PLANNING A NEW BIOTECHNOLOGY POLICY

Senator Al Gore *

From the printing press to the atomic bomb, humankind reveals a penchant to pioneer first and plan later. It is a simple truth that technology develops faster and further than policy. Cars and supercomputers are everyday examples of technologies that have grown beyond the highways and by-ways built to support them.

Pioneers and planners are, by nature, opposites. Pioneers must rebel and revolt against society to renew it. Planners try to relate the novel to the normal to provide continuity and growth.

Biotechnology is the latest example of this phenomenon. Watson and Crick, like Henry Ford, the Wright brothers, and Cray, will be remembered for pioneering a new and powerful technology. Who will be remembered for planning biotechnology policy?

In a recent article in *Scientific American* on high-speed fiber-optic computer networks, I noted how challenging it is for our civilization to make sensible use of that potent technology.[1] Surely the same can be said about biotechnology. The genetic code is the organic arm of the information revolution in which organisms transmit information chemically rather than digitally. In a sense, biotechnology can be described as the art of identifying and relocating genetic information to suit our purposes. Our mastery of that art increases the need for a coherent policy that defines just what our purposes are and should be.

The debate over biotechnology policy is at heart a debate over information policy. At one level the debate covers how to provide intellectual property protection to the tools of biotechnology and the valuable information they produce, such as gene sequences and chromosome maps. At a different and less comfortable level, the debate shifts to questions of how best to distribute information, to empower others to use it, and to prevent its misuse and loss of privacy.

Aided by the new tools of the computer age, biotechnology is developing faster than any previous technology and, in the process, creating a wider gap between practice and policy. Our growing ability to transform genetic information into new products and organisms intended to enhance agriculture, fight pollution, or alter hereditary diseases makes biotechnology a powerful, and threatening tool.

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1. Al Gore, *Infrastructure for the Global Village*, SCI. AM., Sept. 1991, at 108.

There is a very fine line between information and impact in biotechnology. Accordingly, the early debates about biotechnology addressed whether humankind should use this new tool at all, and if so, under what restrictions. There was a fear that using the new technology could lead to irreversible and dangerous impacts on society and the environment. The debates led to an historic example of self-restraint when the scientific community put policy and pioneering on equal grounds in the Asilomar Conference of 1975 and devised a way to develop the technology slowly under certain principles of safety and caution.[2]

But, after answering the question, "Should we do this?," the scientific community turned back to the question, "What can we do?," and pursued it with a new intensity. The result was a cascade of technological achievements that transformed Nobel Prize-winning discoveries into exercises high school students could learn in minutes. The stream of discoveries and knowledge soon pushed into the background questions about the why and wherefore of the new technology.

The evolution of the federal guidelines for recombinant DNA research administered by the Recombinant DNA Advisory Committee ("the RAC guidelines")[3] demonstrates the gradual rise to prominence of technology over policy development. The RAC guidelines were intended to monitor biotechnology research until more was known about the safety of the organisms produced through genetic engineering. But, over the years, the RAC guidelines were relaxed to allow scientists to take the next step, even when there was little, if any, systematic evaluation of the safety of the last step. Now the RAC Committee has virtually relaxed itself out of a job; recently there were suggestions to disband the Subcommittee on Human Gene Therapy because the full RAC Committee had so little to do and the two reviews were redundant.[4]

The speed of current developments in biotechnology contrasts sharply with the lethargy of the policy debate. The network for sharing technology information is well-established. The characterization of the AIDS virus occurred at a rate that would be incomprehensible to scientists of only twenty years ago. The mapping of the human genome is no longer a challenge of concept, but of patience and efficiency.

What is needed to balance our technological prowess is a renewed engagement in the debate over biotechnology policy—not just the ethics of genetic engineering, but the entire relationship between biotechnology

2. The International Conference on Recombinant DNA Molecules, held at the Asilomar Conference Center, Pacific Grove California, February 24–27, 1975.

3. 41 Fed. Reg. 27,902 (1976).

4. D. Gershon, *Cracks in the RAC*, NATURE, Oct. 1991, at 591.

and our future. While there has been much attention to the details of federal regulation of various biotechnology products—as there should be—we cannot lose sight of the larger policy questions that will determine whether our ability to manipulate the basic processes of life will benefit the world community.

To use an analogy, I remember that on the eve of the first hydrogen bomb explosion on Bikini atoll, some scientists raise the concern that the explosion might trigger a chain reaction in the oceans of the world and lead to an unimaginable ecological armageddon. Their bizarre speculation was, of course, rightly dismissed as absurd by those who had a clear understanding of why the laws of physics made it so. But even as such questions were treated with contempt, the deeper and more relevant questions were not really discussed at all—questions such as: Do we really want to spend the next forty years in a dangerous race to develop even more efficient ways to eliminate humankind from the face of the earth and divert many trillions of dollars to the task?

Similarly, while the debate on biotechnology sometimes has been sidetracked into questions about hypothetical disasters that strike those who understand the technology as absurd, the deeper questions have not received sufficient attention: How is this new capacity likely to change the relationship of humankind and nature? How do we ensure that the assumption of an ability to manage the future course of evolution is accompanied by enough wisdom to avoid catastrophic mistakes?

What has set the direction of biotechnology over the last ten years? If there *were* plans for an orderly development of this new field, they have been convincingly overtaken by events. These events have occurred in sterile laboratories and closed board rooms, in closeted courtroom chambers and politically-charged meetings at the White House. Occasionally, watershed events have occurred at town meetings and public fora, but usually the train of events has passed the public by.

The decade's events in science, law, business, government, and the court of public opinion demonstrate how technological progress can quickly outpace policy formulation.

Following the Asilomar Conference in 1975, Genentech became the first firm established to exploit recombinant DNA technology. Soon thereafter, the *Chakrabarty* decision[5] established the patentability—and, hence, the marketability—of genetically-engineered living organisms. Wall Street responded by running up the price of Genentech's stock from thirty-five to eighty-nine dollars in twenty minutes during the

5. Diamond v. Chakrabarty, 447 U.S. 503 (1980).

company's initial stock offering.[6] As I said at the time, this was the selling of the tree of knowledge to Wall Street. A host of new companies were soon formed and began to set records in gathering venture capital and investments:[7] all this fueled by the newly established value of genetic information as manipulated through genetic engineering.

For its part, the government was debating how to review and regulate biotechnology products proposed for release into the environment or use in medicine. The Investigations Subcommittee I chaired in the House of Representatives concluded in 1983 that the absence of good risk assessment practices and methods undermined the government's ability to characterize the safety of these new products.[8] At the same time, the Subcommittee recommended that the government coordinate its approach to biotechnology to facilitate product review and development. The Administration soon rejected the idea of a superagency for biotechnology in favor of an interagency committee where the agencies could share information and plans.[9]

The era of the public's trust in the scientific community's self-restraint came to a close with news of the now-infamous ice-minus rooftop experiments, in which a company conducted unauthorized experiments with an engineered bacterium on trees on its roof.[10] The injury to the industry far exceeded any possible injury to the environment. Not only was good risk assessment missing, but so were candor, judgment, and perception.

In the mid-1980s the Human Genome Project captured the imagination of the science community and began driving technology development, and to its credit, the debate over ethics. In the legal arena, the question of animal patents arose soon after the decision to allow patents for microbes. Farmers, ministers, and patent lawyers tangled in meet-

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6. *See* OFFICE OF TECHNOLOGY ASSESSMENT, BIOTECHNOLOGY IN A GLOBAL ECONOMY 4 (1991) [hereinafter OTA BIOTECHNOLOGY REPORT].

7. *Id.* CETUS Corp. set the record for funds raised in an initial public offering in 1981 when it raised 115 million dollars.

8. *The Environmental Implications of Genetic Engineering: Hearing Before the Subcomm. on Investigations and Oversight and the Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology*, 98th Cong., 1st Sess. 36 (1983); STAFF OF SUBCOMM. ON INVESTIGATIONS AND OVERSIGHT OF THE HOUSE COMM. ON SCIENCE AND TECHNOLOGY, 99TH CONG., 2D SESS., REPORT ON THE ENVIRONMENTAL IMPLICATIONS OF GENETIC ENGINEERING (Comm. Print 1984).

9. *See* 49 Fed. Reg. 50,856 (1984).

10. *See* REPORT OF THE SUBCOMM. ON INVESTIGATIONS AND OVERSIGHT OF THE HOUSE COMM. ON SCIENCE AND TECHNOLOGY, 99TH CONG., 2D SESS., ISSUES IN THE FEDERAL REGULATION OF BIOTECHNOLOGY: FROM RESEARCH TO RELEASE, Serial X, at 29–36 (Dec. 1986) (discussion of ice-minus experiment) [hereinafter ISSUES REPORT].

ings around the country debating the economics, ethics, and constitutionality of patenting cows and sheep.[11]

Commercially, the stock market crash of 1987 halted the investment boom for biotech. The surviving companies began fighting with each other over patent rights and with the government for commercial advantage here and abroad.[12]

After years of anticipation, the Administration finally created the Biotechnology Science Coordinating Committee ("the BSCC") and the Coordinated Framework for Regulation of Biotechnology ("the Framework").[13] The Framework was based on the momentous decision that no new laws were needed to regulate biotechnology, only selected new regulations. The public's unease began to grow in response to the closed nature of the BSCC's decision-making process and the product selection of the private sector. The development of bovine growth hormone represented a kind of thinking aimed at profits, not progress. Critics pointed out that the hormone threatened both the family farm and the viability of the government milk program.

By the end of the decade a new round of events transformed the industry anew. The first trials of human gene therapy were underway—praised as miracles by some and condemned as raising the specter of eugenics by others. Meanwhile, bioremediation was used in the Valdez oil spill and genetically-engineered tomatoes began moving toward the marketplace.[14]

The industry was spared another shock when the California Supreme Court held that a patient had no property rights in a patent based on cells taken from his diseased spleen.[15] This decision put the pot of gold back at the end of the biotechnology rainbow by protecting the research community's right to profit from the isolation and identification of human biological materials.

In 1990, biotechnology stocks and stock funds were the only winners

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11. *See* HOUSE JUDICIARY COMM., THE PATENT COMPETITIVENESS AND TECHNOLOGICAL INNOVATION ACT OF 1990, H.R. 5598, H.R. REP. NO. 960, 101st Cong., 2d Sess. pt. 1 (1990) (discussion of the Transgenic Animal Protection Act of 1990).

12. *See* OTA BIOTECHNOLOGY REPORT, *supra* note 6, at 220 (listing of recent litigation). *See also* Baringa, *Biotechnology Nightmare: Does Cetus Own PCR?*, 251 SCIENCE 739–40 (1991); Schaefer, *Cetus Retains Patent Rights*, NATURE, Mar. 7, 1991, at 6; *More Problems than Products*, NATURE, Jan. 3, 1991, at 5.

13. 51 Fed. Reg. 23,302 (1986).

14. On August 12, 1991, CALGENE submitted a request for an advisory opinion from the Commissioner of the Food and Drug Administration ("the FDA") with respect to the status of FLAVR SAVR (tm) tomatoes as food subject to the same regulations as other tomato varieties. CALGENE engineered the tomatoes to inhibit production of the enzyme associated with cell breakdown, thereby delaying overripening.

15. Moore v. Regents of the Univ. of California, 51 Cal.3d 120 (1990).

in an otherwise bad year for Wall Street.[16] Investment during a five-month period in 1991 set new records.[17] Another trend emerged as Genentech, the pioneer company, was bought by the Swiss company Hoffman-LaRoche and Gen-Probe merged with the Japanese company Chugai Pharmaceutical.[18]

Politically, there was little coordination in the Coordinated Framework. Interagency strife prevented any progress in developing regulations for organisms targeted for the environment.[19] The Food and Drug Administration ("FDA") spent so much time hindering the Environmental Protection Agency's ("EPA's") attempts at regulation that it was caught flatfooted by the flood of pharmaceutical products submitted for approval: The backlog of products awaiting approval threatened to bust the new boom.[20]

By the end of the 1980s the regulatory debate had come full circle as Vice President Dan Quayle's Council on Competitiveness reviewed for the umpteenth time the same questions (What is a deliberate release? Which engineered organisms should be reviewed prior to release and by whom?) that had been posed and examined nearly every year of the decade by different science review panels at different federal agencies.

The political interference in the agencies' regulatory processes for biotechnology led several states and occasionally a county to implement their own regulations for biotechnology.[21] This illustrated another principle that applies to regulating new and strange technologies such as biotechnology: If *you* don't do it, you know somebody else will. Without a unified federal regulatory system, biotechnology companies now faced fifty or more regulatory systems that threatened company success and international competitiveness.

This litany of events provides a background from which several themes emerge.

Product selection and patent protection, not planning, or the public's interests, have been the driving forces behind biotechnology policy in the 1980s. In the environmental and agricultural areas, the decisions to develop ice-minus, herbicide resistant plants, and bovine growth hormone created intense public opposition to biotechnology and lent

16. Jerry Edgerton & Prashanta Misra, *The Good, the Bad and the Mediocre*, MONEY, Feb. 1991, at 118.

17. *See* OTA BIOTECHNOLOGY REPORT, *supra* note 6, at 4.

18. *Id.*

19. *See Proposal to End Regulatory Turf Fights, Amend TSCA Is Drafted by Committee Staff* Chem. Reg. Rep. (BNA) 84–85 (April 27, 1990).

20. *See generally* ERNST & YOUNG, BIOTECH '92: PROMISE TO REALITY (1991).

21. *See* INDUSTRIAL BIOTECHNOLOGY ASSOCIATION, MID-YEAR SURVEY OF STATE GOVERNMENT LEGISLATION ON BIOTECHNOLOGY (May 31, 1991).

credibility to those who argued that biotechnology would make things worse before it made things better. These early product choices indicate that little thought was given to which initial products would increase confidence in biotechnology.

In the pharmaceutical area, the record investments in new companies increased the pressure to focus on lucrative products and to adopt aggressive legal strategies to make patent claims increasingly broad in scope while challenging the broad claims of others. As each case was decided, the losers flooded Congress with private relief bills masquerading as "patent reform." This threatened the stability of the patent system and kept the investment community anxious about the future of their holdings. The demand for special treatment of biotechnology products at the patent office and in Congress contrasted sharply with the arguments that no new regulations were needed for biotechnology food and environmental products because the technology was as old as that for making beer and yogurt.

The economic tides of biotechnology companies and the currents of political infighting within the Administration have drowned out the discussion of the ethics of biotechnology and its use. Of all the government funded projects, only the Human Genome Project dedicates a percentage of its budget (three percent) to studies of the ethics associated with the program. In the private sector, companies argue that social and economic factors should have no relevance to decision-making or regulatory reviews: In other words, they say, "Let the marketplace decide."

The Institutional Biosafety Committees set up to review genetic engineering at public and private institutions have a disappointing record. Controversial experiments have been conducted without notice to the relevant committees[22] and a Government Accounting Office study of these committees found that they were ill-equipped and unwilling to review biotechnology products intended for release into the environment.[23]

While the march of pharmaceutical products to the marketplace is slowed by the FDA's inability to handle the reviews expeditiously, agricultural and environmental problems headed for the marketplace now face problems stemming from the Administration's political reluctance to regulate the field. Political interference in agency decision-making effectively prevented the 1986 Coordinated Framework from laying a clear path from the lab to the marketplace. That interference now

22. *See* ISSUES REPORT, *supra* note 10, at 37–38 (discussion of experiments with OMNIVAC, a pseudorabies virus).

23. GENERAL ACCOUNTING OFFICE, BIOTECHNOLOGY: ROLE OF INSTITUTIONAL BIOSAFETY COMMITTEES, Report RCED-88-64BR, Dec. 14, 1987.

threatens to create a regulatory vacuum opposed by both environmentalists and business, albeit for different reasons.

The courtroom has provided the best testing ground for resolving the conflict between technology and policy. From early court reviews of biotechnology experiments and releases to reviews of patent disputes, the legal community has had to balance the hopes and fears surrounding biotechnology within, and occasionally without, existing law.

Early legal decision have focussed on the debate over technology and the right to exercise it experimentally.[24] Future legal debates will be over the policies to implement the technology. Possible future topics for resolution include the issues of genetic screening in the workplace, DNA fingerprinting, the privacy of personal genetic information, insurability of people with known genetic proclivities for certain frailties and diseases, and ownership of genomic information in agriculture.

Given the interrelatedness of events in the legal, economic, and scientific realms, why has there been so little effort to develop a network where the different players could formulate a unified policy to promote the best uses of biotechnology? Why has there been so little engagement in the effort to develop a consensus approach to introducing biotechnology products into society in place of the current adversarial approach that pits biotechnology companies against the interests of local communities?

These failures in developing biotechnology policy stem from a total lack of leadership in the Administration for the past twelve years, and from our policies on information and technology development. Both government and the biotechnology industry have failed to provide and distribute the information necessary to empower to public to participate adequately in the debate over biotechnology policy. Instead of reaching out to the public in a systematic way (in the mode, for instance, of the Agricultural Research Extension Service) to provide a steady stream of information coupled with opportunities to discuss the information and affect policy, the Administration has consistently tightened the circle of people and interest groups that have access to current information and policy proposals. This process has bred a distrust of biotechnology policy that exacerbates the fear of this new technology itself.

In Congress, each proposal designed to bring regulatory order to biotechnology has met vigorous opposition from the industry and the

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24. *See, e.g.*, Foundation on Economic Trends v. Heckler, 587 F. Supp. 753 (D.D.C. 1984), *modified*, 756 F.2d 143 (D.C. Cir. 1985).

Administration.[25] Without a crisis to focus attention on biotechnology, it is difficult to argue for making regulatory reform in this area a priority, especially when compared to the needs to reform other major environmental laws such as Superfund and the Clean Air Act.

In their rush to develop this new technology, biotechnology companies soon learned that the public will involve itself eventually in decisions affecting their communities with or without an invitation to do so. While some companies have been proactive in providing information and public fora to discuss planned activities, the public still perceives that its involvement comes well after the important steps of product selection and investment. Meetings held to persuade the public to accept products such as bovine growth hormone are qualitatively different from meetings to discuss what kinds of biotechnology products could help local communities and economies.

All of these events that favor technology development over policy development have now come to haunt the place where the biotechnology revolution began—the university community. A decline in government support coupled with increased private investment in university research activities threatens the traditional role of the university as an independent and objective source of information and research.

Bilateral agreements that include stock options and other financial awards for researchers are raising new policy questions relating to the role of the educational institution. Many are concerned about the role of corporations in setting the research agendas at universities and in narrowing the traditionally wide exchange of information within the university and between the university and society.[26]

The university-industry partnership raises questions of the university's liability for biotechnology products gone astray. It invites examination of whether public institutions are now subsidizing private ventures whose products are too expensive for the general public to use or which threaten the economic viability of local groups, especially small businesses and small farms.

We need a better debate over biotechnology to begin. For the last decade, every article on biotechnology began with a recitation of blessings and curses that could be expected as a result of genetic engineering.

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25. In the 101st Congress, there were bills to regulate the patenting of animals, H.R. 3119, H.R. 4970, and S. 2111; to regulate the use of transgenic animals, H.R. 4971; and to regulate the use of novel organisms in the environment, S. 2909 and H.R. 5232.

26. SUBCOMM. ON HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS OF THE COMM. ON GOVERNMENT OPERATIONS, ARE SCIENTIFIC MISCONDUCT AND CONFLICTS OF INTEREST HAZARDOUS TO YOUR HEALTH?, H.R. REP. NO. 688, 101st Cong., 2d Sess. (1990).

There was an aura that we were discussing something that would happen in the future.

Now, after a decade of experience, we must address the issues that biotechnology is affecting and will continue to affect. We must paint a coherent picture of how to apply biotechnology to our national and global needs. We should reclaim a public purpose for biotechnology and enlist the help of industry to achieve it.[27] We should use other tools at our disposal, such as distance learning and the new national high-speed computer network, the National Research and Educational Network,[28] to solve problems cooperatively in a "global village" setting rather than within the context of warring interest groups.

There is a tendency to use the law too often as a shield to defend a technology rather than as a sword to promote its beneficial uses. In the early stages of biotechnology, there has been a focus on using the law to defend intellectual property rights, to defend controversial experiments, and to defeat community resistance to specific products. It is time to use the law to guarantee the availability of information domestically and internationally, to provide safeguards against illegal and unethical uses of biotechnology, and to encourage uses of biotechnology that enhance the economic viability of local communities and interests.

As this powerful technology leaves our shores for the developing world, it becomes vitally important that a thoughtful policy accompany it. The viability of the international food and agricultural systems requires careful use of genetic engineering.

There are fears in tropical countries that large seed and agricultural companies will use biotechnology to corner the market on valuable germplasm resources in the developing world, leading to a new form of technological colonialism. There is concern that biodiversity will be threatened as engineers breed for uniformity to provide predictability and profits in short-term agricultural projects. Cultural conflicts over the ethics of owning and manipulating life forms will spill over into economic and legal relationships that involve biotechnology.

I have long argued that the problem with biotechnology may be that it succeeds too well.[29] For example, successful application of biotechnology to agriculture could lead to overproduction of key crops that

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27. *See, e.g.*, Star Schools Program Assistance Act, 20 U.S.C. § 4081 (West Supp. 1991) (promoting the use of interactive video and audio communications to link colleges, universities, and secondary schools).

28. *See* The High-Performance Computing and National Research and Educational Network Act of 1991, S. 272, 101st Cong., 1st Sess. (1991).

29. Al Gore, *Federal Biotechnology Policy: The Perils of Progress and the Risks of Uncertainty*, 20 MICH. J.L. REFORM 965–79 (1987).

drives up the cost of government subsidies worldwide.[30] Expensive products could drive small farmers out of business in favor of corporate farms. Plants engineered to resist chemicals rather than adverse conditions and insects could lead to continued and increased dependence on chemical farming methods that threaten the health of our topsoil and our water supply.

We must invigorate the policy debate to ensure that biotechnology does not just address technological problems in a socio-economic vacuum, but provides redress for hunger and disease universally and democratically. It is not enough to create more wealth; we must create a greater capacity for more to share its benefits.

The current issues before the Congress focus piecemeal on the problems related to capital formation,[31] patent protection,[32] drug pricing,[33] and research funding. These relate almost exclusively to the economics of biotechnology, not its ethics or future direction. Once again we are building more and faster cars without the highways to carry them. We cannot continue to rush forward with this new tool without considering what is at the end of the road.

I recently co-sponsored with Senator Pat Leahy of Vermont a bill to redirect federal research funds away from creation of herbicide resistant plants and toward sustainable agricultural practices.[34] In addition, I have been and continue to be concerned about the profits enjoyed as a result of government-sanctioned monopolies in the so-called orphan drug market and as a result of patent term extension. There are plenty of other opportunities to address policies that alienate the public from supporting biotechnology if we will only seize them.

The new engagement I speak of can help bridge the gap between science and democracy. It is not easy to overcome scientists' mistrust of the public's allegedly "uninformed" passions and prejudices; nor is it easy to dispel the public's mistrust of an allegedly "elite" scientific community dictating the future from within their labs. We must first develop the means and the habit of communicating with each other; then we can

30. Of course, these subsidies should be eliminated mutually by all countries, but that appears unlikely.

31. *See* The Enterprise Capital Formation Act of 1991, S. 1932, 102d Cong., 1st Sess. (1991).

32. *See* The Biotechnology Patent Protection Act of 1991, H.R. 1417, 102d Cong., 1st Sess. (1991).

33. *See* The Orphan Drug Act Amendment, H.R. 4638, 101st Cong., 2d Sess. (1990) and S. 2576, 101st Cong., 2d Sess. (1990); H.R. REP. NO. 635, 101st Cong., 1st. Sess. (1990).

34. *See* The Herbicide Resistant Plant Act of 1991, S. 1916, 102d Cong., 1st Sess. (1991).

develop the process to make technology an equal partner with this new technology.

The *Harvard Journal of Law & Technology* provides one avenue where policy makers and technologists can learn from each other. The current volume is an example of how to use cross-discipline approaches to forge a better future for a new technology. I hope our society can continue to learn how to communicate across the barriers that divide us—barriers we ourselves established for long-obsolete reasons—so that we can build a better common future.