

**The Recombinant DNA Case:  
Balancing Scientific and Political Decision-Making**

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Approved:



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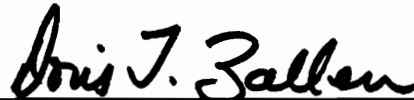
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(ABSTRACT)

The unfolding of recombinant DNA, from research technique to political issue, is described. As a research technique, recombinant DNA (abbreviated rDNA) has opened up new vistas in biological and other fields of research. But its potential yet unproven hazard has created uneasy feelings toward the technique. The controversial nature of the issue finally launched rDNA into the political sphere, involving scientists, the public at large, and Congress in efforts to control the development of the field.

The first group to regulate rDNA was the scientists. The scientific community called for a voluntary moratorium on experiments perceived as potentially dangerous at the time. It was an unprecedented act. The National Institutes of Health subsequently issued guidelines for a safe execution of rDNA experiments to minimize potential dangers to public health and well-being. Efforts of the scientific community to control rDNA was seen, however, as a politics of expertise. Challenges to this "technocratic" approach soon emerged.

Vocal members of the public suspected expert decision makers as being biased toward scientific interests, reducing rDNA to a technical issue. They rejected the experts' tunnel vision and demanded a say in decisions. Public participation in the decision-making process precipitated community debates at locations where rDNA research was ongoing. A democratic approach to decision-making proved to be a viable policy-making mode. The ensuing local and state laws, however, seemed inadequate to cover global consequences of rDNA.

In an effort to unify regulations of the field, Congress attempted to legislate on the subject. Resistance from the scientific community, which regard legislative control as rigid and unnecessary, was one of the causes of diminishing congressional interest in the matter. None of the introduced bills was enacted.

For complex policy areas with uncertain yet far-reaching scientific and societal consequences -- like rDNA -- this dissertation recommends a policy-making process where scientists, interested lay persons, politicians, public administrators, and other relevant parties participate in structured communications *prior* to an emerging controversy. To facilitate the process, establishment of National Science Fora is recommended.

# *Acknowledgements*

It has been a long journey from Jakarta, my hometown, to Blacksburg, Virginia. When I left Jakarta, I did not dream of studying Public Administration, let alone of getting a doctoral degree. I went to Amsterdam, the Netherlands, to study chemistry. It was a blessing in disguise that I ended up at the Center for Public Administration and Policy in Blacksburg. The Center has been good to me.

I dedicate this dissertation to my father and mother who have been a never-ending source of encouragement, support, and love. Without their confidence in my capabilities, I would never have finished this dissertation. Thank you Mom and Dad, for being such wonderful parents.

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I shall always remember my mother's message that has served as my motto in finishing this dissertation, *Carpe diem*.

# *Table of Contents*

<b>Prologue</b> .....	1
<b>One</b>	
<b>Setting The Stage</b>	
Those Powerful Genes .....	4
The Thread of Life .....	6
The Controversial Technique .....	10
Who Should Decide and How? .....	14
The Current Dilemma .....	20
Looking Ahead .....	28
<b>Two</b>	
<b>The Pertinent Literature</b>	
Source Material .....	34

Following Themes . . . . . 38

Supporting Material . . . . . 39

Next Steps . . . . . 47

**Three**

**Expert Decision Makers**

Government and Science . . . . . 53

The Technocratic Paradigm . . . . . 56

Technocracy at Asilomar . . . . . 60

Motives Behind Asilomar . . . . . 66

The Founding of RAC-NIH . . . . . 69

Guidelines and Democracy . . . . . 72

Public Hearings . . . . . 76

Role of the Scientists . . . . . 82

**Four**

**The Public's Voice**

Changing Contexts . . . . . 89

The Michigan Debates . . . . . 94

The Cambridge Experience . . . . . 100

Procedures of the Debates . . . . . 105

Outcomes of the Debates . . . . .	113
Pitfalls of the Debates . . . . .	116
Role of the Public's Voice . . . . .	119

**Five**

**Congressional Control**

Should We Control Science? . . . . .	125
Legislative Interest in rDNA . . . . .	129
Legislative Efforts in rDNA . . . . .	138
Interagency Committee . . . . .	141
Failure of rDNA Legislation . . . . .	148
Another High Technology: Atomic Energy . . . . .	155
Evolution of the AEC . . . . .	159
Role of Legislation . . . . .	161

**Six**

**The Turning Point**

Planning for the Future . . . . .	168
Problematic Characteristics . . . . .	170
Review of Technocratic Policy . . . . .	173
Review of Public Participation . . . . .	174



Review of Legislative Control . . . . .	178
What Have We Learned? . . . . .	181
A Call for Change . . . . .	183
Negotiation by Consensus . . . . .	186
National Science Forum . . . . .	192
<b>Epilogue . . . . .</b>	<b>201</b>
<b>Appendices</b>	
Appendix A: Hearings and Bills . . . . .	204
Appendix B: Gordon Conference Letter . . . . .	207
Appendix C: Berg Letter . . . . .	209
Appendix D: Summary Statement of Asilomar II . . . . .	211
Appendix E: Members of the Original RAC-NIH . . . . .	216
<b>Curriculum Vitae . . . . .</b>	<b>219</b>

# *Prologue*

In the next millennium, our global economy faces many challenges. One of them is the increasing importance of technology as a determinant of our competitiveness in world markets. Without a solid technological base, we face an imminent chance of losing a strong bargaining position in the world economy.

Over the past years, technological advances have transformed significant parts of our lifestyle. Computers and fiber optics expand our communication systems, while medical interventions are capable of prolonging human life. Yet we may reasonably expect many more, undreamed-of technologies to come.

Biotechnology is currently one of the most prominent technological building blocks of our future world economy.<sup>1</sup> During the past few years, genetic engineering techniques have continuously improved. The possibility to use these techniques to produce food, medicine, and medical treatments, to name a few, is no longer a dream. Genetically engineered "FLAVR-SAVR" tomatoes with longer shelf lives, human insulin, "biorational" pesticides that attack specific pests, and human gene therapy are now

available. Recently, a test at the clean-up site of the oil spill at Prince William Sound, Alaska, shows that certain micro-organisms degrade oil and produce environmentally safe by-products. This "bioremediation" process may be just one of many future bioefficient, environmentally safe technologies.<sup>2</sup>

Until today, the marvels of biotechnology have only benefitted the quality of our lives. No monsters, super bugs, or irreversible damage have been created. Accordingly, interest in restricting or slowing development of the technology has slowly diminished. The 1970s debates on controlling biotechnology are now regarded as mere relics of public hysteria of the unknown. So, why study policy-making in recombinant DNA?

It is because additional such technologies will be coming along in the century ahead. For theoretical purposes, studying the history of policy-making in rDNA provides valuable conceptual themes upon which we can build policies for future technologies. We look back in order to anticipate the future. For practical purposes, a novel policy and policy-making process may avoid anti-technology sentiments, thereby easing the way to develop and commercialize upcoming technologies.

Only recently, anti-biotechnology groups dumped milk into streets from cows treated with genetically engineered BST, or bovine somatotropine, a growth hormone to increase milk production.<sup>3</sup> This and other protests, slowing down commercialization of the technology, could endanger the United States' role in the global bioeconomy.

This dissertation explores policy-making processes in the early years of rDNA, one of the first genetic engineering techniques. In the evolution of genetic engineering policy

in the 1970s three alternative policy processes were employed -- these I call the technocratic, democratic, and legislative modes. For analytical purposes of this dissertation, the three policy-making modes are not only interesting, but useful. None of them, so it seems, has been fully successful. Yet in spite of their flaws, each of them offers lessons for policy-making in technologies to come. My thesis is that these lessons can be synthesized to form a practical proposal for public policy-making regarding future esoteric technologies. Consensus negotiation processes in a National Science Forum is recommended.

### *Notes to Prologue*

1. "Biotechnologie Sleutel voor Duurzame Chemie," *Chemisch Weekblad* (The Hague), no. 34 (26 August 1993).
2. The President's Council on Competitiveness, *Report on National Biotechnology Policy* (1991), 2-4.
3. "Milk Hormone on Sale Today; Protests, Milk-dumping Begin," *Roanoke Times & World News*, 4 February 1994.

# *One*

## *Setting The Stage*

### *Those Powerful Genes*

The development of genetically engineered foods, pharmaceutical products, new plant varieties, oil-eating bacteria and other products has surged enormously in the past decade, and it does not look like that this trend is going to decline in the near future. Scientists in the life sciences expect that genetic engineering techniques will be the most prominent research tools of the twenty-first century. The practice of medicine, for example, will change dramatically with the application of genetic engineering to this field. In human gene therapy genetically altered cells are introduced to a patient, allowing these cells to invade the body and produce the necessary substances for normal physical functions. Such a procedure has recently been tested in infants born with Severe

Combined Immune Deficiency Syndrome. An inserted gene into stem cells of the infants produces an enzyme that ultimately provides for a defence against infections.

With respect to semantics, "genetic engineering" is the overarching term for the study of the manipulation of genetic material by using, among other techniques, recombinant DNA (abbreviated rDNA). Generally speaking, "recombinant DNA" is a technique to transfer genetic material from one organism to another. More specifically, rDNA allows for the insertion of foreign genetic material as well as for the deletion of genes from an organism. A more popular term, "biotechnology," defines the use of genetic engineering on production scale. Recently, the Office of Technology Assessment (OTA) defines "new" biotechnology as "the industrial use of rDNA, cell fusion, and novel bio-processing techniques."<sup>1</sup>

Looking back at the history of genetics, it is hardly possible to determine when prehistoric human beings first thought about heredity. Possibly, the domestication of animals and the cultivation of plants were the first instances when transmission of certain characteristics from one generation to the other was dimly understood. The domestication of the dog occurred in Denmark as early as 8000 B.C. Ancient Babylonians and Assyrians knew about female and male date palms in 5000 B.C.<sup>2</sup> Hypotheses of heredity by the ancient Greeks profoundly influenced later geneticists. For example, Hippocrates' "pangensis" (ca. 400 B.C.) was further developed by Charles Darwin in his *Provisional Hypothesis of Pangenesis* in 1868.<sup>3</sup> The nineteenth century showed a remarkable progress in genetics. Gregor Mendel's research on the pea plant, reported in his essay *Experiments*

*in Plant Hybridization* (1865), and Charles Darwin's *The Origin of Species by Means of Natural Selection* (1859) are landmarks in the history of genetics.

Genetics and genetic engineering techniques, as we understand them today, are not based on traditional or trial-and-error knowledge. Current understanding of genetics has been made possible by two revolutions in biological sciences: the DNA revolution and the enzyme revolution. The unraveling of the double helix structure of deoxyribonucleic acid (DNA), the chemical structure of genetic material, and the discovery of specific enzymes that interact with DNA, have opened the door to the possibility of combining genetic material from different species. In the early 1970s, precursor experiments of the rDNA technique were first reported. Since then, rDNA and other genetic engineering techniques have experienced an unprecedented growth.

### ***The Thread of Life***

In March 1953, James Watson and his British collaborator Francis Crick revealed the now famous structure of deoxyribonucleic acid, or DNA, which is the chemical material of genes. The most prominent characteristic of the *double helix* structure of DNA is that it allows for an exact replication of each DNA-strand to occur in the reproduction process. With the unraveling of the DNA-structure and its function in the replication process, the mystery of heredity that had challenged thinkers since the Greek

physician Hippocrates of Cos (460-377 B.C.) and the philosopher Aristotle (384-322 B.C.) at long last was explained in terms of DNA, the chemical building blocks of genetic material. Although the breakthrough in the mechanism of transmission of specific characteristics in living organisms happened almost half a century ago, its significance became evident only in the early 1970s.

The discovery of the chemical structure of DNA opened up new vistas in biological and biochemical research. Yet the application of the science of DNA was possible only after certain enzymes were detected. One enzyme was able to "cut" DNA at specific places, and is called the restriction enzyme. Another enzyme, the ligase, "glues" parts of DNA to each other. Although other enzymes were crucial in other genetic engineering techniques, the cut-and-glue enzymes were the primary enzymes used in the recombinant technique.

In June 1971, at the Cold Spring Harbor Tumor Workshop, the first successful implantation of a monkey tumor virus, known as SV40, in the bacteria *Escherichia coli* (*E.coli*) was reported. SV40 (the fortieth simian, or monkey virus) is known to alter human cells in culture, and hence, known for its potentially tumorigenic characteristic. In the experiment, the monkey virus was reproduced in the replication of *E.coli* -- the host bacteria within which the virus had been inserted. The successful reproduction of inserted genetic material in a host organism marked a milestone in genetic research: the first successful "cloning" of an animal virus had become reality. Yet the primary significance



of this experiment was that it became the precursor of the most well-known as well as most controversial technique in genetic engineering, *viz.*, the recombinant DNA technique.

The cloning was accomplished at Stanford University under the supervision of Dr. Paul Berg. At this same laboratory the first hybrid (recombinant) nucleic acid molecule was constructed. It was a combination of the monkey tumor virus SV40 and an adenovirus. The latter organism, the adenovirus, is not a totally harmless organism. An adenovirus infection in children and young adults can cause an acute respiratory disease.<sup>4</sup> Dr. Berg also constructed another hybrid consisting of bacteriophage lambda, galactose coding genes, and SV40. This hybrid was intended to be a "vector," that is, a carrier of foreign genetic material into bacteria. The use of SV40 was deemed not entirely safe because of its tumorigenic characteristics. More troubling, however, was the linking of animal DNA to bacteria. There was an unproven yet probable hazard of bacteria spreading the inserted animal virus (SV40) to humans and other animals.<sup>5</sup>

From the first experiments in DNA-recombination, scientists today have come a long way toward the application of rDNA in, for example, food production, environmental treatment, pharmaceutical production, and human gene therapy. The FLAVR-SAVR super tomato is an example of a genetically engineered, or "transgenic" food product. An inserted gene ultimately suppresses the production of an enzyme that breaks down pectin, a substance responsible for the firmness of a tomato. In other words, when the enzyme is not produced, pectin stays in the cell wall, and accordingly the ripe FLAVR-SAVR remains firm for a longer time and has a longer shelf life.<sup>6</sup>

"Frostban" is the generic name for bacteria (*Pseudomonas syringae* and *Erwina herbicola*) that lack genes coding for the forming of ice crystals on the leaves of crop plants such as strawberries and potatoes. Frostban thus reduces the forming of frost on leaves. At the Virginia Tech Biotechnology Center, a human gene that is responsible for producing protein C -- which is an important substance for blood clotting -- is introduced in a pig, and regenerated from sow's milk.<sup>7</sup>

In human gene therapy, researchers at the University of Michigan have injected a gene in a skin cancer patient, hoping that this gene stimulates the immune system to attack the cancer cells.<sup>8</sup> Similarly, genetic material has been inserted in the stem cells of children with Severe Combined Immune Deficiency Syndrome, or SCIDS.<sup>9</sup> Defective genes in SCIDS-children prevent the production of a certain enzyme to break down toxic metabolic products. Accumulation of those toxins ultimately leads to the destruction of the immune system and leaves the patients defenseless against infections.<sup>10</sup>

Transgenic rice, maize, and wheat that are resistant against disease, insects, herbicides, or extreme weather conditions, have been cultivated over the past five years.<sup>11</sup> A baculovirus that specifically kills harmful insects in less time than its wild-type, is one of the first transgenic bio-insecticides.<sup>12</sup> Biodegradable plastic has been reported to be produced from transgenic plants.<sup>13</sup>

The stakes in the commercialization of genetically engineered products are high, although direct profits are not anticipated to materialize before the year 2000. Nevertheless, the potential importance of genetic engineering and the commercialization

of its products have led several committees of the U.S. Congress to request a comprehensive study of this topic. Prospects of industrial success have attracted political interest around the world. The Office of Technology Assessment (OTA) has published a report on the global development of commercial uses of genetically engineered products.<sup>14</sup>

As the science of DNA and its modification techniques unfold, researchers become more and more able to advance the thread of life. Life can be better when rDNA is used advantageously. Many aspects of our social and economic life can benefit from this powerful technique. Yet, the unfolding of the power of genetic engineering did not emerge smoothly. Scientists were divided in their opinions, with some advocating the technique ardently and others fiercely opposing it. Meanwhile, lay persons in the general public became uncertain spectators of the controversy.

### *The Controversial Technique*

Not everybody was -- and is -- happy with genetic engineering. At the onset of the development of rDNA, scientists themselves were divided. Some were against genetic engineering and wanted a complete halt of the technique. Others acknowledged the potential dangers, but persisted on going ahead, albeit cautiously. Ethical and religious groups doubted whether the technique ought to be performed at all. They rejected the

idea of scientists tampering with nature, "playing God," and collapsing evolutionary time to a matter of days, or perhaps even a few hours. Visions of a Dr. Frankenstein's monster were created by a sensation-hungry media.

Recently, Mr. Jeremy Rifkin, an anti-biotechnology activist and leader of the Pure Food Campaign, declared the genetically engineered FLAVR-SAVR tomato unsafe for consumption.<sup>15</sup> Although not mandated by the Food and Drugs Administration (FDA), the City of Chicago planned to pass a local law requiring all genetically engineered food products to be labelled as such. Calgene, a biotech company at Davis, California announced on the other hand, that it will display such labels with pride, regardless of the law.<sup>16</sup>

The controversy surrounding genetic engineering stimulated serious debate as well. In the early 1970s, scientists themselves took steps to ensure the safe development of their activities, and placed a moratorium on certain types of experiments. Their initial concern was about the safety of the research itself. Later the issue of research safety became one of control. The 1973 Gordon Conference on Nucleic Acids in New Hampton, New Hampshire was one of the main events that initiated public debate where many pressing questions were asked.

The debates essentially questioned whether scientists could be objective decision makers if they were promoters and regulators at the same time. What I am calling a "technocratic" approach to decision-making by relatively autonomous scientists was thus challenged. Because of the controversial nature and pervasive consequences of rDNA,

some people argued that citizens have a legitimate voice in deciding the future of rDNA. The question, then, became whether it was appropriate to replace such a technocratic approach with a more democratic process whereby broad participation was encouraged. Another option was to regulate rDNA by means of a formal procedure, for example, by federal legislation. This dissertation addresses these issues by analyzing the actual policy-making processes in genetic engineering, especially in rDNA.

In retrospect, we find three alternative decision-making processes have been employed in the regulation of rDNA. First, the technocratic approach granted autonomy to scientists as overseer of their own activities. On October 7, 1974 the National Institutes of Health established an advisory committee, the Recombinant DNA Advisory Committee, or RAC-NIH. The RAC, composed of scientists, issued guidelines for the purpose of regulating rDNA, better known as the NIH guidelines. The scientific expertise of RAC-NIH and the scientifically based NIH guidelines were initially adequate controls for a safe development of rDNA research. The highly regarded RAC-NIH was intended to act as a "supreme court" in rDNA issues.<sup>17</sup>

Challenges to this elitist decision-making procedure however, prompted another, second kind of process: community debates. These occurred at Cambridge, Massachusetts, Ann-Arbor, Michigan, Princeton, New Jersey and San Diego, California over the period 1975-1977. Local citizens participated in deciding the future of rDNA in communities where research was ongoing. These community debates proved to be a viable process of decision-making. They were loci for discussion and dialogue and the

dissemination of information. They eventually eased tension and negative feelings toward rDNA in these respective communities.

A third alternative policy was launched, although in the end it was not implemented. This was to regulate rDNA by national legislation. Several bills were introduced in Congress, but none was enacted. Although national legislation on rDNA failed, another high technology, that is, atomic energy, was regulated this way by means of the Atomic Energy Act of 1946. The Act established the Atomic Energy Commission (AEC) as a controlling body for the development of atomic energy. Instead of providing advice as RAC-NIH has done, the AEC issued policies to regulate the field. In other words, the AEC was a regulatory agency while the RAC was an advisory body.

Although currently the benefits of rDNA seem to outweigh the resentment of the skeptics -- mainly because none of the hypothetical hazards has materialized -- anti-biotechnology sentiments have affected the development of genetic engineering in this country with delays, frustration, and an imminent threat of losing a prominent place in the competitive world market. Hopefully, such undesirable situations can be avoided in future high technologies. It is therefore important to look back at the policy-making processes in genetic engineering in order to be better prepared for future policy-making demands in other areas. To manage a powerful, yet controversial technique successfully, we need a policy that is novel in its process and effective in its outcome. This kind of policy will be increasingly needed in the century to come, when undreamed-of technologies will emerge. The ultimate aim of this dissertation is to prescribe such a policy.

In summary then, this dissertation analyzes prior policy processes in rDNA, which is taken as a case study. In this analysis we will look to the RAC-NIH, community debates, and AEC as models from which to draw ideas. The lessons we learn will serve as a foundation for a novel policy process to guide the development of future high technologies. We must create what Joseph Agassi calls a "social control of technology"<sup>18</sup> to decide in a democratic way how to guide powerful technologies in a beneficial way for our existence on this planet earth.

### ***Who Should Decide and How?***

The opposing opinions among a divided scientific community about the future of rDNA research soon could not be contained. In a January 26-28, 1971 meeting of the Panel on Science and Technology of the U.S. House of Representatives, James Watson -- famous from the double helix structure of DNA -- warned Congress of the social implications of "cloning."<sup>19</sup> Then the June 11-15, 1973 Gordon Conference on Nucleic Acids took place in New Hampton, New Hampshire. Many analysts considered the 1973 Gordon Conference as the starting point of the public debate in rDNA.<sup>20</sup> There, a group of concerned scientists decided to write a letter to the Presidents of the National Academy of Sciences (NAS) and the National Institute of Medicine (NIM). The full text of the

letter appeared in the journal *Science*.<sup>21</sup> As response to the letter, a study panel was created under the aegis of NAS, with among others Paul Berg as participant.

The study panel's reply became well-known as the "Berg letter," which was also published in *Science*.<sup>22</sup> In this letter, members of the panel proposed (1) containment measures; (2) establishment of an advisory committee; (3) an international meeting of involved scientists; and (4) a moratorium for certain types of experiments. Accordingly, the (second) international Asilomar Conference in Pacific Grove, California was held from 24 to 27 February, 1975, the Recombinant DNA Advisory Committee of the National Institutes of Health (RAC-NIH) was established, and the NIH guidelines for containment measures were issued.

The Asilomar Conference extended its invitation to non-scientists such as lawyers, and to a limited attendance of the media (a "pooled coverage").<sup>23</sup> One hundred and fifty three participants from sixteen countries attended Asilomar, the majority of them representing American universities, government and private industries. Roughly a third of the participants were foreign scientists, sixteen represented the press, and four were lawyers.<sup>24</sup>

The conference itself was unique. It was intended to be a "strategy conference" among scientists to discuss the safety measures necessary to continue rDNA research, but ultimately it became "a step in public-policy formation."<sup>25</sup> The debate that followed became focused on *control*, instead of *safety* of the technology. Thus a certain ambiguity



crept into the Asilomar Conference. As a process it was a strategy session, but as a consequence or outcome, it was a policy-making step.<sup>26</sup>

Why did the conference evolve in such a unique way? The main factors that forced Asilomar into the arena of public policy-making were characteristics of its organization, in particular its limited attendance and closed decision-making process. Attendance was by invitation only, and the majority of scientists attending the conference were microbiologists.<sup>27</sup> This limited participation, the elitist agenda setting, and the consequent limited access to the decision-making process, drew much criticism and changed the course of the conference. The importance of the Asilomar Conference justifies exploring these factors more extensively.

In the first place, the attending DNA-experts decided on the topic of the conference, *viz.* biohazard, without consulting other relevant specialists such as epidemiologist and ecologists. The latter scientists were simply not invited to attend Asilomar. The question of biohazard was thus framed by the experts into a mold that reflected their own ideas of the matter and that supported their own interests in pursuing research. In other words, the conference agenda was set by a small group of people with a common interest, which is to continue their own research. Other interests and other scientists were excluded from the discussion. This closed procedure led critics to condemn Asilomar as a "covert exercise of power by a special interest group."<sup>28</sup>

Not surprisingly, this argument eroded the credibility of scientists as decision makers. It appeared that scientists could not be trusted as impartial, neutral regulators or

decision makers. They seemed to be self-promoters. This raised a key question: If scientists could not be trusted as objective decision makers, then who should decide? Should the citizens decide, or government?

Community debates were conducted at the University of Michigan in Ann Arbor and at Cambridge, Princeton, and San Diego. The rDNA debates at Michigan lasted from September 1975 to May 1976. Three separate committees, A, B, and C, looked at different issues of rDNA research at the university. Heated debates between the non-microbiologists members of committee B, rDNA specialists, and University Regents evolved around the issue of how the University should conduct rDNA research. Although the debates took much time and energy of the participants, they felt that their concerns had been heard and in the end, they endorsed the decision-making process. As an outcome of the debates, further restrictions in rDNA research at the University were recommended.

In June 1976, the "Cambridge Experience" took place. Debate erupted whether to approve construction of a P3-laboratory at Harvard University. A P3-laboratory is the second most restrictive facility for rDNA experiments. Led by Mayor Alfred Vellucci, members of the Cambridge citizenry participated actively in the decision-making process. As a result, the Cambridge Experimentation Review Board (CERB) was established to review and approve policies in connection with rDNA research and application. Local ordinances to regulate rDNA in Cambridge followed.

In Princeton, a committee for the study of biohazard was active during the period from January 1977 until May 1977. The committee consisted of scientists and lay people. There were also debates in San Diego, although these discussions did not receive as much attention as the debates in Cambridge and Michigan.

A notable consequence of these local debates was the generation of local ordinances. Local rules such as the Cambridge ordinance did not differ dramatically from NIH guidelines -- the only changes were "cosmetic"<sup>29</sup> -- but they differed in different localities, creating a patchwork of local laws. Obviously, scientists did not welcome a diversity of laws. Strict laws at one locality could hamper research in comparison to places with less strict regulations. For the same reason, industries were equally unhappy with varied local laws. For this and other reasons, attention was then turned to national legislation.

Congressional interest in genetic engineering was primarily influenced by the Cambridge Experience, as well as by a growing opposition of environmental groups against genetic engineering. An August 22, 1976 article in the *New York Times Magazine* by Dr. Liebe F. Cavaliere, member of the Sloan-Kettering Cancer Research Institute and Biochemistry Professor at Cornell University was instrumental in getting the matter on the public agenda.<sup>30</sup> In his article, "New Strains of Life -- or Death," Dr. Cavaliere described the most horrendous effects of genetic manipulation on society's well-being and health. The article made an impression on Senator Edward Kennedy who promptly held a one-day hearing on the issue of rDNA on September 22, 1976.

Legislative efforts culminated during the first session of the Ninety-Fifth Congress in 1977. Senator Edward Kennedy, chairman of the Subcommittee on Health and Scientific Research, had a particular active interest in issues surrounding rDNA. He conducted three public hearings: on April 22, 1975, September 22, 1976, and April 6, 1977. Witnesses appearing during these hearings included prominent scientists such as Dr. Stanley Cohen of Stanford University, Dr. Donald Fredrickson, director of NIH, Dr. Burke Zimmerman representing the Environmental Defense Fund, a Washington DC based environmental organization, as well as Mr. Jeremy Rifkin as a representative of the Peoples Business Commission, Washington DC.<sup>31</sup> The House of Representatives and Senate conducted numerous hearings between March and November 1977. Several House and Senate bills were proposed, although ultimately none was enacted. A list of the hearings and bills is reproduced in Appendix A of this dissertation.

The main factor that ultimately killed any legislation came from the most important stakeholder in genetic engineering itself: the scientific community. First, scientists were satisfied with the NIH guidelines, and they had therefore no need for more rigid regulations of their research activities. Second, they preferred the authority of RAC-NIH above the "shifting sands of Washington politics."<sup>32</sup> The scientists were particularly concerned of arbitrary, inflexible, inappropriate, or politically tainted congressional decisions. The NIH on the other hand, was seen as an institutional friend that promotes research and is in a better position to judge the needs of science and the scientists. Third, genetic engineering was, and still is, a rapidly evolving scientific field. For a developing

field, rigid regulation did not seem appropriate. It would take months, if not years to amend a federal regulation. The NIH guidelines seemed more flexible and more able to adapt to newly created circumstances because they were, in fact, designed to do so.

Hence, failure of national legislation on genetic engineering was not regarded as a set-back. Moreover in subsequent years no impetus to revive the issue emerged. In the 1980s, the Reagan administration leaned toward relaxing government standards of regulation in general. Much to the dismay of environmentalists and other concerned advocates, the 1980s showed a weakening of government regulation on environmental pollution. It is not surprising that new regulation on genetic engineering was not favored by the administration.

### ***The Current Dilemma***

Today, rDNA has become one of the few indispensable tools in genetic research. By using rDNA, scientists can insert well-characterized genes into an organism, usually into the bacterium *E. coli*. And by growing the bacteria, large quantities of the product of the inserted gene, for example, insulin, are produced in a relatively short time. Or, specific genes can be inserted or deleted from plants to create new plant varieties in a few generations. In the preliminary phases of somatic applications of human gene therapy altered cells are introduced in patients to alleviate gene defects. The technique is precise,

effective, and requires less time than traditional production, breeding, or therapeutical methods and often permits steps not possible by traditional means. In spite of these marvelous achievements, the development of rDNA has not been without controversy, as we have seen.

Opponents of the technique have always feared for its potential hazards. The first cloning and hybridization experiments were assumed unsafe because of the pathogenicity of the organisms used in those experiments. Monkey virus SV40 has tumorigenic capacity, while the host bacterium *E.coli*, is common in intestines of a wide variety of mammals, including human beings. Consequently, SV40 in *E.coli* was considered dangerous for its presumed capability to transmit and express the tumor virus in human beings. Although successive rDNA experiments use "enfeebled" (EK2) or "disarmed" (EK3) *E.coli* strains as hosts, the initial fear, unfortunately, persists. An enfeebled EK2 does not multiply in a germ-free laboratory animal, such as a mouse born and developed completely germ-free. When EK2 does not propagate in such an animal, it can definitely not survive in other living beings that are full of germs. Similarly, a disarmed EK3 cannot live outside artificially created laboratory conditions. It can only grow under special laboratory conditions.

In spite of these precautions, antagonists continue to fear for the hazard of recombination techniques. They fear for transfers of rDNA from crippled *E.coli* to healthy *E.coli* which can invade human beings and other animals. Although one cannot completely rule out the possibility of those transfers, theoretically they are not feasible.

Such risks and other potential biohazard related to genetic engineering are hypothetical. Yet there is no total guarantee they could not happen. In short, risks associated with rDNA and genetic engineering are uncertain.

The uncertainty of risks in rDNA research is in part generated by the unpredictability of the evolving science of genetic engineering itself. In an unfolding research field like genetic engineering, the unknowns are revealed in sequences of experiments. Scientists design their experiments based on available theoretical knowledge and in anticipation of certain results, but they cannot entirely prevent unwanted surprises. Thus, although experiments presume certain scientific knowledge and anticipation, it is impossible to guarantee exclusion of undesirable results. Furthermore, the esoteric and uncertain theoretical knowledge itself may lead to unpredictable human decisions, either in anticipation of research results or in experimental design.

Another consequence of the esoteric nature of rDNA is the ensuing disagreement over definitions. For example, what do we understand by "hazardous?" Is rDNA hazardous? Some argue that rDNA itself is not hazardous, because recombination of DNA-pieces occurs all the time in nature. Recombinant DNA is thus a natural process and part of evolution. Others see rDNA as an intervention in the evolutionary process because of its capacity to transfer genes in a short period of time as well as between distant species. Recent studies, however, show that interspecies gene transfer occurs in nature, although the frequency of such transfers is low. There is evidence of natural gene transfer between the bacterial species *Agrobacterium* and a species of the tobacco plant,

between bacteria and animals, and between animal and plant.<sup>33</sup> The oxygen-binding protein in a leguminous plant, for example, is coded by a gene that is remarkably similar to the mammalian haemoglobin gene.<sup>34</sup>

Hence, factual uncertainty in theoretical knowledge, with respect to risks and definitions, is partly responsible for the unpredictability of human actions in experimental designs, anticipation of research results, and decision-making. Yet, there is a third ambiguous factor: moral uncertainty.<sup>35</sup>

The moral uncertainty regarding rDNA involves value judgments. For example, even though interspecies gene transfer is proven to be a natural process, some argue that human intervention in the evolutionary process may lead to biological and social chaos.<sup>36</sup> The "don't-fool-with-mother-nature" philosophy fears that tampering with the evolutionary process is like opening the Pandora Box which will release all evil on mankind.<sup>37</sup> Others insist that rDNA itself is neutral, part of natural processes with no evident benefits or harms. What makes rDNA dangerous is the way people use or misuse the technology.

The esoteric nature of DNA and its manipulation techniques erect a communication barrier between scientific insiders and those who were unacquainted with the technique. The boundaries of discourse among scientists, media writers and members of the general public are further complicated by differences in the language used. Scientists did not seem to realize that they were not communicating the science of rDNA in an understandable manner for non-specialists.



It has always been a difficult task for the press to translate scientific issues in an understandable manner for the lay person. To complicate matters, the warring sides of scientists in genetic engineering seemed intentionally to resort to "esoterica and scientific jargon as soon as the debate grew hot."<sup>38</sup> Obviously, scientific jargon did not help clarify the issue to lay people.

The exotic nature of rDNA was further obscured by the continuously evolving knowledge, adding to the already existing confusion. A telling example is contradictory reports of prestigious scientific organizations in this country. The reports reflect different opinions on "risk assessment" of the release of genetically engineered organisms in the environment.

For example, the 1987 report of the National Academy of Sciences (NAS) sees "no evidence of unique hazards" from releasing genetically modified organisms into the open environment. According to this report, risks associated with such organisms are "of the same kind" as those of unmodified organisms.<sup>39</sup> On the other hand, in 1988, the Office of Technology Assessment (OTA) invites caution toward risk, because there is no "zero risk" situation. It proposes a risk assessment based on results of small-scale tests before approving large scale releases of genetically engineered organisms in the environment.<sup>40</sup>

In 1989, the National Research Council (NRC) published a follow-up report of the 1987 NAS report. The NRC report concludes that "the products of classical and molecular methods are fundamentally similar," and therefore, "no conceptual distinction exists between genetic modification of plants and micro-organisms by classical methods

or by molecular techniques that modify DNA and transfer genes."<sup>41</sup> Yet on the other side, a 1989 report of the Ecological Society of America (ESA) concludes that environmental impacts of genetically engineered organisms cannot be predicted fully.<sup>42</sup> In general, ESA recommends a "[c]areful design of transgenic organisms, along with proper planning and regulatory oversight. . . ."<sup>43</sup>

Hence the reports suggest contradictory assessments of possible biohazard from a planned release of genetically modified organisms. Both the 1987 NAS and the 1989 NRC reports view risks posed by modified and unmodified organisms as similar. The 1988 OTA and the 1989 ESA reports on the other hand, do suggest some caution in assessing risks associated with large scale dissemination of genetically modified organisms.

As just described, the controversy surrounding rDNA in particular and genetic engineering in general is a consequence of the unusual characteristics of the technology itself. Let us restate these characteristics to clarify the substantive context of this policy area. First, the science of DNA and its manipulation techniques are not understandable to the lay public. That is, the policy area is *esoteric*. Second, poor communication and lack of education for the non-scientific public have forced lay people to speculate instead of using reasoned argument to formulate their opinions in genetic engineering. The situation was further complicated by a divided scientific community: some opposed the technique and some were ardent protagonists. Hence the topical area is *controversial*. Third, the situation is complicated by the fact that *uncertainty* prevails in the pertinent

risks, human actions and decisions, and values. Fourth, the technology is, at the same time, continuously *evolving*. Ultimately, these complications widen the gap between opponents and proponents of the technique. Finally, *multiple interests* in the development of rDNA became a fifth disturbing factor, especially in policy-making. In sum, special features of the technology make for special complications for the policy process.

Let us now restate the policy processes that took place in the early years of the rDNA controversy. As previously mentioned, the autonomy of scientists as decision makers in rDNA was challenged. This was because of the ambiguous role of scientists as promoters and regulators at the same time, and hence the perception of presumably untrustworthy decisions. The fact that Big Science is supported by public funds adds to the legitimacy of challenging the scientific community as the sole decision-making authority. Although the RAC-NIH and NIH guidelines were initially effective controls for rDNA research, both became ineffective when rDNA was tested and released in the environment, and thus no longer controllable in laboratories. An even more important factor was the entry of private industry, and thus dollars from products, into the scene -- making the NIH guidelines that applied to only NIH-funded research, ineffective.<sup>44</sup> Criticism of the sole authority of scientists opened up RAC-NIH's decision-making procedure.

Public participation in the decision-making process took place at a few localities. Of all events, the Cambridge Experience received the most press coverage. One of the positive outcomes of the debates was that they eased uncertain, and sometimes negative

feelings about genetic engineering. The varied local laws though, as enacted by local administrations, were cumbersome. Scientists and industries viewed local ordinances as unfair and unnecessary restrictions. Hence, although community debates could be an example for future policy-making processes, its outcome in the form of a "patchwork of laws" was nevertheless not a good example to pursue in future policy-making.

National legislation on rDNA failed at the time it was proposed. Its failure was mainly due to resistance of the scientific community toward rDNA legislation. Opposition from the scientists came in a time when the political climate was to deregulate. But a more important reason for scientists to resist federal regulation is their struggle to maintain relative autonomy by avoiding total submission of their activities to federal regulation. The NIH is not, it should be noted, a regulatory agency. Its mission is to promote research, and scientists view NIH as "a friendly arm" of government.<sup>45</sup>

In conclusion, none of the aforementioned policy-making processes in rDNA has been fully successful. Technocratic control of rDNA could not withstand the legitimate challenge of non-scientists and the political process. Community debates were invaluable as a process, but the ensuing variety of local and state laws attributed to unnecessary confusion and competition. Legislation failed primarily because of opposition from the scientific community.

If these alternative decision making processes are not entirely satisfactory, what kind of process should we implement? It is the intention of this dissertation to search

through these processes for a solution to this dilemma by prescribing a suitable policy process for the regulation of high technologies like genetic engineering.

### ***Looking Ahead***

In initial rDNA regulation by means of a technocratic control, the general public<sup>46</sup> perceived suspiciously the sole decision-making authority of scientists. Scientists could not, in the public's opinion, act as impartial judges. Yet, in esoteric technologies like genetic engineering, scientific input is a *sine qua non* in making decisions. We need scientists and their expert knowledge in the formulation of balanced policies, and decisions must be supported by scientific findings. The RAC-NIH, initially established as an answer to the "Berg letter," is an institution where scientific opinion prevailed in the decision-making processes. The original NIH guidelines, developed by the RAC, were written by scientists for the purpose of scientific research. In the early years of the evolution of genetic engineering, RAC-NIH and NIH guidelines were adequate control processes for rDNA laboratory experiments. But challenges toward the technocratic approach soon emerged.

In the democratic approach, community debates in Cambridge and other localities were positive experiences in decision-making. Community debates allowed for communication of information, education, and dialogue, which eliminated distorted images

of genetic engineering and nourished appreciation of the capabilities of the technology in enhancing society's well-being. Another outcome of the debates was a feeling among participants that their concerns have been addressed. Participants came to trust each other, rather than saw each other as adversaries. In other words, through participation in decision-making, new relationships have been created.<sup>47</sup>

Although national legislation on genetic engineering failed, it should remain an option for future policy. This option can be examined through the atomic energy example. Regulated by the Atomic Energy Act, which established the Atomic Energy Commission (AEC), atomic energy will be examined for its lessons. Although the AEC was dominated by a single interest group of nuclear industries, it provided what some regarded as the needed policy outlook for the development of atomic energy.

As previously mentioned, none of these policies has been fully satisfactory. Still, underlying each policy process was a conceptual definition or premise of value. In the technocratic approach, the importance of expertise and input of scientific knowledge in the decision-making process defined the approach. The democratic approach demonstrates the value of dialogue, debate, and education. National legislation indicates the importance of a unified policy, or guidance system. The synthesis of these concepts -- input of scientific expertise, dialogue, and the significance of a unified policy -- forms a foundation for future policy processes.

The aim of this dissertation is thus twofold. 1. To examine and analyze the actual policy-making processes in rDNA, of which are in effect three. We look back to these

for key concepts which have defined these processes. 2. To prescribe a policy process for future technologies, learning from the rDNA example. A synthesis of the concepts of prior policy processes provides for a basis on which to build future policies.

For high technologies with pervasive and irreversible consequences, particularly those with uncertain risks and multiple stake holders, sound leadership and direction are indispensable in its development. Total control by a group of people or interest is not called for however. A broad approach to define the issue and to propose policy in consensus negotiations is possible.

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## *Two*

# *The Pertinent Literature*

### *Source Material*

The importance of studying rDNA policies may be challenged by two arguments. There is already a wealth of rDNA literature, the first argument goes, leaving nothing of interest to explore. Second, rDNA is *passé* -- people are tired of talking and reading about the subject. Instead of looking back into the past, more pressing, up-to-date issues need to be addressed.

The ample literature argument is valid: it is in abundance. In fact, the existing rDNA literature was this dissertation's main source of information. A few primary sources of information such as newspaper articles, hearings, and original minutes of RAC-NIH meetings provided by the Office of Recombinant DNA Activities of the National

Institutes of Health are available, although most of written material in the field of rDNA is secondary.<sup>1</sup>

The second point, however, is not valid, for by examining the rDNA case we can chart a possible future for the regulation of all esoteric technologies in a democratic context.

Turning now to key sources, Sheldon Krimsky has written about the social history of the rDNA controversy in *Genetic Alchemy*.<sup>2</sup> He provides arguments for differing stances taken by various participants of the rDNA debate, and explores the social and political climate within which the controversy has arisen. He extensively describes the events leading to the two Asilomar conferences, formation of RAC-NIH and its later development, local initiatives for regulating rDNA, and attempts to regulate rDNA federally. The focus of his book is on the relationship between science and society; it is therefore an excellent source for understanding the social context of key events in the rDNA controversy.

Krimsky himself participated in the Cambridge Experimentation Review Board (CERB), a citizen panel to review rDNA. His article on the evaluation of CERB, published in *The Bulletin of Atomic Scientists*, is an invaluable insider's report and analysis of the Cambridge Experience.<sup>3</sup> Others are available as well.

David Jackson and Stephen Stich have edited *The Recombinant DNA Debate*, a collection of articles by several authors.<sup>4</sup> One of them, Alvin Zander, describes the debates at Ann Arbor in "The Discussion of Recombinant DNA at the University of

Michigan." As chairman of "Committee B," a policy committee established during the rDNA controversy at Michigan, Zander provides a full and revealing evaluation of public participation during the debates. Other articles in the volume are grouped into those opposing rDNA and those that support the technique. Effects of funding on decision-making processes, as well as philosophical, legal, and social issues in rDNA are discussed.

Another compilation of articles is *The Gene-Splicing Wars*, edited by Raymond Zilinskas and Burke Zimmerman.<sup>5</sup> Donald Fredrickson, at the time director of NIH, presents in this book NIH's viewpoint of the rDNA controversy. His article primarily supports NIH's position as lead agency in the controversy. The Institutes, more than any other agency, have the scientific competence and administrative staff to coordinate all federal activities in the regulation of rDNA. In "DNA comes to Washington," Burke Zimmerman, as aide to Representative Paul Rogers, explores how rDNA got congressional attention, how interest for the issue diminished, and how it finally died. Other authors discuss, among other topics, the media's role in the controversy, as well as technocratic versus democratic control. Sheldon Krinsky addresses the social concerns and problems associated with rDNA. In a question that bears centrally on this dissertation, he asks: "Are there institutions that can establish priorities for harnessing rDNA technology?"<sup>6</sup>

A book that explores the evolution of the rDNA controversy in depth is *Recombinant DNA. The Untold Story* by John Lear.<sup>7</sup> His description of events such as

the community debate under direction of Cambridge Mayor Alfred Vellucci is engaging and full of details, giving the reader a flavor of the real occasion.

Official viewpoints of the controversy are presented by four organizations involved in science and technology, the National Academy of Sciences, Office of Technology Assessment, Ecological Society of America, and the National Research Council.<sup>8</sup> Each of them focuses on risk assessment, including evaluation of potential risks and the basis for assessing risk, that is, process or product-based. Process-based assessment covers all cases that employ the rDNA technique. Product-based assessment, on the other hand, focuses on risks of the product itself, produced by using rDNA or other methods.

Invaluable information is also found in a multi-volume series of the reports of NIH, *Recombinant DNA Research*, containing documents relating to rDNA research, in particular to the NIH guidelines.<sup>9</sup> Each volume covers NIH activities and contains copies of documents such as original letters and minutes of meetings relevant to a certain period of time starting February 1975.

Lastly a number of journal articles in *Science*, *Nature*, *New Scientist*, and *Bio/Technology* are excellent sources of topical information. They are too numerous to mention individually, but are cited below where appropriate.

## ***Following Themes***

From this rich source of written material on rDNA conceptual clues for formulating the general idea of this dissertation have been extracted. Several authors have written about a particular segment of the controversy, each of them giving leads that could be analyzed further.

For example, Krimsky and several other authors trace the efforts of the scientific community in controlling rDNA. They present excellent descriptions of the regulatory steps taken by scientists, including the Asilomar Conference, RAC-NIH and NIH guidelines. The role of scientists in the rDNA controversy is thus well described. More clarifying details of technocratic control are revealed in the minutes of RAC-NIH meetings and other documents in *Recombinant DNA Research*. Being advocated is regulation of rDNA by the scientific establishment.

Taking a different tack, Zander's article in *The Recombinant DNA Debate* describes and analyzes participation of the general public in rDNA debates at the University of Michigan.<sup>10</sup> He also evaluates costs and benefits of public involvement in the debates. Krimsky, in *Genetic Alchemy*, describes the public debates at Cambridge, as does Lear in *The Untold Story*. The question of who should control rDNA is addressed by Claire Nader in "Technology and Democratic Control," one of the articles in *The Gene-Splicing Wars*. Emerging from these sources is the theme of democratic control of rDNA.

Zimmerman, as previously mentioned, describes the rise and fall of rDNA legislation in "DNA comes to Washington," as part of *The Gene-Splicing Wars*. Official documents in *Recombinant DNA Research* include copies of bills introduced in Congress, letters urging President Gerald Ford to establish an Interagency Committee for the coordination of rDNA matters, and legislative events. Further, a chapter in *Genetic Alchemy* discusses federal legislation on rDNA, another theme to occupy us in the pages to follow.

The aforementioned themes -- scientific control, public participation, and statutory legislation -- are, as stated, the organizing elements of my analysis of the rDNA controversy.

### ***Supporting Material***

We now turn to material that has supported, rather than guided, this work. Works of overall importance to the subject will be mentioned first.

J.R.S. Fincham and J.R. Ravetz, in *Genetically Engineered Organisms*, give a thorough description of DNA manipulation and its application in agriculture, plants, animals, pharmaceuticals and vaccines, and the human genome.<sup>11</sup> Of particular interest is the last chapter of their book, "Managing the uncertainties of risk assessment." Many of the authors' suggestions corroborate the final conclusions of this dissertation.



Another exploration of the development of genetic engineering is presented by Jeremy Cherfas in *Man Made Life*.<sup>12</sup> Cherfas employs scientific achievements in rDNA to tell the story of the development of genetic engineering.

Comparative experiences in rDNA regulations in Britain have been instructive for this dissertation. In *The Politics of Uncertainty*, David Bennett, Peter Glasner and David Travis follow the life cycle of Britain's GMAC or Genetic Manipulation Advisory Committee.<sup>13</sup> There were three phases in GMAC's existence: the establishment years, years of change, and a redefinition of its role. The GMAC was set up as a "quango," or quasi nongovernment organization. After fulfilling its task, GMAC was eliminated and replaced by ACGM or Advisory Committee on Genetic Manipulation (later renamed Advisory Committee on Genetic Modification), an agency under the Ministry of Health, Science and Education.

It is useful to compare the different contexts of GMAC's establishment and RAC-NIH's, its American counterpart. A smallpox outbreak occurred in Britain as a result of escaped viruses from a laboratory. This led to fear of spreading dangerous pathogens. Accordingly, a unanimous agreement was arrived at by GMAC that a compelling need to control rDNA existed.<sup>14</sup> Yet most important for the purpose of this dissertation is GMAC's practice of "unlikely broad participation." It included scientists, industrialists, lawyers, philosophers, trade unionists, psychiatrists, ethicists, lay persons, medical practitioners.<sup>15</sup> In spite of its diverse participants, GMAC worked.

Let us now discuss material that presents different approaches to policy-making, in particular democratic and technocratic policy-making processes and the issue of participation.

Two approaches in science policy, the technocratic and democratic, are presented in *The Fifth Branch* by Sheila Jasanoff.<sup>16</sup> The author's main concern is to make the democratic approach effective. Science advisory committees, as a "fifth branch" of government, should, according to Jasanoff, act as facilitators of negotiations to reduce the differences in opinion between scientists and policy analysts, between the public and private sectors, and between the general public and administrative agencies.

Technocracy, its history, and its impacts on organization and policy are explored in *Technocracy and the Politics of Expertise* by Frank Fischer.<sup>17</sup> It provides an excellent exploration of the idea of technocracy, which is summarized in the introduction of Chapter Three of this dissertation.

Direct as well as representative democracy are discussed in "Democracy: Electoral an Athenian," by Sheldon S. Wolin.<sup>18</sup> In "Democracy and the American Revolution," an article in *Democracy the Unfinished Journey*, Gordon S. Wood lays out the development of democracy in the United States.<sup>19</sup>

In *Technological Decisions and Democracy*, Dorothy Nelkin explores actual public participation events in three countries, Sweden, The Netherlands and Austria.<sup>20</sup> She finds that the mode of participation in each country depends on its political culture and structure of government. She also emphasizes that democratization should take place

early in the policy-making process, and that legitimizing interests (Who should participate?) is a problem. All events are based on participation in the nuclear energy debate, a useful analogue to the rDNA controversy.

Three forms of participation in policy-making in technologies are discussed in "Participatory Analysis, Democracy, and Technological Decision Making" by Frank Laird.<sup>21</sup> Two types of participation, direct participation by individuals and pluralism where representatives of groups or stake holders participate, are juxtaposed. According to Laird, pluralism emphasizes outcome, thus emphasizing ends in a means-ends relationship. In direct participation on the other hand, the process of participation itself is important, and therefore, means are as important as ends. He further suggests a third type of participation: participatory analysis. The essence of participatory analysis is learning, or empowerment of the people to let them understand the issue and learn how to analyze a problem.

*Technology on Trial*, a publication of the Organisation for Economic Co-operation and Development (OECD), argues that informing the public on technical issues is as important as informing policy makers on the demands and needs of the public.<sup>22</sup> To inform the public, several mechanisms are discussed: ad hoc, decentralized "study circles," public information campaigns, science education programs, and dissemination of information through the media. Policy makers, for their part, get information on society's needs and demands by way of advisory bodies, legislative hearings, or special National Commissions such as the National Commission for the Protection of the Human

Subjects.<sup>23</sup> Conflicting interests are reconciled in administrative or regulatory decision-making, and by administrative and judicial appeals. Even more interesting are suggestions for collaborative decision-making in science courts and citizen review boards, such as the Cambridge Experimentation Review Board (CERB). The authors conclude that mediation procedures and consensus policy-making need further exploration.

Articles with regard to mediation and alternative dispute resolution (ADR) are mainly contained in *Negotiation Journal*. Numerous other articles are found in a broad range of journals from *World Politics* to *Journal of Personality and Social Psychology*.

In *Breaking the Impasse*, Lawrence Susskind and Jeffrey Cruikshank describe consensual approaches to dispute resolution.<sup>24</sup> All-gain agreements are possible if all parties "exchange accurate information about their true priorities."<sup>25</sup> Consensual approaches are bottom-up processes, while social reforms are top-down policies, frequently forged by the authorities in charge.

With respect to regulation of rDNA, an article by Krinsky in *Controversy*, edited by Dorothy Nelkin, is of particular interest for this dissertation. In "Regulating Recombinant DNA Research," he gives an overview of the evolution of rDNA regulations in the 1970s.<sup>26</sup> He describes how scientists took the first initiative to regulate rDNA by declaring a moratorium on certain types of experiments. He goes on to discuss the NIH guidelines, a mandatory Environmental Impact Statement (EIS), local participation in rDNA decision-making through citizen panels, and Congressional efforts to regulate rDNA.

An overview of subsequent efforts to regulate rDNA during 1980-1990 is found in "Biotechnology and the Design of Regulation," by Sidney Shapiro.<sup>27</sup> He sees three phases of government's reaction to rDNA. In the first phase, from 1978-1984, NIH guidelines and their modified versions guided the field. The second phase began in 1984 when OSTP (Office of Science and Technology of the President) proposed a "coordinated framework" for biotechnology regulation, which was revised in 1986. In 1985, OSTP created an advisory committee, the BSCC or Biotechnology Science Coordinating Committee. The third phase began in 1986 when agencies started to implement their individual policy statements, specifying "information or criteria an agency would use in resolving an issue."<sup>28</sup>

Sue Tolin and Anne Vidaver are particularly interested in GMOs, or Genetically Modified Organisms, used in field research outside the laboratory. In "Genetically Modified Organisms: Guidelines and Regulations for Research," they call for a "reasonable" policy as a guide for testing GMOs and warn that stringent policy will stifle further research.<sup>29</sup> In "Guidelines and Regulations for Research with Genetically Modified Organisms: A View from Academe," both authors present a detailed overview of the development of guidelines and other modes of control on rDNA and GMOs.<sup>30</sup>

In *Controlling Technology*, Yvonne Cripps was particularly interested in the role of law to regulate rDNA.<sup>31</sup> She distinguishes two modes of control: formal and informal. Informal control includes peer pressure and withdrawal of funds. More formal control is embodied in voluntary guidelines such as NIH guidelines, backed up by peer pressure and

funds withdrawal. The final possibility is legal control.<sup>32</sup> Her description of legislative efforts in the United States is comprehensive and useful.

Insight into the regulatory processes of genetic engineering is furthermore expanded in several government reports. In *Biotechnology in a Global Economy*, a report published by the Office of Technology Assessment (OTA), the problematic issue of a "patchwork of local and state laws" is mentioned.<sup>33</sup> Regulations in Japan and the European Community including France and the United Kingdom are presented. One of OTA's conclusions is that changing or uncertain regulatory climates may have unwanted impacts on biotechnology. For example, they can lead to inhibiting investments and ultimately to losing a competitive place in the world market.

In February 1991, the President's Council on Competitiveness issued a *Report on National Biotechnology Policy*.<sup>34</sup> The administration does not recommend regulation of rDNA by federal legislation. It recommends, however, to improve interagency coordination by clarifying agencies' jurisdictions and addressing inconsistencies among federal, state and local laws.<sup>35</sup>

In *Biotechnology Law for the 1990s*, a report of the Bureau of National Affairs, several issues of importance for writing actual regulations are presented, such as product versus process regulation and jurisdictional questions.<sup>36</sup> Also included are policy statements of the Environmental Protection Agency (EPA) and the United States Department of Agriculture (USDA). Note however, that these reports focus on regulations

in later phases of the development of genetic engineering, not the early years of rDNA, the subject of this dissertation.

Lastly, several congressional hearings, reports, and meetings with regard to the regulation of rDNA provide a variety of information. Only some of the available documents are listed here.<sup>37</sup>

A final bibliographical source area pertinent to our study is regulation of atomic energy. Similar to rDNA, atomic energy has been the focus of attention of researchers, scholars, and lay persons for many years. In this dissertation discussion of atomic energy is restricted to government control, especially federal legislation on its technology.

A detailed account of the events that led to conquering atomic energy is unfolded in *Atomic Quest* by Arthur Compton, who was himself a prominent nuclear physicist.<sup>38</sup> The book is, wrote Compton, "a personal story of the release of the atom's energy."<sup>39</sup> As a scientist, Compton focused on scientists as actors in the atomic quest. In so doing, he narrated the history of the atomic project from their point of view.

For our purposes, *Science, Politics, and Controversy* by Steven Del Sesto is probably the most important source of information on atomic energy regulation.<sup>40</sup> Chapter Two of his book, "Government Control of the Atom: Defining the Political and Administrative Subsystem of Nuclear Energy Regulation," describes the establishment of the AEC or Atomic Energy Commission and its congressional counterpart, the JCAE or Joint Committee on Atomic Energy. It explains how industrial demands dominated the

AEC's zeal in commercializing atomic energy for civilian uses, and how malfunctioning of the AEC and JCAE ultimately led to their demise.

"The Quest for Control of Atomic Energy," a chapter in *The Politics of American Science* by James Penick, Jr. et al., contains excerpts of President Truman's message urging Congress to enact legislation for civilian uses of atomic energy. It also contains testimonies of several prominent figures in the history of atomic energy such as General Leslie Groves and Robert Oppenheimer, director and scientific leader of the Manhattan Project that built the atomic bomb.<sup>41</sup>

### *Next Steps*

In this dissertation, three modes of policy-making in rDNA are analyzed: technocratic, democratic, and legislative. These themes, as previously mentioned, are found in leading source readings of the topic, such as *Genetic Alchemy*, *The Gene-Splicing Wars*, and *The Recombinant DNA Debate*, to name a few.

The unique contribution of this dissertation to the existing literature in rDNA policies is twofold. First, it includes analysis of all three modes of policy-making, rather than just dealing with one or the other. Second, and more important, the dissertation synthesizes the underlying premises of the three modes of policy-making. Each analysis, technocratic, democratic and legislative, offers us -- I argue -- lessons and non-lessons in



policy-making in esoteric technologies. In this sense, I attempt a comprehensive synthesis.

As Zilinskas and Zimmerman, editors of *The Gene-Splicing Wars*, write in their introduction of the book, "effects of major technological advances can be anticipated if guidance is sought in past experiences. This volume looks back in order to look forward."<sup>42</sup> Similarly, this dissertation looks back into rDNA policy processes in order to prescribe a timely policy process for the future.

Several authors have called for a new mode of policy-making. The philosopher Joseph Agassi, in *Technology, Philosophical and Social Aspects*, calls for the creation of a "social control of technology".<sup>43</sup> He asks, among other things, the central question, "What is the social organization best conducive to the solution of major technological problems?"<sup>44</sup> In this dissertation I seek to answer this question.

Similarly, Max Heirich, in *The Recombinant DNA Debate*, raises three unresolved issues:<sup>45</sup>

First, some new device would have to be created for making decisions. . . . Second, some procedure would have to be developed. . . . Third, the range of parties involved in making such decisions would have to be expanded. . . . A social invention is called for, and soon. Who will make the first proposal?

In this dissertation I offer such a proposal.

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## *Three*

# *Expert Decision Makers*

### *Government and Science*

In their traditional role, scientists do research in laboratories, dedicated to the pursuit of scientific knowledge. They are very little, if at all, involved in the formulation of science policy. Accordingly, most people tend to think of scientific activity as an autonomous pursuit. This does not come as a surprise, since government involvement in science is largely a post-World War II phenomenon in the United States. In Europe on the other hand, government and science have had a symbiotic relationship ever since the founding of the first professional associations in the seventeenth century. The Academia dei Lincei in Italy (founded 1603), the Royal Society in England (founded 1660), and the Royal (or, Paris) Academy of Sciences (founded 1666) advised government in matters

with potential military and industrial benefits, such as gun powder, navigation, and artillery.<sup>1</sup>

In the United States, the National Academy of Sciences (NAS) was chartered by Congress in 1883, some two centuries later. The NAS was to advise the government -- if the latter requested NAS to do so -- although in actuality NAS was more a honorary organization than an advisory body. During World War I, the NAS established a separate organization to perform its advisory function, the National Research Council (NRC).

The relationship between government and science intensified during World War II, when scientists were involved in the government-sponsored Manhattan Project to develop the atomic bomb. Big research laboratories such as Los Alamos, Oak Ridge and Argonne were founded specifically for this purpose.

After the war, policy makers and the scientific community began to plan the future of scientific research. War-experience showed that big research teams, generously supported by government, were successful. "Bigness had become indispensable in many fields of research," and science had become "Big Science."<sup>2</sup> Further government support for science was institutionalized by the founding of the National Science Foundation (NSF), uniting science and government in a partnership that has lasted until today.

The explosion of scientific and technological activities after World War II created an enormous expansion of government administration in science and technology. New research fields were established, such as medical technology, biotechnology, and computer sciences. Accordingly, new industries joined the bandwagon to help turn scientific results

into novel products. Government on its part, became increasingly involved in sponsoring and supporting these activities.

Nowadays, government support for science is frequently translated into government involvement in the direction of research. Previously independent scientists have become increasingly aware of government intrusion in their activities. Part of this is caused by a growing demand of interested factions of the general public for justification of public funds spent on scientific research. Responding to this demand, government becomes increasingly involved in the regulation of scientific activity.

For the scientists, more regulations mean spending more time on administrative and policy issues, thereby changing the traditional image of a scientist into what is sometimes called a "manager scientist."<sup>3</sup> A manager-scientist understands the intricacies of science policy, and at the same time is able to create a conducive research environment for the "traditional scientists."

In a few cases, manager scientists seek to advance their administrative careers further to become "research administrators," or "scientist administrators."<sup>4</sup> They have been called the "politician scientists." Usually politician-scientists are at the other end of the government-science spectrum, focusing their efforts on the regulation of scientific activity. The growing number of scientists holding official government positions, for example as science advisers or heads of agencies, can also be attributed to the complexity of contemporary science and technology, creating a need within government for experts



who can translate scientific and technological issues into matters that could be subjected to rules and regulations.

Although the partnership between government and science in this country is relatively new, it is intense. As just described, a by-product of this partnership is an increase in the numbers of manager- and politician-scientists directing the development of science and technology. It therefore seems that nowadays technocracy has infiltrated and dominated American politics in science and technology. The idea of a government run by scientists, or a government advised by scientists, is not new. Technocracy is an old idea.

### *The Technocratic Paradigm*

In today's society, the term "technology," which is frequently used synonymously with the term "technique," is well entrenched and widely employed. At the first instance, one thinks of technology as machines or sophisticated methods of production, usually based on scientific research. Thus, automobiles, space aviation, biotechnology, and atomic energy are among a few technologies we recognize. The pervasive influence of science and technology in our social, economic and political lives, however, has added a complexity in the meaning of technology. In a broader sense, technology can be seen as a mind-set. In this sense, it refers to "the totality of rational methods designed to

efficiently organize human activities in general, both material and social activities."<sup>5</sup> And thus, technocracy emerged. Although the term "technocracy" was first used in 1919 by an American engineer, William Henry Smyth, the notion has a long genealogy. This section traces the roots and development of technocracy.<sup>6</sup>

The idea of technocracy was conceived in seventeenth century Europe with the emergence of "modernity." The Enlightenment's Sir Francis Bacon, a pioneer in empirical and scientific thinking, replaced Plato's "philosopher kings" with a new technical elite who would utilize objective and neutral tools, and were therefore -- according to Bacon's view -- better equipped to make unbiased decisions. The father of technocracy though, is attributed to Claude Henri de Rouvroy, Lecomte de Saint-Simon, a nineteenth century thinker. His famous "parable of the idlers" refers to the class struggle between the old regime of clergy, nobility, and bar, with scientists and technicians. Saint-Simon envisioned a new system of "expert management," freeing society of political battle. His "Administrative State" was such a utopian society.

Saint-Simon's disciple, Auguste Comte, developed a so-called positive methodology, better known as "positivism." In his "Positive State," Comte envisioned technocracy as a means to guide "ignorant masses." The development of technocracy in general and positivism in particular, however, cannot be separated from utilitarianism. Founded by Jeremy Bentham in nineteenth century England, utilitarianism provided the normative argument for positivism. Until today, the utilitarian dogma, "the greatest good

for the largest number of people," is still used to defend positive analyses such as modern-day cost-benefit analysis.

Concomitant with the rise of technocracy, the science of organization emerged. Max Weber was impressed by the idea of technocracy and its new societal dimensions, or classes. Accordingly, Weber viewed organizations as machines with hierarchical structures. Managerial elites on top directed lower echelons of his pyramid-like structure of organizations.

In the United States, political and organizational life from the Progressive to the Post-industrial era have been profoundly influenced by technocracy. Our obsession with planning, expert management, and policy-making, to name a few, is a legacy of technocracy. Thus the emergence of large corporations, Frederick Taylor's scientific management, and Thorstein Veblen's radical theories of technocracy, are early manifestations of technocratic ideas. During the New Deal era, the primary task of the President's Committee on Administration Management, headed by Charles Meriam and Luther Gulick, was to put a rational management of governance in place.

During and after World War II, technocracy in the United States prospered. Post World War II military-industrial complexes, the Keynesian approach of government intervention in economy, and several budgetary planning "systems" such as the Planning, Programming, and Budgeting System (PPBS), all sought efficient, rational and predictable outcomes.

Not only institutional arrangements, but also theoretical thinking was influenced by technocracy. This is exemplified by Harold Lasswell's "policy sciences," John Kenneth Galbraith's "technostructure," strategic economic planning as replacement of the "invisible hand," and Don K. Price four estates, which includes the scientific estate. The information-based post-industrial era, first heralded by Daniel Bell, has even a greater need for professional experts in decision-making and governance, although the expert-elites in this modern version of technocracy are supposed to *share* their power with politicians.<sup>7</sup>

In the original idea of technocracy, experts, who embodied a new class of power, replaced politicians. Expert-elites were supposed to take over the tasks of politicians. Bacon, for example, envisioned a ruling technical elite in the place of philosopher kings. During the development of technocracy however, the idea of complete take-over by experts was modified. Modern-day technocracy, for example in Daniel Bell's vision, denotes a sharing of power between experts and politicians in a new type of politics, the so-called "politics of expertise."<sup>8</sup> This is exemplified in the phenomenon of "think tanks," where policy makers and academicians work as a team. To summarize then, there has been a shift in the meaning of technocracy, from a ruling expert-elite class to a shared-power conglomerate between experts and politicians. It is this latter meaning of technocracy that will be employed henceforth.

## *Technocracy at Asilomar*

The regulation of rDNA is a prominent case of politics of expertise. But in many ways it was uniquely so. Debates surrounding rDNA were initiated by traditional scientists, and not by politician-scientists -- the technocrats -- as we might have expected.

Initially, the scientists were primarily concerned about the safety of the technique. They felt it was their moral responsibility to protect society from potential biohazard, although they disagreed with the opinion that unproven hazards alone are sufficient reason to discontinue research. The scientists thus faced a dilemma. On the one hand, they wanted to maintain technocratic authority and continue their research. But on the other hand, their obligation to protect society's well-being left them with no other choice than to discuss rDNA in public spheres. These counteracting forces, opening up the issue for public discussion versus maintaining technocratic authority, were embedded in the policy struggles during the early years of the rDNA episode. Let us now explore these policies by following the events that took place during the 1970s.

The first International Conference on Recombinant DNA Molecules (Asilomar "I") was held on 22-24 January 1973 at the Asilomar Conference Center in Pacific Grove, California. At that time, scientists were alarmed by the potential hazard of certain hybridization experiments which included cancer-inducing viruses such as SV40. Asilomar I was convened to discuss these concerns. It was attended by researchers from a broad range of scientific fields, including representatives from government agencies such

as the National Institutes of Health and the Center for Disease Control. The conference had two goals: compiling all information about viruses, and deciding how to proceed with virus experiments.<sup>9</sup> Hence, Asilomar I was basically a "virus conference" and a prelude to the emerging rDNA debates.

In the rDNA controversy itself, one of the most important events was the Gordon Conference on Nucleic Acids, held in New Hampton, New Hampshire, from 11 until 15 June 1973, shortly after Asilomar I. Founded in 1931 by Neil E. Gordon, Professor of Chemistry at the Johns Hopkins University, the Gordon conferences are scientific meetings on one single topic at the cutting-edge of new areas. They are traditionally held in New Hampshire, Rhode Island.<sup>10</sup>

The 143 participants of the June 1973 Gordon Conference on Nucleic Acids represented researchers from a wide variety of scientific disciplines, as well as from public, private, and not-for-profit organizations. Although the conference was intended to be a scientific meeting for a technical discussion of DNA-research, the co-chairpersons of the conference, Maxine Singer and Dieter Söll, managed to arrange a short discussion of the societal issues surrounding rDNA. This informal, yet well-attended discussion resulted in a vote to write an open letter on the subject.

The letter was sent to the directors of the National Academy of Sciences and the National Institute of Medicine, and printed in the issue of *Science* published on September 21, 1973. (For a reprint of the letter, see Appendix B.) The letter explained what rDNA is, its risks and benefits, and recommended that an expert study panel be established.<sup>11</sup>

It was thus at the Gordon Conference that the controversial nature of rDNA was brought to the attention of those involved in recombinant work. Note that traditional scientists, experts in rDNA who understood the possibility of potential dangers of the technique, launched the first open discussion of societal aspects of rDNA. Publication of the Gordon Conference letter in *Science* took the issue one step further. It introduced rDNA into the public sphere, thereby opening up the ensuing rDNA debate.

Following the recommendation of the Gordon Conference letter, a panel for the study of rDNA hazards was established. The study panel, chaired by Dr. Paul Berg of Stanford University, met at the Massachusetts Institutes of Technology on April 17, 1974. All participants of the panel were eminent scientists. One of them was James Watson -- well known from the double helix structure of DNA. The National Academy of Sciences subsequently turned the study panel into an official NAS "Committee on Recombinant DNA Molecules Assembly of Life Sciences."<sup>12</sup> The Committee's most crucial and famous outcome was its report to the Assembly of Life Sciences of the National Research Council (NRC-NAS). This report, better known as the "Berg letter," was published in *Science* of July 26, 1974. (A reprint of the Berg letter is also included as Appendix C.)

The Berg letter recommended to continue rDNA work, but caution was the message: it called for a world-wide voluntary moratorium on certain types of experiments. Further, it urged NIH to establish an advisory committee and to develop guidelines for rDNA research. It also recommended an international conference for the discussion of biohazard related to rDNA. Thus following the recommendations of the Berg letter, the

Recombinant DNA Advisory Committee of NIH (RAC-NIH) was established, NIH guidelines were to be developed, and the second Asilomar conference was held.

The second Asilomar conference met during 24-27 February, 1975. Compared to the first conference which was attended by a broad range of participants, Asilomar II was a closed meeting. The organizers, who were all prominent DNA-researchers, framed the conference agenda. They limited the boundaries around the discussions to a technical discussion of rDNA, in particular to a discussion of its potential hazards and safety precautions. Discussions of political, social, ethical, or legal aspects of rDNA were not on the official conference agenda. The conference participants were carefully selected by the organizers through internal networks, and, consequently, a certain homogeneity prevailed in backgrounds and interests of the participants.<sup>13</sup> Almost all participants actively worked with DNA and were experts "who could provide special information and insight to the question of assessing and dealing with the potential hazards of such work."<sup>14</sup> This narrow selection of participants and a limited issue-boundary created a conference that was useful for those who would benefit most from continuing rDNA research. It seemed that Asilomar II was convened for purposes of self-interests of the scientific community.

Not surprisingly, critics perceived Asilomar II as an embodiment of "politics of expertise," controlled by a small group of experts. Sheldon Krimsky, author of *Genetic Alchemy*, used the term "disciplinary authority" to describe the decision-making process at the conference.<sup>15</sup> He concluded that two goals of disciplinary authority were reached



at Asilomar: (1) definition of the issue remained in the hands of those who benefitted most, and (2) authority was placed at the NIH -- a federal agency that promotes and supports biomedical research -- through its newly established Recombinant DNA Molecule Advisory Committee, or RAC-NIH. The RAC, following the recommendation of the Berg letter, was assigned to draft guidelines for rDNA research. In short, authority was placed in the hands of the defenders of rDNA. Consequently, both organization and outcome of Asilomar II were typical technocratic processes. But why had Asilomar II become such a bastion of technocracy?

Prior to Asilomar II scientists from a broad spectrum of academic disciplines as well as from public and private institutions were involved in several meetings and conferences in the field of DNA. Asilomar II however, appeared to mark a departure from this tradition. Analysts and critics alike, viewed Asilomar II as a closed decision-making process, although the general composition of its participants did not reveal the restricted conference setting. There were 153 participants, including fifty scientists from fifteen foreign countries, representatives from U.S. public and private research institutions, sixteen press representatives including one foreign representation, and four lawyers.<sup>16</sup> The conference was convened under the aegis of NAS, and financially supported by NIH and the National Science Foundation (NSF). Why then, did Asilomar II so persistently develop into a technocratic decision-making process?

To explore technocracy at Asilomar II, we should start with the Berg letter, issued by the NAS Committee on Recombinant Molecules. The letter recommended an

international convention of DNA scientists, which was realized as Asilomar II. Of particular interest is the wording of the Berg letter describing the goal of the conference:

. . . to review scientific progress in this area [rDNA] and to further discuss appropriate ways to deal with the potential biohazard of recombinant DNA molecules. . . .<sup>17</sup>

In other words, the meeting was intended to be a *scientific* discussion of rDNA and its safety. Accordingly, the organizers of Asilomar II -- Paul Berg was one of them -- arranged a scientific meeting of those who worked with rDNA, thereby creating a closed decision-making procedure.

The organizing committee was not oblivious of its "expert management" style, evident from the conference report issued by the organizers of Asilomar II. They wrote that,

To ensure both the greatest opportunity for effective discussions of the relevant scientific issues and the most frank and searching analysis of the potential risks, attendance at the Conference was limited.<sup>18</sup>

The conference organizers assumed that technical discussions among rDNA experts was the best means to achieve desired goals. Accordingly, participation was limited, and rDNA was reduced to a technical discussion, specifically of its potential hazards. Asilomar II created the appearance of, and in actuality it was indeed, a technocratic decision-making process.

## *Motives Behind Asilomar*

By the time scientists understood the enormous potential but not the uncertain risks of the technology, they were confronted with the full complexity of the issue. Trouble began when scientists tried to control rDNA. Three different types of argumentation could support the motives of rDNA experts for controlling the field.

The first might be their noble intention to continue to protect society. The scientists argued that the best protection methods would develop from discussions among those knowledgeable in rDNA. Recombinant DNA was difficult to comprehend not only for lay persons, but also for scholars and scientists outside the field of nucleic acids. To relieve lay persons from unnecessary burdens, the experts kept this complex issue to themselves, assuming they had done a favor to the general public. This happened at Asilomar II. To simplify issues, the conference organizers reduced rDNA to a technical discussion among experts. But, unfortunately, by so doing they created an appearance of technocratic control of rDNA.

Yet rDNA was complex in another way, allowing a second line of supporting argument. It was not only technically esoteric, it had also many ramifications extending far beyond technical boundaries. This created argumentation. Many individuals were against rDNA because of ethical or moral beliefs, or simply because they questioned its necessity. The opponents included a number of prominent scientists. This troublesome situation had not gone unnoticed to the defenders of rDNA. The disagreement among

scientists could have been a major reason for the rDNA defenders to take charge forcefully, in order to out-manuever opponents. Thus a second motive for controlling rDNA could be less noble.

A third argument that could support technocracy in rDNA was fear of excessive regulation imposed by outsiders, for example by the Congress, if scientists could not agree among themselves.<sup>19</sup> As one of the participants of Asilomar II argued, "if the scientists cannot reach consensus, the issue will be taken out of their hands."<sup>20</sup> And hence, defenders of rDNA presented one front to the outside world, creating the image of technocracy even further.

To recapitulate then, the rDNA proponents did not question whether research should proceed. They were confident that rDNA research was to continue. To secure this aim, they developed measures for a safe development of the field. Either intentionally or unintentionally, they acted as if they were a disinterested group of scientists whose only objective was to further science for the benefit of the people. In this way, one could argue that it was not entirely ill intention that moved the organizers of Asilomar II to technocracy. The organizers were convinced that a technical discussion among experts would produce the best results, and hence, would benefit society the most.

They erred however, in taking for granted that scientific values are synonymous with societal values. Many lay persons were still unsure whether to continue with rDNA at all. Religious, ethical, and anti-biotechnology groups had grave concerns about the need of such research. Consequently, while conflict of interest was a non-issue for the

organizers of Asilomar II, it became one of the most important criticism of the conference.

One could therefore also argue that, after all, the defenders of rDNA were not so naive as they appeared. When they realized the complexity of the issue, they tried to "depoliticize" the issue and reduce it to technicalities. Recombinant DNA and its potential biohazard were framed by the organizers of Asilomar II into scientific and technical issues, ignoring other sides of the issue. This was exemplified in a statement issued by the organizing committee of Asilomar II. To allow rDNA to proceed the statement relied on physical and biological containment measures only -- and thus on purely scientific precautions to achieve safety.<sup>21</sup> The critics perceived that Asilomar ignored possible misuse of the technology for purposes such as biological warfare and precautions to prevent those abuses were ignored. In so doing, the scientists in effect denied the separability of scientific and societal values. This error became one of the principal reasons for later insistence on broader participation in the decision-making process.

But although technocracy was criticized, it is undeniable that scientific input is crucial in discussions of esoteric technologies. As Dr. Donald Fredrickson, at the time director of NIH, wrote,

I agree with the appearance of a conflict of interest. It was unavoidable. It was bothersome all the way. One of the most important lessons to be learned about controversy over use of high technologies, however, is the absolute requirement for expert opinion. . . .<sup>22</sup>

Dr. Fredrickson argued that the most knowledgeable persons are usually those who work with the technique, and that expert knowledge is patently necessary to make responsible decisions in esoteric fields. But on the other hand, one might argue that legitimate concerns of the lay audience must not be dismissed, especially in a technology with pervasive and irreversible consequences as rDNA. The point then, is to find ways to combine technocratic opinion with participatory democracy in decision-making processes of high technologies.

### *The Founding of RAC-NIH*

In the previous sections we have described the organization of Asilomar II following a recommendation of the Berg letter to convene an international meeting of rDNA scientists. A second recommendation of the letter, to establish an advisory committee, is the focus of this section.

The conceptualization of scientists as decision makers in rDNA would be incomplete without describing the life-cycle of RAC-NIH, or the Recombinant DNA Advisory Committee of NIH. In short, RAC-NIH is an example of the institutionalization of the phenomenon of expert decision makers. Put another way, through the establishment of the RAC, scientists succeeded in maintaining authority, and thereby

control, in the development of rDNA. Let us at this point sketch in the founding of the committee more fully.

The Berg letter of July 26, 1974 recommended that the Director of NIH establish an advisory committee. The committee, according to the letter, shall be charged with

(1) overseeing an experimental program to evaluate the potential biological and ecological hazards. . . ; (2) developing procedures which will minimize the spread of such molecules. . . ; and (3) devising guidelines. . . .<sup>23</sup>

Thus the "NIH Recombinant DNA Molecule Program Advisory Committee," later renamed as the "Recombinant DNA Advisory Committee" or RAC-NIH, was established on October 7, 1974.

The RAC was to advise the Secretary of Health, Education, and Welfare (HEW), the Assistant Secretary for Health, and the NIH Director,

concerning a program for developing procedures which will minimize the spread of such molecules within human and other populations, and for devising guidelines to be followed by investigators working with potentially hazardous recombinants.<sup>24</sup>

In other words, RAC's immediate task was to develop guidelines for a safe development of rDNA research. Obviously, for the RAC there was no doubt that at least some recombinant work should continue. The RAC also advised the NIH Director on conditions that should apply to rDNA projects supported by NIH funds and on national needs of containment facilities for rDNA research.<sup>25</sup>

The committee took its task to develop guidelines seriously. As previously mentioned, the guidelines were primarily meant as instructions for the safe conduct of rDNA experiments. Prior to issuance of NIH guidelines, the RAC recommended use of

containment measures as proposed in the conference report of Asilomar II, *Summary Statement of the Asilomar Conference on Recombinant DNA Molecules*, as guidelines for rDNA work. The *Statement* was published in *Science*, *Nature*, and the *Proceedings of the National Academy of Sciences (PNAS)*.<sup>26</sup> (The *Summary Statement* is reprinted in Appendix D.)

The *Summary Statement* recommended physical and biological containment measures for different types of experiments, where kind of containment should match type of experiment. Four levels of physical containment were suggested: minimal risk, low risk, moderate risk, and high risk. Except for minimal risk containment, all containment measures were required to use safe vectors and safe host-bacteria as additional means of biological containment.

The Committee's preoccupation with safety was also reflected in other activities. The RAC published *Recombinant DNA Technical Bulletin*, a newsletter on new techniques to improve safety of recombination experiments. It promoted research on the construction of low-risk organisms through special grants for such projects. It also initiated training courses for safe handling of rDNA, and distributed safety studies to all interested persons.<sup>27</sup>

It was obvious that the RAC viewed rDNA as a technical issue, for it was not supposed to consider other aspects of the technique. The guidelines were accordingly meant as instructions for a technical development of rDNA. Hence, similar to Asilomar II, the RAC was a technocratic organization.



The technocratic image of RAC did not come as a surprise. Members of the original RAC were all scientists, most of them molecular biologists.<sup>28</sup> (A list of participants of the original RAC is reprinted in Appendix E.) This composition could be expected, since the idea to establish RAC-NIH was initiated in the same Berg letter that convened Asilomar II. Although in actuality the RAC was an *advisory* committee, and not a policy-making body, critics generally perceived the RAC as a group of scientists acting as autocratic decision makers.

Since developing guidelines was the Committee's major preoccupation, the evolution of RAC is best seen in light of the development of guidelines -- the third recommendation of the Berg letter.

### ***Guidelines and Democracy***

The first meeting of RAC-NIH took place on February 28, 1975, one day after Asilomar II, at the Bellevue Hotel in San Francisco.<sup>29</sup> Nine committee members were present, three staff members of NIH, and a liaison representative of NSF, all of whom had attended Asilomar II. Ten press representatives were present, six of whom were also at Asilomar II. It was a closed meeting for a selected few. But the Committee was not, so it seemed, ignorant of its public character. The minutes of the meeting stated that,

In accordance with Public Law 92-463 of January 5, 1973, the meeting was open to the public.

But although it was open to the public, no representatives of the public attended the meeting. It is not known how much publicity, if any at all, was given to the establishment of RAC-NIH and its first meeting.

During its first meeting RAC did not concentrate on drafting guidelines. Reflecting upon the genesis of the guidelines, Dr. Hans DeWitt-Stetten Jr., acting chairman of RAC's first meeting, said in retrospect,

At our first meeting there was a wild discord among the participants. I came home personally despairing that that [*sic.*] we would ever come out with anything that would be useful. . . .<sup>30</sup>

The Committee kept to a few procedural matters.

Membership seemed to be a hot issue for RAC. The RAC discussed the composition of its membership as early as its first meeting. According to the minutes of this meeting,

With regard to membership, the Committee felt that representation of the areas of animal virology, plant pathology and epidemiology would be desirable. It was felt that the scope of the Committee should be broad at the beginning. The Committee specifically recommended that one lay representative be appointed. . . .<sup>31</sup>

In spite of efforts to broaden its scope, RAC still kept its purview restricted. According to the minutes,

It was felt, however, that the Committee can not deal with ethical aspects; it will have to restrict itself to considerations of safety and containment.<sup>32</sup>

This statement suggests that the Committee's restricted scope remained unchanged, as was substantiated in its end product, the NIH guidelines. In a critique of these guidelines, Dr. Robert Sinsheimer, a well-known DNA scientist, said,

They [NIH guidelines] had dealt reasonably well with immediate health hazards, but had given no thought to the evolutionary question.<sup>33</sup>

The addition of scientists from other fields of research, as suggested at RAC's first meeting, obviously did not broaden RAC's scope. As a non-scientist representative, RAC included Emmette S. Redford, Ashbel Smith Professor of Government and Public Affairs of the University of Texas at Austin.<sup>34</sup> But the task of this lay representative was unspecified. The Committee did not spell any responsibilities for Dr. Redford. Could it be only for window-dressing? The minutes of RAC's second meeting merely stated that, "a lay person is defined as a non-biologist."<sup>35</sup> Possibly, the Committee itself was initially undecided on this person's responsibilities. It could also be the case that RAC's lukewarm suggestion for adding a lay member was merely a halfhearted response to a general pressure for more participatory democracy.

The second meeting of RAC took place at the Holiday Inn of Bethesda, Maryland on May 12 and 13, 1975. During this meeting the Committee agreed that the guidelines could not be written by the Committee as a whole. Thus a subcommittee was formed with the specific task to draft guidelines.

Dr. David Hogness of Stanford University was appointed chairman of the subcommittee. He was a rDNA expert who had worked closely with Dr. Paul Berg and was one of the authors of the Berg letter. The remaining three members of the

subcommittee were rDNA specialists as well. Although according to the minutes of RAC's second meeting, *ad hoc* consultants would join effort in drafting the guidelines,<sup>36</sup> the appointment of Dr. Hogness as chairman only emphasized the technocratic image of the subcommittee. Control of the development of rDNA remained in the hands of rDNA defenders. Dr. Elizabeth Kutter from Evergreen State College at Olympia, Washington, a consultant at RAC's second meeting and later added to RAC to broaden its membership, recalled the appointment of Dr. Hogness as chairman of the guidelines-subcommittee as a "tactical mistake."<sup>37</sup> Dr. Hogness was too much involved in recombinant work.

The "Hogness draft" of guidelines was discussed at RAC's third meeting at the National Academy of Sciences Summer Study Center at Woods Hole, Massachusetts, on 18 and 19 July 1975.<sup>38</sup> The discussion resulted in another draft, called the "Woods Hole draft." This version was presented and debated at the annual meeting of bacteriophage researchers at Cold Spring Harbor (CSH) the following August. The opinions were so divergent, however, that even after a second informal discussion no agreement could be reached. It was then decided to send a petition to RAC's chairman. The petition primarily presented the disagreements with regard to the Woods Hole draft. On its turn, the petition solicited a large number of reactions from both sides of the controversy: those who argued the proposed guidelines were too conservative, and those who wanted stricter guidelines.

A compromise was reached by drafting another version of the guidelines. This time, Dr. Elizabeth Kutter was assigned to draft the document. Hence, three different

versions of guidelines existed: the "Hogness", the "Woods Hole," and the "Kutter" drafts. To be able to discuss the three versions simultaneously, RAC's chairman composed a "Variorum Edition" of the guidelines for RAC's fourth meeting at the La Valencia Hotel in La Jolla, California, on December 4 and 5, 1975. Following Horace Furness' *New Variorum Edition of Shakespeare*, the three versions of the guidelines were placed side by side in the Variorum Edition of Guidelines.<sup>39</sup> This draft was discussed thoroughly at La Jolla. The result was a final draft of guidelines, to be presented and debated at the meeting of the Advisory Committee to the NIH Director (DAC-NIH) on February 9 and 10, 1976.<sup>40</sup>

Of the RAC itself, Dr. DeWitt-Stetten, first chairman of RAC who initially despaired on the functioning of the Committee, later recalled that,

By the time the meetings [in La Jolla] were over, the committee was truly functioning as one might wish a committee to function, with a commonality of purpose. . . .<sup>41</sup>

### ***Public Hearings***

At the time the final draft of guidelines was finished, NIH's decision-making process was two-tiered. As the "technical committee," RAC had prepared and discussed several versions of the guidelines. The RAC was thus the first tier in the decision-making

process. The second tier was the Advisory Committee to the NIH Director, or DAC-NIH. The DAC was the "policy committee," which was a more policy-oriented advisory body.

The Advisory Committee, DAC-NIH, was founded on May 9, 1966. As a public advisory body, it was established by authority of Section 22 of the Public Health Service Act. Chaired by the NIH Director, its purpose was to advise NIH

on matters relating to the broad scientific, technological, academic, managerial, and socio-economic setting in which the continuing development of the biomedical sciences, research training, and biomedical communications must take place.<sup>42</sup>

During the evolution of RAC though, the two-tiered decision-making process was revised. The second-generation RAC combined the technical and review functions, thereby collapsing the two tiers into a one-step process. Compared to the original, first-generation RAC whose members were only scientists, the new RAC was composed of scientists and non-scientists to suit its new function.<sup>43</sup>

The final draft of guidelines was subjected to public hearings held at a meeting of the Advisory Committee to the NIH Director (DAC) on February 9 and 10, 1976. Many critics saw these public hearings as a ploy to demonstrate NIH's willingness to incorporate broad participation in highly technical decision-making. Dr. Donald Fredrickson, NIH Director, was at the time impressed by the public hearings on the supersonic transport (SST) project, held by the Secretary of Transportation.<sup>44</sup> Very few other people expected the hearings.

DAC's February meeting "took nearly everyone by surprise. . . . Public interest groups were also invited, but were caught unprepared."<sup>45</sup> The only environmental group

that testified during the meeting was the Environmental Defence Fund (EDF). Dr. Burke Zimmerman, representing EDF, questioned the legal jurisdiction of the guidelines. He pointed out that private industries and possible military misuse of rDNA for warfare could formally not be subjected to the guidelines. He also asked whether the guidelines contained provisions to deal with human error.<sup>46</sup>

There was a truly broad representation at the DAC meeting. The consultants of DAC, for example, included a graduate student, the president of the National Academy of Sciences, and the Honorable David L. Bazelon, Chief Judge of the United States Court of Appeals for the District of Columbia Circuit, to name a few. Judge Bazelon actively participated in the discussions. Other participants were experts in law, public policy, and ethics. Dr. Donald Fredrickson, director of NIH, presided the meeting, and said,

the purpose of this meeting is to seek your advice on proposed guidelines setting conditions for the conduct of certain experiments with recombinant DNA molecules. .

. .<sup>47</sup>

At the hearings, members of RAC presented scientific and technical evidence to defend the guidelines. The members of DAC however, looked at their broader implications. Their discussion surrounded two main points. The first was whether the guidelines provided an adequate response to, and thereby an adequate protection from, the potential hazards of rDNA. The second point concerned the procedure by which the guidelines were formulated, in particular the degree of participation in it.<sup>48</sup>

On whether the proposed guidelines adequately protect people from the potential biohazard of recombinant work, RAC members defended them from a technical point of

view, while the other participants looked further into implementation of the guidelines. One issue was the jurisdiction of the guidelines. Theoretically they could only be imposed on research projects that received NIH funds. Research at private sector laboratories as well as non-NIH government facilities could not be subjected to the proposed guidelines if they were not supported by the NIH. This weakness becomes a real problem if we think that adequate protection of the human race can be achieved only by global implementation of guidelines or their equivalent. Another issue was the penalty for non-compliance. Although some participants, in particular those who were involved in research, argued that peer review was an adequate control method, many others questioned its effectiveness. But there was agreement too. It seemed that almost everybody felt the need for flexibility in the guidelines. In a fast and changing technology it would be necessary to accommodate new findings and new processes in a timely manner. Guidelines or other modes of control must not paralyze the development of the field.

The second big topic, whether the formulation process of the guidelines had been sufficiently participatory, encountered much disagreement. Many criticized RAC for its technocratic decision-making process. Scientists were blamed for taking authority in their own hands to decide what was good and desirable for the rest of society, ignoring the possibility of conflict of interests. As a participant said,

It would seem unlikely to me that a committee [RAC] with this composition could judge the hazards unacceptable. By saying that, I am not questioning the integrity of the members of the committee, but it is well known that scientists often have a greater



tolerance of hazards associated with their experiments than the members of the population at large.<sup>49</sup>

Another participant pointed to the closed agenda setting and decision-making process, so that certain issues were not brought "to the attention and treated in a jury type of fashion." The same speaker further continued that,

neither at Asilomar nor at the meetings of this NIH committee has there ever been a hearing of testimony. No one has ever invited me to come and give my two cents in a testimony-type fashion. I have been invited to meetings to sit on the outside. . . .<sup>50</sup>

At least, as one participant put it, an "image of responsibility. . . [and] an image of fair play" is important.<sup>51</sup> Judge Bazelon argued in favor of public participation, because

. . . the public is entitled to know this [rDNA]. . . and if the public doesn't accept it, it just isn't worth a good damn. . . .<sup>52</sup>

He furthermore emphasized the importance of societal values, and the necessity to balance scientific expertise with these values.

The RAC was also criticized for its failure to prepare an Environmental Impact Statement (EIS) in compliance with the 1969 National Environmental Policy Act (NEPA). An EIS should be published in the Federal Register before any government action could take place. The NIH breached this legal requirement by issuing guidelines without an EIS. In other words, NIH took action (issuing guidelines) without prior release of an EIS. Eventually, NIH released both a draft and final EIS.<sup>53</sup>

Discussions of rDNA guidelines were not limited to public hearings at the DAC meeting. They were also discussed with representatives of federal agencies at an

interagency meeting of April 8, 1976, held at the NIH campus in Bethesda, Maryland. The meeting concluded that agencies directly involved in the regulation of rDNA -- OSHA, EPA, and CDC -- must review their jurisdictions to allow precise formulation of their regulatory roles. The meeting furthermore recommended to include Congress in an effort to get government-wide acceptance of the guidelines.<sup>54</sup>

On June 2, 1976 a similar meeting was held at the NIH with representatives of the private sector. The industries were pleased to be informed about the guidelines, but they were also concerned about premature disclosure of research information as required by the guidelines. Disclosure of research findings could eliminate prospects for patent rights. The meeting recommended that a special committee be established to explore the compatibility of NIH guidelines with needs of private industries. Also, representatives of the private sector preferred voluntary compliance with the guidelines. They made their wish clear for minimal government intervention.<sup>55</sup>

On June 23, 1976 the guidelines were officially released at a press conference of the Department of Health, Education, and Welfare (HEW) under which NIH resided. Both the U.S. Congress and State Department were notified, as well as U.S. embassies and scientific attaches, and foreign embassies in the United States. The NIH guidelines were published in the Federal Register on July 7, 1976 for public comment.<sup>56</sup>

Between the publication of the Berg letter on July 26, 1974 and the release of NIH guidelines on June 23, 1976, almost two years had passed. It took RAC sixteen months to issue guidelines from its first meeting on February 28, 1975.

## ***Role of the Scientists***

What did scientists achieve as expert decision makers? Initially, they were praised for their self-imposed moratorium on certain experiments. It showed their moral obligation to avoid harm and to protect society's health and well-being. But the second Asilomar conference, also convened by scientists, did not receive much praise. On the contrary, it was criticized as being a technocratic, closed decision-making process. As previously expounded, Asilomar II was technocratic for multiple reasons.

Probably, the scientists bore no ill will. In their zeal to protect society from potential hazards they claimed that "scientists know better," and that the best results would follow from a discussion among experts in rDNA. But in the opponents' viewpoint they erred in taking for granted that scientific values were the only values worth considering in the decision-making process.

It is also possible that scientists had intentionally controlled rDNA for their own, selfish interests. They understood the complexity of rDNA, not only in a technical sense, but also with respect to many unresolved ethical and social controversies of the issue. Since the scientific community itself was already divided over the issue, defenders of rDNA took charge in a closed decision-making process to guarantee continuation of their work.

The scientists were also aware that someone else might made decisions for them if they could not reach a consensus. In their eagerness to continue research, the rDNA

defenders seized the opportunity at Asilomar II and took charge of the development of the field.

But criticism against Asilomar's technocracy was not left unheard. The NIH organized public hearings at the February 1976 meeting of DAC, as we have seen. Although motives to open up the process might be somewhat selfish, that is, to show NIH's support for participatory democracy, it was the first step in the democratization of RAC. Much of the problem however, was that RAC's effort to open up its procedures was too late and too little. A participant in the public hearings of DAC was quoted earlier as saying that, ". . . there has [n]ever been a hearing of testimony. . . . I have been invited to meetings to sit on the outside. . . ."57 The lesson to be learned from this episode is that scientists could function as expert decision makers, but they had to incorporate lay representatives in an early stage of the decision-making process.

In a complex matter such as rDNA, scientific expertise is indispensable in the decision-making process. Decisions in high technologies must be based on scientific findings provided by the experts. Also, as knowledgeable persons, scientists have an obligation to raise public awareness of technologies that are potentially hazardous. Scientists deserved praise for voluntarily raising the controversial issue of rDNA to the forefront of public attention. Their initiative to open up the rDNA debate was an unprecedented step in the history of public policy-making. The pervasiveness of rDNA and its consequences, good or bad, justify public participation in the decision-making process. In conclusion then, from a political viewpoint the lesson of Asilomar and RAC

is that scientists could not and should not, take all authority in their own hands in matters that affect everyone.

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39. In the Shakespearian New Variorum Edition, notes and comments by other authors are placed in the original text as sources of illustration and criticism. Thus Horace Furness, editor of the New Variorum wrote, "In the present volume will be found, . . . such notes and comments from all sources as I have deemed worthy of preservation, either for the purpose of elucidating the text, or as illustrations of the history of Shakespearian criticism." See Horace Howard Furness ed., *A New Variorum Edition of Shakespeare. Macbeth*, rev.ed. Horace Howard Furness Jr., 6th ed. (Philadelphia: Lippincott, 1873), iv.
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41. Testimony Dr. Hans DeWitt-Stetten. See National Institutes of Health, *Recombinant DNA Research Volume 1*, 174.
42. Krimsky, *Genetic Alchemy*, 169.
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46. National Institutes of Health, *Recombinant DNA Research Volume 1*, 294.
47. *Ibid.*, 149.
48. Testimony of Dr. David Baltimore at the February 9, 1976 meeting of DAC-NIH. Although Dr. Baltimore had no role in developing the NIH guidelines, he was one of the members of the NAS study panel that issued the Berg letter and a member of the organizing committee of Asilomar II. He pointed to at least two major topics that dominated subsequent discussions among the "lay" participants of the DAC meeting the following day. See National Institutes of Health, *Recombinant DNA Research Volume 1*, 248.
49. Testimony of Dr. Susan Wright, historian of science at the University of Michigan, at DAC's public hearing on February 10, 1976. See National Institutes of Health, *Recombinant DNA Research Volume 1*, 268.



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## *Four*

# *The Public's Voice*

### *Changing Contexts*

As was mentioned in the previous chapter, a growing opposition emerged to scientists as expert decision makers in the rDNA debate. Opponents rejected the closed decision-making process whereby rDNA was discussed as merely a technical issue. They challenged the "tunnel vision" of expert decision makers and questioned the right of scientists to make decisions for all people. It was obvious that a technocratic approach could not resolve the controversy.

In this chapter, the term "public" includes all people, scientists, non-scientists and lay persons involved in the rDNA debate, in particular those opposed to a technocratic

decision-making process. The principal objection of the opposition was that autocratic decisions were being made by a small group of rDNA specialists. The critics questioned the legitimacy of decisions made by a limited group of people that ultimately would control the development of a technique with immensely far-reaching and global consequences. It was felt that such decisions must, in principle, be made by a broad range of people, not by rDNA experts only. Scientific values are not automatically synonymous with societal values, and therefore, it is only fair and important for the public to have a say in scientific decision-making. Moreover, the public at large has a legitimate right to know what kind of research is financed with public funds, making scientists accountable for their activities. A technocratic approach to decision-making kept non-specialists out of the process, leaving their voice unheard.

A "public voice" emerged not unexpectedly in the rDNA controversy. In January 1971, Dr. James Watson, one of the discoverers of the double helix structure of DNA, testified before the Committee on Science and Astronautics of the U.S. House of Representatives. Dr. Watson's testimony was on human clonal reproduction. He said,

This is a decision not for the scientists at all. It is a decision of the general public --do you want this or not? It is not a question for a group of scientists to decide, do we want to do this? It is a decision which the people as a whole must make.<sup>1</sup>

It was evident that Dr. Watson saw public participation in the decision-making process as a prerequisite for smooth development of genetic engineering of humans.

The idea of public participation, or involvement of non-specialists in the determination of science and technology policy, has roots that go further back in time

than Dr. Watson's 1971 testimony. In the United States, the movement for wider participation in public policy-making has been a growing force since World War II. Dissatisfaction with government in general as well as with the scientific establishment in particular started with post-war changes in the social, political, and ethical contexts of the relationship between government, science and society.

Although Americans were euphoric when the atomic bombs were successfully detonated in 1945, ordinary people and scientists alike subsequently became disillusioned by the sacrifices related to federal funding for war research. Still, during the Cold War era in the 1950s, early voices of resentment could not stop the flow of federal funds into war-related research projects. Yet outrage toward a presumed misuse of federally supported research came to the surface during the Viet Nam War period in the 1960s. University campuses became battleground between those who did not believe that federally supported research projects contributed to the disastrous effects of the war, and those who opposed misuse of scientific research for other ends than pure scientific development.

Overall, the social climate of the 1960s was tainted by a disillusionment with Viet Nam. The academic community questioned the use of scientific research as a tool to wage war. The general public became increasingly critical toward the war effort and federal spending on war-research and research in general. A significant change in the social perception of science and the scientific establishment was occurring.

The late 1960s also saw the emergence of the Ecology Movement. People became conscious of their fragile living environment, and questioned excessive human intervention in it. Both factors, anti-war sentiment and the environmental movement, nurtured a growing critical attitude toward motives of the government and scientists. Ultimately people lost confidence in the scientific community as source of objective findings, as well as in government as financier and regulator of scientific activities.<sup>2</sup>

In the meantime the politics of funding science changed dramatically. Before World War II, basic research in the United States was primarily supported by private patrons. Philanthropist-endowed institutions such as the Rockefeller Institute for Medical Research and the Carnegie Institution of Washington were established for the advancement of basic science.<sup>3</sup> During WW II, government intervened in scientific research through the development of the nuclear bomb.

After the war, government continued its support for basic science. Now scientists could depend on the government for research funds rather than on private patrons. Federal funds were available only on a competitive basis, however, which meant that most research projects were subjected to "peer review." Unlike in privately funded research, where scientists were free to do almost any kind of research as long as it was agreed upon by their patrons, they now had to secure the approval of the quality of their work from their scientific peers. Under "serial-funding" arrangements, continued money was available for successful projects, with renewal dependant on research results. This

funding mechanism inevitably forced scientists to "produce," and in the competitive world of funding, scientists became entrepreneurs.<sup>4</sup>

With people's confidence in both government and the scientific establishment declining, the growing competitive urge of entrepreneur-scientists to produce results at any cost exacerbated concerns about accepting science as a matter of trust. Can scientists and their research results be taken at face value? Peer review has the propensity to enforce conformity rather than revolutionary innovation in research. Perceptions of an established, entrenched scientific elite grew. On certain occasions errors, misunderstandings, or downright fraud came to light in scientific findings. Criticisms were also raised to the effect that experts might be asking the wrong questions, for example, using DDT as an insecticide without asking what it would do to harmless or beneficial insects.<sup>5</sup>

Moreover, it is questionable whether scientists can impose limits on themselves. Will they have the courage and integrity to discontinue their own research when it is deemed unethical by societal standards?<sup>6</sup> Such ethical issues became particularly pronounced in the rDNA controversy. The appropriateness of human intervention in the evolutionary process by way of manipulating genetic material was seriously challenged.

The increasing suspicion toward the scientific establishment and its output, coupled with the pervasive consequences of high technologies like rDNA, spurred public participation in science and technology policy. Vocal members of the general public felt they could no longer leave important decisions in determining the course of development of science and technology to a selected group of experts. In rDNA specifically, several

occasions arose where lay people demanded a say. The best known and most publicized events occurred at the University of Michigan in Ann Arbor and at Harvard University in Cambridge.

### ***The Michigan Debates***

Even before rDNA experts published the famous Berg letter and called for a voluntary moratorium on certain potentially dangerous experiments, the University of Michigan had already considered a policy for the safe development of recombinant work at the University. The impetus to consider methods for controlling potential hazards came from a group of microbiologists at the Medical School, the Ad Hoc Committee for Microbiological Safety. But after the publication of the Berg letter in July 1974, the ad hoc committee at the Medical School suggested that a university-wide committee would be more suitable to handle the issue. Hence, in December 1974 the Committee on Microbiological Research Hazards was established. The Committee consisted of seven faculty members from three different colleges.<sup>7</sup>

One of the proposals of the Microbiological Research Hazards Committee was to renovate three laboratories to become "moderate risk containment facilities" for recombinant experiments. The renovation was necessary to accommodate rapidly

increasing rDNA research at the Michigan campus. The University's Biomedical Research Council, responsible for campus-wide planning of Biomedical research, supported the plan.

Meanwhile, the Council detected a growing distrust toward rDNA research. It therefore recommended that three committees be established to consider separate aspects of recombinant work so that "the future of research in recombinants be given further and more differentiated study by the campus as a whole."<sup>8</sup> Committee A was responsible for the rDNA facilities, supervising the planning and safety of laboratories for recombinant experiments and developing the needed funds. Committee B was to formulate policies to guide recombinant research. Committee C had a certifying function; it checked and verified the qualifications of laboratories for recombination experiments.

The public's voice played a particularly important role in the work of Committee B. The nature of the Committee's work, that is, developing policies for rDNA research, made it especially vulnerable to public attacks in the ensuing debates. Committee B was a "lay" committee, as none of its eleven members were microbiologists. They came instead from diverse fields such as philosophy, biochemistry, English, history, internal medicine, physics, social work, genetics, law, psychology, and religion.<sup>9</sup> After a few initial deliberations, the Committee decided to work on a set of practical guidelines for local use within the University. Note that the NIH guidelines were not yet issued at the time, as Committee B began drafting its local guidelines in September 1975.



While Committee B was preparing the guidelines, certain events at the University of Michigan changed the Committee's course and pace of work. The most significant of these was involvement of the University's Regents in the rDNA decision-making process, plus the upcoming public debates on rDNA. The triggering event for the Regents' involvement was the previously mentioned recommendation by the University's Biomedical Research Council to renovate three laboratories at a cost of about \$306,000. The Regents approved the renovation, and soon this decision was publicly announced in campus and community media.

Immediately thereafter several faculty members questioned the Regents' approval. Following an initial telephone inquiry to the Regents, the opponents addressed their objections during a public meeting of that body. They then sent a letter to Committee B, requesting that a public forum be organized. The forum, they argued, was needed on the one hand to inform and educate the wider community about rDNA, and on the other hand to provide Committee B with inputs from the community. Simply put, the core of the opponents' argument was the compelling necessity of community involvement in the decision-making process.

On March 3 and 4, 1976 a community forum took place at the University of Michigan. Around 400 people attended each day. Speakers included scientific and legal experts from outside the University, yet more time and attention was reserved for comments from the audience. Faculty members and lay audience alike had ample opportunity to ask questions, voice doubts and express opinions pro and con. The

chairman of Committee B later recalled that the audience was inclined to play off pros and cons against one another, leading to polarization of the issue. At one time, the discussion became emotional when a speaker from another university "climbed the stage and took over the microphone when it was not his turn. . . ."10 Another problem was the audience's misinformation and misunderstanding of some of the issues. It was an embarrassing task for the experts to attempt to correct these misunderstandings in the emotional atmosphere that ensued.

The polarization was sharpened by the time Committee B issued its report. Critics of the report tried to win their position by damaging the credibility of the Committee. They also demanded extra time for additional discussions and debates to press their viewpoints. They argued that more of the "public's voice" should be heard, claiming for even wider participation in the decision-making. What they really seemed to want however, was to arouse more support for their views, thereby politicizing the issue even further.

One of Committee B's weaknesses, according to its chairman, was a lack of experts. Since it was itself misinformed, Committee B was oftentimes unable to provide quick and precise rebuttals. The criticism against NIH guidelines was a case in point. One of the critics requested Committee B to study the NIH guidelines carefully (a draft was meanwhile available) because these guidelines were created by rDNA specialists, and therefore, in the opinion of the critic, were suspect. This person argued that the rDNA specialists developed the national guidelines based in their own interest to proceed with

the technique while disregarding potential hazards, leading to untrustworthy decisions. It seemed that Committee B did not have a ready response to this allegation. The chairman of Committee B admitted only in retrospect that the experts who developed NIH guidelines had thought about potential hazards more thoroughly than Committee B itself ever could have done.

By the time Committee B presented its report to the University Regents, the Regents were unwilling to make decisions based solely on it. As has been mentioned, the debates were prompted by the Regents' initial approval for the renovation of three laboratories for rDNA research. Now it was time for the Regents to decide whether to endorse their initial approval for the renovation, thereby supporting rDNA research, or to withdraw their earlier approval. It is interesting to note, that during the whole controversy the Regents never showed interest or support for community-wide participation in the decision-making process. A Regent observed, "If every decision had to be made by a plebiscite, we'd never make any decision at all."<sup>11</sup> They argued that as public representatives, Regents act in the interest of the public who elected them.

The report of Committee B recommended that, "recombinant DNA research should, in principle, go forward so long as it is submitted to appropriate controls."<sup>12</sup> It accordingly recommended use of NIH guidelines, complemented with additional restrictions. These restrictions required approval for all P4 (highest risk) experiments from the Regents. (Recombinant DNA laboratories were classified from P1 to P4, P1 being for research with the lowest risks, while P4 for the highest risk experiments that

were permissible.) Those experiments classified as P3 (moderate risk) must be supplemented with biological containment measures using EK2 (enfeebled) host-bacteria when appropriate. The report was endorsed by all committee members with one dissenter, a historian. This dissent and a response by the lawyer-member of Committee B were added to the report as an Appendix.

The Regents, however, remained undecided after reading the recommendations of Committee B. Their reaction was to reverse themselves and turn to a form of public participation. On May 12, 1975 the Regents organized a "mini-forum." Speakers from outside the University were invited, including Dr. Paul Berg of Stanford University. There were several speakers from campus as well, including a member of Committee B (a geneticist), a zoologist, a microbiologist, and a historian of science.<sup>13</sup>

The mini-forum was very instructive. Supporting as well as opposing viewpoints were aired in a constructive way. It seemed to be more successful than the earlier community forum, partly because the question asked at the mini-forum was technical, that is, whether to renovate the laboratories. But a more important factor in the mini-forum's success was the way it was conducted. The mini-forum was conducted in a "review" approach. The Regents -- as reviewers -- requested for supporting and opposing opinions before they made a final decision. The public forum on the other hand, was dominated by an "adversarial" approach, where ultimately a win-loose situation prevailed, dimming the possibility of reaching consensus.

At its June meeting, the Regents finally decided to continue their initial approval for renovation of the rDNA laboratories. From September 1975, when Committee B began its task to develop local guidelines, until June 1976 when the Regents approved going ahead with rDNA work, nine months had passed. Was it worth this time to come to such a conclusion? Most members of the university community seemed to think so. They felt that their voice had been heard. They had ample opportunity to raise questions and to convey their concerns. But costs were involved. Members of Committee B spent much time and anxiety during that time.

Meanwhile, another public debate surrounding rDNA was raging at Cambridge, Massachusetts. The Cambridge debates, so it seemed, were not influenced by the debates at the University of Michigan. Debates at Cambridge erupted when a plan of Harvard University to build a moderate-security lab for rDNA experiments leaked to the press. Fueled by intimidating actions of their Mayor, the citizens of Cambridge demanded a public hearing.

### *The Cambridge Experience*

On the evening of June 23, 1976, the day NIH guidelines were released by the Department of Health, Education and Welfare in Washington DC, an open meeting of the

Cambridge City Council was convened by the flamboyant Mayor of Cambridge, Alfred M. Vellucci. The Mayor could not have chosen a better day for a public discussion of such a hot topic as rDNA. Hundreds of citizens jammed the City Hall, and to dramatize the event even further, the Cambridge public high school choir sang "This land is your land" under the heat of the lights of TV cameras. John Lear, in his *Recombinant DNA The Untold Story* wrote,

No one has more succinctly described the essence of the evening than William Bennett, science editor of *Harvard University Press* and Joel Gurin, a free-lance writer from California, did [*sic.*] in a subsequent report they published in the *Atlantic Monthly*. "The most pained people in the room," they wrote, were the "scientists who had been summoned" by Mayor Vellucci. "Physical discomfort and sweat were the least of their problems. Suddenly their careers hinged on the ability to defend highly technical biochemical work in plain English, a language some of them had not spoken for years."<sup>14</sup>

The often hostile debates lasted until almost one in the morning, and Mayor Vellucci's proposal for a two-year ban on all rDNA research in Cambridge survived. How did Cambridge citizens become involved in the rDNA controversy this way?

The Cambridge debate was prompted by the intention of Harvard University to build a P3-facility for moderate risks experiments. Harvard intended to build a P3 lab on the fourth floor of an old building, the Harvard Biological Laboratories. The plan itself was already controversial, since a number of Harvard scientists were against rDNA. The University had been unsuccessful in resolving the controversy internally. It became public when the *Boston Phoenix* printed a front-page article on June 8, 1976, titled "Biohazards at Harvard," with the accompanying headline "Scientists Will Create New Life Forms --

But How Safe Will They Be?"<sup>15</sup> The article described, among other things, how Pharaoh ants colonized the building and could not be destroyed, indicating that the old Biological Laboratories building was not suitable for the planned P3 lab. Dr. Ruth Hubbard, a rDNA opponent at Harvard, argued that if Pharaoh ants could travel from Egypt to Cambridge and nobody could get rid of them, then escaped microorganisms were far more dangerous, as they could travel anywhere and no one would even notice because nobody could see them.<sup>16</sup> The article caught the attention of Cambridge citizens, moving the issue from the campus to the community.

Some argued that even without the publication of Harvard's controversial building plans the rDNA controversy would have erupted, because of strong opposition of Science for the People (SESPA).<sup>17</sup> The Genetics and Social Policy Group of SESPA, composed of a group of scientists from the Boston area, had already raised questions about such matters as genetics and intelligence and genetic screening.<sup>18</sup> It was probably inevitable that they would have eventually raised the issue of rDNA.

But in retrospect, it seemed that the most direct cause of the debates was Harvard's inability to solve an internal dispute among its own scientists. Some of the scientists supported rDNA, while others were strongly opposed. Although somewhat exaggerated, Mayor Vellucci said of the occasion,

So we had this meeting. I didn't realize it was going to be the stormiest meeting of my political life. There were scientists versus scientists; doctors versus doctors; biologists versus biologists. They were disagreeing. Then they were getting heated. And then they were getting overheated. And then they began calling each other names. And then. . . they began to call each other liars!<sup>19</sup>

The very outspoken Mayor had already gained much political clout from attacking Harvard on earlier occasions.<sup>20</sup> "Mayor Vellucci of Cambridge had been feuding for many years with Harvard University and happily seized this new opportunity to make trouble," wrote a scientist commenting on the event.<sup>21</sup> True to form, Mayor Vellucci exploited town-gown tensions by, in effect, alerting the media and public that "Frankenstein Monsters" were approaching from Harvard Yard.<sup>22</sup>

On July 7, 1976 a second meeting of the Cambridge City Council was convened. The Council voted down Mayor Vellucci's proposal for a two-year ban on all rDNA experiments. Instead, a "good faith" moratorium of three months on P3 research was adopted. Hence, to the relief of rDNA researchers, P1 and P2 experiments could proceed uninterrupted.<sup>23</sup> Meanwhile, the City Council recommended an independent review board to study the adequacy of NIH guidelines for the protection of Cambridge citizens. Following this recommendation, James L. Sullivan, City Manager of Cambridge, formed the Cambridge Experimentation Review Board (CERB). The Board first met on August 26, 1976. Consisting entirely of non-scientists, its chairman was the newly appointed City Commissioner of Health and Hospitals and the remaining members, four men and four women, represented most of Cambridge ethnic groups. They had educational backgrounds ranging from a high-school degree to the PhD.



The CERB worked diligently on the assessment of NIH guidelines in order to decide whether they were adequate measures for the protection of Cambridge citizens.

The group had weekly meetings on Tuesday and Thursday.

Altogether, seventy-five hours were spent in testimony taking, followed by twenty-five hours of study and deliberations, illuminated by tours of the Harvard and MIT laboratories and a mock experiment that demonstrated all the steps in the recombinant DNA process.<sup>24</sup>

On alternate weeks opponents and supporters of the NIH guidelines voluntarily appeared before CERB. At the height of its investigation, CERB held a court-like hearing. Harvard and MIT teams countered teams of local critics. Members of CERB raised questions and cross examined the teams. The well-attended hearing lasted for over five hours. Sheldon Krinsky, a CERB member, wrote that the hearing was

an extraordinary expression of accountability by scientists to local citizenry on the potential hazards of the new gene splicing technique.<sup>25</sup>

At last, on January 5, 1977 a press conference was called for the official release of CERB's recommendations. First, CERB concluded that NIH guidelines as such were inadequate. Therefore rDNA research would be permitted in Cambridge only if additional and more stringent requirements were fulfilled. Second, CERB recommended to include NIH guidelines plus these extra requirements in a city ordinance. To monitor rDNA research and ensure compliance to guidelines the Cambridge Biohazard Committee was formed. In a third recommendation, a proposal was made for Congress to legalize NIH guidelines for all rDNA research in public and private institutions. A national registry of all rDNA-workers was also suggested.

On February 7, 1977, by vote of six to three, the Council incorporated CERB's recommendations into the City's ordinances, and lifted the ban on P3 experiments. During almost eight volatile months the citizens of Cambridge voiced their arguments through participation in the decision-making process. It was a difficult time for scientists, but the citizens seemed satisfied with the outcome of the debates. The City had made peace with rDNA.

### *Procedures of the Debates*

Although public debates at Cambridge took place after those at Ann Arbor, there was no evidence that the Michigan debates influenced debates in Cambridge. But the Cambridge Experience, so it seemed, started the cause of public participation in several other places.

In July 1976, the University of California at San Diego began deliberations on rDNA. The University, trying to avoid a "Cambridge-style confrontation," informed Mayor Pete Wilson of its intention to build two P3 (moderate risks) laboratories.<sup>26</sup> The San Diego DNA Study Committee was established. In its functions it resembled CERB, although in contrast to CERB's end result, no local legislation was enacted at San Diego.<sup>27</sup> Instead, the Study Committee issued a report endorsing the use of NIH guidelines plus

some more stringent requirements such as refraining from all P4 (highest risks) experiments, confining all experiments to P3 facilities, and notifying the City of any P3 experiments that required the strictest biological containment.<sup>28</sup>

In December 1976, Princeton University was involved in public debates around its plan to build a P3 lab for rDNA experiments. It all began when certain adenovirus experiments were discontinued for lack of suitable laboratory space. At the time, Princeton's existing laboratory was a half-century old building lacking necessary safety measures for rDNA experiments. To accommodate recombination experiments at Princeton, the rDNA subcommittee of the University Research Board proposed to build suitable research facilities in compliance with NIH guidelines.<sup>29</sup> But approval to build the facilities was met with resistance. The New Jersey Health Department claimed authority to set safety regulations, and so did the Public Health Council.<sup>30</sup> To complicate matters, the citizens of Princeton who were interested in the issue also wanted a say in the decision-making process.

Similar to Cambridge's CERB in task and performance, the eleven-member Princeton committee, six men and five women, was supposed to act as a non-expert committee. It consisted of "two medical doctors, three writers, three scientists, one school teacher, one Presbyterian minister, and one retired housekeeper."<sup>31</sup>

They began their task in January 1977. Testimonies from experts in related fields were heard, as well as from citizens expressing their views and concerns. All meetings were open to the public. In May 1977, after four months of deliberation, the committee

concluded its task by issuing not one, but two reports. The majority report recommended to continue rDNA research under slightly stricter conditions than required by the NIH guidelines. The minority report recommended a ban on all rDNA experiments that needed specially equipped laboratories under the NIH guidelines. The Princeton Borough Council, the final decision maker, was thus compelled to re-examine the issue. Nine months later, by vote of five to one, the Council decided to endorse the majority report.<sup>32</sup> By March 1978 Princeton had its local laws for rDNA.<sup>33</sup>

Krimsky summarized the evolving public debates and the ensuing local and state laws as follows:

The Cambridge event touched off a series of local and state activities. By 1981 local ordinances were also passed in Princeton, New Jersey, Amherst, Boston, and Waltham, Massachusetts, and Berkeley, California; state legislation was enacted in New York and Maryland; resolutions were passed in the city councils of Emeryville and Del Mar, California; bills were introduced in the state assemblies of Wisconsin, Massachusetts, New Jersey, California and Illinois.<sup>34</sup>

Thus the Cambridge debates ignited a chain reaction, while debates at Ann Arbor were a one-time university happening. Why this difference?

Possibly, differences in the contexts of the events at Ann Arbor and Cambridge were responsible. At Michigan, the debates were confined to the University campus, but at Cambridge they spilled over into public view and became a national event. A significant factor at both places was the role of the Mayors and their relationships with the universities. The Mayor of Ann Arbor, Albert H. Wheeler, admitted that the City was little involved in the controversy. The University Regents did not invite the City

administration to participate in decision-making, and the City had not asked to do so. Town and gown had a history of good relationships in Ann Arbor. The fact that Mayor Wheeler had received his PhD in Public Health and Microbiology from the University of Michigan might have eased any possible tension.<sup>35</sup> Also, the Michigan scientific community was not yet entangled in a controversy over rDNA when the public debates began. The debates emerged only after several scientists voiced their concern about a plan to renovate laboratories. All these factors, that is, a good relationship between the University and the City, practically no community involvement of the City in the campus debates, and an absence of internal controversy, enabled the Michigan debates to remain localized.

At Cambridge, on the other hand, the Mayor had a significant role in achieving publicity for the debates. Mr. Vellucci was a colorful figure, but he was more than that: "beneath the mask of the loudmouthed absurdly gesticulating clown, however, was a shrewd and practical judge of situations. . . ." <sup>36</sup> In short, he was a person to be reckoned with. The existing rivalry between Harvard and the Mayor increased the intensity of the rDNA controversy. In spite of differing accounts on how Mayor Vellucci got Dr. George Wald's support in the Cambridge debate, the public appearance of this respected scientist and Nobel prize winner added to the newsworthy character of the debates. Due to the *Boston Phoenix* article and Mr. Vellucci's active campaign, the Cambridge debates received ample media attention. The first meeting was televised nationally. The NIH sent Dr. Maxine Singer as representative and defender of its guidelines. Dr. Singer was

a well-known figure in the rDNA controversy. She was, together with Dr. Dietrich Söll, the author of the famous Gordon Conference letter that launched rDNA into public sphere. She was also member of the organizing committee of the second Asilomar conference, and at the time, she was head of the Nucleic Acid Enzymology Section of the Biochemistry Laboratory at the National Cancer Institute of NIH.

An even more important factor in the dramatic culmination of events was the controversy within Harvard since the University's scientists were unable to resolve the rDNA conflict internally. This left Mayor Vellucci with two workable options. The first was to ask the federal authorities for extra assurance that the citizens of Cambridge were in no danger. His second option was "to tackle the problem head on," which Mr. Vellucci eventually did by announcing a public debate and placing a moratorium on P3 experiments.<sup>37</sup>

For our analysis, the most important aspect of both debates was the process followed. Both debates were conducted in an adversarial procedure. Opposing and supporting views contradicted each other, and opponents and supporters cross-examined each other. At Ann Arbor, the debates included faculty members, opposed rDNA specialists and rDNA supporters. As mentioned earlier, the chairman of Committee B recalled that the adversarial process of the Michigan debates led to polarization of the issue, and henceforth to widening the gap between critic and supporter. This created a win-lose situation that ultimately turned into hostility between the two sides.

Similarly, at Cambridge, Harvard and MIT teams defended their positions against the City Council's antagonism. At the first public meeting, "long, often angry and openly hostile exchanges" took place.<sup>38</sup> The television cameras faced Harvard and MIT teams on one side and Mayor Vellucci and the public on the other side. Mr. Vellucci warned, "please refrain from using your alphabet. We are laymen, and don't understand your alphabet. So spell it out for us. . . ." Any simplification that followed did not leave the two sides communicating well.<sup>39</sup> While the university teams approached the issue from a technical point of view, the public group saw the controversy primarily as a political issue and was more interested in procedural issues.

The adversarial procedure was not conducive to a constructive debate. No new, useful ideas emerged and nothing was resolved.<sup>40</sup> At Michigan, the outcome of the public forum and the recommendations of Committee B were not sufficiently convincing for the University Regents to make final decisions. The Regents organized their own mini-forum to come to a conclusion. Similarly, the decision-making process at Cambridge was taken over by CERB.

The mini-forum and CERB followed a different procedure than the public, or community debates. During the mini-forum at Ann Arbor, a review, instead of an adversarial approach, was followed. The Regents reviewed both sides of the issue, and made decisions based on information presented to them. The President of the University of Michigan acted as moderator of the forum, and each of the Regents had an opportunity to ask questions. A list of the most commonly asked questions was prepared by the

**The Public's Voice**

chairmen of Committee A and B. The chairman of Committee B wrote that "[i]t was a thoughtful and instructive session that obviously helped and settled the Regents."<sup>41</sup> The review approach was less controversial than the adversarial approach. Neither the proponents nor the opponents of the issue had to "win" the debate. Rather, both camps were advisers to a jury, or referee (the Regents), who ultimately made the decision.

At Cambridge, CERB listened to testimonies from both sides of the controversy in a court-like hearing. Krimsky used the term "citizen court" to emphasize its similarity and differences from a "science court."<sup>42</sup>

Similar to a science court procedure, supporting and opposing views of an issue were presented. The difference was that whereas a science court reviews a technical matter, a citizen court views the issue from a "citizens," or political perspective. One of the criticisms levied against science courts is that the technical nature of the presented arguments is accompanied by an assumption that "fact" can be separated from "value" in the presentation of evidence.<sup>43</sup> A science court ignores the role of human judgment in decision-making. This is a serious flaw. It is hardly possible to make wise decisions in esoteric fields based solely on pure technical findings, for there are many "unknowns," or grey areas in such areas. To complicate matters in rDNA, scientists disagreed among themselves and interpreted data in different ways. Hence, political judgment, involving values of the decision makers, is an inevitable part of the decision-making process.

Also, science and citizen courts differ with respect to procedure. A science court follows an adversarial approach where opponents and supporters of an issue try to defeat



the other side, as in a court of law.<sup>44</sup> The citizen court at Cambridge, similar to the mini-forum at Ann Arbor, followed -- as we have seen -- a review approach. Harvard and MIT teams presented their opinions, and critics and CERB members asked questions. Similar to the Regents of the University of Michigan, CERB was interrogator, referee and decision-making body at the same time.<sup>45</sup> This procedure was constructive and useful: CERB's recommendations were unanimously accepted by the City Council, and at Michigan the Regents were finally able to make decisions.

To summarize, then, public participation in the rDNA decision-making process at Ann Arbor and Cambridge was conducted in two stages. The first was a community-wide session. At Michigan it was the public forum, and at Cambridge it was the public debate between scientists, City Council, and citizens under the command of Mayor Vellucci. These truly "public" events were not very instructive. As just described, the adversarial process of the debates created issue-polarization, a win-lose situation, and ultimately, ill-feelings. Most likely, lack of communication between opposing groups as well as misunderstanding about certain aspects of the issue increased the animosity between participants of the debates.

Fortunately though, there was a second stage in both debates. The Regents at Michigan organized a mini-forum and the Cambridge City Manager established the CERB, an independent body that consisted of lay persons. A review approach guided this part of the participatory process. In essence, it allowed scientists to be accountable to lay persons on what they were doing. The review approach was especially interesting

because of the multi-functional role of the Michigan Regents and CERB members. They were interrogator, arbiter, and decision-maker at the same time. To perform three functions simultaneously was not an easy task, but it seemed that both bodies were successful in fulfilling their tasks. They were able to make decisions that were acceptable for all relevant parties.

### ***Outcomes of the Debates***

What was the effect of public participation in the rDNA decision-making process? Did it really make a difference in resolving the conflict? First and foremost, it is undisputable that public debates provide citizens with the opportunity to be heard. Lay persons get a chance to voice their concerns and explain their viewpoints. If the technocratic approach was criticized for excluding non- scientific values, the participatory approach allowed these values to be considered in decision-making.

Ultimately, participation in the decision-making process created trust and acceptance among the public. Citizens felt that their concerns had been addressed in a fair procedure. Critics at the Ann Arbor debates for example, were proud of their participation and felt they had positively influenced the decision-making process.<sup>46</sup> In essence, public participation was a means for dialogue between experts and non-experts.

Establishment of citizen panels to investigate the issue further also helped in building public confidence. Citizens became more open to accept recommendations of such panels. The City Council of Cambridge, for example, unanimously supported CERB's recommendations. As a panel composed of lay persons, the CERB was seen as an impartial jury having no vested interest in rDNA. And hence, for Cambridge citizens, it was a credible decision-making body.

The crucial importance of public participation in the decision-making process could not have been better formulated than in CERB's report. It stated that,

Knowledge, whether for its own sake or for its potential benefits to human kind, cannot serve as a justification for introducing risks to the public unless an informed citizenry is willing to accept those risks.<sup>47</sup>

The principle of "informed consent" conveying the benefits and hazards of the technique to a certain part of the community -- usually the scientific community and its constituency -- must therefore be expanded to include the general population. "Community consent" is more appropriate in decisions for high technologies like rDNA. A way to achieve community consent is by allowing lay persons to participate in the decision-making process.

The two different approaches to participation, the adversarial and review approaches, also determined some of its outcomes. The adversarial approach in the first stage of the participatory process seemed especially effective in challenging the scientific community and its vested interests. The critics of Committee B of the University of Michigan said that their deliberate efforts to polarize the issue made Committee B "think

harder."<sup>48</sup> In other words, the critics tried to make rDNA supporters more sensitive toward a broader range of values and concerns. Also, the adversarial process compelled scientists to evaluate the meaning of their work for a broader public. During angry and sometimes hostile debates at public meetings in Cambridge, scientists were forced to provide accountability for their actions.

The review process was particularly effective in assessing the controversy surrounding rDNA. The citizen panel of Cambridge, CERB, as well as the Michigan Regents, listened and questioned opposing perspectives on the issue. This approach made it possible to pinpoint the locus of disagreement, and from there make recommendations that accommodated the needs and demands of all parties as generously as possible.

It should be underscored that the neutrality and credibility of the reviewing panel was crucial for public acceptance of its recommendations. It is also important to note that the recommendations after the debates did not differ substantially from the initial decisions. Thus, the CERB recommended NIH guidelines plus more stringent safeguards. Similarly, the Regents endorsed their initial approval to renovate the rDNA laboratories. Few radical ideas were produced, and hence, the crucial function of public participation was not to change policy but to nurture dialogue, creating trust and acceptance.

A disconcerting outcome of the public debates was that their public nature led to public action. They produced, across the country, a variety of local and state laws. Although these laws did not differ significantly from the NIH guidelines, each was slightly different. Such a "patchwork of laws" could be confusing for researchers as well

as for industries. A flight from areas with strict laws to localities with less stringent rules could occur. Yet the ultimate danger of such policy could be that regional laws become meaningless. Potential hazards of rDNA cannot be contained locally by enacting strict laws if other places do not adhere to the same laws. Also, genetically modified organisms will not "obey" such laws if released into the environment.<sup>49</sup> A national set of standards on the subject seems absolutely necessary.

### *Pitfalls of the Debates*

The call for a voluntary moratorium on potentially dangerous experiments was an act never done before by scientists. Likewise, public participation in rDNA decision-making processes at the University of Michigan and at Cambridge was unprecedented. Krimsky called the Cambridge citizen court a "social experiment."<sup>50</sup> As in every other experiment, the Cambridge experience faced unanticipated pitfalls. The participatory processes were therefore not free from flaws.

The main pitfall of public participation was most probably education, or lack of it, on the part of lay persons who were engaged in the decision-making process. Recombinant DNA is a difficult subject to comprehend, even for researchers and scholars from other academic disciplines. Committee B at Michigan was a case in point. It was

composed of faculty members of the University, although none of them were rDNA specialists. Although the members were instructed in recombinant and safety techniques by microbiologists, Committee B could have resolved the dilemmas and uncertainties it faced sooner if there had been expert knowledge available. Committee B's chairman admitted that the task of the Committee was tougher than was anticipated because of lack of specialists. He aptly summarized the need of expert knowledge:

Expert knowledge about microbiology and the methods of microbiologists is needed to make sound judgments about the effectiveness of these safety measures and about the criticism being made of them.<sup>51</sup>

In retrospect, the chairman of Committee B regretted the exclusion of microbiologists. Were expert knowledge available within the Committee, misunderstandings and other uncertainties would be corrected immediately. Also, experts were more critical toward the safety of their work, more than lay persons could have ever thought about.

A similar situation occurred in Cambridge. The lay members of CERB encountered difficulties in comprehending simple things such as the structure and mechanism of a cell. Needless to say, they struggled to understand the complexity of recombination processes. Much time was spent educating CERB's lay members. Testimonies by experts helped clarify the issue somewhat, but scientists were not accustomed to explain rDNA in terms that lay persons could understand. A communication barrier between expert and non-expert became a real problem during the Cambridge debates. Another factor that added to the communication problem was the prejudice of scientists. They seemed to be more reluctant to speak to lay persons than

to peers assuming that lay people would misinterpret their true intentions. Sometimes this prejudice was pushed to an extreme. "An appalling cynicism about the intelligence of people who are not scientists was displayed again and again as the day wore on. . . ," wrote John Lear.<sup>52</sup>

Not surprisingly, in spite of all efforts to educate lay members, at times they were frustrated with the complexity of the issue, while at other times they were intimidated by the experts. Another constraint was time. The weekly meetings of CERB on Tuesdays and Thursdays lasted for several hours, leaving little time for reading material and other educational activities.

Another pitfall at the Cambridge debates was the unpreparedness of CERB to tackle the issue. The procedure was not planned in advance. Such questions were not addressed as, who should testify before CERB? Were there sufficient critical testimonies to counter balance Harvard and MIT scientists? Would a science court be better suited for the task of CERB? Krimsky argued that a science court would be an excellent supplement to a citizen court. In an esoteric field like rDNA, technical findings and value judgments are intertwined in many "grey" areas. "There is a danger," wrote Krimsky, "in trying to divide the issues into factual and policy components."<sup>53</sup> In other words, policy-making in high technologies always involves human judgment. Some kind of citizen body rather than a science court seems best to solve controversies in high tech areas.

## ***Role of the Public's Voice***

Before the public debates began, decisions in rDNA were made in a technocratic way whereby rDNA was discussed as a technical issue. Criticism against such tunnel vision resulted in many changes, among them the opening up of the process to public participation. The public's voice was thus a novel element in the decision-making process of rDNA. As stated above, it was an experiment with both successes and pitfalls.

The main argument for endorsing public participation is its consideration of a broad range of values in scientific decision-making processes. Decisions in esoteric fields cannot be based solely on scientific or technical findings. The political side of the issue must be discussed and decided by both lay persons and scientists. Another compelling reason for allowing public participation is that it creates trust and confidence, assuming that lay persons are relatively independent and do not have vested interests in the issue. Skeptics who doubt whether lay persons could make a substantial contribution to the decision-making process, need to be assured that opening up the process for lay participation alone can induce a measure of trust and acceptance among the citizenry.

Public participation at Ann Arbor and Cambridge showed that lay persons have a legitimate role in debates. In disagreements among scientists, lay persons could act as a jury who would understand the terms of the disagreement and resolve it from a public interest perspective. In this way, lay persons act as referee and decision maker. As



interrogators, they assume the role of devil's advocate to force scientists to "think harder." Also, "common sense" may lead to questions that are not resolved or detailed by scientists.<sup>54</sup> All three functions, that is, interrogator, referee and decision maker, are contributions the public's voice can make to the decision-making process. In the final analysis, solutions for controversies in high technologies must be not only technical, but also social and political.

Certainly, public participation has pitfalls. At the CERB, it was an arduous effort to educate lay persons to understand the mechanism of DNA recombination. Without adequate expert knowledge, lay persons can be intimidated by scientific testimonies -- creating situations dominated by scientists. Also, misunderstanding and misinformation may lead to meaningless debates, and quite likely, to wrong decisions.

To summarize then, as we have argued earlier in Chapter Three, a technocratic approach that excludes participation of lay persons is unacceptable. But, on the other hand, public participation that excludes experts does not work either. Henceforth, we must conclude that public participation is useful only when experts share their responsibility in making decision with lay persons. Scientists must listen to the views of lay persons, and on their part, lay persons need expert knowledge to make decisions. There must be a symbiotic relationship between experts and non-experts.

There is, however, an unresolved side effect of this decentralized participatory approach obtained for the rDNA matter. As previously mentioned, the "patchwork of local and state laws" is not conducive for the development of the field. It creates

unnecessary competition and is unable to provide uniform protection. The consequences of rDNA cannot be contained locally by local or state law. The potential hazards of the technique are irreversible and pervasive, effecting all places and living beings. Hence, the decision-making mechanism must be national in scope. The following chapter discusses congressional involvement in the regulation of rDNA, as well as a comparison with atomic energy regulation by the Atomic Energy Act.

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*Five*

*Congressional Control*

*Should We Control Science?*

Whether we should or should not control the development of science and technology is a longstanding dispute. One camp defends the independence of scientific research, while the other wishes to curb the authority of what are regarded as too powerful scientists.

Those who challenge the issue of control usually refer to the principle of freedom of inquiry. This freedom, they argue, must not be abridged, and must be protected at all costs. No limits, restrictions, bans, or other methods of control should be imposed on research. Scientists have the privilege to proceed with whatever inquiries they choose to

pursue. This orthodox standpoint thus allows "full and unqualified freedom" to scientific researchers.<sup>1</sup>

Others justify independence of science in another way. Scientists, they argue, are seeking the "truth," and should therefore be left to themselves in their scientific activities. They must not be curbed or told to do things that may distract them from their quest for truth. In actuality, this line of reasoning endorses the separation of science from political control. Government is not entitled to decide on scientific choices and priorities by, for example, manipulating federal research grants. In other words, government must not intervene in the course of scientific research.<sup>2</sup>

Freedom of inquiry and the quest for truth are not the only justifications for permitting scientific freedom. Another is the acceptance of a "social contract" or gentleman's agreement between scientists and society.<sup>3</sup> In exchange for giving society the benefits of scientific advance, scientists are permitted to make scientific decisions in the name of society, thus giving them autonomous control on science and technology. One may legitimately challenge the social contract thesis, however, by questioning the source or even implicit existence of any such a right or mandate.

Absolute scientific freedom may also be challenged from an ethical standpoint. Since knowledge is power, so is science. If this is the case, we may legitimately ask in a democratic society: Should governance of science be left to scientists alone?<sup>4</sup> The problem seems to lie not in whether science is controlled, but how and when.

In rDNA, some kind of control on the development of the field was inevitable. As described in Chapter Three, "manager" and "politician" scientists increasingly play major roles in the development of science and technology. In rDNA, "traditional" scientists together with manager and politician scientists deliberated on the fate of recombination experiments during a closed meeting at the Asilomar Conference Center in California in 1975. In order to contain potential hazards they prescribed physical and biological containment provisions for certain experiments. In 1976, the National Institutes of Health released guidelines for recombination experiments. In essence though, the NIH guidelines were self-regulating measures administered by scientists in behalf of scientists. In this system, technocrats in the federal government and in the scientific establishment were in control of rDNA.

The idea of technocratic control of science, as has been argued previously, is contrary to the idea of democratic control of science. The latter notion requires experts to share the levers of control with non-specialists and lay people. Chapter Four described how public participation in several venues broadened the basis of decision-making and influenced it positively. The crucial effects of such participation are hard to deny: psychologically, people felt they had been heard and their concerns addressed; procedurally, they raised new questions. The Cambridge Experimentation Review Board for example, was interrogator, reviewer, and decision maker at the same time. As a non-partisan decision-making body, the CERB yet provided room for dialogue, and such characteristics paved the way for public acceptance of decisions.



Public participation in high technologies is profoundly complicated by the esoteric nature of these matters. Although recombination techniques have the potential of opening whole new vistas to society, its unknown and potential dangers are threatening to everyone. Both uncertainty and excitement have thus brought fear and hope, simultaneously. In rDNA, the confusion was exacerbated by disagreement among scientists themselves, further complicating the communication of scientific findings. Concerned lay observers were left with difficult and vague issues, leading to responses frequently based on speculation instead of reason.

When hysteria is created, public participation in decision-making almost inevitably becomes less effective. Dr. Hans DeWitt-Stetten Jr., the first chairman of NIH's advisory body on rDNA matters (RAC-NIH), shared with many other scientists the perception that misinformed participants could disrupt the decision-making process. Seeing that process as comprising two stages, technical and policy, Dr. DeWitt-Stetten argued that in the first non-experts could not importantly contribute to discussions and hence their participation in this stage was inappropriate.<sup>5</sup> Such a view -- and even such a simple dichotomy -- can be seriously questioned, however. Especially in esoteric issues of science, one can argue, facts and values, and accordingly scientific and human judgments are intertwined.

This chapter describes lay "interference" in rDNA matters at the most authoritative level possible -- congressional efforts to regulate rDNA. It examines a movement to legislate which culminated by the first half of 1977. At that time, even the scientific community -- which opposed legislation on rDNA -- perceived that the passage of a

statute was inevitable.<sup>6</sup> But by the end of that year's congressional session the tide turned: support for rDNA legislation waned, and ultimately none of the proposed bills was enacted. A development potentially so significant had died with a whimper.

In another technical and esoteric area this withdrawal of Congress had not occurred, though. This was the regulation of peaceful applications of nuclear energy. The Atomic Energy Act was signed into law by President Truman in 1946. Although the circumstances surrounding atomic energy and rDNA were very different, it is important for our analysis to follow both legislative episodes. We shall see from the atomic energy case how "lay" decision-making can become something quite different -- control by special interests.

### *Legislative Interest in rDNA*

As early as 1971 Congress held hearings on the new field of genetics. As previously mentioned, Dr. James Watson testified before the Committee on Science and Astronautics (later renamed in the Science and Technology Committee), on the possible social consequences of genetic cloning, in particular human clonal reproduction.<sup>7</sup> The Proceeding was followed in November 1972 by a Report to the same Committee. Congressional interest in the new technique was vividly shown in the following quote from the Report.

The fact that genetic engineering seems to be approaching immediate application is adding to the depth of concern that legislative attention to the legal, ethical, and social implications of these developments is necessary. This concern has not gone unnoticed by Congress.<sup>8</sup>

Future commercialization of genetic engineering and prospects of economic gain had alerted Congress on the importance of legislation.

On April 22, 1975 Senator Edward Kennedy held hearings before the Senate subcommittee on Health of the Committee on Labor and Public Welfare. The hearings explored the role of the general public in decisions concerning science and technology. During a special session on genetic engineering, four prominent scientists testified. The witnesses were Stanley Cohen, M.D. of the Department of Medicine of Stanford University; Dr. Donald Brown of the Department of Embryology of the Carnegie Institute of Washington in Baltimore, Maryland; Dr. Willard Gaylin of the Institute of Society, Ethics and the Life Sciences at Hastings-on-Hudson, New York; and Halsted Holman, M.D. of the Stanford School of Medicine. Two of them, Drs. Cohen and Brown, had reservations toward public intervention in the course of scientific research.

Dr. Cohen "expressed concerns that the research not be impeded by the development of unnecessary and burdensome requirements." Although Dr. Brown admitted that scientists were accountable to the public, he was not sure to what "degree . . . the public should become part of a formal decision-making process."<sup>9</sup> But Dr. Holman viewed decision-making in science and technology as a shared domain between experts and non-experts, including the public at large. Similarly, Dr. Gaylin testified that

the public could not be denied participation because of their a legitimate right to monitor the development of science.<sup>10</sup>

The hey-day of legislative efforts on rDNA took place during the Ninety-Fifth Congress -- beginning on January 4 and ending on December 22, 1977. The peak of legislative interest occurred during the late spring and early summer of 1977. During the first session of this Congress, sixteen bills on the topic of rDNA were introduced. Several others were prepared but never reached the formal stage of introduction. In all, twenty-five hearings were held, with nearly a hundred witnesses heard.<sup>11</sup>

In 1977, legislative interest was fueled by several factors. A major force was the Cambridge debates and the ensuing resolution to appeal for federal regulation on rDNA. Media coverage of the Cambridge event increased people's curiosity for the new technique. A second major factor was the limited jurisdiction of NIH guidelines. The guidelines were officially enforceable only on NIH projects, thus leaving other research formally unregulated. Further congressional interest in rDNA was precipitated by anxiety over press articles, a rising anti rDNA-movement among environmentalists, and complications in patenting rDNA inventions. The patchwork of local and state laws as a consequence of local debates (see Chapter Four) was initially not a significant factor in prompting congressional attention, although it eventually became a major obstacle to passage of legislation.

The major force behind Congress' 1977 actions was the Cambridge debates. As previously described in Chapter Four, public participation in Cambridge was a reaction

to the closed procedure in rDNA decision-making. Members of Congress were not insensitive toward such issues. Senator Edward Kennedy of Massachusetts became increasingly attentive toward the controversy surrounding rDNA in his home state. But, more important, CERB's resolution to appeal for federal regulation on rDNA was a loud and clear signal for Congress to take action.

The visibility of the Cambridge debates was further enhanced by media attention for the event. Cambridge Mayor Alfred Vellucci's zest in attacking Harvard and MIT caused much upheaval. The theatrical arrangements for the event, combined with Mr. Vellucci's fondness of talking about monsters and Frankensteins, gave the media much colorful copy.<sup>12</sup> The debates attracted not only national, but also international attention. Congress, naturally, was not oblivious of the turbulence in Cambridge.

A second major reason for considering legislation on rDNA was the limited jurisdiction and legality of NIH guidelines. Formally, the guidelines were only applicable to research projects conducted at NIH or supported by NIH grants. Other research, either privately or publicly funded, was not subject to them. As a result, industrial research, for example, remained a vast area that was essentially uncontrolled. Many in Congress knew that commercialization of rDNA might have significant social and economic implications. Thus, by 1977 much sentiment existed in Congress for legally binding regulations that would cover all rDNA research throughout the United States.

The voluntary nature of enforcement of NIH guidelines also raised questions. Next to peer pressure, terminating funds for projects that violated the guidelines was in

principle NIH's only sanction. In addition, NIH lacked monitoring procedures. Shortly after issuance of the guidelines, cases of non-compliance were in fact reported. At the Biochemistry and Biophysics Department of the University of California in San Francisco, a "vector" was used which was not certified by the NIH.<sup>13</sup> At the Harvard Medical School, Dr. Charles A. Thomas failed to file a Memorandum of Understanding and Agreement (MUA), mandated by NIH guidelines.<sup>14</sup>

The fact that both cases happened fairly soon after issuance of the guidelines may mean that this non-compliance with NIH rules stemmed from confusion and unfamiliarity with a new system. Unfortunately, lacking a method of inspection, NIH itself did not detect the breaches. The University of California affair became public when rumors started about an insulin gene experiment, reported in *Science*, that was successfully completed in an unusually short time -- three weeks. It was discovered that a similar experiment had been done earlier with an uncertified vector. Harvard's non-compliance was detected after a request for investigation was filed under the Freedom of Information Act by the Environmental Defense Fund, one of the leading environmental organizations. Hence, the limited jurisdiction and legal power of NIH guidelines were in fact the prime reasons for developing regulation that would cover all rDNA research.

Attention to the rDNA issue was further increased by articles published by prominent scientists. On June 4, 1976, Dr. Erwin Chargaff wrote an article in *Science*, "On the Dangers of Genetic Meddling."<sup>15</sup> Known from his discovery of the same quantity of the DNA bases adenine (A) and thymine (T), as well as that of guanine (G) and

cytosine (C), he criticized the choice of *E. coli* as host bacteria in recombinant experiments. Using such common bacteria, according to Chargaff, would lead to unprecedented dangers. He warned readers of the irreversibility of recombination: once new life is formed it could not be stopped or taken back. The NIH guidelines, wrote Chargaff, were developed by scientists who had neither dealt with far-reaching issues such as the creation of new life forms, nor with the ethical and social consequences of such possibilities.

The same issue of *Science* that published Dr. Chargaff's article also contained a letter from Francine Robinson Simring, written in behalf of the Committee for Genetics of the Friends of Earth (FOE), an environmental organization. Simring directly challenged the adequacy of NIH Guidelines. She pointed out that "unquantifiable problems," such as "genetic risk to future generations, human fallibility. . ." were not addressed by the creators of the guidelines.<sup>16</sup>

Drs. Maxine Singer of NIH and Paul Berg of Stanford University, both well-known rDNA experts and proponents, wrote a rebuttal to both Chargaff and Simring in a subsequent issue of *Science*. Their letter, "Recombinant DNA: NIH Guidelines," was published in the July 16, 1976 issue of the journal. They vigorously defended NIH's authority and legitimacy to formulate guidelines, and they were confident that the guidelines "were directed toward eliminating or minimizing real and imagined hazards.

. . . "17

Dr. Robert Sinsheimer, well-known for his work on  $\phi$ x174, a harmless virus that attacks *E. coli*, became another famous opponent of rDNA. In 1970, as an advocate of the technique, he had proclaimed the beneficial wonders of genetic engineering. But in an October 1976 interview in *Science*, he changed his mind. He was particularly opposed to mixing prokaryotes and eukaryotes, which "nature has kept apart for a good reason." Breaking the genetic barrier, he argued, would irreversibly damage the evolutionary process.<sup>18</sup>

Among all public statements of well-known rDNA scientists at this time, the most sensational was penned by Dr. Liebe F. Cavalieri of Cornell University. It was published in the *New York Times Magazine* of August 22, 1976 under the head "New Strains of Life -- or Death." Cavalieri forecasted global disasters caused by the recombination technique, and predicted that ". . .the future will curse us for it."<sup>19</sup> Cavalieri's article shocked many readers.

Among the readers troubled by Dr. Cavalieri's article were several members of Congress.<sup>20</sup> Senator Kennedy responded to the Cavalieri article by holding a one-day hearing on September 22, 1976. A month later the article was included in the *Congressional Record* by Senator Jacob Javits.<sup>21</sup> Clearly, Dr. Cavalieri's article had intensified suspicion toward scientists whose research was presumably directed not to public health and safety but solely to their own glory and interest. Although Mr. Kennedy did not follow his September 22 hearing with a bill, Senator Dale Bumpers and Representative Richard Ottinger, as we shall see later, did take action.<sup>22</sup>



Intensified lobbying by environmental groups pressured Congress' involvement in rDNA even more. The Coalition for Responsible Genetic Research initiated a mass letter-writing campaign to promote its visibility. The Friends of the Earth charged NIH with violating the 1969 National Environmental Policy Act (NEPA) because of NIH's negligence in drafting an Environmental Impact Statement (EIS) before issuance of the guidelines (See Chapter Three). Dr. Donald Fredrickson, director of NIH, decided to issue an EIS only after he was alerted of his obligation by numerous critics at the meeting of NIH Director's Advisory Committee (DAC-NIH). Thus, the NIH violated NEPA by issuing an EIS *after* official publication of the guidelines. Dr. Fredrickson defended his position by arguing that the sooner the guidelines were issued, the better the general public would be protected.<sup>23</sup>

Environmental groups marked their formal entry into the rDNA debate when lawyers of the Environmental Defense Fund (EDF) and the Natural Resources Defense Council (NRDC) filed a petition with the then Department of Health, Education and Welfare. Both organizations challenged the decision-making procedure in rDNA and the limited jurisdiction of NIH guidelines. They petitioned for public hearings to allow interested parties address their concerns, and for the adoption of legal regulations covering all rDNA research, whether publicly or privately sponsored, throughout the United States.<sup>24</sup>

Another factor that prompted congressional attention was an increasing uneasiness surrounding the patentability of rDNA discoveries. Drs. Stanley Cohen of Stanford

University and Herbert Boyer of the University of California at San Francisco, applied for patent protection for a method of constructing self-reproducing hybrid rDNA molecules. This method called for insertion of an insulin-producing gene in the molecules, allowing them to become vehicles for mass-production of insulin.<sup>25</sup>

The patent application was most likely filed before November 1974, since the United States rules required application within one year after publication of research results, which Drs. Cohen and Boyer did in November 1973. Because their research was done under an NIH grant, patent policies of the Department of HEW would apply. At that time, one of HEW's policies was to enter an Institutional Patent Agreement (IPA) reserving the first option for owning inventions to the research institution. Because rDNA was a volatile issue surrounded by public controversy, Dr. Robert Rosenzweig, Vice President of Public Affairs of Stanford University, requested NIH for a formal opinion of its patenting policies on rDNA inventions.<sup>26</sup>

An important issue at stake here was whether withholding information for patent application purposes would interfere with the freedom of information required under NIH rules. In Europe no patent would be granted once research results are published. Furthermore, patenting rDNA processes might incite industries to invent less certain, but patent-free procedures.<sup>27</sup> Congress itself was directly alerted to the issue by Representative John J. LaFalce, who revealed that one of his constituents had pointed out that results from rDNA research supported by NIH grants, and thus by public funds, were public information which could not be patented.<sup>28</sup>

The uneasy situation surrounding rDNA patent procedures was further exacerbated by a notice from Dr. Betsy Ancker-Johnson, Assistant Secretary of Commerce for Science and Technology. The notice, published in the *Federal Register* of 13 January 1977, announced an accelerated procedure of patent applications for industries abiding to NIH guidelines. Her action was understandable, since it was the Commerce Department's objective to encourage production and commercialization of scientific results. But announcing an accelerated patent procedure at a time when voices to slow down were sounding all around was a risky strategy. Politically, this step was even more reckless. By announcing in the rules that the Commerce Department had formulated its own policy, the authority of the NIH and Congress was bypassed. Eventually, the secretaries of HEW, Joseph Califano, and Commerce, Juanita Kreps, agreed to withdraw the accelerated patenting order, and the initial notice was revoked in the *Federal Register* of 9 March 1977.<sup>29</sup> Patenting rDNA became such a visible issue in Congress that only the full legislative process could deal with it.

### ***Legislative Efforts in rDNA***

On January 19, 1977, Representative Richard Ottinger introduced a resolution, H.Res. 131, in the House of Representatives, calling for the Secretary of HEW to establish regulations for all rDNA research. Soon thereafter, on February 4, 1977, Senator

Dale Bumpers introduced S. 621 into the Senate. The "DNA Research Bill of 1977" was "To provide for guidelines and strict liability in the development of research related to recombinant DNA."<sup>30</sup> The bill assigned the Secretary of HEW responsibility for the regulation of rDNA research and gave the Secretary authority to issue licenses. S.621 also included provisions for the establishment of an inspectorate, as well as penalties for violations. Penalties included "imprisonment for not more than one year, or a fine of not more than \$10,000, or both."<sup>31</sup> The recombinant scientists, who had not dealt previously with strict regulation of their activities, were outraged by the penalty provisions.

In the House of Representatives Mr. Stephen Solarz introduced H.R. 4232 on March 1, 1977.<sup>32</sup> As suggested by its title, "Commission on Genetic Research and Engineering Bill of 1977," this particular bill proposed the establishment of a one-year national study commission of seventeen members. The Commission was to be composed of two officials from the executive branch, two Senators, two Representatives, and eleven members appointed by the President including state and local government officials, members of the scientific community, and representatives of citizen groups and associations. The Commission was to report its findings and recommendations, including recommendations for legislation, to the President and Congress. H.R. 4232 thus took S. 621 one step back, since it acknowledged the need for further study and inquiry (which was to be done by the Commission) prior to any legislation effort.

On March 8, 1977 a second bill was introduced into the Senate. The "Recombinant DNA Standards Bill of 1977," or S.945, was introduced by Senator Howard

Metzenbaum.<sup>33</sup> This bill, according to one commentator, embodied the best features of the Bumpers and Solarz measures and accordingly had two parts.<sup>34</sup> The first recommended regulation of rDNA, which was the essence of S. 621, introduced by Mr. Bumpers. The Secretary of HEW was to be given responsibility for establishing regulations covering all rDNA research. These regulations should be at least equivalent to, but not less stringent than NIH guidelines. An inspectorate to enforce regulations was recommended, as well as penalties for non-compliance. The second part of the bill, following Mr. Solarz' H.R. 4232, proposed the establishment of a temporary National Commission for the Study of Recombinant DNA Research and Technology, comprising of thirteen members. A maximum of six members could be persons "who are or who have been engaged in recombinant DNA research. . . ," while the rest of the members should be non-experts. Its primary task was to conduct a comprehensive study of the science of rDNA, and of the social, ethical, and legal implications of rDNA research and technology. The Commission was to report periodically to the President, Congress, and Secretary of HEW.

One day after S. 945 was introduced, Mr. Paul Rogers of the House of Representatives introduced H.R. 4759, the "Recombinant DNA Research Act of 1977," on March 9, 1977.<sup>35</sup> The Secretary of HEW was assigned responsibility for rDNA regulation, while the NIH guidelines would serve as a scientific basis for regulations. An interesting feature of the bill was its recommendation for creating ten national "centers" for P4 experiments (highest risks on a scale from P1 to P4), limiting high-risk

experiments to those performed in the assigned centers. The bill furthermore dealt with licensing, inspection, and penalties for violators (\$1,000 per violation).

More importantly though, H.R. 4759 contained a provision that eventually became the most hotly contested issue in the legislative history of rDNA. Under Section 478(b), state and local governments were allowed to impose their own regulations if they were "the same as, or more stringent than" the requirements in H.R. 4759. No one had anticipated that the "patchwork of local laws" would be legalized, but with the introduction of H.R. 4759 the possibility became imminent. Another novelty of the bill was its recommendation for an advisory, rather than a study, committee. The Recombinant DNA Research Advisory Committee was to advise the Secretary of HEW.

### *Interagency Committee*

In the meantime the Ford administration, so it seemed, was not intending to be a passive onlooker from the sidelines on this issue. Its true motives in joining the legislative bandwagon were, however, not fully apparent. Dr. Burke Zimmerman, a previous staff member of the Environmental Defense Fund, an environmental organization, who was an aide to Representative Paul Rogers during the rDNA debates in Congress, offered an interesting version of the motives. He saw the administrative maneuver as a "preemptive strike" toward Congress. He wrote: "Believing that legislation was a

certainty and fearing the worst from Senator Kennedy, the administration drafted its own bill."<sup>36</sup> Indeed it is not uncommon for the Congress and Administration to vie for preeminence when such issues are placed on the policy agenda.

Administrative efforts to legislate in the rDNA field had already begun, however. Senators Edward Kennedy and Jacob Javits, in a letter dated July 19, 1976, urged President Gerald Ford to take measures for the implementation of NIH guidelines in all sectors of rDNA research. (Note that in 1976 Congress had not yet begun introducing rDNA bills; its first resolution, H.Res. 131, was introduced on January 19, 1977.) In their letter, the Senators recommended the NIH guidelines as requirements for a national regulation on rDNA, but faced the stumbling block of their limited jurisdiction. They addressed this problem to President Ford as they wrote,

We urge you to implement these guidelines immediately wherever possible by executive directive and/or rulemaking, and to explore every possible mechanism to assure compliance with the guidelines in all sectors of the research community, including the private sector and the international community. If legislation is required to these ends, we urge you to expedite proposals to Congress.<sup>37</sup>

Before long, on September 22, 1976, President Ford sent his reply to the Senators. After consulting Mr. David Matthews, the Secretary of HEW, Mr. Ford ordered the establishment of an interagency committee "to review the activities of all Government agencies conducting or supporting recombinant DNA research or having regulatory authority relevant to this scientific field."<sup>38</sup> On the same day, President Ford issued a memorandum to the heads of relevant agencies notifying them about his intention to form the interagency committee. By October 1, 1976, the Secretary of HEW requested the

agencies to nominate their representatives.<sup>39</sup> The "Interagency Committee on Recombinant DNA Research" first met on November 4, 1976, at the NIH campus in Bethesda. The director of NIH served as chairman of the Committee. As written in its charter, the purpose of the Committee was

To coordinate Federal programs and activities relating to recombinant deoxyribonucleic acid (DNA) research, to assist in facilitating compliance with a uniform set of guidelines. . . and to facilitate communication and exchange of information among Government agencies.<sup>40</sup>

Twenty agencies were represented in the Committee.

The Committee delegated its task to develop guidelines to a subcommittee which started drafting the guidelines by considering existing related statutes. Some, conceivably, could authorize rDNA legislation. It subsequently concluded, however, that none of the reviewed laws could cover all requirements for the task. The following laws were considered by the subcommittee: the Occupational Safety and Health Act of 1970 (Public Law 91-596); the Toxic Substance Control Act (Public Law 94-469); the Hazardous Materials Transportation Act (Public Law 93-633); and Section 361 of the Public Health Service Act (42 U.S.C. Section 264).<sup>41</sup>

Under the Occupational Safety and Health Act, the Occupational Safety and Health Administration (OSHA) has broad powers to require employers to provide a safe work place for their employees. The Act, however, excludes self-employed persons. Furthermore, the Act is mandatory for federal agencies, but is voluntary for states and their subdivisions. At the time, twenty-six States were not subject to the Act.



Accordingly, state universities in those twenty-six States were also not subject to OSHA requirements. These conditions were obviously not suitable for the regulation of rDNA.

The Toxic Substance Control Act (TSCA), administered primarily by the Environmental Protection Agency, could not cover the requirements for rDNA regulations either. Section 6 of TSCA regulates the "manufacture" of "chemical substances" that presents an "unreasonable risk of injury to health or the environment. . . ." A "chemical substance" is defined in Section 3 of the Act as organic and inorganic substances of a particular molecular identity, and would therefore be suffice to cover materials used in rDNA.<sup>42</sup> Yet the term "manufacture" is defined as meaning "to import. . . produce, or manufacture," and is thus not exactly what scientific experiments are. Moreover, EPA can regulate rDNA under TSCA only when rDNA "presents an unreasonable risk of injury to health or the environment," and thus prevents covering *all* rDNA research. Section 5 of TSCA opened an even larger loophole: "small quantities. . . solely for purpose of . . . scientific experimentation or analysis" are exempted from a requirement to notify EPA prior to manufacturing.<sup>43</sup> At that time rDNA was primarily in an experimentation stage, making TSCA inappropriate to regulate the field.

The Hazardous Materials Transportation Act (HMTA) and Section 361 of the Public Health Service Act (PHSA) give authority to the Department of Transportation and the Center for Disease Control (CDC) to regulate interstate transport of hazardous materials, including biological products. They are, however, aimed at imposing labeling, packaging, and shipping requirements.

Section 361 of PHSA, so it seemed, was the most promising candidate for the legal basis of rDNA regulation. This section of the PHS Act was specifically directed toward organisms that are communicable and can cause human disease. It was also supported by two environmental groups. On November 11, 1976, a week after the interagency's first meeting, the Environmental Defense Fund and the Natural Resources Defense Council petitioned HEW to use this particular section of PHSA for rDNA regulation.<sup>44</sup> But Section 361 of PHSA posed an insurmountable problem. Even if it could be interpreted more broadly and used as a legal basis for rDNA regulation, this Act would have to be interpreted as assuming that all rDNA research cause human disease, making DNA hazardous material. It furthermore "does not apply to plants, animals, or the general environment."<sup>45</sup>

After lengthy consideration of existing laws, the interagency committee concluded in its report of March 15, 1977, that "no single legal authority or combination of authorities currently exists which would clearly reach all such research and all requirements."<sup>46</sup> Hence new legislation was required. On March 16, the new HEW Secretary, Mr. Joseph Califano, officially announced the intention of the administration to draft legislation.<sup>47</sup>

On April 1, 1977, only two weeks after the administration announced its intention to draft new legislation, Secretary Califano had the administration bill introduced in the Senate by Mr. Kennedy.<sup>48</sup> This was the "Recombinant DNA Safety Regulation Bill," or S. 1217. On April 6, 1977 Representative Paul Rogers introduced his version of the

administration bill, the "Recombinant DNA Regulation Bill," or H.R. 6158, into the House.

S. 1217 became a hotly contested bill because of its preemption provision. As previously mentioned in Chapter Four, local and state laws differed slightly from each other, creating a confusing and varied patchwork of laws. The scientific community opposed such a situation, and rejected any provision that permitted local and state laws. If there was to be any legislation at all, the scientists demanded that federal laws preempted local and state laws.

S. 1217 did not provide for federal preemption. Rather, it allowed local and state rules if they were "as stringent as, or more stringent than" the requirements of the federal government. The scientists were infuriated. On July 22, 1977, Senator Kennedy introduced S. 1217 with an amendment. In the amended version of S. 1217, local and state governments could impose their own laws if it is "relevant and material" to the health and environmental concerns of their situation. Still, the scientists would not budge.

On August 2, 1977, Senator Gaylord Nelson, sympathetic to the scientists' concerns, introduced another amendment, S. 754, as a substitute to S. 1217. In S. 754 local and state laws were allowed if they were "more stringent" than federal law, and if they were "necessary" to protect health or the environment as required by "compelling local conditions."<sup>49</sup>

Another provision of S. 1217 that angered the scientific community provided for the establishment of an autonomous regulatory commission, the National Recombinant

DNA Safety Regulation Commission. The eleven-member Commission of six non-specialists and five DNA experts was to be appointed by the President, as was the chairman of the Commission. The scientists were outraged, in as much as such a free-standing regulatory commission diminished the authority of HEW-NIH, their main ally in rDNA politics.

Mr. Nelson's substitute, S. 754, was a better alternative for the scientists. While the Secretary of HEW was responsible for rDNA regulation, the bill recommended an advisory, rather than regulatory commission, to advise and make recommendations to the Secretary. The Secretary was charged with appointing the seventeen members of the commission.

In the House of Representatives, Mr. Rogers introduced the administration bill under H.R. 6158 on April 6, 1977. The "Recombinant DNA Regulation Bill" contained the same preemption provision as S. 1217. It allowed state and local governments to impose their own rules if they were as stringent as, or more stringent than the federal law.

Earlier, on March 9, 1977, Representative Rogers had introduced his first bill on rDNA, H.R. 4759, into the House. After Mr. Rogers introduced the administration bill, he introduced two other versions of his first bill (H.R. 4759) into the House. These were H.R. 7418 introduced on May 24, 1977 and H.R. 7897 introduced on June 20, 1977.

The two latter versions were virtually the same. The Secretary of HEW was responsible for regulating rDNA, NIH guidelines served as interim standards, licensing and penalty provisions were included, and both bills allowed local and state rules if they

were "necessary" to protect local health and environment. In addition, both bills recommended a national advisory committee to the Secretary of HEW. Obviously, Mr. Rogers' advisory committee, putting the Secretary of HEW in charge, was favored by the scientific community.

The administration bill, introduced by Mr. Kennedy into the Senate as S. 1217, and by Mr. Rogers into the House as H.R. 6158, had thus been drastically changed. In the first place, the preemptive provision was altered in favor of federal preemption, making it increasingly difficult for local and state governments to impose their own laws. Second, the regulatory commission in S. 1217 was transformed into an advisory commission in Mr. Nelson's substitute (S. 754). Although both changes were in favor of the scientific community, in the end none of these bills was signed into law.

### ***Failure of rDNA Legislation***

It is hardly possible to narrow down the reasons for failure of rDNA legislation to pass to a single factor. As several factors prompted legislative interest, many led to its failure. According to Dr. Zimmerman, aide to Representative Paul Rogers, a major reason for the demise of legislation was Congress' waning interest in the issue.<sup>50</sup> Nothing spectacular was happening with respect to rDNA -- no monsters, plagues, or deadly bugs

were lurking to endanger society. Without real threats, rDNA was a "boring" topic for the Congress, as it did not offer any political advantages to congressmen.

The course of the legislation was intercepted by another force, the scientific lobby. During the 1940s, scientists lobbied for civilian control of atomic energy. Likewise, in the 1970s they organized themselves under the American Society for Microbiology (ASM) to prevent legislation on rDNA. The ASM was drawn into the rDNA issue when Congress feverishly tried to regulate rDNA. For the scientists, legislation was interpreted as an usurpation of their authority.

The American Society for Microbiology is a professional organization of bacteriologist, founded in 1899. The ASM promotes applied and fundamental fields related to microbiology, such as food technology and genetics, to name a few. It is a well-organized institution with a large membership. It has a Council Policy Committee, similar to a board of directors, and a Public Affairs Committee, responsible for recognizing and responding to the impact of microbiology on public policy and vice versa.<sup>51</sup>

Under chairman Harlyn O. Halvorson, the ASM became a powerful lobby. Dr. Halvorson, at the time director of the Rosenstiel Basic Medical Sciences Research Center at Brandeis University, was not only a scientist, but also a diplomat. He sought professional advice on how to organize a lobby from lawyers of the American Civil Liberties Union. Accordingly, he developed friends and contacts in Congress and educated ASM members in the ways of Washington. But most important, he had a clear

position, as expressed in ASM's "nine principles relative to recombinant DNA legislation."<sup>52</sup> Among its achievements, the ASM persuaded Senator Gaylord Nelson to introduce a bill, S. 754, that reflected the wishes of the scientific community.

A great deal of dissatisfaction among scientists was probably caused by misunderstanding. It seemed likely that the general parties did not fully comprehend the legislation's processes and provisions. On one hand, the science of rDNA was difficult to comprehend for congressmen. On the other, scientists had trouble understanding the complexity of writing good regulations. Zimmerman notes what a law for this would require:

Any such law would have to specify a mechanism for implementation, a seat of responsibility for administering such standards, procedures for promulgating regulations, a mechanism to change them as new data became available, the treatment of propriety data, the relationship of federal law to state and local authorities, and a means of enforcement.<sup>53</sup>

It was not easy to include all these requirements in a well-written law.

Scientists were outraged by such provisions as penalties for violating the law which included jail time, as well as licensing, inspection of laboratories, and complex reporting systems.<sup>54</sup> For relatively autonomous scientists who never before had been under strict control, these provisions were unacceptable. As mentioned earlier, two provisions in the pending bills outraged the scientists even more.

One of these provisions was Senator Kennedy's proposal to establish a national commission that would have regulatory rather than advisory powers. The scientists naturally saw their authority would be threatened by this new layer of bureaucracy. In

its April 1977 resolution, the National Academy of Sciences (NAS) opposed such a commission, because it "would set a dangerous precedent for regulating other areas of science." The Secretary of HEW opposed the idea as well, seeing such a body as "a useless and expensive bureaucracy." Dr. Fredrickson believed that such a commission "will cost more than the research it intends to regulate," and that it would not be capable of "setting standards, review of research protocols, and oversight of operation. . . ."55

Mr. Kennedy defended his proposal to establish a separate regulatory commission on two grounds. First, an independent commission would avoid conflict of interest with the NIH. NIH's task was to promote research. By establishing a separate regulatory commission, he prevented NIH from being both a regulating and a promoting agency for rDNA. Second, as a champion of public participation, Senator Kennedy found an independent commission as a more effective channel of public concerns than the NIH would be. As a promoting agency for biomedical and rDNA research, NIH was perceived to be biased toward concerns of scientists.<sup>56</sup>

A second major contested provision was the preemption clause. If there would be any legislation on rDNA at all, scientists insisted on federal preemption of state and local laws. Congress responded to this demand by making it increasingly difficult for state and local governments to impose their own laws. Initially, state and local governments could impose laws which were "as stringent as, or more stringent than" federal law. Later, such laws were allowed if they were "relevant and material" to human health and the



environment. In the end, state and local laws were only possible if they were "necessary" for human health and the environment as required by compelling local conditions.

In the end, environmental groups indirectly contributed to the demise of legislation by rejecting the federal preemption clause. Environmentalists supported state and local rules, because regional administrations were more susceptible to inputs and concerns of the public, including their own interests. By the time it became increasingly difficult for local and state governments to impose their own laws, environmentalists preferred to have no laws at all rather than a federal law that immobilized local efforts.

Letters from famous and influential scientists contributed significantly in changing the minds of congressmen. The scientific lobby used these letters to campaign against the legislation. One of the letters was from Roy Curtiss III of the University of Alabama Medical School in Birmingham. Initially, Dr. Curtiss was convinced rDNA could pose real hazards. To minimize dangers, he painstakingly developed an "enfeebled" *E.coli* (host bacteria) that could only survive in artificial laboratory conditions.

But in a letter of April 12, 1977 to the Director of NIH, Dr. Curtiss publicly changed his mind. The letter had wide impact. Similarly, Dr. Stanley Cohen of Stanford University, one of the rDNA pioneers, persuaded Congress that recombination processes occurred in nature, and hence did not violate natural evolutionary processes.<sup>57</sup>

The majority of participants of the 1977 Gordon Conference on Nucleic Acids signed an open letter, published in *Science* of July 15, 1977, petitioning Congress to avoid legislation on rDNA. Legislation was unnecessary and could only hamper research in this

field.<sup>58</sup> Four years earlier, it should be reminded, participants of the 1973 Gordon Conference on Nucleic Acids brought the controversial nature of rDNA to the attention of fellow scientists and public by publishing the Gordon Conference letter in the *Science* issue of September 21, 1973.

Another important factor that turned the tide in Congress was the Falmouth Conference. As a response to the criticism of excluding relevant scientists in developing NIH guidelines, in its September 1976 meeting RAC-NIH recommended a workshop that would bring all these other scientists together. The workshop took place in Falmouth, Massachusetts on 21 and 22 June 1977. It was chaired by Dr. Sherwood Gorbach, an enteric disease specialist of Tufts University. As a conclusion of the workshop, Dr. Gorbach issued a "Consensus Agreement" in a personal letter to the NIH Director, Dr. Fredrickson, stating there was an "unanimous" agreement that the host bacteria in rDNA experiments, *E.coli K12*, could not become an endemic pathogen, and that potential hazards of rDNA were "overstated."<sup>59</sup> Although not all participants of the workshop endorsed the Consensus Agreement, it soon found its way to Capitol Hill and was widely distributed among congressmen.<sup>60</sup>

Probably the ultimate blow to rDNA legislation was conflict of power between congressmen who had been jockeying for position over the issue. The scientific lobby found in Gaylord Nelson a Senator who was sympathetic to their concerns. He was the only member of the Committee of Human Resources who voted down the Kennedy bill, keeping it from reaching the Senate floor. Persuaded by the scientific lobby, Senator

Nelson eventually introduced a substitute for the Kennedy bill, S. 754. The Nelson bill was preferred by the scientists, because it preempted local and state laws and placed responsibility to regulate rDNA with the Secretary of HEW, thereby avoiding the creation of a separate regulatory commission.<sup>61</sup>

Meanwhile, the scientists got support from an unexpected front. Senator Adlai Stevenson, chairman of the Subcommittee on Science, Technology, and Space, lost some of his jurisdiction when responsibility for NIH and NSF was put under Senator Kennedy's Subcommittee on Health and Scientific Research. Not surprisingly, Mr. Stevenson wanted to win back some territory. Although initially he kept out of rDNA, he eventually became involved. After a meeting with a group of scientists, he was convinced that legislation on rDNA was inappropriate. He made a sweeping speech on the Senate floor, and held three days of hearings. On both occasions he was on the side of the scientists.<sup>62</sup>

Challenged by Senators Nelson and Stevenson, Mr. Kennedy sensed a change of attitude in Congress. These were not Senator Kennedy's only worries, however. In addition, he had to deal with vested interests of Harvard and MIT, two world-famous universities in Massachusetts, his home state. Fortunately, Dr. Stanley Cohen's letter -- confirming that rDNA was a process occurring in the natural world -- provided a legitimate excuse for Mr. Kennedy to withdraw his bill. Since recombination is part of natural processes, the reason for regulating rDNA becomes obsolete.<sup>63</sup>

Another pending bill was H.R. 7897, introduced by Representative Paul Rogers in the House. Representative Harley Staggers, chairman of the Interstate and Foreign

Commerce Committee, refused to convene the Commerce Committee, however, thereby preventing the Rogers bill from reaching the floor. Staggers, whose son graduated from Harvard, had always been sympathetic to the scientists. Ultimately, Representatives Rogers and Staggers made a compromise: a simpler bill, H.R. 11192, was introduced in place of H.R. 7897.

In spite of all these efforts, the House Rules Committee never granted a rule to allow a bill to be debated and voted upon on the floor. Thus in the end, none of the rDNA bills became law.<sup>64</sup>

Although legislation on rDNA failed, it does not mean that legislation on all high technologies is doomed to fail. Atomic energy, comparable to rDNA in its sophistication, significance, and potential dangers and benefits, was in fact regulated pursuant to federal statute -- by the Atomic Energy Act of 1946. Because this example of technology lawmaking may contain lessons for our case at hand, we now outline the legislation on nuclear energy and the establishment and development of the United States Atomic Energy Commission.

### ***Another High Technology: Atomic Energy***

There are parallels between rDNA and atomic energy. Both are so-called high technologies, esoteric in nature, immensely powerful yet potentially dangerous. Also,

both have great potential for applications in numerous fields. As a source of energy, the atom was used in bombs that destroyed much of Hiroshima and Nagasaki in August 1945. In its peaceful uses, it is a major source of electrification.

When the nuclear chain reaction became feasible, thereby releasing an enormous amount of energy, its potential use in military warfare was evident. Dr. Leo Szilard, a new immigrant to the United States, felt particularly uneasy knowing that German scientists were probably working on nuclear weapons. At the time, he was guest researcher at the Physics Laboratory of Columbia University. Dr. Szilard's concern about the potential destructive use of atomic energy in warfare was shared by Professor Eugene Wigner of Princeton University, also a refugee from war-torn Europe.

Both men decided to alert the United States government about this threat. They drafted a letter to President Franklin Roosevelt in order to bring the potential military use of nuclear energy to the attention of the President. Dr. Albert Einstein, the discoverer of relativity theory and also an émigré to the United States, signed the letter of August 2, 1939. Mr. Alexander Sachs, an economist who knew President Roosevelt personally, acted as intermediary. Mr. Sachs handed the letter in person to the President on October 11, 1939.<sup>65</sup> Here we find another parallel with rDNA: in both cases, it was scientists who alerted outsiders concerning new technology.

In late summer of 1942, President Roosevelt ordered that an atomic weapon be developed. Brigadier General Leslie Groves, an Army Corps of Engineers officer, was charged with leadership of the Manhattan project. Dr. J. Robert Oppenheimer directed

the scientific work at Los Alamos, where the A-bombs were constructed. On August 6, 1945 the bomb was dropped on Hiroshima, and two days later Nagasaki was destroyed. Hundreds of thousands were dead or injured.

After the war, a consensus emerged to place atomic energy under some kind of government control to direct its peaceful uses.<sup>66</sup> Yet no one was quite sure what form this control should take. Should an executive agency control nuclear energy directly? If so, should this be done under military or civilian auspices? How should Congress be involved? The entire development of A-bombs had been shrouded by secrecy, and for national defense purposes it did not seem likely in 1945-1946 that the normal processes of democratic politics, such as open investigations and debates, would appropriately apply.<sup>67</sup>

Legislation on atomic energy was introduced quickly. On September 6, 1945 Senator Brian McMahon introduced S. 1717, which was known as the McMahon bill. Meanwhile, the War Department had drafted its own bill. Not surprisingly, the May-Johnson bill, named after Senator Edward Johnson, ranking member of the Military Affairs Committee in the Senate and Representative Andrew May, Chairman of the House committee, placed substantial control in the hands of the military and emphasized military uses of atomic energy. The scientists and their lobby, tired of the secrecy surrounding their wartime research and the strict disciplinary control of the military, opposed the May-Johnson bill. After several amendments, the McMahon bill was adopted by both houses

on July 26, 1946. On August 1, 1946 President Truman signed the bill into law. It became known as the Atomic Energy Act of 1946.

This important statute placed control in a civilian commission of five commissioners, the Atomic Energy Commission. Dr. David Lilienthal, former director of the Tennessee Valley Authority, became its first chairman. The AEC had total control of atomic energy: it controlled ownership, production, and use of fissionable material either for military or civilian utilization.<sup>68</sup> The Act of 1946 also established the Joint Committee on Atomic Energy (JCAE), as "watchdog" of AEC. By law, the AEC was obliged to inform JCAE of all its activities, allowing a free flow of information from AEC to JCAE. Hence, AEC was accountable to JCAE. At the same time, the JCAE was given powers to get all necessary information from other executive branch agencies, including the CIA and FBI. Not surprisingly, many saw the creation of the AEC and JCAE as a violation of the separation of powers principle.<sup>69</sup>

To assist the civilian commissioners of AEC, the Act of 1946 provided for establishment of "advisory committees." The General Advisory Committee (GAC), chaired by Dr. Robert Oppenheimer, was to advise AEC on scientific and technical matters. The Military Liaison Committee (MLC), consisting of representatives of the War Department and Navy, was to advise AEC on issues relating to military applications of atomic energy. Next to these committees, the AEC established its own advisory committees, such as The Advisory Committee for Biology and Medicine, and The Industrial Advisory Group, to name a few.<sup>70</sup>

## *Evolution of the AEC*

The destructive power of the atom, as just described, was one of the reasons for government control on atomic energy. But moral responsibility for the disastrous consequences of the atomic weapon was ultimately the major reason for directing nuclear power toward peaceful uses. The "Findings and Recommendations" section of the Atomic Energy Act of 1946 stated,

. . . it is hereby declared to be the policy of the people of the United States that the development and utilization of atomic energy shall be directed toward improving the public welfare, increasing the standard of living, strengthening free competition among private enterprises so far as practicable, and cementing world peace.

But in the years following directly after the war, atomic energy was mainly applied to military purposes. Civilian development of atomic energy did not come easy, mainly because of AEC's inheritance of contracting methods from the Manhattan Project.<sup>71</sup> The two major contractors were General Electric and Westinghouse, leaving little room for free competition with other companies.

To promulgate the intent of the 1946 Act toward peaceful uses of atomic power, the AEC established its Reactor Development Program in 1948 -- a first concrete step toward realization of a government-industry partnership in developing nuclear energy for civilian use. Yet true industrial participation did not really materialize. It was an expensive technology, and by law AEC owned all production equipment and materials. To open up the field for greater industrial participation, the 1946 Act was amended in 1954. This change permitted private ownership of nuclear reactors under AEC licensing,



although the AEC retained ownership of fissionable materials.<sup>72</sup> Realizing that the United States could not maintain secrecy and monopoly in atomic energy any longer, President Dwight Eisenhower helped promote the field in his famous "Atoms for Peace" speech on December 8, 1953 at the United Nations.

Still industry was not eager to commercialize atomic energy. One barrier was liability concerns. Private commercial insurers were willing to cover \$60 million on liabilities, which was obviously too little. Congress acted once again in favor of the private sector and drafted the Price-Anderson Act of 1957, named after its sponsors, Representative Melvin Price and Senator Clinton Anderson. This law relieved private industries from financial liabilities by providing government subsidies to cover liabilities up to \$500 million, thereby totaling liability costs up to \$560 million per accident.<sup>73</sup>

With Price-Anderson enacted, the way to private commercialization of atomic energy was paved. The AEC meanwhile continued to involve private industries. It ultimately became so immersed in promoting atomic energy that it forsake its controlling function. From the beginning the agency faced a conflict of interest between promoting atomic energy and regulating it, and that conflict was resolved in favor of promotion. The AEC and the nuclear power industry were more than partners in the commercialization of nuclear energy -- they became the building blocks of a government-industry complex.

## ***Role of Legislation***

Legislation on rDNA failed for numerous reasons. Waning congressional interest in rDNA, opposition of the scientific lobby, and an internal power struggle between congressmen, were major forces that ultimately killed legislation. Yet I argue that failure to legislate rDNA was due to an even more critical factor: a lack of consensus that government control was necessary. As long as the NIH guidelines were capable of guiding the development of rDNA, and no real disasters were looming, strict control was seen as superfluous.

In nuclear energy, on the other hand, the destructive powers of the atom and moral responsibility for its consequences inspired the public and government alike that control was needed. This was the force behind the enactment of the Atomic Energy Act of 1946 and the establishment of a civilian controlling body, the Atomic Energy Commission. As mandated in its establishing charter, the AEC was to promote civilian uses of atomic energy. But the enormous expenses to develop and build nuclear power reactors for generating usable energy pressured AEC to sell atomic energy. In its feverish effort to promote commercialization of atomic energy, the AEC became an advocate of one interest group, the nuclear industry.

It is undeniable that legislation on atomic energy had a positive effect in controlling the development of the field. The energy of the atom was directed toward peaceful uses, such as electrification. But the establishment of AEC was not so

successful. It was torn apart by its dual tasks of promoting and controlling atomic energy. In the end, promotion prevailed and the AEC became a champion of industrial interests, supported by legislative provisions benefitting this particular interest group. As a controlling body the AEC neglected its tasks. This conflict of interest was ultimately responsible for AEC's demise.

For purposes of our analysis, we must underline the importance of the separation of power principle. Violation of this principle in the establishment of the JCAE and AEC and in their assigned powers had substantial consequences, leading to failure of both organizations. JCAE's initial "watchdog" function faded away, allowing the JCAE and AEC to become "pals" instead of adversaries. As a result, flaws in AEC's operations, for example its lack of concern for reactor safety and radioactive waste, were not detected by JCAE in time. Both organizations became biased toward industrial interests, forsaking their more important controlling functions. Lax control was one of the factors that subsequently led to the failure of nuclear reactors, exemplified by the Three Mile Island accident. An equivalent of this calamity must be prevented from happening in the future.

The lesson of AEC then, is that in spite of its imperfections it has been a positive force in controlling the development of nuclear energy in a specific direction. Such a unifying guidance may be needed in other high technologies.

## *Notes to Chapter Five*

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## *Six*

# *The Turning Point*

### *Planning for the Future*

In the preceding chapters we have looked at three alternative ways of policy-making in rDNA. First, the classic approach to solving policy problems in science and technology was described in Chapter Three. In this approach, scientists were, at the same time, expert problem solvers and policy makers. The boundaries between politics and expertise became blurred. Technocracy prevailed.

Challenges to the technocratic approach by lay citizens prompted a second mode of policy-making. Chapter Four described community debates held at several locations during mid-1970s. The debates permitted participation of a broader public in deciding the future of rDNA. Compared to a technocratic approach, where a few selected experts

decide for the rest of the people, community debates are more democratic approaches to policy-making.

In Chapter Five we explored congressional attempts to legislate rDNA. Legislation, a bureaucratic way of policy-making, is the third alternative policy mode. Although efforts to regulate the field on national level failed at the time, it showed us the potential importance of a unified policy or guiding system.

What is the value of these past policy processes? In the first place, studying the history of policy-making in rDNA allows us to make sense of what has happened. Many scholars (see Chapter Two) provide excellent descriptions of events in rDNA policy-making. None of them, however, distill out the essence of each event, let alone attempt a synthesis that lays the basis for a balanced approach for future democratic control of esoteric technologies.

Our technique is to evaluate the past in order to plan for the future. With a little imagination, we can expect that the future will bring us many more sophisticated technologies. A recent article reports an extension of the application of genetic techniques in revolutionizing public health.<sup>1</sup> Antigens of devastating human diseases are incorporated into plants through genetic engineering techniques. Seeds of such plants, when planted and grown, will deliver antibodies as edible vaccines in fruits or vegetables. What about a banana containing vaccines against cholera or AIDS?

Based on common features of high technologies, it is reasonable to anticipate that the problems we have encountered in biotechnology will reappear in the future -- perhaps

in several realms of science -- if no timely precautions are taken to prevent them from happening. Although every high technology has its own set of specific features, certain problematic characteristics are universal for all of them. They will recur in other technologies. One is the difficulty of lay understanding. Another is the public fear for the unknown. A third is the rapid evolution of science. A fourth is uncertainties of safety, costs, and payoffs for society. We need a *plan* for dealing with these issues. We must anticipate how we are going to deal with esoteric technologies in the future.

Responding to the need to plan ahead, we have analyzed and evaluated three past policy processes in rDNA: the technocratic, the democratic, and the legislative approaches. The next step is to synthesize the concepts, or premises that underlie each process, in order to lay the foundation for a balanced approach that embraces key advantages of each. It is time for us to turn around, and start something new. We must think through a new style of policy-making for future technologies.

### ***Problematic Characteristics***

Characteristics of rDNA that have had implications for its policy-making processes have been mentioned in Chapter One. These characteristics are: esoteric, uncertain in outcome, controversial yet evolving, and complex because of a multitude of actors who

have a stake in the technology. All these features contribute to special complications in the policy process.

The most disturbing feature of high technologies is their difficulty to be comprehensible. Esoteric knowledge is understood by insiders only. In rDNA, comprehension of the technique is complicated by the complexity of the organisms. Time and effort to communicate the subject to non-specialists are hidden costs in policy-making. And, in general, such costs are overlooked or underestimated in policy-making processes. As a result, most processes lack special provisions to overcome such hurdles.

During debates at the public forum of the University of Michigan at Ann Arbor rDNA experts had a hard time correcting misunderstandings and misinterpretations of non-specialists. From the beginning, rDNA was controversial, but ignorance polarized opinions even further and tore a deep rift between pro and con.

At the Cambridge debates, scientists were unable to communicate their science in plain language understandable to the general public. The problems in communication were exacerbated by scientists who presented rDNA as a technical issue, while the general public was more interested in procedural issues to control the technique. Lack of a common goal of these actors prevented them from reaching consensus in a timely manner.

Another problem is the evolving nature of rDNA and the need to respond quickly to such rapid development. Legislative efforts to regulate rDNA nationally were initially resisted by scientists because of their concerns of rigid legislation. In a rapidly moving field like rDNA, with so many uncertainties in outcome, the scientific community

preferred a flexible mode of regulation. Scientists argued that the lengthy time needed to amend legislation would hinder a smooth development of the field.

Lastly, multiple interests in rDNA should be accommodated in its policy-making process. As expert decision makers, scientists were challenged by lay people who wanted reassurance with regard to safety of the technique. On the other hand, anti-biotechnologists such as Jeremy Rifkin want to halt work in biotechnology entirely. Recently, a group of scientists, the Union of Concerned Scientists, issued a report questioning the wisdom of cultivating transgenic plants on production scale.<sup>2</sup> These and other actors should have the opportunity to voice their opinion in the decision-making process.

A novel policy-making process for high technologies must provide means for accommodating differing views and addressing the aforementioned problems. The esoteric nature of the issue should be communicated in understandable terms for all people. Hence, education and communication are important aspects of policy-making in high technologies. To accommodate multiple interests, the policy-making process should be open to a broad range of participants. As for policy outcomes, it seems that a flexible guidance system is more suitable for rapidly evolving technologies.

## ***Review of Technocratic Policy***

Publication of the Gordon Conference letter in *Science* of September 21, 1973 brought the issue of rDNA into the public sphere. Following this letter's recommendation, an expert panel was established. The panel issued another letter, the "Berg letter," published in *Science* of July 26, 1974. The Berg letter recommended a moratorium of certain types of experiments, an international conference of experts (Asilomar II), establishment of an expert advisory committee (RAC-NIH), and development of guidelines (NIH guidelines).

Asilomar II turned out to be a closed decision-making procedure. The conference agenda was framed by rDNA specialists, conference participants were carefully chosen through internal channels, and the discussion of rDNA was confined to a technical discussion. In a word, the conference exemplified technocratic decision-making. In technocratic procedures, authority is placed in the hands of defenders of the issue, in this case, defenders of rDNA.

In retrospect, it seemed plausible that the scientists had manipulated the esoteric nature of rDNA for their own advantage. Esoteric knowledge was reserved for experts, so they argued, and as a disinterested group of experts their aim was to further science for the benefit of the people. In this way, the scientists justified their technocratic decisions under the guise of "public interest," wrongly justifying particularist claims by implying universalist, common good. They deliberately depoliticized the issue to avoid

public conflict. Also, by keeping authority to themselves, they centralized the decision-making process.

Although expert decision-making may be viewed with suspicion by outsiders because of its closed process and tunnel vision, the availability of expert knowledge is patently necessary. As we have seen, it was wrong to exclude experts from the decision-making process precisely because of the esoteric nature of the subject matter. Committee B's chairman of the University of Michigan admitted that "rDNA experts who developed the NIH guidelines had thought about potential hazards more thoroughly than the Committee ever could have done."<sup>3</sup>

Dr. Donald Fredrickson, then NIH director, acknowledged the appearance of conflict of interest in expert decision-making. But, as he said, "it was unavoidable."<sup>4</sup> His argument for unavoidable expert involvement in decision-making is valid. Yet the appearance of conflict of interest must be avoided. To correct this image, I suggest to open up the decision-making process to broad participation. Then, experts can partake in decision-making without the image of being inherently biased.

### ***Review of Public Participation***

Public involvement in rDNA decision-making processes was exemplified by community debates at Cambridge, Ann Arbor, Princeton, and San Diego. Community

debates offer an opportunity to consider rDNA from several viewpoints, based on varying values and ethical standards. This process inevitably politicizes the issue. Opening up discussions to a wider audience also decentralizes the decision-making process. Rather than a privilege of a few chosen experts, authority is now dispersed among the participants of the discussions. Simply put, a shift of the decision-making locus from scientists to general public, has taken place.

For the purpose of our analysis, a dual assessment of the public debates is necessary. First, the debates are assessed in procedural terms. This assessment evaluates the procedure by which the debates have been conducted. A second way of assessing the debates is through their outcome. As we have noted, there were positive and negative results. From both assessments, procedural and outcome related, we can extract valuable lessons for planning future policy-making processes in high technologies.

With regard to procedure, debates at Cambridge and the University of Michigan at Ann Arbor reveal two approaches to public participation. These are the adversarial and review approaches. Each approach took place at two separate stages of the debates. The first stage -- which is the truly public, or community debate, such as the Cambridge community meeting convened by Mayor Vellucci -- was adversarial. Yet in the second stage of the debates, the mini-forum of the Michigan Regents and CERB's citizen court at Cambridge, were conducted in a review approach.

The adversarial approach was not effective for solving policy problems in rDNA. Opposing and supporting views contradicted each other, primarily because of the



underlying win-lose attitude of the participants. They were adversaries: each side trying to win its own position. As a consequence, the issue became polarized and differences in opinions sharpened. Hence, an adversarial approach diminished possibilities for reaching consensus.

The review approach was much more effective in settling disputes, possibly because of the different attitudes of the contending parties. Both supporters and opponents provided testimonies, or advice, to a jury. They knew that their presence was not to "win" the argument. At the mini-forum in Michigan, the University Regents were the decision makers. Also, they were interrogator and jury at the same time. Similarly, the Cambridge Experimentation Review Board (CERB) listened to testimonies of both sides of the controversy in a court-like hearing. Hence the practical importance of a review approach is its effectiveness in assessing a controversy and, therefore, its capability for creating consensus.

With regard to the outcome of public participation in decision-making, community debates mainly function as a catalytic agent. They provide a forum for dialogue between experts and lay people. One of the main hurdles in reaching consensus, as we have seen, is distrust between experts and non-experts. Lay people lose trust in the integrity of the scientific establishment, while scientists suspect that lay people do not understand their true intentions.

Restoring trust between experts and non-experts must therefore be on the agenda of every policy maker in esoteric policy fields. "If trust between scientists and the public

is to be restored, the scientific community must be willing to listen to worried citizens. . . ."<sup>5</sup> And, what better media can we provide than community fora where participants are allowed to present an issue according to their own values?

Impartial decision-makers, with no vested interests in the controversial issue, certainly enhances the image of neutrality and credibility of the forum. Procedures tend to be seen as fair, while participants have a positive feeling that they have been heard and their concerns addressed. Hence, I argue that such a forum is an appropriate locus for dialogue, as well as a means for creating trust and public confidence.

As previously mentioned, a disturbing factor in community decision-making is lack of knowledge in the subject matter -- especially that of the lay participants. Without experts' help, lay persons might well be intimidated by the complexity of the issue and end up in unnecessary frustration. Expert knowledge is also necessary to correct misunderstanding, bias, and misrepresentation, as we have seen before. One may therefore argue that without expert participation, community dialogues in high technologies are meaningless.

Another pitfall of local decision-making is the variation in its recommendations. The variety of laws following local decisions is not a recommended policy to regulate esoteric technologies like rDNA. The pervasive and irreversible consequences of high technologies require a unified policy.

## *Review of Legislative Control*

By the time Congress was attempting to regulate rDNA, most participants of the rDNA controversy would not deny the necessity of regulation covering all rDNA research. Hence, the question was not whether to regulate or to deregulate, but the kind of regulation that was appropriate.

Scientists were content with the NIH guidelines as a means to control the field. The guidelines provided sufficient instruction for a safe execution of experiments, and this suited their needs. Consequently, they did not see the urgency of federal legislation. But the NIH guidelines became increasingly criticized because of their limited jurisdiction and legal reach. The whole field of industrial research, for example, remained officially unregulated.

Meanwhile, members of the general public conducted their own decision-making experiment in the form of community debates. Their representatives enacted local ordinances which in most cases were stricter versions of NIH guidelines. The problem, however, is that local laws slightly varied from each other and, as mentioned before, such policies are not recommended for the regulation of high technologies.

Finally, Congress was urged to take action by several factors: the public's demand to participate, unresolved challenges to the NIH guidelines, a rising anti-rDNA movement corroborated by an increasing number of prominent scientists publicly denouncing rDNA. Bills to regulate the field were introduced by several House and Senate members. The

administration established an Interagency Committee to draft its own bill which was introduced into Congress after substantial modifications.

Yet legislation was perceived as inflexible and cumbersome by the scientific community. Jail penalties for violations, for example, as well as complex inspection and reporting systems, were seen as unthinkable. Moreover, legislative control was generally identified with diminished scientific freedom. The issue between Congress and the scientific lobby ultimately became a struggle between freedom of inquiry and congressional intervention.

Controversial recommendations of the bills also contributed to the demise of legislation. Scientists were disturbed by a proposal for an autonomous national commission to regulate the field. An autonomous regulatory commission in effect eliminates their professional autonomy, while NIH was not known as a regulatory agency, but as a promoter of rDNA. If a national commission was unavoidable, the scientists preferred an advisory body, not a regulatory commission.

Another disputed issue was the federal preemption clause. Scientists favored federal preemption to avoid variable local laws, while environmentalists rejected federal preemption. Environmentalists favored local and state regulations because of their greater influence on local jurisdictions. In the end, however, nothing happened and legislation failed.

Although legislation on rDNA failed, we have mentioned earlier that atomic energy -- another esoteric technology -- was regulated under the Atomic Energy Act.

After World War II, a sense of moral responsibility for the consequences of nuclear war precipitated a unanimous agreement to harness the atom's power for peaceful ends. Unlike the situation in rDNA, an imminent reason and need for controlling atomic energy obtained. Congress passed the Atomic Energy Act of 1946, creating the Atomic Energy Commission and its congressional counterpart, the Joint Committee on Atomic Energy.

AEC's mandate to direct atomic energy for peaceful uses became its over-arching policy. The AEC focused on civilian uses, and thus commercialization of atomic energy. All legislation was directed towards this end, and accumulated in a unified policy.

Establishment of the JCAE was intended to keep AEC's powers in check. A blurring of separation of powers between the AEC and JCAE prevented the latter from performing its "watchdog" function, however. As a result, AEC -- a regulatory agency - - could do whatever it saw fit, since JCAE complied with all of the AEC's wishes. Consequently, AEC's flaws, such as its lax safety control, were not detected until it was too late. These errors stemmed, moreover, from AEC's problematic dual role as promoter and regulator at the same time.

But the AEC was flawed in more than one way. It was a classic example of an agency "going native," captured by the interests of the regulated. In its zeal to promote atomic energy for civilian uses, the AEC became overprotective of industrial needs, and finally it was dominated by the private nuclear industry. Needless to say, such errors must be avoided in policies for future technologies.

## *What Have We Learned?*

Assessment of these three modes of policy-making has taught us lessons for formulating timely policies in future technologies and what to avoid. As previously mentioned, recommendations based on actual events in the rDNA controversy should apply to other high technologies as well.

First and foremost, we have learned that decision-making in rDNA should be an open process. A technocratic approach, in contrast, reserves authority to insiders, or specialists of the technology. Although expert decision-making is efficient, it is certainly not the most effective procedure. It is efficient because expert decision makers have a thorough knowledge of the subject matter. This saves time and effort in explaining and communicating the subject. But outsiders tend to distrust technocratic recommendations, making it ineffective. They usually suspect those recommendations as biased towards self interests of the experts.

In principle, all citizens have a legitimate right to participate in an open decision-making process in order to argue their standpoint according to individual norms and values. Science is not ethically neutral; its meanings are not absolutely measurable but "socially constructed."<sup>6</sup> In esoteric areas, the boundaries between value judgments and scientific assessments are even more vague due to uncertainties in knowledge and outcome. It is therefore justified that a broad spectrum of participants present their views prior to decisions.

Public participation also holds ideological and psychological virtues.<sup>7</sup> Ideologically, public participation is appropriate from the standpoint of democratic norms. Psychologically, participation enhances trust and community consent, easing the way to legitimizing decisions.

In high technologies, however, an open decision-making process with broad participation is only constructive alongside expertise. The esoteric nature of the subject mandates participation of experts in order to help explain and communicate the knowledge and educate non-experts, empowering the lay participants. Moreover, the presence of experts is essential to listen to and evaluate values that are not necessarily compatible with scientific values.

In view of this, a review approach, as over against an adversarial approach, is the preferred method to conduct decision-making processes in high technologies. A review approach facilitates the assessment of a controversy, allowing consensual decision-making. A presiding impartial jury, simultaneously acting as reviewer and decision maker, enhances fairness, neutrality, and credibility of the decision-making body.

Although an additional layer of bureaucracy is frequently perceived as superfluous, decision-making processes in high technologies are probably best implemented in an advisory body, rather than a regulatory commission. At the same time, establishment of an advisory commission must not violate the separation of powers principle, and agency capture must be prevented. Also, a unified yet flexible policy seems necessary for controlling high technologies like rDNA.

## *A Call for Change*

The history of policy-making in rDNA, as analyzed in the foregoing, shows that its process has been strained by dilemmas between politicization and depoliticization, centralization and decentralization, particular and public interests, as well as legislation and no legislation. To formulate a new kind of policy-making for future technologies, our task in this array of opposing forces is to find a balance that can preserve the most of the competing advantages.

The lessons we have learned from the rDNA controversy and its ensuing dilemmas point to a circular relationship between science, policy, and politics. If science ignores politics, the rDNA controversy shows that technocratic decision-making will be challenged by the general public. And if science and politics are not in agreement, policies -- legislation or otherwise -- will fail. Only when science, politics, and policies are congruent can a successful guiding system, or "democratic control" of high technologies, be feasible.

A democratic control for high technologies must, however, be legitimate. As we have learned from the rDNA case, certain minimal criteria are necessary to legitimize decisions. First, the policy-making process itself must be "bottom-up." Second, the policy makers must be approved and respected by all. And third, the policy process must be embodied in a formal decision-making body. Let us now explore these criteria, beginning with the bottom-up process.



It is not uncommon that acceptance of certain policies is forged by the power of authorities. But for potentially controversial fields like rDNA, a top-down process by which government attempts to instill new values seems unlikely to succeed.<sup>8</sup> The controversial nature of the subject, and accordingly, diverse interests of the multiple actors, complicated by far-reaching consequences of the decisions, require that policies in high technologies are accepted by all involved parties. Otherwise, the underlying tensions might be too forceful to break up whatever agreement is decided upon. A top-down formulated policy, simply put, cannot acquire the legitimation it needs. For high technologies, a bottom-up decision-making process is more likely to obtain acceptance and respect. In a bottom-up process, participants consciously deliberate on an issue with the ultimate aim of formulating a policy. The community debates on the rDNA issue at Cambridge, Ann Arbor, and other locations exemplify the crucial importance of the bottom-up process.

A second criterion for a legitimate decision-making process in high technologies is the choice of decision makers. As we have seen, the Michigan Regents and CERB functioned as interrogator, reviewer, and decision maker at the same time. I argue that legitimizing decisions in complex, esoteric policy areas can only be achieved when *all* participants of the decision-making process simultaneously perform the three tasks. Participants must therefore be selected in light of their capability to perform these tasks. This multi-functional task is not new, however; participants in consensus negotiation processes, assisted or unassisted, embody all these tasks at the same time. We have also

concluded from the "technocratic" and "democratic" approaches to decision-making in rDNA that experts and non-experts alike are crucial for the process. Discussions among "lay" persons without expert knowledge are meaningless, while the presumed tunnel vision of experts is unacceptable for far-reaching decisions that affect everyone. A balanced participation of experts and non-experts is recommended.

A third criterion that legitimizes policies in high technologies is the visibility of the policy-making process itself. Policies risk a greater chance of being perceived as less legitimate if their formulation processes remain obscure from the scrutiny of the general public. Embodiment of the policy-making procedure into a formal decision-making body is therefore suggested. Visibility contributes to the authority and legitimacy of the policy process. Also, a single decision-making body has the ability to produce a unified policy outlook. In spite of its flaws, the AEC promoted atomic energy for civilian uses.

In summary, a successful democratic control of high technologies requires a new mode of policy-making. The decision-making process should be bottom-up. Policy makers should be credible, respected, and skillful. The process itself should be implemented in a formal organization. What then, is this policy-making process?

I recommend that decisions in high technologies be achieved through multi-party negotiations by consensus, within an institutional setting established for this purpose. The scope and substance of high technologies call for such a process.

## *Negotiation by Consensus*

Conflict resolution through processes other than formal litigation or adjudication, has been widely used for a long time. In ancient China, the thinker Confucius, believing in a natural harmony in human existence and processes, recommended moral persuasion, not coercion, to resolve disagreements and disputes. In Japan, mediation is a longstanding practice. Leaders of religious groups practice mediation, as well as ethnic groups in the United States through their own mediation fora such as the Chinese Benevolent Association and New York City's Jewish Conciliation Board.<sup>9</sup>

The 1960s was a tumultuous time full of strife and dispute over morality, new life styles, and the Viet Nam war, to name a few. Previously unheard disputes overflowed court dockets, resulting in delays, frustration with the legal system, and a growing trend of alternative dispute resolution. The Civil Rights Act of 1964 established the Community Relations Service in the U.S. Department of Justice to help settle racial and community disputes.<sup>10</sup> The Federal Mediation and Conciliation Service (FMCS) and the American Arbitration Association (AAA) are among the founders of the Society of Professionals in Dispute Resolution (SPIDER).

In the 1970s alternative dispute resolution (ADR) in environmental cases became increasingly popular. The American Bar Association established a Special Committee on Alternative Means of Dispute Resolution in 1976.<sup>11</sup> As a result, mediation and other non-coercive dispute resolutions caught the interest of scholars and practitioners alike.

On the theoretical level, one of the pioneers in alternative dispute resolution is Mary Parker Follett (1858-1933). In her 1924 essay, *Creative Experience*, she called for a forum to challenge experts and "fact-worshippers." She believed in the social construction of "facts," and concluded that facts are relatively unreliable, enabling experts to choose among facts depending on their needs. Facts can also differ in meaning depending on the contexts, and consequently, decisions based on incomplete facts could be disastrous.<sup>12</sup> This timely advice is particularly useful for negotiations in complex policy areas like rDNA where fact and value are oftentimes intertwined. Follett's ability to perceive things as they are has made her advice as timely as ever.

Follett saw three main ways of dealing with conflict: domination, compromise, and integration. Through the process of "integration," nowadays called a win-win situation, "desires have found a place, [and] neither side has had to sacrifice anything."<sup>13</sup> She argued that conflicting parties should face the real issue, that is, the significant rather than the dramatic features of the issue. Yet her most important contribution to conflict resolution is the recommendation that integration is a *process*, "genuine integration occurs in the sphere of activities, and not of ideas or wills."<sup>14</sup>

In practice, technological conflict resolution was attempted in September 1977 when a sixteen-member panel of clinicians, scientists, and lay people evaluated novel medical technologies with important social consequences such as mammography. The consensus panel was a response to a growing demand of non-clinicians wanting a say in

decisions for "better-quality wisdom."<sup>15</sup> Dr. Donald Fredrickson, NIH Director and convener of the meeting, wrote of the consensus panel,

We believe that the scientific community must avoid all pretension of ultimate wisdom in these exercises. If we lay out the state-of-the-art -- what it is we know and do not know from data scientifically derived -- we will serve medicine and society through provision of a sounder base on which further value judgments can be laid.<sup>16</sup>

Six consensus panels, each studying different medical technologies, were formed. An evaluation study of these panels concludes some important points for consensus making in high technologies in general. First, the process of interaction, "facilitative interaction," is crucial for the quality of the outcome. Facilitative interaction allows "members to participate freely" to air their opinions and exchange information. Second, a skillful chairperson who can maintain "free and uninhibited discussion and preventing the discussion from wandering aimlessly" while facilitating exchange of novel information, also determines the outcome. And third, personal satisfaction of the participants depends more on the process of interaction and the information exchanged and less on the outcome.<sup>17</sup>

For our purpose of developing consensus negotiations in high technologies, conflict resolutions in international affairs and environmental disputes also shed some light. Both involve multi-parties that are hard to define and to detect yet are inter-dependent. The scope and complexity of the issue in question also resemble that of high technologies.

An international experience in consensus negotiation is illustrated by the United Nations Conference on the Law of the Sea (UNCLOS).<sup>18</sup> Evaluation of consensus making

at UNCLOS reveals two major points: the need to formalize consensus rules and the development of an "active consensus procedure."

Consensus rules, or "rules of the game," is a checklist to remind participants of points-to-do during negotiations.<sup>19</sup> *A priori* principles of negotiations, or a protocol to manage the process, is crucial for successful negotiations. Negotiation by consensus cannot entirely depend on "common sense," thus certain reminders of what to do are important. Lack of planning of the Cambridge Experimentation Review Board is a case in point. The CERB was unprepared to tackle the issue, creating unnecessary strain in the process.<sup>20</sup>

An "active" consensus procedure is needed when negotiations are becoming endless without prospect of an end result. In this situation, the chairperson should take action, for example by generating proposals and asking feedback from the participants, without imposing decisions. Thus the chairperson must be a diplomat, actively steering the process without dominating it. Personality of the chairperson plays a major role in successful negotiations, he or she must be knowledgeable, impartial, fair yet diplomatic, and have personal prestige, power, and influence to be respected by all.<sup>21</sup> A wrong chairperson could be disruptive, as we have seen at the Cambridge debates under direction of Mayor Vellucci.

Another example of international negotiations is foreign policy-making. The State Department's Senior Seminar on Foreign Policy held a week-long study in April 1977 on the topic of negotiation.<sup>22</sup> For consensus negotiations in high technologies a lesson to be

learned from foreign policy negotiations is the importance of internal and external negotiation. External negotiations take place among the participants of the negotiation process, while internal negotiations are those between the participants and their respective constituencies. Opportunity to negotiate internally at their home bases allows representatives of the diverse parties to get approval and endorsement of their positions.<sup>23</sup> In high technologies, the range of consequences of the technology and the limited number of representatives in the negotiation process justify internal negotiation.

Another interesting and important lesson in consensus negotiation is the "ongoing efforts at team building."<sup>24</sup> In successful negotiations, participants negotiate as a team with a certain identity and purpose. The Recombinant DNA Advisory Committee of the NIH illustrates this point. As Dr. Hans DeWitt-Stetten Jr., chairman of RAC's first meeting, recalled, "wild discord" among the participants of the first meeting was transformed into a committee functioning "with a commonality of purpose" after the fourth meeting.<sup>25</sup>

The GMAC (Genetic Manipulation Advisory Committee), RAC's British counterpart, is another illustration. The GMAC was notable for diversity of its participants, but was successful in spite of this diversity. Interpersonal relationship might be the key to GMAC's success. Sir Gordon Wolstenholme, chairman of GMAC summed up its success as follows:

Perhaps the most vital quality of membership was a sense of humour, but there was a healthy readiness to accept each other as people and not as stock representatives of big science, management or employees. The technicalities may have remained beyond

comprehension but the elements of health and safety were made clear, and each member found an important personal role.<sup>26</sup>

In other words, participants of consensus negotiations must act as a community facing a shared problem and finding ways to resolve it.

Lastly, for optimal functioning of consensus negotiations, factors such as open meetings, confidentiality, and the media should be addressed.<sup>27</sup> Closed meetings are the norms in consensus negotiations in general. Exemptions from the Federal Advisory Committee Act (FACA), mandating open meetings, can be provided in the establishing charter of the negotiation team. Confidentiality of discussions must be defined in the protocol, or rule-of-the-game of the negotiation process. For example, whether notes of participants have official status, or whether "minutes" of each meeting will be distributed. As the issue becomes more public, the attention of media increases. Perhaps appointing a spokesperson for the negotiating team, for example the chairperson, may be useful to hold all contacts with the media on pre-approved issues in order to avoid misinformed or biased reports.



## *National Science Forum*

As mentioned before, legitimizing democratic control on high technologies requires fulfillment of minimum criteria. These are a bottom-up process, where decision makers are simultaneously interrogators and reviewers, embodied in a formal, visible organization.

The first two of these criteria, a bottom-up process and multi-functional participants, are embodied in consensual negotiation processes. In the foregoing section we extracted characteristics for consensus making in high technologies from negotiations in fields similar in complexity and scope. To recapitulate, successful negotiations involving complex issues and multi-parties must have certain typical characteristics.

A *laissez faire* attitude based on common sense must not dominate the procedure. The process must be structured without becoming rigid. A protocol to guide the process and remind the participants of salient points in each phase of the negotiation may function as a structuring device. This framework must not, it should be underscored, stifle the process. Participants must feel free to participate, voice their opinions and concerns, and exchange information. They must "face the real issue," as Mary Parker Follett has written, as a shared problem. Participants must also have the flexibility to negotiate internally with their constituencies. Although participants should negotiate as a team with a common culture, leadership is crucial. The chairperson could have a passive role as facilitator, or go-between, yet in some cases, he or she should take a more active role by generating suggestions but not suppressing participants' interests and positions.

As for the third criterion, embodiment of the process in a formal organization, I propose that National Science Fora be established. From our analysis of the rDNA case we may suggest the RAC-NIH as such a forum. The problem with the RAC, however, is its initial founding as a technocratic advisory committee with sole expert participation. In its early years, hardly any "lay" input was sought. The RAC first opened up its decision-making process to a wider audience during public hearings at the Director's Advisory Committee of NIH (DAC-NIH) meeting on February 9 and 10, 1976. "Lay" people testified that non-expert input was too late and too little.<sup>28</sup> Ignorance for broader issues was further exemplified by NIH's violation of its legal obligation to file an Environmental Impact Statement before issuing guidelines. Although RAC's membership was gradually expanded with non-experts, it could hardly shake off its technocratic image.

Other than the RAC-NIH, we may suggest the National Biotechnology Forum of the Keystone Center in Colorado as an organization to facilitate negotiation processes. Founded in 1975, the Keystone Center is a non-profit organization for facilitating conflict resolutions. It also provides education programs in environmental studies. In 1989, the Keystone Forum initiated several workshops that were attended by a broad range of participants.<sup>29</sup> Their existence, however, does not seem to be widely known among the lay public.

The proposed National Science Forum should in the first place avoid RAC's flaws. It must start with a broad range of participants, accessible for new information when relevant. Another lesson we have learned from the past is to convene a forum *before* a

crisis situation erupts. On local level, we have seen that the severity of antagonism at the Cambridge debates was mainly due to an unresolved internal dispute among Harvard scientists. For future technologies, we recommend the National Academy of Sciences (NAS) to assume a triggering function. The NAS should summon the convention of a forum for a technology with potentially controversial societal consequences.

Unlike the Keystone Forum that is established by a non-profit organization, the proposed National Science Forum is a government institution. The visibility and prestige of the National Science Forum contribute to a wide recognition of its existence. Its organization, membership, and purpose should be communicated through national media. Also, international participation must be contemplated when the state of affairs required for such a participation.

The proposed National Science Forum will deal with one single issue or technology at a time. It accordingly has limited existence: it exists only as long as the situation demands its mediating function. More fora could be formed if more than one pressing issue arise at the same time. Establishment of science fora is preferably regulated by a generic law containing minimal requirements for such organizations. It should, for example, ensure financial resources through formal budgetary appropriation processes. The budget must cover a honorarium for the participants and a reimbursement of their expenses. Guidelines for the size of the forum, the nature of its membership, the appointment procedure of its chairperson could all be recommended in its founding statute. These issues seem trivial, yet are important in the legitimation of a forum.

A chairperson appointed by the President of the United States with approval of the Senate confirms its prestige and legitimacy. The chairperson, on its turn, appoints the members of the forum. The members would be allowed ample opportunity to negotiate internally with their constituents. An approximately twenty-member forum is recommended, with representations of ten experts and ten non-experts. A balanced membership with equal scientific and political interests adds to the impartiality and neutrality of a forum. The non-experts may include "politician scientists" as representatives of government agencies and advocates of the public interest as well. They also include lay members representing different viewpoints of the issue. When specific issues call for more opinions and thereby for broader participation, special subcommittees could be formed. In spite of the limited number of participants, the National Science Fora must be accessible to interested persons and new information. I recommend that the Science Fora allow public input in the form of testimonies or presentation of survey data on certain opinions at specially designated times during its meetings.

A National Science Forum is likely to be an advisory body. The case of the Atomic Energy Commission showed that combining promotional and regulatory powers had grave consequences: the AEC was "captured" by one particular interest group. It also showed the importance of the separation of powers principle. Violation of this principle, as argued earlier, was the major factor of AEC's demise. Unable to perform its adversarial function, the congressional Joint Committee on Atomic Energy did not detect AEC's errors in time.

As an advisory body, however, a Science Forum faces a dilemma: on the one hand, it can merely advise; yet on the other, its reason for establishment is to create consensus. As an advisory body, enactment of its recommendations into federal regulations or mandatory guidelines is decided by a relevant department, for example in the rDNA case by the Secretary of the Department of Health and Human Services. But if a forum does not have the statutory authority to issue regulations, can it unify the field?

A Science Forum copes with this dilemma through its "positive role of authority."<sup>30</sup> This means that appreciation for its advice must emanate from trust. Trust, on its part, is developed from the forum's broad participation and consensual decision-making processes. In esoteric issues trust is especially crucial, since only a limited number of people would fully comprehend the issue. Negotiation by consensus, I argue, is particularly suitable to inform participants and to create trust. It represents diverse values. Its facilitative procedure allows free exchange of information, creates a foundation for new relationships, and hence, a common bond among the participants. Communication between representatives and their constituencies through "internal negotiations" further disseminates the legitimate authority of the forum and its agreements. Advice from a forum is therefore more than advice -- it is an agreed-upon commitment.

Authority of a National Science Forum also derives from its superiority of knowledge, insight, experience, expert advice, and integrity of the participants.<sup>31</sup> A Forum must be able to defend its recommendations through logical reasoning. Thus, its source

of authority is not coercive power, but capacity to elaborate the reasons of its decisions based on agreed-upon facts. In this sense, participation of experts is a must.

As a "locus to create and communicate meaning,"<sup>32</sup> a Science Forum brings diverse interests together. In this sense, the primary task of a National Science Forum is to define the issue. Differing viewpoints are not perceived as obstacles but as a contribution to balanced decisions. Mary Parker Follett wrote earlier,

It is possible to conceive conflict as not necessarily a wasteful outbreak of incompatibilities, but a *normal* process by which socially valuable differences register themselves for the enrichment of all concerned.<sup>33</sup>

Follett continued that such a process is an "art of cooperative thinking." She does not suggest that contending parties will make concessions, "but there often comes a moment where there is a simultaneous revaluation of interests on both sides and unity precipitates itself."<sup>34</sup> Then, a Science Forum not only defines an issue, but also proposes a policy.

Follett was not explicit on the techniques to achieve "revaluation of interests." It is probably impossible to predict how we can actively evoke the crucial moment that precipitates uniform interests. I argue that the chairpersons must have an active role as catalytic agents to induce such moments. I furthermore recommend that public administrators, as agents of the people or "Agential Leaders," should attempt to fulfill this role. They must act as "agent trustee[s] for all the citizens of the nation, perhaps even those of future generations."<sup>35</sup> In this capacity, they have the potential of modifying adversity into a more balanced perspective of the issue.

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# *Epilogue*

Balancing scientific and political decision-making for a democratic control on controversial high technologies rests on the creation of an opportunity to bring the diverse parties together. For this purpose, the establishment of National Science Fora is recommended.

The Fora, as loci for structured dialogue, diminish antagonism and facilitate change. Long-nurtured antagonism between contending parties can be modified when they are offered another way of looking at the issue, thereby creating a foundation for new relationships between the parties. Differences in standpoints can probably not be eliminated altogether. Even though a "unified policy" might not be achieved, a Forum can develop a balanced perspective of the issue. Supporting and opposing opinions should respect each other, and all parties should try to achieve the best possible solution.

Education and communication of information are therefore crucial, especially in esoteric policy fields like rDNA. By reaching out to the public through communication

of its recommendations and activities, a Forum could reinstate trust between scientists, politicians, and lay persons, thereby creating a "science for the people" movement.

Finally then, our task to analyze the policy-making processes in rDNA and to synthesize the key advantages of each policy mode has come to an end. Our recommendation to establish National Science Fora is a first proposal toward a novel management of policy-making processes in esoteric, complex policy areas. Implementation of the proposed National Science Fora for future technologies must show the viability of the proposal.

# *Appendices*

## *Appendix A*

### **Hearings and Bills**

Reprinted from *Recombinant DNA Research Volume 2. Documents Relating to "NIH Guidelines for Research Involving Recombinant DNA Molecules." June 1976- November 1977, 506-07.*

FEDERAL DNA LEGISLATION-95TH CONGRESS, FIRST SESSION

HEARINGS AND MARK UPS

House

Subcommittee on Health and the Environment <sup>1</sup>	3/17/77
" " " " " "	3/18/77
" " " " " "	3/19/77
" " " " " "	5/3/77
" " " " " "	6/7/77
" " " " " "	6/8/77
" " " " " "	6/10/77

Subcommittee on Science, Research, and Technology <sup>2</sup>	3/29/77
" " " " " "	3/30/77
" " " " " "	3/31/77
" " " " " "	4/27/77
" " " " " "	4/28/77
" " " " " "	5/3/77
" " " " " "	5/4/77
" " " " " "	5/5/77
" " " " " "	5/25/77
" " " " " "	5/26/77
" " " " " "	9/7/77
" " " " " "	9/8/77

Committee on Interstate and Foreign Commerce <sup>1</sup>	10/12/77
" " " " " "	10/18/77

Senate

Subcommittee on Health and Scientific Research <sup>3</sup>	4/6/77
Committee on Human Resources <sup>3</sup>	6/16/77
Subcommittee on Science, Technology, and Space <sup>4</sup>	11/2/77
" " " " " "	11/8/77
" " " " " "	11/10/77

1) Chaired by Representative Paul Rogers (D-Fla.), this Subcommittee is part of the Interstate and Foreign Commerce Committee which is chaired by Representative Harley Staggers (D-W. Va.).

2) Chaired by Representative Ray Thornton (D-Ark.), this Subcommittee is part of the Committee on Science and Technology which is chaired by Representative Clin Teague (D-Texas).

3) Chaired by Senator Edward Kennedy, this Subcommittee is part of the Committee on Human Resources which is chaired by Senator Harrison Williams (D-N.J.).

4) Chaired by Senator Adlai Stevenson (D-Ill.), this Subcommittee is part of the Committee on Commerce, Science, and Transportation which is chaired by Senator Warren Magnuson (D-Wash.).

FEDERAL DNA LEGISLATION-95TH CONGRESS, FIRST SESSION

BILLS AND RESOLUTIONS

House

<u>Bill</u>	<u>Chief Sponsor</u>	<u>Date</u>
H. Res. 131	Richard Ottinger (D-N.Y.)	1/19/77
H.R. 3191 (Identical to S. 621)	" " "	2/7/77
H.R. 3591 ( " " " )	" " "	2/16/77
H.R. 3592 ( " " " )	" " "	2/16/77
H.R. 4232	Stephen Solarz (D-N.Y.)	3/1/77
H.R. 4759	Paul Rogers (D-Fla.)	3/9/77
H.R. 4849 (Identical to H.R. 4759)	" " "	3/10/77
H.R. 5020 (Identical to S. 621)	Ottinger	3/14/77
H.R. 6158 (Administration bill)	Rogers	4/6/77
H.R. 7418	"	5/24/77
H.R. 7897	"	6/20/77

Senate

S. 621	Dale Bumpers (D-Ark.)	2/4/77
S. 945	Howard Metzenbaum (D-Ohio)	3/8/77
S. 1217 (Administration bill)	Edward Kennedy (D-Mass.)	4/1/77
S. 1217 (As reported: accompanied by Report 95-359)	" " "	7/22/77
S. 1217 (Amendment 754 in the nature of a substitute)	Gaylord Nelson (D-Wisc.)	8/2/77

## ***Appendix B***

### **Gordon Conference Letter**

Reprinted from *Science* 181 (21 September 1973): 1114



## LETTERS

### **Guidelines for DNA Hybrid Molecules**

Those in attendance at the 1973 Gordon Conference on Nucleic Acids voted to send the following letter to Philip Handler, president of the National Academy of Sciences, and to John R. Hogness, president of the National Institute of Medicine. A majority also desired to publicize the letter more widely.

We are writing to you, on behalf of a number of scientists, to communicate a matter of deep concern. Several of the scientific reports presented at this year's Gordon Research Conference on Nucleic Acids (June 11-15, 1973, New Hampton, New Hampshire) indicated that we presently have the technical ability to join together, covalently, DNA molecules from diverse sources. Scientific developments over the past two years make it both reasonable and convenient to generate overlapping sequence homologies at the termini of different DNA molecules. The sequence homologies can then be used to combine the molecules by Watson-Crick hydrogen bonding. Application of existing methods permits subsequent covalent linkage of such molecules. This technique could be used, for example, to combine DNA from animal viruses with bacterial DNA, or DNA's of different viral origin might be so joined. In this way new kinds of hybrid plasmids or viruses, with biological activity of unpredictable nature, may eventually be created. These experiments offer exciting and interesting potential both for advancing knowledge of fundamental biological processes and for alleviation of human health problems.

Certain such hybrid molecules may prove hazardous to laboratory workers and to the public. Although no hazard has yet been established, prudence suggests that the potential hazard be seriously considered.

A majority of those attending the Conference voted to communicate their concern in this matter to you and to the President of the Institute of Medicine (to whom this letter is also being sent). The conferees suggested that the Academies establish a study committee to consider this problem and to recommend specific actions or guidelines, should that seem appropriate. Related problems such as the risks involved in current large-scale preparation of animal viruses might also be considered.

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## *Appendix C*

### **Berg Letter**

Reprinted from *Science* 185 (26 July 1974): 303

## LETTERS

### Potential Biohazards of Recombinant DNA Molecules

Recent advances in techniques for the isolation and rejoining of segments of DNA now permit construction of biologically active recombinant DNA molecules *in vitro*. For example, DNA restriction endonucleases, which generate DNA fragments containing cohesive ends especially suitable for rejoining, have been used to create new types of biologically functional bacterial plasmids carrying antibiotic resistance markers (1) and to link *Xenopus laevis* ribosomal DNA to DNA from a bacterial plasmid. This latter recombinant plasmid has been shown to replicate stably in *Escherichia coli* where it synthesizes RNA that is complementary to *X. laevis* ribosomal DNA (2). Similarly, segments of *Drosophila* chromosomal DNA have been incorporated into both plasmid and bacteriophage DNA's to yield hybrid molecules that can infect and replicate in *E. coli* (3).

Several groups of scientists are now planning to use this technology to create recombinant DNA's from a variety of other viral, animal, and bacterial sources. Although such experiments are likely to facilitate the solution of important theoretical and practical biological problems, they would also result in the creation of novel types of infectious DNA elements whose biological properties cannot be completely predicted in advance.

There is serious concern that some of these artificial recombinant DNA molecules could prove biologically hazardous. One potential hazard in current experiments derives from the need to use a bacterium like *E. coli* to clone the recombinant DNA molecules and to amplify their number. Strains of *E. coli* commonly reside in the human intestinal tract, and they are capable of exchanging genetic information with other types of bacteria, some of which are pathogenic to man. Thus, new DNA elements introduced into *E. coli* might possibly become widely disseminated among human, bacterial, plant, or animal populations with unpredictable effects.

Concern for these emerging capabilities was raised by scientists attending the 1973 Gordon Research Conference on Nucleic Acids (4), who requested that the National Academy of

Sciences give consideration to these matters. The undersigned members of a committee, acting on behalf of and with the endorsement of the Assembly of Life Sciences of the National Research Council on this matter, propose the following recommendations.

First, and most important, that until the potential hazards of such recombinant DNA molecules have been better evaluated or until adequate methods are developed for preventing their spread, scientists throughout the world join with the members of this committee in voluntarily deferring the following types of experiments.

► *Type 1:* Construction of new, autonomously replicating bacterial plasmids that might result in the introduction of genetic determinants for antibiotic resistance or bacterial toxin formation into bacterial strains that do not at present carry such determinants; or construction of new bacterial plasmids containing combinations of resistance to clinically useful antibiotics unless plasmids containing such combinations of antibiotic resistance determinants already exist in nature.

► *Type 2:* Linkage of all or segments of the DNA's from oncogenic or other animal viruses to autonomously replicating DNA elements such as bacterial plasmids or other viral DNA's. Such recombinant DNA molecules might be more easily disseminated to bacterial populations in humans and other species, and thus possibly increase the incidence of cancer or other diseases.

Second, plans to link fragments of animal DNA's to bacterial plasmid DNA or bacteriophage DNA should be carefully weighed in light of the fact that many types of animal cell DNA's contain sequences common to RNA tumor viruses. Since joining of any foreign DNA to a DNA replication system creates new recombinant DNA molecules whose biological properties cannot be predicted with certainty, such experiments should not be undertaken lightly.

Third, the director of the National Institutes of Health is requested to give immediate consideration to establishing an advisory committee charged with (i) overseeing an experimental program to evaluate the potential biological and ecological hazards of the above types of recombinant DNA molecules; (ii) developing procedures which will

minimize the spread of such molecules within human and other populations; and (iii) devising guidelines to be followed by investigators working with potentially hazardous recombinant DNA molecules.

Fourth, an international meeting of involved scientists from all over the world should be convened early in the coming year to review scientific progress in this area and to further discuss appropriate ways to deal with the potential biohazards of recombinant DNA molecules.

The above recommendations are made with the realization (i) that our concern is based on judgments of potential rather than demonstrated risk since there are few available experimental data on the hazards of such DNA molecules and (ii) that adherence to our major recommendations will entail postponement or possibly abandonment of certain types of scientifically worthwhile experiments. Moreover, we are aware of many theoretical and practical difficulties involved in evaluating the human hazards of such recombinant DNA molecules. Nonetheless, our concern for the possible unfortunate consequences of indiscriminate application of these techniques motivates us to urge all scientists working in this area to join us in agreeing not to initiate experiments of types 1 and 2 above until attempts have been made to evaluate the hazards and some resolution of the outstanding questions has been achieved.

PAUL BERG, *Chairman*  
DAVID BALTIMORE  
HERBERT W. BOYER  
STANLEY N. COHEN  
RONALD W. DAVIS  
DAVID S. HOGNESS  
DANIEL NATHANS  
RICHARD ROBLIN  
JAMES D. WATSON  
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#### References and Notes

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## *Appendix D*

### **Summary Statement of Asilomar II**

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## Summary Statement of the Asilomar Conference on Recombinant DNA Molecules\*

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### I. INTRODUCTION AND GENERAL CONCLUSIONS

This meeting was organized to review scientific progress in research on recombinant DNA molecules and to discuss appropriate ways to deal with the potential biohazards of this work. Impressive scientific achievements have already been made in this field and these techniques have a remarkable potential for furthering our understanding of fundamental biochemical processes in pro- and eukaryotic cells. The use of recombinant DNA methodology promises to revolutionize the practice of molecular biology. Although there has as yet been no practical application of the new techniques, there is every reason to believe that they will have significant practical utility in the future.

Of particular concern to the participants at the meeting was the issue of whether the pause in certain aspects of research in this area, called for by the Committee on Recombinant DNA Molecules of the National Academy of Sciences, U.S.A. in the letter published in July, 1974\*\* should end; and, if so, how the scientific work could be undertaken with minimal risks to workers in laboratories, to the public at large, and to the animal and plant species sharing our ecosystems.

The new techniques, which permit combination of genetic information from very different organisms, place us in an area of biology with many unknowns. Even in the present, more limited conduct of research in this field, the evaluation of potential biohazards has proved to be extremely difficult. It is this ignorance that has compelled us to conclude that it would be wise to exercise considerable caution in performing this research. Nevertheless, the participants at the Conference agreed that most of the work on construction of recombinant DNA molecules should proceed provided that appropriate safeguards, principally biological and physical barriers ade-

quate to contain the newly created organisms, are employed. Moreover, the standards of protection should be greater at the beginning and modified as improvements in the methodology occur and assessments of the risks change. Furthermore, it was agreed that there are certain experiments in which the potential risks are of such a serious nature that they ought not to be done with presently available containment facilities. In the longer term, serious problems may arise in the large scale application of this methodology in industry, medicine, and agriculture. But it was also recognized that future research and experience may show that many of the potential biohazards are less serious and/or less probable than we now suspect.

### II. PRINCIPLES GUIDING THE RECOMMENDATIONS AND CONCLUSIONS

Although our assessments of the risks involved with each of the various lines of research on recombinant DNA molecules may differ, few, if any, believe that this methodology is free from any risk. Reasonable principles for dealing with these potential risks are: (i) that containment be made an essential consideration in the experimental design and, (ii) that the effectiveness of the containment should match, as closely as possible, the estimated risk. Consequently, whatever scale of risks is agreed upon, there should be a commensurate scale of containment. Estimating the risks will be difficult and intuitive at first but this will improve as we acquire additional knowledge; at each stage we shall have to match the potential risk with an appropriate level of containment. Experiments requiring large scale operations would seem to be riskier than equivalent experiments done on a small scale and, therefore, require more stringent containment procedures. The use of cloning vehicles or vectors (plasmids, phages) and bacterial hosts with a restricted capacity to multiply outside of the laboratory would reduce the potential biohazard of a particular experiment. Thus, the ways in which potential biohazards and different levels of containment are matched may vary from time to time, particularly as the containment technology is improved. The means for assessing and balancing risks with appropriate levels of containment will need to be reexamined from time to time. Hopefully, through both formal and informal channels of information within and between the nations of the world, the way in which potential biohazards and levels of containment are matched would be consistent.

\* Summary statement of the report submitted to the Assembly of Life Sciences of the National Academy of Sciences and approved by its Executive Committee on 20 May 1975.

Requests for reprints should be addressed to: Division of Medical Sciences, Assembly of Life Sciences, National Academy of Sciences, 2101 Constitution Avenue, N.W., Washington, D.C. 20418.

\*\* Report of Committee on Recombinant DNA Molecules: "Potential Biohazards of Recombinant DNA Molecules," *Proc. Nat. Acad. Sci. USA* 71, 2593-2594, 1974.

Containment of potentially biohazardous agents can be achieved in several ways. The most significant contribution to limiting the spread of the recombinant DNAs is the use of biological barriers. These barriers are of two types: (i) fastidious bacterial hosts unable to survive in natural environments, and (ii) nontransmissible and equally fastidious vectors (plasmids, bacteriophages, or other viruses) able to grow only in specified hosts. Physical containment, exemplified by the use of suitable hoods, or where applicable, limited access or negative pressure laboratories, provides an additional factor of safety. Particularly important is strict adherence to good microbiological practices which, to a large measure can limit the escape of organisms from the experimental situation, and thereby increase the safety of the operation. Consequently, education and training of all personnel involved in the experiments is essential to the effectiveness of all containment measures. In practice, these different means of containment will complement one another and documented substantial improvements in the ability to restrict the growth of bacterial hosts and vectors could permit modifications of the complementary physical containment requirements.

Stringent physical containment and rigorous laboratory procedures can reduce but not eliminate the possibility of spreading potentially hazardous agents. Therefore, investigators relying upon "disarmed" hosts and vectors for additional safety must rigorously test the effectiveness of these agents before accepting their validity as biological barriers.

### III. RECOMMENDATIONS FOR MATCHING TYPES OF CONTAINMENT WITH TYPES OF EXPERIMENTS

No classification of experiments as to risk and no set of containment procedures can anticipate all situations. Given our present uncertainties about the hazards, the parameters proposed here are broadly conceived and meant to provide provisional guidelines for investigators and agencies concerned with research on recombinant DNAs. However, each investigator bears a responsibility for determining whether, in his particular case, special circumstances warrant a higher level of containment than is suggested here.

#### A. Types of containment

1. *Minimal Risk.* This type of containment is intended for experiments in which the biohazards may be accurately assessed and are expected to be minimal. Such containment can be achieved by following the operating procedures recommended for clinical microbiological laboratories. Essential features of such facilities are no drinking, eating, or smoking in the laboratory, wearing laboratory coats in the work area, the use of cotton-plugged pipettes or preferably mechanical pipetting devices, and prompt disinfection of contaminated materials.

2. *Low Risk.* This level of containment is appropriate for experiments which generate novel biotypes but where the available information indicates that the recombinant DNA cannot alter appreciably the ecological behavior of the recipient species, increase significantly its pathogenicity, or prevent effective treatment of any resulting infections. The key features of this containment (in addition to the minimal procedures mentioned above) are a prohibition on mouth pipetting, access limited to laboratory personnel, and the

use of biological safety cabinets for procedures likely to produce aerosols (e.g., blending and sonication). Though existing vectors may be used in conjunction with low risk procedures, safer vectors and hosts should be adopted as they become available.

3. *Moderate Risk.* Such containment facilities are intended for experiments in which there is a probability of generating an agent with a significant potential for pathogenicity or ecological disruption. The principle features of this level of containment, in addition to those of the two preceding classes, are that transfer operations should be carried out in biological safety cabinets (e.g., laminar flow hoods), gloves should be worn during the handling of infectious materials, vacuum lines must be protected by filters, and negative pressure should be maintained in the limited access laboratories. Moreover, experiments posing a moderate risk must be done only with vectors and hosts that have an appreciably impaired capacity to multiply outside of the laboratory.

4. *High Risk.* This level of containment is intended for experiments in which the potential for ecological disruption or pathogenicity of the modified organism could be severe and thereby pose a serious biohazard to laboratory personnel or the public. The main features of this type of facility, which was designed to contain highly infectious microbiological agents, are its isolation from other areas by air locks, a negative pressure environment, a requirement for clothing changes and showers for entering personnel, and laboratories fitted with treatment systems to inactivate or remove biological agents that may be contaminants in exhaust air and liquid and solid wastes. All persons occupying these areas should wear protective laboratory clothing and shower at each exit from the containment facility. The handling of agents should be confined to biological safety cabinets in which the exhaust air is incinerated or passed through Hepa filters. High risk containment includes, in addition to the physical and procedural features described above, the use of rigorously tested vectors and hosts whose growth can be confined to the laboratory.

#### B. Types of experiments

Accurate estimates of the risks associated with different types of experiments are difficult to obtain because of our ignorance of the probability that the anticipated dangers will manifest themselves. Nevertheless, experiments involving the construction and propagation of recombinant DNA molecules using DNAs from (i) prokaryotes, bacteriophages, and other plasmids, (ii) animal viruses, and (iii) eukaryotes have been characterized as minimal, low, moderate, and high risks to guide investigators in their choice of the appropriate containment. These designations should be viewed as interim assignments which will need to be revised upward or downward in the light of future experience.

The recombinant DNA molecules themselves, as distinct from cells carrying them, may be infectious to bacteria or higher organisms. DNA preparations from these experiments, particularly in large quantities, should be chemically inactivated before disposal.

1. *Prokaryotes, Bacteriophages, and Bacterial Plasmids.* Where the construction of recombinant DNA molecules and their propagation involves prokaryotic agents that are known to exchange genetic information naturally, the experiments

can be performed in minimal risk containment facilities. Where such experiments pose a potential hazard, more stringent containment may be warranted.

Experiments involving the creation and propagation of recombinant DNA molecules from DNAs of species that ordinarily do not exchange genetic information, generate novel biotypes. Because such experiments may pose biohazards greater than those associated with the original organisms, they should be performed, at least, in low risk containment facilities. If the experiments involve either pathogenic organisms or genetic determinants that may increase the pathogenicity of the recipient species, or if the transferred DNA can confer upon the recipient organisms new metabolic activities not native to these species and thereby modify its relationship with the environment, then moderate or high risk containment should be used.

Experiments extending the range of resistance of established human pathogens to therapeutically useful antibiotics or disinfectants should be undertaken only under moderate or high risk containment, depending upon the virulence of the organism involved.

2. *Animal Viruses.* Experiments involving linkage of viral genomes or genome segments to prokaryotic vectors and their propagation in prokaryotic cells should be performed only with vector-host systems having demonstrably restricted growth capabilities outside the laboratory and with moderate risk containment facilities. Rigorously purified and characterized segments of non-oncogenic viral genomes or of the demonstrably non-transforming regions of oncogenic viral DNAs can be attached to presently existing vectors and propagated in moderate risk containment facilities; as safer vector-host systems become available such experiments may be performed in low risk facilities.

Experiments designed to introduce or propagate DNA from non-viral or other low risk agents in animal cells should use only low risk animal DNAs as vectors (e.g., viral, mitochondrial) and manipulations should be confined to moderate risk containment facilities.

3. *Eukaryotes.* The risks associated with joining random fragments of eukaryote DNA to prokaryotic DNA vectors and the propagation of these recombinant DNAs in prokaryotic hosts are the most difficult to assess.

*A priori*, the DNA from warm-blooded vertebrates is more likely to contain cryptic viral genomes potentially pathogenic for man than is the DNA from other eukaryotes. Consequently, attempts to clone segments of DNA from such animal and particularly primate genomes should be performed only with vector-host systems having demonstrably restricted growth capabilities outside the laboratory and in a moderate risk containment facility. Until cloned segments of warm-blooded vertebrate DNA are completely characterized, they should continue to be maintained in the most restricted vector-host system in moderate risk containment laboratories; when such cloned segments are characterized, they may be propagated as suggested above for purified segments of virus genomes.

Unless the organism makes a product known to be dangerous (e.g., toxin, virus), recombinant DNAs from cold-blooded vertebrates and all other lower eukaryotes can be constructed and propagated with the safest vector-host system available in low risk containment facilities.

Purified DNA from any source that performs known functions and can be judged to be non-toxic, may be cloned with currently available vectors in low risk containment facilities. (Toxic here includes potentially oncogenic products or substances that might perturb normal metabolism if produced in an animal or plant by a resident microorganism.)

4. *Experiments to be Deferred.* There are feasible experiments which present such serious dangers that their performance should not be undertaken at this time with the currently available vector-host systems and the presently available containment capability. These include the cloning of recombinant DNAs derived from highly pathogenic organisms (i.e., Class III, IV, and V etiologic agents as classified by the United States Department of Health, Education and Welfare), DNA containing toxin genes, and large scale experiments (more than 10 liters of culture) using recombinant DNAs that are able to make products potentially harmful to man, animals, or plants.

#### IV. IMPLEMENTATION

In many countries steps are already being taken by national bodies to formulate codes of practice for the conduct of experiments with known or potential biohazard.††,‡‡ Until these are established, we urge individual scientists to use the proposals in this document as a guide. In addition, there are some recommendations which could be immediately and directly implemented by the scientific community.

##### A. Development of safer vectors and hosts

An important and encouraging accomplishment of the meeting was the realization that special bacteria and vectors which have a restricted capacity to multiply outside the laboratory can be constructed genetically, and that the use of these organisms could enhance the safety of recombinant DNA experiments by many orders of magnitude. Experiments along these lines are presently in progress and in the near future, variants of  $\lambda$  bacteriophage, non-transmissible plasmids, and special strains of *Escherichia coli* will become available. All of these vectors could reduce the potential biohazards by very large factors and improve the methodology as well. Other vector-host systems, particularly modified strains of *Bacillus subtilis* and their relevant bacteriophages and plasmids, may also be useful for particular purposes. Quite possibly safe and suitable vectors may be found for eukaryotic hosts such as yeast and readily cultured plant and animal cells. There is likely to be a continuous development in this area and the participants at the meeting agreed that improved vector-host systems which reduce the biohazards of recombinant DNA research will be made freely available to all interested investigators.

##### B. Laboratory procedures

It is the clear responsibility of the principal investigator to inform the staff of the laboratory of the potential hazards of

†† Advisory Board for the Research Councils, "Report of the Working Party on the Experimental Manipulation of the Genetic Composition of Micro-Organisms. Presented to Parliament by the Secretary of State for Education and Science by Command of Her Majesty, January 1975." London: Her Majesty's Stationery Office, 1975, 23pp.

‡‡ National Institutes of Health Recombinant DNA Molecule Program Advisory Committee.

such experiments before they are initiated. Free and open discussion is necessary so that each individual participating in the experiment fully understands the nature of the experiment and any risk that might be involved. All workers must be properly trained in the containment procedures that are designed to control the hazard, including emergency actions in the event of a hazard. It is also recommended that appropriate health surveillance of all personnel, including serological monitoring, be conducted periodically.

#### C. Education and reassessment

Research in this area will develop very quickly and the methods will be applied to many different biological problems. At any given time it is impossible to foresee the entire range of all potential experiments and make judgments on them. Therefore, it is essential to undertake a continuing reassessment of the problems in the light of new scientific knowledge. This could be achieved by a series of annual workshops and meetings, some of which should be at the international level. There should also be courses to train individuals in the relevant methods since it is likely that the work will be taken up by laboratories which may not have had extensive experience in this area. High priority should also be given to research that could improve and evaluate the containment effectiveness of new and existing vector-host systems.

#### V. NEW KNOWLEDGE

This document represents our first assessment of the potential biohazards in the light of current knowledge. However, little is known about the survival of laboratory strains of bacteria and bacteriophages in different ecological niches in the outside

world. Even less is known about whether recombinant DNA molecules will enhance or depress the survival of their vectors and hosts in nature. These questions are fundamental to the testing of any new organism that may be constructed. Research in this area needs to be undertaken and should be given high priority. In general, however, molecular biologists who may construct DNA recombinant molecules do not undertake these experiments and it will be necessary to facilitate collaborative research between them and groups skilled in the study of bacterial infection or ecological microbiology. Work should also be undertaken which would enable us to monitor the escape or dissemination of cloning vehicles and their hosts.

Nothing is known about the potential infectivity in higher organisms of phages or bacteria containing segments of eukaryotic DNA and very little about the infectivity of the DNA molecules themselves. Genetic transformation of bacteria does occur in animals, suggesting that recombinant DNA molecules can retain their biological potency in this environment. There are many questions in this area, the answers to which are essential for our assessment of the biohazards of experiments with recombinant DNA molecules. It will be necessary to ensure that this work will be planned and carried out; and it will be particularly important to have this information before large scale applications of the use of recombinant DNA molecules is attempted.

The work of the committee was assisted by the National Academy of Sciences-National Research Council Staff: Artemis P. Simopoulos (Executive Secretary) and Elena O. Nightingale (Resident Fellow), Division of Medical Sciences, Assembly of Life Sciences, and supported by the National Institutes of Health (Contract NO1-OD-5-2103) and the National Science Foundation (Grant GBMS75-05293).



## *Appendix E*

### **Members of the Original RAC-NIH**

Reprinted from *Recombinant DNA Research Volume 1. Documents Relating to "NIH Guidelines for Research Involving Recombinant DNA Molecules." February 1975- June 1976, 69-70.*

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Born from Chinese ancestors in Jakarta, Indonesia, Hong Lim finished her high school at her hometown. During her senior year at high school she was a junior journalist for the youth section of *Pos Indonesia*, a daily newspaper.

She continued her studies at the *Vrije Universiteit* in Amsterdam, the Netherlands, where she earned her Bachelor of Science degree in Chemistry with honors and her Master of Science degree in Biochemistry. She has also been awarded a teaching qualification by the same university.

As a student in Amsterdam she worked part-time as a desk editor in the science department of Elsevier North-Holland Publishing Company. After finishing her Biochemistry studies, she taught Chemistry at the Reformed Grammar School in Amsterdam. Thereafter, she worked at the Netherlands Technology Foundation as a program officer. The Foundation awarded her a fellowship to continue her studies in the United States.

Her second Master's degree was in Science and Technology Studies from *Virginia Polytechnic Institute & State University* in Blacksburg, Virginia. She continued her studies at the *Center for Public Administration and Policy* of the same university where she earned her Doctor of Philosophy degree in Public Administration.

Ouelly