Drawing the Line in Genetic Engineering

self-regulation and public participation

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On 6 November 1974, David Baltimore presented an informal talk to an interdisciplinary faculty group at MIT. He entitled it "Where Does Molecular Biology Become More of a Hazard Than a Promise?" and described the new recombinant DNA techniques and the possibility that they could give rise to "the potential for public health problems." Baltimore explained that the Asilomar conference scheduled for February 1975 was an attempt to show that scientists could regulate themselves and was a way "of avoiding governmental responses" which would be too rigid, too hard to reverse, and too hard to work within. He concluded: "We're stuck between self-determination of limits and imposition of orthodoxy. We're stuck between self-interest of scientists and the public interest" (Baltimore 1974). As I listened I was impressed with this effort for responsibility and self-regulation, but I wondered how it was possible to *exclude* the public in a matter that *should* be of public concern.

That was the beginning of my interest in the subject. As a historian of contemporary science focusing on social responsibility issues, I was drawn to it. In 1975 I started a project to document the development of the "recombinant DNA controversy" while events were happening, while recollections of participants

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were still fresh, and while ephemeral documents were still available. The project received extraordinary cooperation from the participants, who agreed that these historically important developments should be documented and studied. By 1979 we had deposited for research use in the MIT Archives transcripts of detailed oral history interviews with 120 individuals, including organizers and participants at the 1975 Asilomar conference, researchers, policymakers, legislators, lobbyists, journalists, and members of local citizens review boards. The interview transcripts supplemented thousands of other documents, including letters, memoranda, minutes and reports, and more than 100 videotapes and audiotapes of meetings and hearings (Weiner 1979a; Dorman 1980). Now known as the Recombinant DNA History Collection, this archive of material has been widely used (Krimsky 1982; Wright 1994; Gottweis 1998).

These materials and my own observations show biologists' deep concern with public response, and their efforts to anticipate, influence, and control it. Biologists feared that the public's apprehension about hazards could lead to political intervention that might threaten funding for research using recombinant DNA techniques, and they worried that scientists might lose control over research choices and procedures. Several historical examples illustrate these concerns.

THE 1973 GORDON CONFERENCE LETTER

At the 1973 Gordon Conference on Nucleic Acids, the participants decided to write a letter to ask the National Academy of Sciences to study the potential hazards of the newly developed recombinant DNA techniques and to devise a plan to do something about them. They voted by a large majority to compose the letter, which was then written by Maxine Singer and Dieter Söll, and they approved the content of it. They also voted, this time by a slim margin, to send a copy of the letter to be published in *Science*. The reluctance of many of the participating scientists to call public attention to the problem was an indication of a continuing conflict. They were concerned about a possible public health problem, and yet they feared that talking about it publicly might bring intrusion, as they saw it, into the scientific process. The Gordon Conference letter, replete with technical language, was intended for other scientists. It was published in *Science* in 1973 and did not generate much public attention (Singer and Söll 1973).

THE BERG LETTER

The National Academy asked Paul Berg to consider the issues raised by the Gordon Conference letter, and he set up a group of biologists, including a few who had previously worked with him to organize a conference at Asilomar in January 1973 on biohazards in research use of viruses. Most of the assembled group had both a potential stake in doing recombinant DNA experiments and the necessary background and desire to do them. They met at MIT on 17 April

1974, and planned a conference for February 1975 to evaluate the hazards of the research and ways of dealing with them. Feeling a sense of urgency, they also drafted a letter to alert the larger community of biologists. Two months after the MIT meeting, Berg described these actions and the group's motivations in a letter to a colleague in England:

> We met at MIT for a day and settled on the idea of calling a conference next February of those scientists working on methods of joining DNA molecules and particularly those involved in constructing hybrid DNAs. It was our plan that one of the major purposes of the Conference, besides a report on the scientific progress, would be a wide ranging discussion of potential hazards growing out of these types of experiments. Were there any experiments that should not be done? How could such a moratorium be proposed or enforced? In short, we expected a frank and searching review of what people were doing or wanted to do, particularly from the point of view of whether they should be done. But as we talked we realized that the pace of events might not wait for February and that some of the experiments many people would agree could be hazardous would be done by then (e.g., attempts to fuse portions of Herpes DNA to appropriate plasmids for cloning in E. coli were imminent). Since the technology for constructing hybrids has become ridiculously simple, that fear was well founded.
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> Consequently we decided to devise a letter to be submitted to Science and Nature calling on scientists to defer certain kinds of experiments until these potential hazards could be better evaluated and certainly until there was an opportunity to discuss the issues at the February meeting. (Berg 1974)

Drafts of the Berg committee letter were circulated privately among the relevant scientists, and in July 1974 the final version was published in *Science* and in *Nature* (Berg et al. 1974). Why did they go public? Because the committee felt it was the quickest way to bring the potential hazards to the attention of the community of researchers who would be likely to use the new recombinant DNA techniques. They felt that the situation was urgent, because of pending experiments and because the power and fruitfulness of these research tools rapidly would attract many scientists to the field who were not experienced in handling pathogenic organisms. When the letter was about to be published, a press conference was held in order to inform and influence journalists so that they would not alarm the public.

The Berg "moratorium letter" was generally well received by scientists in the field. When it was published in *Nature*, it was followed by responses from leading British biologists. Michael Stoker, head of the Imperial Cancer Research Fund, observed that "it is encouraging that the very leaders in the field have taken the initiative. . . . For many it will be a test of self denial and social responsibility in the face of strong intellectual temptation" (Stoker 1974). The statement by Kenneth Murray of the University of Edinburgh is especially interesting because of what it says about the future applications of recombinant DNA techniques, and because of his concerns about public perceptions:

> The NAS request is both reasonable and responsible and deserves to be universally respected. . . . Fears that the proposed limitations to experiments will seriously obstruct research in vital areas of biology seem unfounded. The NAS initiative, by focusing attention on the hazards involved, could well promote rather than hinder work on in vitro recombination in animal viral systems, an area believed by many to hold the key to gene therapy in its broadest terms.. . . if we follow the moderate tone set by the NAS we shall be careful not to oversell the social benefits devolving from recent experiments. (Murray 1974)

Amid the excitement they felt over the power and potential applications of the new recombinant DNA, biologists recognized that they had to address the possibility of immediate laboratory safety problems in order to proceed with the research without alarming the public and risking governmental regulation.

THE 1975 ASILOMAR CONFERENCE

What happened at Asilomar? The recombinant DNA issue was defined as a technical problem to be solved by technical means, a technical fix. Larger ethical issues regarding the purposes of the research; long-term goals, including human genetic intervention; and possible abuses of the research were excluded. The focus at Asilomar in 1975 was on the safety of the newly developed technical tools for genetic engineering—on the means, not the ends. As a result, the media ignored the social and ethical consequences of genetic engineering (Goodell 1987; Nelkin 1994).

The motive from the start was to reduce potential hazards and to proceed with the research, avoiding public interference by demonstrating that scientists on their own could protect laboratory workers, the public, and the environment. Of course, this action contained a contradiction: they were dealing with a public health issue and simultaneously attempting to keep the public out of it. Initially, some journalists were told that the conference was to be closed (Perlman 1975, pp. 72–73; Rogers 1977, p. 54; Wade 1975, pp. 6–11). However, at their 10 September 1974 meeting, the organizers decided to limit press attendance to eight invited reporters, with the requirement that they attend all the sessions and that they agree not to report on the conference until it was over, because things would be too much in flux. Ultimately sixteen journalists were included in the publically funded conference (Organizing Committee 1974; Baltimore 1975, pp. 89–93; Berg 1975, pp. 75–81; Lewis 1975, pp. 7–36; Roblin 1975, pp. 78–81; D. Singer 1975; M. Singer 1975, pp. 51–59).

In his opening remarks at the Asilomar Conference, David Baltimore expressed the views of the organizers about the limited focus of the meeting:

> There are two issues which are peripheral to this meeting and which could confuse it in a number of ways. One of these is the utilization of this technology in what's been called gene therapy or genetic engineering. Which leads one into complicated questions of what's right and what's wrong, of complicated ques-

> tions of political motivations, and which I do not think this is the time to discuss. And secondly, an issue which is very serious and which many of us care about and have cared about for a long time, which is the possibility to utilize such technology in biological warfare. And, again, although I think it's obvious that this technology is possibly the most potent potential technology in biological warfare, this meeting is not designed to deal with that question. The issue that does bring us here is that a new technique of molecular biology appears to have allowed us to outdo the standard events of evolution by making combinations of genes which could be immediate natural history. These pose special potential hazards while they offer enormous benefits. We are here in a sense to balance the benefits and hazards right now and to design a strategy which will maximize the benefits and minimize the hazards for the future. (Asilomar 1975)

The four-day meeting focused on presentation and discussion of reports of technical working groups, but one evening session featured presentations by lawyers on policy and liability questions, especially the legal responsibility of researchers for damage resulting from their laboratory research. A persistent theme that comes through on the tapes of discussions at the 1975 Asilomar meeting is worry by biologists about public perceptions and political consequences. Here are some examples: "we are trying to give to the public some assurance that we are thinking seriously about what we are doing"; concerns that the Asilomar guidelines document would be "crystallized in legislation . . . so we'd better be sure it's right"; and frequently expressed anticipation of negative public impact if the participants did not come up with a consensus (Rogers 1977; Wade 1977). A hard-fought consensus was reached and was published soon after (Berg et al. 1975).

PUBLIC RESPONSE TO THE NIH GUIDELINES

The first meeting of the NIH Recombinant DNA Advisory Committee was held immediately after the Asilomar conference, and it began the task of turning the conference recommendations into safety guidelines for all recombinant DNA work at all institutions receiving NIH funding. During 1975 and 1976, scientists on the NIH Recombinant DNA Advisory Committee (RAC) argued about whether the proposed laboratory safety guidelines were too strict or too permissive, and the document went through many drafts (NIH 1976–). The committee members were designing safety protocols that had the potential for restricting their own work. Furthermore, these controls were to be administered by the NIH, which funded and encouraged the research and therefore was itself in a position of conflict of interest. NIH officials acknowledged the potential conflict, and maintained that although NIH was not a regulatory agency, it had the best expertise in the field and needed to act in the absence of any other government group playing a role. Similar efforts were also underway in other countries. All of this occurred in the absence of risk assessment experiments.

At the same time, scientists at laboratories throughout the country were tooling up to use the new technique and were impatiently waiting for the green light that would allow them to proceed as rapidly as possible. They exerted a great deal of pressure on the RAC and the NIH. The process of establishing safety rules involved a series of compromises aimed at achieving a consensus within that portion of the scientific community affected by the guidelines, while at the same time providing assurances to the public that they would be protected from potential hazards (Krimsky 1982; Wright 1994).

The long-expected NIH guidelines were released on 23 June 1976. When the green light flashed, an extraordinary event took place in Cambridge, Massachusetts. Scientists from MIT and Harvard and representatives of the NIH appeared at a special City Council hearing. They had been invited to explain to the citizens of Cambridge why the scientists themselves had been arguing about the safety of recombinant DNA, and whether the guidelines were adequate to protect the communities in which the research was to be done. Was there any danger to citizens? Who was going to monitor and enforce the safety standards? Could the scientists and their universities be trusted to regulate themselves? Testimony by several biologists that recombinant DNA techniques posed few risks and that they could be contained by the new guidelines was countered by testimony from other biologists, who argued that the guidelines were inadequate and that they were formulated by self-interested advocates of the research. After a second hearing in July 1976, the City Council established a citizens review board to examine the problem and, pending the outcome of the board's deliberations, placed a temporary ban on experiments classified in the guidelines as posing moderate to major hazards.

The nine-member Cambridge Experimentation Review Board met twice weekly for a total of more than 100 hours over a four-month period. About one half of the time was used for testimony by 35 witnesses, 26 of whom were proponents of the research. The Board recommended the creation of a city biohazards committee to oversee adherence to the NIH guidelines for all recombinant DNA work in the city, whether funded by NIH or not, and they also recommended several additional safeguards on experimental procedures, containment, and testing of organisms (Cambridge 1977; Krimsky 1982). These community confidence-building measures were incorporated in a City Council ordinance passed in February 1977, which was the first recombinant DNA legislation in the United States and was interpreted by many as a qualified public endorsement of the NIH guidelines (Goodell 1979). This innovative citizen involvement in Cambridge was a serious democratic process, although some subsequent commentators have focused on the flamboyant statements of the city's mayor in their characterization of the Cambridge proceedings as a hysterical response and a circus.

A major fear of the recombinant DNA scientists was that their own early concern about laboratory safety had initiated public scrutiny of the new research.

This was emphasized by the events in Cambridge and in other communities, such as Ann Arbor, San Diego, New Haven, and Princeton, where academic biologists were tooling up to use recombinant DNA techniques. By 1978, 16 separate bills had been introduced in Congress to regulate recombinant DNA safety standards by making the NIH guidelines mandatory for both publically and privately funded research and by providing enforcement and punishment provisions for any violations. Research universities and scientific organizations vigorously lobbied to oppose or influence local and national legislation which they saw as public "overreaction," threatening their control of laboratory safety procedures and jeopardizing funding for recombinant DNA research. A slogan popular among several MIT biologists at the time was "Shut up or be shut down." Who was overreacting? Several prominent biologists who had shared the early concern about possible safety hazards of the research publicly recanted, and a resolution to Congress signed by most of the participants at a 1977 Gordon Conference stated that they previously had overstated the risks and now could provide reassurance that the work was safe (Gilbert 1977).

At a RAC meeting that I attended in 1977, some members of the committee declared that they were now acting "scientifically" when they maintained that the conjectured risks were overstated, and that they previously had acted "politically" when they had voiced concern about such risks. During the lunch break at that same meeting, two RAC members rushed from the NIH in Bethesda to Capitol Hill to inform lawmakers working on recombinant DNA legislation that the NIH advisory committee had just narrowed the definition of recombinant DNA in the preamble of the revised guidelines. Their aim was to make the proposed legislation less inclusive and less restrictive. Clearly science and politics were as intertwined as the strands of the double helix. In the end, no legislation was passed by Congress.

COMMERCIAL APPLICATIONS AND "GEE WHIZ" JOURNALISM

Downgrading of the NIH guidelines coincided with rapid commercialization of the field and the involvement of academic scientists in biotechnology companies. In November 1974, during the moratorium period, a patent application for the recombinant DNA technique was filed. Starting in the late 1970s, biologists and their universities got involved in what soon became almost a complete commercialization of the work. By the early 1980s, all of the 11 signers of the 1974 Berg letter were involved with biotechnology companies. In the 1980s' political climate of deregulation, the U.S. biotechnology industry was promoted as a national priority. The media amplified government, industry, and university claims of impending medical, practical, and economic benefits of the research and the need to develop the industry. The news coverage shifted from risks to "gee whiz" (Goodell 1980). Critical questions about the health and environmental safety of

research techniques and products were met by arguments that if the United States did not move forward rapidly in biotechnology, the country would lose out in international economic competition. Similar efforts to promote the field were pursued in many countries by advocates of biotechnology, including commercially involved academic scientists. They argued that biotechnology's economic promise for applications in medicine, industry, and agriculture provided the hope for national leadership in a new "high-technology" arena (Gottweis 1998). The "gene gap" argument was deployed to resist special regulation of the field.

THE ICE-MINUS CRISIS

As the guidelines faded away for most laboratory work, attention shifted from the accidental escape of genetically engineered microorganisms to the intentional release of these organisms into the environment for agricultural purposes. By that time, the NIH had approved industry and university proposals for small-scale field testing of a genetically modified organism that was to be sprayed on strawberry and potato plants to prevent frost damage. The "ice-minus" controversy of the mid-1980s involved approvals by the NIH, the EPA, and California agencies, legal challenges by genetic engineering critic Jeremy Rifkin, congressional and local government hearings, and protests and demonstrations by citizens in the community near Asilomar, where field testing was to occur. As in Cambridge several years earlier, the citizens asked, "Why are we the last to know?" The strawberry test plot was definitely in their back yard, but they were not informed of its exact location because the company conducting the tests wanted to protect its proprietary interests. Public trust was further diminished when the company was fined by the EPA, after a whistleblower revealed that the firm had secretly conducted open-air experiments on the roof of its building without approval. The community was concerned about unresolved safety questions raised by ecologists and the uncertainty about the outcomes of this new technology. By the time the tests were finally conducted in 1987, the NIH's role in approval of environmental release of genetically modified organisms had been superceded by the EPA (Krimsky and Plough 1988).

The controversy spurred calls for more effective government oversight of biotechnology's agricultural applications and alarmed the burgeoning industry. Once again, the need for meaningful and timely public involvement in health and environmental safety decisions had been demonstrated.

GENE TRANSFER EXPERIMENTS ON HUMAN SUBJECTS

Another example of the tensions between self-regulation, commercialization, and protection of the public interest is the ongoing controversy about gene transfer experiments on human subjects—generally referred to as "gene therapy"—to promote the as-yet-unrealized hopes of its advocates. In 1985, the

NIH issued *Points to Consider for Design and Submission of Human Somatic Cell Therapy Protocols*, developed by the RAC as a framework for evaluation of proposals. The approval process by the NIH and the Food and Drug Administration includes reliance on reviews of safety and the protection of human subjects by committees at the researcher's home institution (Walters and Palmer 1997). These procedures involve significant self-regulation. Their adequacy was challenged by Congress and government agencies after a series of media reports, beginning in September 1999, revealed serious violations at several institutions. The scientific and regulatory lapses included abuses of informed consent procedures, failure to monitor the effectiveness of the treatments, neglect in reporting adverse effects and harm to human subjects, and conflicts of interest due to commercial involvements of the investigators and their institutions. The FDA shut down several clinical trials and an intense review was initiated. A year after the death in September 1999 of an 18-year-old subject of a gene transfer experiment at the University of Pennsylvania, his family filed a lawsuit against the institution, the scientists involved, and the bioethicist who advised them (Nelson and Weiss 2000). Subsequently the bioethicist was released from the lawsuit, which was then settled out of court. In December 2000 the U.S. Food and Drug Administration began proceedings to disqualify the chief scientist involved from conducting any future clinical trials. The claims of medical benefits are unfulfilled and the public's trust has been eroded.

Despite the current crisis in human somatic cell genetic intervention some advocates are actively urging that germ-line human gene transfer should be considered ethically acceptable. Several leading biologists are even promoting germline interventions to "enhance" human characteristics. These proposals for a new eugenics of designer babies have been condoned or supported by some bioethicists, who seem to focus on shifting rather than drawing the line. When I interviewed biologists after the 1975 Asilomar conference about their roles in the recombinant DNA safety issues, I also asked some of them about their views on limits to human genetic manipulation. They felt that the ethical line should be drawn before human gene therapy, and that the whole society should decide whether to initiate somatic cell interventions. They volunteered that they were personally opposed to germ-line interventions.

At the 25th anniversary Asilomar conference in 2000, an open letter urging participants to support a ban on human germ-line engineering was distributed by a public interest group, the Exploratory Initiative on the New Human Genetic Technologies. Among the 200 signers were academics, including scientists, from several universities. Although the letter was not discussed at the meeting, it showed the public concern with this issue and desire to participate in relevant decisions. The appeal for the support of the Asilomar 2000 participants was a timely reminder that projected applications of genetic engineering are not inevitable, that they need not be determined by market driven pressures, and that they should be decided by the society as a whole.

CONCLUSION

The scientists involved in the 1975 Asilomar process devoted a great deal of time and effort to their attempt to anticipate, assess, and reduce the potential safety hazards of their research. However, their framework of self-regulation limited public involvement and gave rise to public controversies. And by excluding consideration of the longer term ethical issues, an opportunity was lost. Conflicts of interest related to the subsequent rapid commercialization of the field contributed to public perceptions of a credibility gap.

At a 1979 conference of biologists, where the Asilomar process and its aftermath was evaluated, I offered some recommendations that are still relevant today:

> Nothing will be solved by facing the future with a "scientists versus the public" attitude. Instead of belittling and ridiculing public concerns it would be far more constructive to attempt to understand the basis of public perceptions and the need for public participation in decisions. In addition, confidence in the credibility of technical experts could be enhanced rather than diminished if they are open and explicit about their professional and financial interests in the outcome of the issues being discussed; and if they admit when they do not have the answers, or when the available data are ambiguous, or when uncertainty prevails, or when there is disagreement among experts. (Weiner 1979b, p. 287)

The laboratory safety guidelines for recombinant DNA that were developed in the 1970s helped to accelerate the growth of a research field that has had enormous societal consequences. Self-regulation is not adequate for today's urgent social and political choices about the directions, priorities, and limits to human and agricultural applications of genetic engineering and biotechnology. Despite current efforts to keep these decisions under the control of scientists and their organizations and institutions in a context of pervasive commercialization, they must be decided in the public arena and take account of concerns for social justice and moral values, as well as effects on health and environmental safety. Serious consideration should not exclude the options that have been adopted in numerous countries of banning applications, such as reproductive cloning and inheritable human genetic modification. Scientists can contribute their knowledge and experience to this democratic process, transcending their professional and financial self-interests. Social responsibility in the life sciences involves more than safety or clinical medical ethics, and it should not be deferred or compartmentalized by separating the technical issues from the ethical issues and relegating the latter to bioethicists. Nor should the decisions be determined by commercial pressures or by autonomous personal choices.

The dogma of "inevitability" encourages passivity and acquiescence. It discourages meaningful public involvement and inhibits scientists from considering the social implications of their research choices and from speaking out about their concerns for the uses and abuses of their work. The choices are on the table now and require full public debate and participation. Concerned biologists can

make significant contributions to this effort. Their participation would provide an opportunity for them to consider how their views on many technical issues are influenced by their roles, and how others see the issues. It would allow them to exercise their responsibility to anticipate and attempt to prevent negative or unintended consequences of their work.

In 1974, when I first learned of biologists' concerns about the possible safety hazards of the new recombinant DNA techniques, I became aware of the challenges they faced in trying to protect the public from harm while protecting their own research and professional interests. In the decades since then, I have witnessed the changes in their roles and in the context of their work due to their commercial involvements, as well as the increasing power of tools for genetic manipulation and of the knowledge and applications that they have made possible. Today's challenges go far beyond reducing safety hazards. They require more than preparing society to cope with possible negative impacts of the "inevitable advance" of science as claimed by the genome projects. The challenge now is to involve the entire society in making choices about the uses and abuses of this science and to draw the line to prevent unacceptable applications. In 1971, Leon Kass observed that "biomedical technology makes possible many things we should never do" (Kass 1971, p.788). Now that many more things are possible or proposed, including human germ-line intervention for medical or "enhancement" purposes, we must not let the market decide. We need to be prepared to "just say no."

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