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FEDERAL REGULATION OF BIOTECHNOLOGY

Monograph 85-7

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$3.00

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Federal Regulation of Biotechnology

Harold P. Green

The Regulatory Background

Ever since the emergence in the mid-1970s of recombinant DNA research as a major element in biotechnology, there has been a strong undercurrent of interest in whether and how the research and resulting technology should be regulated. For a time there was intense activity at the state and municipal levels to impose various forms of regulation. At the same time, Congress was considering proposed legislation that would create a federal regulatory structure. Congressional interest was temporarily diminished when the scientific community presented evidence that the hazards of recombinant DNA research were substantially less than had originally been thought. More recently, however, interest in regulation has revived in reaction to proposed experiments that would release genetically engineered microorganisms into the open environment. It is useful, therefore, to consider the events of the first decade of gene-splicing as an example of how social, legal, and political institutions respond to the emergence of an important new technology.

The regulatory history of biotechnology began with a call by a number of scientists most involved in recombinant DNA research for a moratorium on further experiments in this area pending an international conference on recombinant DNA research.[1] Such a conference, it was asserted, would consider the possible hazards of the recombinant DNA technology and decide whether the moratorium should be continued, modified, or abandoned. The international conference was held at Asilomar in February 1975, and concluded that the moratorium should be continued with respect to certain kinds of experiments, while other experiments might be conducted subject to appropriate levels of physical and biological containment.[2] The fact that the call for the moratorium emanated from the scientists working in the gene-splicing area is in itself a notable model of public influence. Beyond this, the fact the proceedings at Asilomar were widely reported by several members of the press who were present and witnessed all of the deliberations adds to the significance of this model.

At the time of the Asilomar Conference, almost all recombinant DNA research in the United States was funded by federal agencies, primarily the National Institutes of Health. Shortly after Asilomar, NIH promulgated Guidelines for Recombinant DNA Research which essentially

implemented the conclusions and recommendations reached at Asilomar.[3]

The point of this is that only ten years ago, the leading scientists in recombinant DNA research and the primary funding source both had genuine concerns that the results of such research could have quite detrimental impacts on life, health, environmental and ecological values, and the moral fiber of the community.

NIH, and its parent organization, the Public Health Service, had a statutory charter primarily to promote the public health, with only limited authority to regulate to protect the public health. Accordingly, the NIH Guidelines have been applicable only to institutions which receive research funding from NIH (although other federal agencies have also made the Guidelines applicable to recipients of research funded by them). An institution that performed research in violation of the Guidelines would become ineligible for further government funding. Entities that were not recipients of such government research funds were urged to undertake to comply voluntarily with the Guidelines, and, so far as is known, all have done so.

Promulgation of the Guidelines, which was accompanied by an Environmental Impact Statement[4] in compliance with

the National Environmental Policy Act, provoked two diametrically opposed reactions. First, a number of scientists and lawyers argued that the Guidelines' restrictions violated a constitutional right to scientific freedom, e.g., the right to do science, and these arguments found some support from legal scholars.[5] At the other extreme, two states (New York and Maryland) enacted legislation directed towards regulation of recombinant DNA activities, and a number of municipalities (e.g., Cambridge, Massachusetts) considered ordinances that scientists feared would severely restrict recombinant DNA research within the city limits. Indeed, perhaps a dozen municipalities actually enacted regulatory ordinances, although none of these seems to have had a really inhibiting effect.

The Constitutional Issue

The argument that the NIH Guidelines unconstitutionally restricted scientific freedom had little substance. To begin with, the Guidelines were not regulatory in nature, but merely established conditions for the expenditure of public funds. It is well established constitutionally that the government may spend its money as it chooses, and establish non-discriminatory conditions for receipt of government funds.[6] Moreover, even if NIH had, as a

matter of outright regulation, prohibited certain kinds of experiments (assuming that statutory authority existed), there seems to be no doubt that such regulation would be constitutionally permissible if there were a rational basis for the regulation. The mere fact of the moratorium, the Asilomar Conference, and the Conference's conclusions clearly established a rational basis for such regulation. The Guidelines in no way interfered with the freedom of scientists to think, to put their ideas on paper (or into computers), and to communicate their ideas freely. All that was prohibited were certain actions, specifically experiments, where there was a rational basis for belief that these actions could be harmful to the public health and safety. Surely, the asserted implied constitutional right to scientific freedom could have no greater dignity than the explicit constitutional right to freedom of speech, and constitutional doctrine has long recognized a basic distinction between pure speech, which is constitutionally protected, and action (for example, picketing, demonstrating, and flag burning), which may not be constitutionally protected.

Moreover, there have been many precedents of overt federal regulation of scientific activities far more restrictive of scientific research than the NIH Guidelines--the food and drug laws, the Atomic Energy Act, and anti-vivisection laws, to mention only a few by way of example.

State and Local Regulation

The interest of State and municipal governments in regulating recombinant DNA technology was generally stimulated by intense political activity on the part of concerned members of the public. The prospect of such regulation was thoroughly disconcerting to the scientific community which visualized a "scientific checkerboard" that would make the conduct of recombinant DNA research dependent upon purely geographic considerations. Moreover, no recombinant DNA researcher could be certain that his or her research activities would not be abruptly interfered with by new state or municipal regulations. They argued in favor of federal preemption of the area, so that all recombinant DNA research would be subject only to regulation imposed by the federal government. Such an argument against state and local regulation cuts across the grain of American federalism under which protection of the health and safety of the public is essentially a state function unless and until the federal government adopts a regulatory scheme that so comprehensively occupies the field as to leave no latitude for state regulation. Obviously, the scientists who opposed state and local regulation were also opposed to a comprehensive federal regulatory scheme which they believed was totally unnecessary.

The above considerations are now largely matters of only historical significance, although, to be sure, the issue of violation of a constitutional right to scientific freedom has not been completely laid to rest. Two circumstances have contributed to the changed situation.

First, the NIH Guidelines have been substantially relaxed in a series of amendments as a result of a revisionist proposition that has gained general scientific acceptance that recombinant DNA activities involve far less hazard than was speculated about in the mid-1970s. Scientists today have much more leeway and flexibility than they had under the original Guidelines. Accordingly, there has been less cause to complain about restraints on scientific freedom.

Second, since the late 1970s, a biotechnology/genetic engineering industry has emerged. Paradoxically, the "regulation" of the technology under the NIH Guidelines has applied on a mandatory basis only to research in the academic area, while the profit-seeking industrial entities have complied with the Guidelines only on a voluntary basis.

Not surprisingly, this anomaly has shifted attention from the question of the Guidelines' impairment of scientific freedom to the question of how the biotechnology industry should be regulated. If gene splicing indeed involves risk to the health and safety of the public, the risk is presumably more likely to be found in the industrial than in the academic arena. On the other hand, the new forms of academic-industrial consortia that have evolved in the last five years or so leave the academic scientific community with an acute interest in the regulatory fate of the industry.

The New Era of Regulatory Concern

Many of the products of the biotechnology industry are clearly subject to one or more forms of conventional regulation. For example, food additives, pharmaceuticals, and biologicals are subject to regulation by the Food and Drug Administration; and other products may be subject to regulation by the Department of Agriculture. Activities within industrial facilities that may affect employees are subject to regulation by the Occupational Safety and Health Administration. But activities within the facility that may impact on the outside environment and experiments conducted in the open environment have had no clear

regulatory locus. There has been a growing belief that recombinant DNA activities, at least those conducted by industry, should be subject to affirmative regulation.

There are at least two reasons why NIH is not the appropriate agency to regulate the industry or, indeed, to regulate academic recombinant DNA research. NIH has never had any regulatory authority and therefore has no regulatory competence or experience. Its principal function has been to promote and support biomedical research. Aside from the question of its regulatory competence, an attempt to vest it with real regulatory responsibility would lead to the same kind of conflicting promotional and regulatory responsibilities that detracted so severely from the regulatory credibility of the Atomic Energy Commission before it was abolished in 1974. Since almost by definition regulation operates to slow development of the regulated activity, it seems clear, particularly after the atomic energy experience, that Congress will not be disposed to place important regulatory responsibilities in the hands of an agency whose primary mission is to accelerate the development of the technologies it is also regulating. (See ch. 6 of this volume for a critique of the Dept. of Defense as both sponsor and regulator of chemical weapons research).

It is useful at this point to recall some wisdom expressed by one of the 20th century's most important technologists, Admiral Hyman Rickover, father of the nuclear navy, in 1965. In his Guildhall lecture before the British Association for the Advancement of Science, entitled "A Humanist Technology,"[7] Rickover called attention to the tendency "to treat every attempt by society to regulate... [technology] in the public interest as if it were a modern repetition of the persecution of Galileo." This must remind one of the attack on the NIH Guidelines as a suppression of scientific freedom. Rickover went on to discuss what he termed the pattern of opposition to regulation:

> "I have mentioned efforts to confuse the issue by arguing as if a law of science were at issue when in fact the proposed legislation deals with technology, not science. If this argument fails, the need for the proposed law is then categorically denied. Warnings of scientists are rejected as 'unproven' and 'exaggerated.' Later, when these prove to have been entirely correct, the argument shifts from the substantive question of whether a technology is harmful to an attack on the legitimacy of any kind of protective legislation. Such legislation would violate basic liberties, it is

claimed; it would establish government tyranny and subvert free democratic institutions. If all this proves futile and legislation is imminent, there will be urgent demands it be postponed until 'more resarch' can be undertaken to establish the appositness of the proposed law."

Rickover's bottom line was the plea that no technology be used until "reliable tests ... have been made to prove it will be useful and safe" (emphasis added).

The general trend of federal laws relating to technology has been pre-clearance to establish efficacy and safety before products may be used. Of course, it is never possible to demonstrate complete safety, and each regulatory regime has its own approach, derived from statutory language, legislative history, and judicial decisions, to the determination of how safe is safe enough. We find the concept of safety pre-clearance, going back in history, in the Food and Drug Act, and of more recent vintage in many of the environmental laws enacted in the past 15 years. Under such laws, a technology or product is deemed unsafe unless and until it has been demonstrated to be safe. For example, food is deemed to be adulterated if it contains a chemical additive that has not been approved by FDA. On the other

hand, in the atomic energy area, we see exactly the opposite approach -- a virtual presumption that a piece of technology is safe unless there is evidence that it is harmful. Indeed, this departure from the prevailing regulatory approach may explain in part the apparent lack of confidence in the nuclear regulatory structure that has been so prevalent in some sections of the public.

Scientists engaged in recombinant DNA research and technology have a high degree of confidence that their activities do not involve any extraordinary hazards. They firmly believe that to the extent hazards are present they are no greater than those found in nature or in other more conventional laboratories, and that they can be minimized by sound research practices and procedures. In other words, they seem to be following the pattern described by Rickover of characterizing the "warnings of scientists as 'unproven' and 'exaggerated'." There are, however, three interrelated social factors that make it difficult for industry and academia alike to argue that regulation is unnecessary.

First, the technology cannot escape the heritage of its past--the moratorium, Asilomar, and the early NIH Guidelines--all of which turned upon the publicly proclaimed assumption that recombinant DNA activities

involved possible hazards of sufficient dimension to require dramatic forms of intervention. It is hardly surprising, now that technology--much of it profit-oriented--has emerged, that some segments of the public will have reservations about the revised estimates of risk. Indeed, some scientists who were proponents of the call for the moratorium now seem to believe, in retrospect, that their action served no useful purpose, but merely led to undue public concern.

Second, public perceptions may be more important than reality in the political process. These perceptions often are ignited and fueled by politicians in search of issues as well as by outsiders who wrap themselves in a public interest mantle. Scientists and technologists have a great tendency to advocate public education programs to rectify inaccurate public perceptions. While no one can be critical of genuine educational efforts, too often they backfire because they are perceived by the public at whom they are directed as self-serving propoganda. It should be observed, for example, that the atomic energy establishment has been notably unsuccessful in its efforts to educate the public as to the benign effects of nuclear power plants.

Third, the industry is inevitably linked by the phrase "genetic engineering" to fundamental and legitimate moral and policy concerns relating to the use of reproductive biology technology and to the potential use of gene splicing techniques to improve human beings. These concerns arise out of a changed social function of biology, a change from essentially understanding and coping with biological life to the capacity to remake and improve the forms of life. There has been a persistent interest in establishing some kind of permanent oversight commission to monitor developments in these areas of real moral and ethical concern. Although the biotechnology industry is not a direct target of these efforts, there is a relationship that may increase public apprehension with respect to industrial applications of genetic engineering.

The Alternatives for Regulation

At the present time, the biotechnology industry is essentially unregulated, and lives very comfortably under the system of voluntary compliance with the NIH Guidelines and the essentially benevolent oversight of the Recombinant DNA Advisory Committee ("the RAC"). The RAC, incidentally, is constituted with significant lay representation as well as representation of scientists from areas other than gene-splicing. Indeed, the RAC may

be regarded as still another mechanism for fostering public participation.

As noted above, the industry's products may be subject to regulatory review by FDA, EPA, or USDA, but such review impacts only tangentially, if at all, on how the industry conducts its scientific and technological activities. Nevertheless, it seems inevitable that the industry itself, as well as its products, will become subject to positive regulation of some kind, and it is important to consider the four alternative modes of regulation that might be adopted. In the discussion that follows, it is assumed that existing agencies such as FDA and the Department of Agriculture will continue to regulate to the extent that they presently have clear regulatory authority. The question considered is the optimum locus of regulatory authority over aspects of gene splicing that are unique and, therefore, presently not subject to regulation.

First, NIH might attempt to stretch the laws under which it presently operates so as to bring all recombinant DNA activities, academic and industrial alike, under mandatory and real regulation. This approach seems unlikely and undesirable for the reasons discussed above relating to NIH's lack of regulatory experience and the problem of

conflicting responsibilities for regulation and promotion. Granting regulatory responsibility to NIH would also invoke great uncertainty as to the character of the regulation to which biotechnology would be subject. Academia would probably find this new brand of regulation to be stifling, while industry would be faced with perplexing questions arising out of a novel regulatory scheme. There may, therefore, be compelling reasons for leaving academic research under the NIH Guidelines, and looking elsewhere for regulation of industrial activities. It may, however, be illogical, impractical, or senseless to have a dual set of rules with different requirements applicable, depending upon whether an activity is academic or industrial.

On the other hand, NIH has created a superb technical resource--the RAC--which should not lightly be discarded. It is, I believe, a safe assumption that, in one way or another, the RAC will survive--perhaps even in expanded and strengthened form--to provide the scientific expertise and inputs that are so essential to sound health and safety decisions, applicable to both academia and industry, in this area.

A second alternative for regulation of the industry would be to rely upon some other existing agency with present

statutory authority that could be made applicable to the industrial gene splicing technology. The obvious candidate for this regulatory role is the Environmental Protection Agency, which believes, although the matter is not free of legal doubt, that the array of statutes it presently administers, particularly the Toxic Substances Control Act (TOSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), gives it authority to regulate recombinant DNA activities. Any doubt that does exist about EPA's authority could be neatly resolved by a simple amendment to EPA's organic legislation. Of course, EPA regulation would not exclude regulation by other agencies such as FDA and USDA with respect to matters within their jurisdiction. One advantage of EPA regulation from industry's standpoint is that the Agency has a track record and established procedures that would provide some degree of certainty as to how the regulatory system would work.

The third alternative would be enactment by Congress of new legislation, analogous to the statutes now being administered by EPA, that would establish criteria and procedures specifically applicable to the industry's activities. Such a statute could be administered by EPA or some other agency. If this route were to be followed, the resulting legislation would be shaped by unpredictable

political currents and would have an unpredictable content with attendant uncertainties as to its implementation. Moreover, the very existence of a new law, specially targeted at the biotechnology industry, would carry a probably incorrect connotation that the industry involves unique hazards.

The fourth alternative is one that is not implausible. There has been legislative concern about scientific research in "gene splicing" directed towards interventions in the treatment of human beings or, more broadly, in evolutionary processes. It has been suggested that a new federal "watchdog" commission be established to monitor developments in this area. Such a commission was contemplated in legislation enacted by the 98th Congress, but the legislation was vetoed by President Reagan for budgetary reasons not related to the proposal for creation of such a commission.[8] These proposals have usually explicitly or implicitly recognized that perhaps such a Commission should also keep its eye on what the biotechnology industry is doing.[9] It is not difficult to visualize scenarios in which such a commission would evolve into a regulatory agency. Such an evolution would inevitably confuse innocuous activities of the industry with issues of human, evolutionary, and ecological impacts which do involve genuine moral, ethical, and policy concerns.

The actually emerging framework for regulation was revealed by the Reagan Administration in its December 21, 1985 publication for public comment of its proposal for a "coordinated framework for regulation of biotechnology." The proposal, which is essentially consistent with the considerations discussed above, envisions coordinated regulation by FDA, EPA, and the USDA. In general, FDA would regulate food additives, drugs, and other products within its jurisdiction; USDA would regulate plant pests, animal biologicals, and other agricultural products within its jurisdiction; EPA would regulate pesticides and industrial products. Regulatory review would be conducted by all three agencies on a case-by-case basis in similar ways and each would have its own scientific advisory group. A Biotechnology Science Board would be established by the Department of Health and Human Services to oversee and coordinate the biotechnology activities of the three regulatory agencies, as well as NIH and the National Science Foundation.

Applicability of NEPA

The question of federal regulation of the biotechnology industry should be considered in the context of the applicability of the National Environmental Policy Act to NIH decisions under the Guidelines. It is clear that NIH

actions, particularly relating to release of genetically engineered microorganisms into the environment, may be "major federal actions significantly affecting the quality of the human environment." As a consequence, before such actions may be taken it would be necessary for NIH to comply with the National Environmental Policy Act (NEPA).[10]

The National Environmental Policy Act was enacted in 1969. It requires that before any federal agency take a major action that would "significantly affect the quality of the human environment" it prepare an environmental impact statement. The environmental impact statement must first be circulated in draft form to elicit the comments of other federal agencies and the interested public, on the basis of which comments the final environmental impact statement is prepared. The environmental impact statement is required to include, among other things, a "detailed statement" of the environmental impact of the proposed action, adverse environmental impacts that cannot be avoided, alternatives to the proposed action, and the relationship between short-term uses of the environment and the maintenance and enhancement of long-term productivity.

When NIH initially promulgated the Guidelines, it did so after preparation of an environmental impact statement in compliance with NEPA. It is plausible, therefore, that any major changes in the Guidelines should also require an environmental impact statement, or at least a formal environmental assessment resulting in a so-called "negative declaration" that the proposed action is not a major action that will significantly affect environmental quality. Moreover, it is well established that a federal agency's grant of a license or permit to a private applicant may trigger the applicability of NEPA. Indeed, a significant modification of a pre-existing license or permit may require an environmental impact statement.

The requirements of NEPA are sweeping and amorphous. It has spawned literally hundreds of lawsuits brought by members of the general public seeking to block or reverse federal actions on the ground of non-compliance with NEPA. The judicial decisions have generally given an expansive interpretation to the statute.

NEPA is, of course, an important tool for public involvement in Federal decisionmaking affecting the environment. Nevertheless, of all the regulatory formats that the genetic engineering industry has to fear, the most fearsome is probably the one in which regulatory

actions affecting the industry would be subject to review under NEPA. This would not only involve the long delay inherent in the time-consuming agency compliance with the procedural hurdles imposed by NEPA, each of which would provide an opportunity for ideologically motivated members of the public to litigate regulatory decisions that facilitates advance of the technology. The litigation would be based on allegations that the agency had not undertaken the kind of environmental review mandated by NEPA and/or that the product of such a review--the environmental impact statement--was deficient in content and/or candor. The litigation could be endless and enormously expensive in terms of both time and dollars. These are precisely the tactics that the opposition to nuclear power have used so effectively and that have contributed so substantially to the present plight of the nuclear industry.

One conspicuous advantage of regulation by the Environmental Protection Agency is that, since that agency is presumably single-mindedly dedicated to promotion of environmental quality, its regulatory actions are exempt from the requirements of NEPA.[11] This in itself would warrant industry's embracing the concept of EPA regulation as the optimum alternative.

In discussing the question of regulation of biotechnology, it is necessary to keep in mind the two separate communities that are involved, and also the fact that the two communities have become significantly intertwined. The community of academic science can probably live quite comfortably under the NIH Guidelines, and there is no reason to assume that the interests of the public would be adversely affected by academic science done in accordance with the Guidelines and with customary scientific prudence. Where, however, science and its resultant technology are directed towards economic profit, experience teaches us that a firmer and more positive regulatory structure is probably needed. Whatever questions may exist in the academic context about the impact of regulation on scientific freedom, they surely are not present, at least to the same degree, in the context of science and technology practiced in the industrial sphere.

Conclusion

The gene-splicing technology was destined almost from its inception to spawn controversy and debate. The decision "to go public" with their concerns by those scientists who pioneered in the early research set the course for decades to come. Whether or not the technology involves hazards

that warrant or necessitate regulation has become almost irrelevant. The fact that the leading scientists called for a moratorium on research and that the NIH Guidelines imposed restrictions created public perceptions and political forces that cannot be undone by development of new scientific knowledge. It is too early to predict how many of the regulatory issues will be resolved. At the moment, at least, the exercise of regulatory authority by the Federal government does not seem to threaten the police power of the states and their subsidiaries. Within the federal establishment, the ultimate substance and form of regulation is more likely to be shaped by unforeseeable occurrences that feed public concerns and the perceived needs of politicians than by scientific objectivity.

FOOTNOTES

1 Berg, Paul, et al. "Potential Hazards of Recombinant DNA Modules" Science 185 (1974):303.

2 U.S. Dept. of Health, Education and Welfare, Provisional Statement of the Conference Proceedings, DHEW Pub. No. (NIH) 76-1138, p.59; Berg, Paul, et al., Summary Statement of the Asilomar Conference on Recombinant DNA Molecules." Proceedings of The National Academy of Sciences, 72 (1976):1981-84.

3 U.S., Federal Register, 1976, 41:27911-43.

4 U.S., Dept. of Health, Education and Welfare, Environmental Impact Statement on NIH Guidelines for Research Involving Recombinant DNA Molecules, DHEW Pub. No. (NIH) 1489.

5 Testimony of Thomas I. Emerson, U.S. Cong., House Comm. on Science and Technology, Subcomm. on Science, Research and Technology, Hearing, 95th Cong., 1st Sess. (1977), pp.875-885; Robertson, John A. "The

Scientist's Right to Research: A Constitutional Analysis." So. Cal. L. Rev 51 (1978): 1203, et seq.; Delgado, Richard and Millen, David. "God, Galileo, and Government: Toward Constitutional Protection for Scientific Inquiry." Washington L. Rev. 53 (1978): 349, et seq.; Stetten, DeWitt. "Freedom of Enquiry." Genetics 81 (1975): 416, et seq.

6 United States v Butler, 297 U.S. 1 (1936); Steward Machine Co. v Davis, 301 U.S. 619 (1937).

7 Unpublished, but distributed in typewritten form by the U.S. Atomic Energy Commission.

8 U.S. Cong., S.240, 98th Cong., 2d Sess. (1984); vetoed Oct. 30, 1984.

9 U.S., President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Splicing Life (1982), p. 81, et seq.

10 Foundation on Economic Trends, Inc. v Heckler, 756 F.2d 143 (D.C. Cir. 1985).

11 U.S., Federal Register (1974), 39:16186; Fed. Reg. (1974) 39:37119.