bureau of Economic Analysis introduced its so-called economic-environmental accounting framework to calculate the country's "Green GDP."[6] Just as a conventional accounting ledger includes an entry for depreciation of plant and equipment, the bureau's system attempted to record the "degradation of natural assets." In this theory of accounting, U.S. government grants for solar energy research could be considered *income*, while funding on nuclear energy could be counted as *expenditures* and grants from the World Bank to radical environmental groups could be counted among the bank's *income*, while the value of electricity from a new dam financed by the organization could be counted among the bank's *expenditures*.

Gore tried to move his ideas into international relations by a policy that would punish countries that didn't go along. At Gore's direction, the State Department produced *Environmental Diplomacy*, a slick but bizarre document with forewords by the vice president and Secretary of State Madeleine Albright. It includes statements such as "[the world bank should factor] environmental

6. "Al Gore and the Environment." http:/www.whitehouse/gov/wh/eop/ovp/html/Enviro_GDP.html, May 1, 1996.

implications into its lending decisions," with which few would disagree, but, on balance, it reads like a Greenpeace manifesto or, not coincidentally, like Gore's *Earth in the Balance*, echoing the claim that "[c]lassical economics defines productivity narrowly and encourages us to equate gains in productivity with economic progress. But the Holy Grail of progress is so alluring that economists tend to overlook the bad side effects that often accompany improvements."

The statement ignores the repeated efforts of economists to incorporate and evaluate externalities in their assessments, but Gore's proposed remedy for the "fault" he had identified was to redefine the relevant measures of economic activity. As adopted by the State Department, the new accounting system had a clear purpose: to enable governments to obscure the costs of environmental protection by calling them "benefits" and to force businesses to list wealth-creating activity as societal "costs." The effects of this doublespeak, if widely implemented, would be profound: companies around the world would see their regulatory expenses skyrocket and their markets shrink. Consumers would pay inflated prices for fewer products and higher taxes to support bloated bureaucracies.

*Environmental Diplomacy* stated that the State Department would focus its regional and bilateral environmental diplomacy on several key areas, one of which was "land use."[7] The State Department would add decisions about foreign countries' "local and national leaders weigh[ing] the competing goals of protecting a forest against providing additional croplands" in deciding on U.S. foreign policy. Such purely domestic actions by sovereign nations acting in what they consider to be their best interests "have social, environmental, and economic implications, which in turn affect our foreign policy." Mr. Gore and Ms. Albright in-

7. *Environmental Diplomacy* (Washington, D.C.: U.S. Department of State, 1997).

tended that U.S. policy toward foreign countries should turn on those countries' domestic economic decisions—whether, for example, the French government chose to harvest an old-growth forest in Burgundy or Mexico City decided to build additional highways instead of a subway system.

If this U.S. policy seems extreme, so are its philosophical underpinnings, as laid out in *Earth in the Balance*. The apocalyptic central thesis of Mr. Gore's book is that we need to take "bold and unequivocal action . . . [to] make the rescue of the environment the central organizing principle for civilization." The events of September 11, 2001, and the ensuing efforts against international terrorism illustrate how unspeakably myopic and self-absorbed was this view of the "civilization's" appropriate priorities.

## Gore's Policies and Science at Federal Agencies

Citizens, business people, members of consumer and environmental groups, and officials of state and local governments who have business with the federal government seldom interact directly with the White House or the State Department. Instead, their routine contacts are with federal agencies, such as the Food and Drug Administration (FDA) or the Environmental Protection Agency (EPA). Gore-influenced appointments to those agencies tilted FDA and EPA to his antitechnology, antibusiness positions, with potentially long-lasting consequences for the health of the nation's citizens and the nation's applications of science and technology to its problems.

### Dr. Kessler's FDA

There is wide agreement that reform of the FDA has long been necessary. Bringing a single new drug to market in the United

States now takes twelve to fifteen years and costs the manufacturer on average more than $800 million, by far the highest price tag in the world. Profits only sometimes offset these costs, and a Duke University study reveals a sobering corollary—fewer than three out of every ten drug products generate revenues that cover their development costs.[8]

This trend is at least partly the result of the FDA's capricious decisions about clinical trials necessary to establish the safety and efficacy of new drugs and its continual raising of the bar for approval. The average number of clinical trials performed on an average drug increased from 30 in the early 1980s to 68 during 1994–95; the average number of patients in clinical trials for each drug more than tripled; the average time required for clinical trials of a new drug increased from 85 to 92 months between the first and second halves of the 1990s. In all, between five and eight years are necessary for basic research, preclinical (animal) studies, clinical trials, and review time before a drug receives marketing approval from the FDA (if approval is granted).

During the 1990s, the FDA changed rules and policies that added further costs and time to the development of new drugs, but provided little or no additional protection of public health. The agency's policies mean that drug companies increasingly can afford to develop only products that are potential financial blockbusters, while drugs for life-saving but narrower uses are neglected. Already-huge drug companies find it necessary to merge in order to achieve even greater economies of scale.

When he became FDA commissioner in 1991, David Kessler promised dramatic changes, that—to use a term he repeated in many lectures—he "would teach the elephant to dance." And Kessler did—to a tune called by flacks and politicians. Right out

8. H. G. Grabowski and J. M. Vernon, "Returns to R&D on New Drug Introductions in the 1980s," *J. Health Economics* 13 (1994): 383–406.

of the gate, Kessler chose a high-profile but ludicrous case that was calculated to get him on the evening news in a virile demonstration of being tough on industry. Defective heart valves, a contaminated vaccine, a drug causing sudden death? No, Citrus Hill orange juice. Kessler commanded federal marshals to confiscate 15,000 gallons of juice. Was it spoiled, contaminated, unfit for human consumption? Nope. It was labeled "fresh" when it was actually made from concentrated orange juice. Federal guidelines say it is inaccurate to call orange juice "fresh" if it's made from concentrate.

On CBS' *60 Minutes*, Kessler expressed his indignation, "[the juice] was made from concentrate. My grandmother could have told you, I mean, it wasn't fresh. It wasn't very hard [to tell the difference]."

Wouldn't consumers have been justified in asking Dr. Kessler: "If we can so easily tell by taste that the juice came from concentrate and is inferior, why not simply let *us* decide whether we like the product well enough to buy it again? Why aren't you more concerned about our taxpayer dollars footing the bill for FDA's regulatory compliance staff and lawyers, and for the federal marshals who corralled the outlaw juice? And doesn't FDA have anything more important to worry about?"

One suspects that Kessler's *grand-mère* might have been more pragmatic. In private and public, Kessler admonished his staff to "get tough," publicly he said that FDA is an "enforcement agency" and that, by God, industry will know it. (I know from personal experiences that Kessler took a different line when meeting privately with industry. He explained that the bluster about enforcement was just for show, to keep FDA's left-wing critics off his back. He assured them that he was very sympathetic to industry. Kessler's statements reflect the overtones expressed by Gore when he said that it was important that people who agreed with

him regulate because otherwise someone else would. Someone else, of course, wouldn't do it right.)

Pressures to alter FDA's practices and methods had been building for years, and they continued in the early years of the Clinton administration, reaching fruition in the sweeping Drugs and Biological Products Reform Act of 1996, HR 3199. The bill went down to ignominious defeat. The demise of this attempt to reform the nation's premier regulatory agency offers an interesting case study in political dishonesty and mendacity.

The bill would have permitted the FDA to dispense with the requirement that manufacturers turn over voluminous raw data from clinical trials. Manufacturers instead would have delivered condensed, tabulated, or summarized data—just as they do now in submissions to the FDA's foreign counterparts—and the agency would have retained authority to obtain additional material when needed.

The legislation would also have established a more liberal approval standard for drugs intended to treat any "serious or life-threatening" condition. Like the then-current standard for review and approval of AIDS drugs, the new criterion would have allowed easier patient access to a drug when there is "a reasonable likelihood that the drug will be effective in a significant number of patients and that the risk from the drug is no greater than the risk from the condition." That common-sense, humane principle would have extended to patients with diseases like stroke, multiple sclerosis, Alzheimer's disease, emphysema, crippling arthritis, and heart failure the benefits reserved for those with AIDS.

The bill would also have ameliorated to a large extent the FDA's censorship of scientific and medical information concerning off-label uses by permitting the legitimate dissemination of information about non–FDA approved uses of drugs to health professionals and the public via textbooks and articles from peer-

reviewed journals.[9] It would also have permitted retrospective evidence from clinical research to be used for approval of additional, off-label uses of drugs already on the market. Normally, FDA requires expensive and time-consuming new studies for such uses even when some data from the original tests (collected in studies to address other medical conditions) are perfectly adequate. Such reforms would have cut down both on the time and the costs involved in securing FDA approval for additional uses of drugs.

The legislation's most significant reform—along the lines of proposals made by William C. Wardell and me in the Progress and Freedom Foundation's study, *Advancing Medical Innovation*—would have introduced nongovernmental alternatives to some FDA oversight.[10] Under its provisions, pharmaceutical manufacturers could have opted for product review by FDA-accredited nongovernmental organizations—private- or public-sector (e.g., academic) entities. Each of these institutions would have been subject to periodic FDA audits, and strict requirements backed by civil and criminal sanctions would have assured the confidentiality of data and the absence of conflicts of interest. Alternatively, the manufacturer could still have opted for review by the FDA, and in all cases the agency would have retained the responsibility for final sign-off of marketing approvals.

Of course, permitting both governmental and private-sector alternatives while maintaining FDA's sign-off on its competitors' recommendations is rather like giving the Coca-Cola Company

9. Drugs that are developed, approved, and marketed for a particular disease or diseases are sometimes found to be effective for other diseases, for diseases that don't appear on the "label" that describes the benefits of the drug. About half of all prescriptions are written for such "off-label" uses.

10. W. C. Wardell and H. I. Miller, "Therapeutic Drugs and Biologics," in R. A. Epstein et al., *Advancing Medical Innovation* (Washington, D.C.: Progress and Freedom Foundation, 1989), pp. 79–102.

the right to sign off on Pepsi taste tests. In spite of such shortcomings, had it been enacted the bill would have been a significant step toward loosening the FDA's monopoly grip on drug testing and evaluation and making drug regulation more efficient.

Politics sealed the fate of HR 3199. The FDA and its supporters in the Clinton administration saw the legislation as a threat to the federal government's regulatory hegemony, and they pulled out all the stops to defeat it. Phil Lee, the Assistant Secretary of Health and Human Services, dismissed the bill and anything resembling it as nothing more than veto-bait. FDA Commissioner David Kessler registered the FDA's opposition to the House bill in a nine-page statement, "The Impact of the House FDA Reform Proposals," that was remarkable for revealing the lengths to which an agency head will go to protect the status quo.[11]

Kessler asserted, "FDA would be forced to approve new drugs using summaries of safety data prepared by drug companies." Untrue. The bill would have allowed FDA experts to depend on condensed, tabulated, or summarized data (when considered adequate) rather than reviewing the voluminous raw data from clinical trials, often running to hundreds of thousands of pages. In all cases, agency reviewers would have had access to additional materials as well, and could have obtained them by a simple request from an FDA supervisory official.

To make his case, Kessler cited the example of a drug called Dilevalol, which he said was approved in Japan, Portugal, and England on the basis of data summaries. Americans, he said, were spared morbidity and mortality because "the FDA medical reviewer noted in the raw data evidence that some patients had severe liver injury." Another untruth. The record shows it was

11. Food and Drug Administration. "The Impact of the House FDA Reform Proposals [background paper]" (Washington, D.C.: FDA, 1996), 9 pp.

the *company*, Schering-Plough, that identified the toxicity and ultimately withdrew the application for U.S. approval.[12]

Kessler claimed that the legislation would weaken the effectiveness standard for drugs and that the FDA would be forced to approve a new use for a drug on the bases of "anecdotal evidence of effectiveness" and "common use by physicians (with no objective evidence)." The price, he concluded, would be "the unnecessary pain and suffering patients would undergo until they were given an effective treatment." These are more distortions of the truth. The reality is that, as surveys and analyses have shown repeatedly, the FDA's policies have made life progressively more dangerous for patients and difficult for physicians.[13]

Congress abandoned HR 3199 in face of the Clinton administration's vehement opposition and the threat of a presidential veto. This was a significant loss, given the consensus within the scientific and public policy community that real reform was badly needed. Neither before nor since has Congress tackled FDA reform so aggressively, although the agency's policies and performance have begged for it. The legislation that eventually passed in the next congressional session was meager and disappointing.

It is ironic that "get tough" Kessler left the FDA under a cloud, resigning three weeks after public accusations that he had falsified travel vouchers, double-billed travel expenses, and the like. Eventually, he made partial restitution to the government.

## Dr. Henney's FDA

As the FDA's Deputy Commissioner from 1992 to 1994, Jane Henney had demonstrated a willingness to play politics with products

12. A. R. Giaquinto, Schering-Plough Research Institute, letter to House Commerce Committee, May 14, 1996.

13. See, e.g., Anon., "A National Survey of Oncologists Regarding the Food and Drug Administration" (Washington, D.C.: Competitive Enterprise Institute, 1995), 4 pp.

under review by America's most omnipresent regulatory agency, which is charged with assuring the safety of food, drugs, and medical devices, with a value of more than $1 trillion annually. While she occupied the number-two job at the FDA, Henney's decisions gave the appearance of being motivated by politics and self-interest.

As the co-chairman of the Public Health Service Task Force on Breast Implants in 1992, she collaborated prominently in the disastrous government decisions that needlessly left millions of women fearful and confused and that destroyed the silicone implant industry. As an FDA official, Henney was willing to delay the approval of products such as bovine somatotropin, a protein that enhances milk production in cows, because genetically engineered products were thought to be politically incorrect by Vice President Gore and his staff. She expedited others, such as a female condom with a high failure rate, after being instructed to do so by Health and Human Services Secretary Donna Shalala, who lauded it as a "feminist" product. President Clinton rewarded Henney for such actions by appointing her as FDA Commissioner.

## EPA: Neither the Best Nor the Brightest

Since its creation in 1972, the EPA has been subject to nearly continual criticism for ignoring or misusing science in its regulatory actions. It has been criticized too for skirting the regulatory process and imposing large costs on industry without ever having "to show its work" about any scientific justification. One of the best-known examples was initiated in the late 1980s, well before Clinton and Gore reached the White House, when the Natural Resources Defense Council (NRDC) launched a media campaign against Alar, an agricultural chemical that permits apples to ripen uniformly and increases yield. In response to NRDC's promoted public outcry about Alar, the EPA pressured apple growers to

abandon using it. Because of "inescapable and direct correlation" between exposure to UDMH" (the primary degradation of product of Alar) and "the development of life threatening tumors," Assistant Administrator John Moore "urged" farmers who were using Alar to stop. He also said that EPA would soon propose banning Alar. Coming from Dr. Moore, a senior federal regulator, his statement was akin to an armed mugger "urging" the victim to relinquish his wallet. Separately, EPA admitted that no data supported a finding of carcinogenicity.[14]

During the Alar episode, one of Moore's senior subordinates, lawyer Steven Schatzow, attempted to intimidate the members of an advisory panel because their opinion differed from his own:

> Apparently, the EPA officials had expected the SAP [Scientific Advisory Panel] to rubber-stamp its decision [that Alar or UDMH was a carcinogen]. When it did not, Uniroyal [the manufacturer of Alar] officials were jubilant. But after the meeting, Steven Schatzow, then director of EPA's Office of Pesticide Programs, herded SAP members into his office. The angry Schatzow demanded, "How can you do this to us?" After a heated exchange with the scientists, he concluded, "Look, I can't tell you what to do, but you might like to think about this one again." The scientists were stunned by such flagrant interference, and all refused to back down.[15]

Often EPA has ignored scientific evidence and bona fide public health considerations in favor of unsubstantiated fears expressed by influential special-interest groups. As long ago as 1992, an expert panel commissioned by then-EPA Administrator William Reilly reported: "(i) The science advice function—that is, the pro-

14. P. Shabecoff, "Hazard reported in apple chemical: E.P.A. cites a risk of cancer but will not bar use yet," *New York Times*, February 2, 1989, p. 23.

15. M. Fumento, *Science Under Siege* (New York: Morrow, 1993), pp. 19–44. See also R. J. Bidinotto, "The Great Apple Scare," *Reader's Digest*, October, 1990, pp. 55–56.

cess of ensuring that policy decisions are informed by a clear understanding of the relevant science—is not well defined or coherently organized within EPA. (ii) In many cases, appropriate science advice and information are not considered early or often enough in the decision making process."[16] And while "(iii) EPA should be a source of unbiased scientific information . . . EPA has not always ensured that contrasting, reputable scientific views are well-explored and well-documented."[17] Most damning of all, the panel concluded that "EPA science is perceived by many people, both inside and outside the Agency, to be adjusted to fit policy. Such "adjustments" could be made consciously or unconsciously by the scientist or the decision maker.[18]

The panel was charitable. The EPA was by far the most scientifically challenged agency that I encountered in almost two decades of public service, a period during which I interacted frequently with many government departments and agencies.

The EPA's capacity to propose and apply flawed scientific assumptions or paradigms to regulatory policy is intimately related to the manner in which the agency handles its advisory process, and scientists on advisory panels who offer independent perspectives anger EPA officials. For example, University of California microbiologist Dennis Focht, an academic member of the EPA's Biotechnology Science Advisory Committee, wrote a letter to the committee's chairman that said a policy decision to regulate on the basis of genetic technique rather than on an assessment of risk was based on nonscientific considerations. In response, EPA Assistant Administrator Linda Fisher, a lawyer, sent this distin-

16. Anon., *Safeguarding the Future: Credible Science, Credible Decisions, The Report of the Expert Panel on the Role of Science at EPA* (EPA document no. 600/9-91/050) (Washington, D.C.: U.S. Environmental Protection Agency, March 1992).

17. Ibid.

18. Ibid.

guished scientist a written rebuke that chided him on his inability to "provide the Agency with [an] unbiased assessment of the scientific issues at hand," and, in effect, invited him to resign from the committee.[19]

In accord with the federal government's unwritten rule that no bad deed goes unrewarded, the current Bush administration has reappointed Fisher to EPA and promoted her to Deputy Administrator. Not unexpectedly, the combination of an agency head —the scientifically unschooled EPA Administrator Christie Whitman—with an aggressive, unscientific, unprincipled deputy has been anathema to the creation of sound public policy (and a source of continuing embarrassment for the Bush administration).

Focht, an eminent and principled academic scientist, had acted as would be expected of an extramural adviser genuinely committed to providing rigorous, objective, and apolitical advice to federal regulators and officials at agencies like the National Institutes of Health (NIH) and FDA. NIH and FDA usually ask their advisers to provide narrow scientific expertise in reviewing and ranking grant applications, expressing opinions about research areas for additional or reduced funding, or evaluating the results of clinical trials. A different and perverse situation frequently prevails at the EPA. Instead of narrow scientific questions, the biotechnology-related committees are often asked for opinions on policy issues, and asked in such a way as to invite rubber-stamping of a course of action that directly benefits EPA.

The EPA consistently chooses policy directions that serve bureaucratic ends (such as larger budgets and regulatory empires), while disadvantaging academic and most industrial research. This places extramural advisers in a position that is, at the least,

19. L. J. Fisher, EPA assistant administrator, letter to Dennis Focht, University of California, August 21, 1992.

uncomfortable, and at worst, frankly conflicted. It is noteworthy that at the time that the EPA was proposing and its advisory committees were recommending scientifically indefensible and regressive policies, some chairmen and members of EPA's Biotechnology Science Advisory Committee were receiving substantial agency funding.

Some of EPA's programmatic and policy deficiencies can be ascribed to career civil servants with their own agendas, who manipulate EPA-inexperienced political appointees (most often lawyers). A pertinent example is Dr. Elizabeth Milewski, an EPA mid-level manager who has had primary responsibility for biotech policies in the Office of Pesticides and Toxic Substances. At a 1991 interagency meeting that I attended, she announced that the EPA could not accept a certain scientifically based policy because "our constituency won't stand for it."

Most civil servants apprehend their "constituency" to be the American taxpayers and consumers who offer the government their trust and treasure, but Milewski and others have something quite different in mind. Their "constituency" is a small but vocal and highly organized minority composed of politically potent, antibiotechnology activists at such groups as Environmental Defense, National Wildlife Federation, Union of Concerned Scientists, and Greenpeace who think of government regulation as something with which to bludgeon technologies, products, industries, or companies they dislike. In other words, not without justification, they see themselves allied with government in a war against capitalism and "globalization."

## Government That Was Neither Leaner Nor Less Mean

I have heard it said that Bill and Hillary Clinton are the enemy of normal people. But the epitome of that description is Al Gore,

whose cynical and erroneous view of science and its role in public policy places him among an infinitesimal minority and serves as a reminder that ignorance is not a simple lack of knowledge but an active aversion to knowledge—the refusal to know—issuing from hubris or laziness of mind. More disturbing still, because of its practical implications, is his philosophy of government, particularly with respect to the federal oversight of new technology and environmental protection. Gore's views are (to borrow a phrase from George Will) paradigmatic of paternalistic liberalism, of government that is bullying because it is arrogant, and arrogant because it does not know what it does not know. President Clinton repeatedly promised "leaner but not meaner government," but what we got was quite the opposite.

## No Reason for Optimism

There appears little likelihood that science policy will become less politicized or more rational and centered on science. Unhappily, there are several reasons for this pessimism.

There is no important constituency for sound science policy. On the contrary, politicization often represents little more than pandering to the fears, which sometimes verge on superstition, of a scientifically illiterate and statistics-phobic public. Federal regulator-bureaucrats excel at the Emperor's New Clothes school of formulation of self-serving policy. They have learned to confer legitimacy on almost any policy, no matter how flawed or antithetical to the public interest, by moving from step to bureaucratic step according to the specified rules, with everyone pretending that the evolution and substance of the policy are plausible. There is a saying in Washington that something that has been said three times becomes a fact, and adherence to the requirements of federal rule-making—publishing appropriate notices in the *Federal Register*, holding public meetings, responding to public com-

ments, publishing final rules, and so on—is the apotheosis of that idea.

In the end, regulatory policy is often crafted under the influence of a kind of "happy conspiracy" among activists, government regulators, and even some segments of industry. Clemson University economist Bruce Yandle has proposed the "bootleggers and Baptists" model of policymaking. Yandle points out that in the American South, Sunday closing laws make it illegal to sell alcohol on Sunday. These laws are maintained by a coalition of Baptists and bootleggers. The Baptists (and other religious denominations) provide the public outcry against liquor on Sunday, while the bootleggers (who actually sell liquor on Sunday) quietly persuade legislatures and town councils to maintain the closing laws.[20]

An application of this theory about public choice is apparent in the formulation of policy toward the regulation of science and technology. The Baptists are the environmental and other antitechnology groups, and the bootleggers are the companies that are seeking excessive regulation that will create market-entry barriers to competitors. Then, when the competition has been eradicated, they'll lobby for a loosening of the strict regulation that was needed in the first place only in order to "permit the public to gain confidence in the technology."

The government's self-interest in the process is best served not by doing as little as possible as efficiently as possible, but by taking on greater responsibilities, demanding bigger budgets, and expanding bureaucratic empires. Too often, any correlation between government policymakers' self-interest and the public interest is purely coincidental.

20. B. Yandle, "Bootleggers, Baptists, and Global Warming," in T. L. Anderson and H. I. Miller, eds., *The Greening of U.S. Foreign Policy* (Stanford: Hoover Institution Press, 2000).

During my quarter century in or studying government, I have seen nothing to disprove historian Barbara Tuchman's observation, "Mankind . . . makes a poorer performance of government than of almost any other human activity."[21]

21. B. Tuchman, *The March of Folly: From Troy to Vietnam* (New York: Knopf, 1984), p. 4.