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RECOMBINANT DNA AND THE REGULATION OF BIOTECHNOLOGY: REFLECTIONS ON THE ASILOMAR CONFERENCE, TEN YEARS AFTER

by

JOHN E. BARKSTROM

The year 1985 marks the tenth anniversary of the International Conference on Recombinant DNA Molecules held at the Asilomar Conference Center, Pacific Grove, California in late February, 1975. The entire field of genetic engineering technology or “gene splicing” is not much older than the Conference itself. Many articles and much discussion have been occasioned by the recombinant DNA debate, including legal symposia held by the Universities of Southern California and Toledo. This article looks back at the events which led to Asilomar, the debate which followed, and some of the legal and ethical problems involved in the debate.

What is known today as genetic engineering really has no beginning apart from previous biomedical research. However, if it were possible to pinpoint the events which mark the birth of the technology, they would probably be certain experiments carried on at Stanford University in the early 1970s. Researchers in the departments of biochemistry and medicine were pursuing separate avenues of research, yet these avenues would soon converge to produce a new technology. The biochemistry department, focusing on an animal virus, somehow stumbled on a method of slicing DNA so cleanly that it could re-form at the cut and go on to infect cells. The medical department, focusing on bacteria rather than viruses, developed a method of constructing a tiny molecular messenger, capable not only of carrying a foreign “blueprint” into a bacterial cell, but also of getting the bacteria to “read” and copy the tiny message.

Modern genetic engineering or gene splicing is full of unique terms. Replicons, hosts, vectors, restriction enzymes, and plasmids are a few such terms. However, in order to understand what went on at Stanford, only a few very simple concepts need to be understood. In fact, only one concept is really needed, the concept of how a bacterial “factory” turns itself on and off. Whether a cell is dividing or producing a needed protein, there are on-switches called “promotors” or “initiators” which start the process, and off-switches called “terminators” which stop the process.

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2The biochemistry of a cell is quite complex. However, in terms of labeling the major processes or cycles of a cell, three parallel but separate terminologies are applied to the start-stop mechanisms. The three cellular functions can be separated into: 1) cell division, 2) messenger RNA template formation, or the duplication of DNA by RNA (transcription), and 3) the ribosomal synthesis of protein utilizing messenger RNA (translation).
DNA forms the master blueprint of a cell. In order to facilitate production of needed products, the cell makes templates of messenger RNA, (i.e., RNA copies or duplicates of the DNA original). The messenger RNA is sent out into the cell where ribosomes will attach to it. The messenger RNA is similar to a railroad track. As a ribosome moves down this RNA track, it attracts and connects molecules until it has constructed the trailing chain of molecules into a protein. An “initiator sequence” tells the ribosome where the RNA track begins and a “terminator” tells it where it ends.

Logic would suggest that the only on-off switches recognized by the various parts or systems of a bacterium should be those of the bacterium. However, this is not the case. Nature has provided some near-perfect impostors. Bacterial viruses, bacteriophages, contain molecular sites recognized by bacterial components as valid promoter and initiator sequences. Thus, when a bacteriophage injects its DNA (or RNA) into a bacterium, it can quickly cause the bacterium to not only duplicate the viral DNA, but also to produce viral enzymes which will stop bacterial metabolism. So perfect are the viral sites that bacteria produce new phage organisms until they fill up the bacterial cell and burst or lyse the cell wall. As many as 20,000 phage per bacterium can be produced before lysis.

Another impostor is not as lethal as the bacteriophage. Small DNA plasmids can fool bacteria with their on-off systems. Plasmids, many times smaller than bacteria, are DNA ‘particles’ which reside inside bacterial cells. Carrying only a few genes (or DNA sequences representing proteins), plasmids nevertheless contain complete start-stop systems which can be utilized to control sophisticated chemical pathways. For example, once inside a cell, a single plasmid can induce chemical changes to keep other plasmids of a similar group

1) Cell division
When a cell divides, the two DNA strands must separate and construct new strands of DNA, i.e., the DNA chain must replicate itself before cell division takes place. The total unit or segment of DNA replication is called a “replicon.” The starting point of replication is called the “origin of replication” and DNA replication ends at the “terminus.”

2) Transcription
When DNA in a cell “transcribes” its message unto a messenger RNA “template,” i.e., creates an RNA duplicate of itself, the beginning and end points form a “transcription unit.” The start-switch, or beginning point for the transcription unit is known as a “promoter” which itself contains an initial “startside” or “start-point.” The end-point is known as a “terminator.”

3) Translation
The ribosomal “translation” of the messenger RNA template begins when ribosomes recognize an “initiation sequence” and ends when the ribosomes encounter the “terminator.” “Elongation,” the synthesis of a protein chain by the ribosome, is a definitional description of what happens between the “initiator” and the “terminator” sites.

See B. Lewin, Genes. (1983). For DNA replication and the terms “replicon,” “origin of replication” and “terminus,” see Id. at 503 and the Chapter 31 discussion following.

For RNA template formation during transcription and the terms “template,” “transcription unit,” “promoter,” “startpoint,” and “terminator,” see Id. at 76, 165-66, and 174.

For ribosomal translation and the terms “initiation sequence,” “elongation,” and “terminator,” see Id. at 87-102 and 143-62.

See C.K. Mathews, Bacteriophage Biochemistry. 52-66, 100-187 (1971). For RNA phages see Id. at 288-310.
from entering the cell. Plasmids have also been responsible for conferring resistance to antibiotics on bacteria.4

Plasmids and bacteriophages have, for millions of years, been performing remarkable feats of genetic engineering on bacterial cells. They provide the natural models on which modern genetic engineering is patterned. They have, in fact, been more than models, for by incorporating segments of DNA into a plasmid or phage itself, the natural control systems can be used directly to control the bacterial system.

Foreign DNA can be inserted into a bacterial cell. However, without a promoter or initiator sequence familiar to the cell, the DNA is essentially ignored and usually diluted out as the cell divides.5 In 1971, researchers at Stanford were researching the promoter/initiator sequence, when they developed the idea of using a bacteriophage to carry a monkey virus known as simian virus 40 or SV40 into an intestinal bacteria known as Escherechia Coli (E. Coli). Unfortunately, the researchers had no idea what might result from the experiment. The idea was mentioned to a cancer researcher, Robert Pollack, at a summer workshop. Although Pollack did not know whether the experiment would be successful, he did know SV40 could transform human cells in tissue cultures into something that resembled tumor cells. Alarmed that the experiment might prove too successful, resulting in a new and continuing source of virus, Pollack called the head of the Stanford research team, Paul Berg. Berg, after some discussion and thought, decided that the experiment might indeed prove dangerous and temporarily shelved it.6 But, Berg and his team of researchers had other work which would eventually prove as revolutionary in practice as the SV40 experiment appeared in theory.

In order to produce a product such as insulin by using gene splicing techniques, it is necessary to isolate those genes essential for insulin production. It is important, therefore, to have a tool which can cut DNA in a very precise and predictable manner. What is needed is a molecular scalpel. It was Berg’s team of researchers which uncovered the clues leading to the discovery of one such molecular scalpel. While Berg had deferred the SV40 experiment, Berg’s lab continued to work with other aspects of SV40 research. In 1972, a biochemist, Herbert Boyer, provided the Stanford lab with a bacterial enzyme named Eco R1. It was a form of enzyme called a “restriction enzyme.”7

To understand the significance of Eco R1, portions of the story of research into the bacterial viruses known as bacteriophages mentioned above are

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*ROGERS, BIOHAZARD, 40-41 (1977); LEWIN, supra note 2, at 224. For plasmid incompatibility see Id. at 518-20. For antibiotic resistance see Id. at 301-02.


*ROGERS, supra note 4, at 35-38.

7Id. at 39.
helpful. Most individuals are familiar with Alexander Fleming's discovery of penicillin in 1928. Fleming noticed a mold had contaminated a bacterial culture dish and had cleared a circular path free of bacteria in the immediate vicinity of the mold.

The discovery of the bacteriophage in 1915 was a similar story. An English researcher, F.W. Twort, discovered that a bacterial culture had been infected by something which killed the bacteria and turned the culture dish from creamy white to near transparent. The “something” proved as effective at infecting other cultures as it was lethal. Two years later, a French researcher, observing similar results, named the “something” bacteriophage — “eaters of bacteria.” Unlike penicillin, bacteriophage or simply “phage,” did not work well against bacteria inside the human body, and therefore research along such lines was eventually abandoned. Research on the bacteriophage, however, continued. 8

Eco R₁, the restriction enzyme which Herbert Boyer brought to the Stanford labs, was the result of work in the field of phage research. It was a bacterial enzyme, part of a bacterial defense mechanism utilized by bacteria to defend against phage infection or attack. In 1952, it had been reported that certain phage strains had trouble killing bacteria. This phenomenon was called “host-induced modification.” Host-induced modification resulted when the intended bacterial host released chemicals which could repel a phage attack. Because the system restricted phage growth, this was also referred to as a “restriction system.” 9 Out of an E. Coli restriction system, Boyer had isolated the Eco R₁ restriction enzyme.

Restriction enzymes are an interesting set of chemicals. Although bacteria are single-celled organisms, a bacterial restriction system parallels the human body’s immune system in its ability to recognize and degrade foreign DNA. The 1952 results merely hinted at the diversity of systems and of the enzymes which compose these systems. Restriction enzymes do not react chemically in the same way against foreign DNA. Some enzymes will attack and cut both strands of the DNA double helix, others will cut one strand. Other enzymes can travel along a DNA strand and cleave DNA at the specific sites of a recognized chemical bond. Still other enzymes are not site-specific, but will travel a measured distance along the DNA and cleave whatever is positioned at that site. 10

Eco R₁ exhibited several similar properties. It was a site-specific enzyme. Another important trait was discovered when it was mixed with the SV40 virus in various 1973 experiments. It could cleave the SV40 DNA, but the

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1Id. at 24-25.
2MATTHEWS, supra note 3, at 124.
3OLD, supra note 5, at 12-14.

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cleavage site consisted of "sticky ends," or single strands of the DNA which protruded or overlapped at the cleavage site. These "sticky ends" displayed a strong molecular attraction for other such molecules coming in close proximity to the sticky ends. To the surprise of the Stanford observers, even after SV40 had been cleaved by Eco R1, it could recircularize or reform at the cleaved site in a circular manner, and begin infecting cells as if nothing had happened.11

The implications were astonishing. Since DNA strands are composed of essentially only four types of molecules, an Eco R1 enzyme could recognize and cleave bonding sites on two entirely different DNA strands, which could be combined utilizing the sticky ends at the cleavage sites.

Thus, the biochemistry department's contribution to genetic engineering was the department's experimental observations of Eco R1's cleavage of SV40. The other contribution came from Stanford's medical department. A researcher, Stanley Cohen, was studying plasmids. Plasmids are tiny particles of DNA capable of directing the cellular activity of bacteria, in much the same manner as bacterial viruses can direct such activity. Where Berg's group had supplied the scalpel, Cohen's team provided the crucial on-off switch.

Cohen suspected that a plasmid could be used to carry foreign DNA into bacteria. If a small DNA strand could be incorporated or "sewn" into a plasmid's DNA, a bacterium might "read" the piggyback fragment as a valid command of the plasmid itself. This theory proved correct. Incorporating DNA from an African frog species into plasmid pSC101, Cohen, John Morrow, and Eco R1 researcher Herbert Boyer observed that once inside an E. Coli cell, the frog DNA was replicated by the host E. Coli cell. The plasmid on-off switch actually worked.12 The researchers were both ecstatic and alarmed. They were alarmed not because it had been done, but because it had been done with relative ease.

In June 1973, participants at the Gordon Conference on Nucleic Acids, in New Hampshire, heard Herbert Boyer present the paper detailing the frog-plasmid combination experiment. One participant commented after Boyer's presentation: "Now we can put together any DNAs we want to."13 The remark is said to have prompted the co-chairs of the conference, Maxine Singer of the National Institutes of Health and Dieter Soll of Yale, to ask for a vote on the safety of recombinant DNA work. Of the ninety-odd participants, seventy-eight voted to send a letter of concern to the National Academy of Sciences. A second vote decided on the publication of the letter.14 The Asilomar Conference became almost a foregone conclusion.

11ROGERS, supra note 4, at 39.
13ROGERS, supra note 4, at 42.
14Id. at 42.
The "Singer-Soll" letter requested that the National Academy of Sciences and the National Institute of Medicine appoint a committee to study the hazards of recombinant DNA and to recommend specific action or guidelines on its use. Since Paul Berg had been instrumental in the development of the technology, had been involved in attempts to determine the ethical and safety aspects, and was among the most knowledgeable in the field, he was requested to advise the National Academy. Since his work had contributed to getting the Academy into its unexpected predicament, perhaps his expertise could help get it out.

Berg sought the advice of James Watson, the co-discoverer of the structure of DNA. At an informal meeting in late 1973, both agreed that a larger group discussion would be helpful. In April 1974, that group, consisting of only ten researchers, decided that still another, larger meeting was necessary. This meeting was tentatively set for February of 1975. However, more than simply another round of meetings grew out of the discussion. Almost abruptly, the group reached a consensus that many experiments might well be dangerous and should be stopped. A decision was made to request, and even to demand that certain experiments not be done, and that a temporary moratorium be instituted on further research. Calling themselves "The Committee on Recombinant DNA Molecules, Assembly of Life Sciences," the group's members drafted a letter to Science magazine, setting forth their decision and the reasons for it. On July 18, 1974, a few days before the letter's publication, Paul Berg, David Baltimore, and Richard Roblin held a press conference to announce the moratorium and explain this letter. The letter not only publicized the moratorium, but also announced the February 1975 meeting to be held at Asilomar.

Despite the initial fears raised by the specter of recombinant DNA work, the final Asilomar invitation list numbered only 155; 83 U.S. participants from research, government and industry, 51 participants from foreign countries, and 21 news media and lay people. The proceedings themselves were not unusual, considering the egos that are involved in any gathering of the top minds in a field. Collateral issues often derailed discussion, each new working group report produced heated argument, and debate covered everything from the range of risk to the arrangement of sentences. Nevertheless, between the Monday morning opening and the Thursday afternoon close, the participants succeeded in reaching agreement on a draft of the "Statement of the Con-
ference Proceedings” (Statement). While the Statement expressed caution and provided some guidance for research, its central message was that the moratorium could be lifted for all but the most dangerous experiments. Therefore, work on recombinant DNA molecules could proceed with “appropriate safeguards.”

Formalizing the results of Asilomar into actual guidelines for research was left to a committee of the National Institutes of Health, which began its task the day after the close of the Asilomar Conference. To the extent that there would be any formal government involvement in the control of recombinant DNA work, it would come in the form of the NIH Guidelines which were finally released in the summer of 1976.

THE LEGAL FRAMEWORK

In 1977, sixteen bills were introduced in Congress specifically aimed at controlling recombinant DNA research, yet none passed. Only seven or eight such bills were introduced in the 1978-79 session of Congress. By 1980 this number was reduced to one. The NIH Guidelines are virtually the only form of government control for recombinant DNA research and even that control focuses primarily on contracts involving government funding for research procured through the NIH.

This article will not discuss at great length the history of legislative or regulatory control of recombinant DNA research. First, the subject has been amply covered by past articles. Second, any discussion of legislation is largely academic. Except for the now almost monthly press announcements of a newly synthesized hormone or drug, most research goes largely unnoticed. A combination of factors was probably responsible for the demise of legislative activity. The research is still viewed very favorably as a significant factor in the ultimate conquest of disease, especially of cancer, and it takes a great deal of effort fueled by public outcry to push legislation through Congress. Furthermore, since no catastrophies have occurred, the consensus in the scientific community is that it is safe.

As previously observed, the worldwide framework of control needed to prevent such research is simply impractical. The research is neither com-
plicated nor expensive, nor does it require elaborate laboratory equipment. Because the techniques are so simple, it would be difficult to prevent even if there was sufficient pressure for legislation, and, internationally, the consensus is to push ahead as fast as possible.25

Because NIH Guidelines provide a basic background, and because a good portion of proposed legislation incorporated the Guidelines, the history of legislation given here begins with the NIH Guidelines. The state laws and local ordinances which have been enacted are discussed, not for their individual significance, but for an understanding of Congressional efforts to pass “umbrella” legislation. Finally, because of the resulting products or waste-by-products involved, a brief overview or list of statutes which affect engineering work is provided.

THE NIH GUIDELINES

The day after Asilomar, on February 28, 1975, when the NIH Advisory Committee met to draft guidelines, it may or may not have sensed the coming storm. Most of the biomedical research community was basking in the triumphant afterglow of the meeting. The Committee would probably later attest it was “baking” in the intense “after coals.” Initially this committee voted to adopt the Asilomar guidelines until more extensive study could be conducted.

When the Committee drafted proposed guidelines, controversy stirred appreciably. Meeting at Woods Hole, Massachusetts in July of 1975, the Committee essentially overrode a draft prepared by a subcommittee and, it was charged, considerably weakened some recommended safety measures.26 Led by Harvard Medical School’s Richard Goldstein, forty-eight biologists petitioned the NIH, complaining that the Committee’s draft lowered “substantially” the safety standards deemed necessary by the scientific community.27

Extremely sensitive to the criticism, the Committee reviewed drafts of three proposed guidelines, and from these developed a final proposed set of guidelines. Finally, after public meetings and hearings, the formalized Guidelines were issued on June 23, 1976.28 The Guidelines were a compromise between the twin goals of promoting hoped-for research results and eliminating potential hazards. As the Director of the NIH stated: “[O]ur problem then has been to construct guidelines that allow the promise of the methodology to be realized while advocating the considerable caution that is demanded by what we and others view as potential hazards.”29

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27Wade, Recombinant DNA: NIH Group Stirs Storm by Drafting Laxer Rules, 190 SCL. 767-68 (1975).
29Id. at 27,911.
The Guidelines as formulated in 1976 can be divided into two areas, 1) administrative and 2) technical or technological. The administrative can be described as chain-of-command or committee-upon-committee. Each school or other NIH-funded institution was responsible for the work of a “principal investigator,” whose duties included evaluation of potential hazards, the choosing of appropriate lab procedures, and the application for NIH approval. An institution had to have a policy-setting and reviewing Institutional Biohazards Committee (IBC). Also, the NIH had Initial Review Groups (Study Sections) which reported ultimately to the NIH Recombinant DNA Molecule Program Advisory Committee (RAC). Ultimately, the NIH could decide whether an experiment would proceed or not.30

On the technological side, the Guidelines required essentially that “something” couldn’t escape from the lab, but if it did, that it couldn’t live for long. The Guidelines set up a dual system of controls. First, physical containment or barriers would prevent the escape of microorganisms from the lab. Second, biological controls would ensure the death of any organism which escaped. There were four physical levels, from P1, for experiments deemed of “minimal” risk, to P4, for experiments designated “high” risk.31 The second system of controls, biological, was divided into three levels, EK1, EK2, and EK3. These three “host-vector systems” consisted of a “host,” the cell in which inserted DNA would be “grown” or would replicate, and a “vector,” the DNA carrier which could both carry DNA into a host cell and also switch on the host cell’s replication mechanism. Initially, a plasmid or a bacteriophage was the usual vector. In the “host-vector” system the intent was that it would “self-destruct.” But, the E-K designation was somewhat inexact. An EK1 label applied to then “presently available systems,” while EK3 was simply an EK2 system which had been “validated” by independent experiments in animals. Since EK3 was to be the highest level of containment, no system could attain that designation without NIH certification.32

The 1976 Guidelines took several pages to simply list the P and E-K systems which were to be used in different types of experiments. Birds, for example, required a P3 physical containment level in combination with an EK2 host-vector system.33 In some ways the 1976 Guidelines provide an historical perspective and insight on the then current scientific assessment of the hazards of DNA research. By June of 1983, when a subsequent set of new NIH Guidelines were promulgated, the most dangerous experiments had to have specific approval of the various advisory committees.34 However, in 1976 such experiments had been absolutely forbidden. This class of experiments included

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*Id. at 27,920-27.
*Id. at 27,912-13.
*Id. at 27,915-17.
*Id. at 27,917-20.

toxins such as botulism and diphtheria or insect and snake venoms.\textsuperscript{35}

It is the precautions for high risk, as assessed and contained in the 1976 Guidelines, which provide the imagination with the most interesting scenarios. At the high risk P-4 level, a facility was to be engineered with "monolithic walls," air locks, double-door autoclaves for the sterilization and removal of waste, a separate negative pressure (inward) ventilation system, and Class III Biological Safety Cabinets (enclosed cabinets with arm-length rubber gloves).\textsuperscript{36}

From a technical standpoint the NIH Guidelines represented a "best-guess" assessment of what experiments were dangerous and of what optimum physical and biological means were available to control or eliminate the dangers. From a legal standpoint, however, the Guidelines were quite weak, not even achieving the status of a regulation. It was generally felt that the only legal basis for enforcement arose from contract law.\textsuperscript{37} Institutions which received funds from the NIH could lose such funds for violation of the Guidelines.\textsuperscript{38} To provide a stronger contractual basis for the revocation of funds, the NIH initially required a "Memorandum of Understanding and Agreement" to be signed by an institution indicating that it would abide by the Guidelines.\textsuperscript{39}

With contract law providing the means of enforcing compliance, there was a rather large loophole in enforcing the Guidelines. Individuals or organizations not dependent on the NIH for funding were not required to comply with the Guidelines.\textsuperscript{40} From a comprehensive standpoint, the legal basis for the Guidelines left many questions unanswered. In an attempt to remedy the situation, legislative bodies at the local, state, and federal levels became involved.

**LOCAL AND STATE LAW**

Recombinant DNA research provoked some very hot debate, particularly in communities where large universities were set to begin work in the field. Except for a brief mention of some highlights of local ordinances, the purpose of bringing local laws into this discussion is primarily for background to Congressional debate.

The city which spearheaded an intense though chaotic effort to halt DNA research was Cambridge, Massachusetts. A June 8, 1976, article on "Biohazard at Harvard," appeared in the Boston Phoenix. A few weeks later

\textsuperscript{31}Id. at 27,914-15. \textit{See also} 45 Fed. Reg. 27384 (1980).

\textsuperscript{32}41 Fed. Reg. 27,913-27.

\textsuperscript{33}\textit{See} Korwek, \textit{The NIH Guidelines for Recombinant DNA Research and the Authority of FDA to Require Compliance With the Guidelines} 35 \textsc{Food Drug Cosm. L.J.} 633, 636 (1980).

\textsuperscript{34}Cavalieri, \textit{Science as Technology}, 51 S. Cal. L. Rev. 1153, 1159 (1978) (such funding was $2.5 billion in 1977).

\textsuperscript{35}41 Fed. Reg. 27,921. The "Memorandum" was eliminated by the November 1980 amendments to the Guidelines.

THE REGULATION OF BIOTECHNOLOGY

the Cambridge city council began holding public hearings, the first of which culminated in a resolution by Mayor Alfred Vellucci to ban all recombinant DNA research in Cambridge for two years. At a subsequent meeting the city council voted down a two-year ban, but opted for a three-month moratorium. Undaunted, Mayor Vellucci, at a meeting of the United States Conference of Mayors, offered a different resolution prohibiting such research in any city until a public hearing could be held.

In terms of public debate, other communities followed the lead of Cambridge. The cities of Ann Arbor, Michigan; Shrewsbury, Massachusetts; Princeton, New Jersey; Madison, Wisconsin; Bloomington, Indiana; and San Diego, California were drawn into the controversy. Some cities only debated. In others the debates resulted in legislation. The states of New York and Maryland also enacted legislation.

Whether a city council has the legal authority to regulate university research is open to debate. Congress's concern over its preemptive powers, in opposition to the application of widely varying local ordinances and state statutes, became a key question in the Congressional debate.

FEDERAL LEGISLATION

If the Asilomar Conference is any indication, it could be said that the biomedical research community is concerned about the prospect of federal involvement in research. By requiring substantial time and effort to obtain a NIH grant, the research community was hopeful that its efforts at self-regulation would stop or at least slow any new federal regulations.

Countless bills are introduced in Congress every year. However, many are permanently lost in committee. For a bill to get serious consideration, Representatives or Senators must perceive a strong public interest in a particular piece of legislation. By raising the issue of safety, calling for a moratorium, and holding a meeting at Asilomar, scientists should have expected the introduction of at least one bill in Congress, simply because legislators respond to media coverage, the media is perceived as a shaper of public opinion and a barometer of its strength.

Writing legislation is an intense process which does not happen simply because public pressure is increasing. If an existing law will suffice, Congress can shift the focus of public pressure to enforcement agencies. When possible

4Gottleib, Biohazards at Harvard, Boston Phoenix, June 8, 1976, at 9, col. 1.
4ROGERS, supra note 4, at 191-92.
laws were scrutinized in 1977, they were not encouraging to Congress. A committee composed of eighteen federal agencies, which looked into the applicability of existing laws to rDNA work, concluded that none of the existing statutes completely answered the specific problems posed by recombinant DNA research. Certain aspects of research did fall within the preview of existing statutes, but if challenged in court, agencies promulgating regulations based on a broad interpretation of other statutes would have difficulty defending such regulations. The committee looked primarily at the Toxic Substances Control Act, the Hazardous Materials Transportation Act, the Occupational Safety and Health Act of 1970, and Section 361 of the Public Health Service Act. After evaluating these statutes, the committee concluded a new law would be needed to reach all aspects of the new biotechnology.\footnote{Interim Report of the Federal Interagency Committee on Recombinant DNA Research: Suggested Elements for Legislation, 2 (Mar. 15, 1977); Toxic Substances Control Act, 15 U.S.C. §§ 2601-2629 (1983); Hazardous Materials Transportation Act, 49 U.S.C. §§ 1471, 1472, 1655, 1761, 1762, 1801-1812 (1983); Occupational Safety and Health Act of 1970, 29 U.S.C. §§ 651-78 (1985); Public Health Service Act, 42 U.S.C. § 264 (1983).}

As public opposition to research seemingly arose from nowhere in the mid-1970's, scientists must have been a little daunted. Congress looked intent on passing some form of new law. Nevertheless a scientific lobby was formed. Harlyn Halvorson, a Brandeis University microbiologist who led the lobbying effort, decided that the best tactic was not blind opposition to all legislation, but selective support of the bill most favorable to the scientific community.\footnote{Culliton, Recombinant DNA Bills Derailed: Congress Still Trying to Pass a Law, 199 Sci. 274-76 (1978).} The bill chosen was H.R. 7897, introduced by Congressman Paul Rogers in March 1977.\footnote{Swazey, supra note 18 at 1069.}

Rogers' bill placed regulatory authority in the hands of the Secretary of HEW, and required all federal agencies to comply with the NIH Guidelines. Rogers' bill looked inviting when contrasted with the bill introduced by Senator Edward Kennedy. While Rogers' bill allowed for local variation if "special circumstances" or "need" existed, Kennedy's bill did not provide for federal preemption. Local as well as federal control could exist even without special circumstances.\footnote{Culliton, supra note 47, at 274-75.} If localities merely required compliance with the NIH Guidelines, this specter would not have seemed prohibitive. However, the addition of a myriad of local variations would have posed a serious problem. Later in the year Senator Gaylord Nelson introduced a bill providing for federal preemption. The bill, unlike Senator Kennedy's placed overall authority in the hands of HEW. Scientists urged support of Nelson's bill and eventually Kennedy announced he was withdrawing support for his own bill.\footnote{Culliton, supra note 47, at 276-77.}

What may have turned the tide against federal legislation was simply the
passage of time, the accumulation of experimental data, a scientific reassessment of the perceived risks, and a speech by Senator Adlai Stevenson III in September 1977. Stevenson noted new developments indicating the safety of rDNA research, pointed to the inadequacy of legislation hastily enacted, and urged the Senate to delay action until more hearings could be held. It was shortly after this speech that Kennedy announced the withdrawal of support for his own bill. The fight in Congress for a new umbrella law was all but over.

PRESENT FEDERAL REGULATION

When courts have difficulty interpreting a statute, they will often turn to the statute's legislative history for an indication of what the legislature intended. In the case of rDNA, the legislative history shows a clear intent by Congress to not regulate rDNA research as a distinct technology. But the absence of federal umbrella legislation does not provide rDNA work with a form of blanket immunity from federal law. While Congress did not act to control rDNA work, it also did not act to exempt it. No amendments were added to health, safety, or environmental laws to lift regulation simply because of the results that arose from rDNA research.

In general, any law relating to health or the environment will interface with rDNA work at some point. The problem with applying the health and environmental statutes to rDNA technology was that most statutes required some evidence of danger. Without some supporting evidence of a hazard, an administrator would run afoul of the Administrative Procedure Act and Due Process considerations.

Furthermore, language in four of these acts is somewhat vague. The Toxic Substances Control Act provides that the manufacture or use of a substance can be prohibited if there is a "reasonable basis" for concluding that its manufacture or use presents an "unreasonable risk" of injury to health or the environment. The Federal Food, Drug and Cosmetic Act prohibits the adulteration of food and drugs. Adulterated food is defined as containing a poisonous or "deleterious" substance. The FDA can also require compliance with good manufacturing practices (GMP). Again, unless there is some factual basis for charging that rDNA produces a "deleterious" substance or that rDNA manufacturing is not in conformance with good manufacturing practices, the FDA lacks a strong basis for regulation.

In 1978, Senators Edward Kennedy, Jacob Javits, Gaylord Nelson, Adlai Stevenson, Harrison Williams, and Richard Schweiker, in a letter to the Secretary of HEW, Joseph Califano, suggested that regulations governing

34 21 U.S.C. §§ 331, 342, and 351 (1972). See also Korwek, supra note 37, at 640.
rDNA activities be promulgated based on Section 361 of the Public Health Service Act. That section authorizes regulations “necessary to prevent the introduction, transmission, or spread of communicable diseases.” Secretary Califano declined. Subsection (a) of Section 361 limits its application to human beings. Secretary Califano noted that the Federal Interagency Committee on Recombinant DNA Research had reviewed Section 361, and concluded that application of it to rDNA research would rest on the “tenuous” conclusion that products of all rDNA research caused or might cause human disease.\(^{55}\)

Finally, the Federal Insecticide, Fungicide, and Rodenticide Act allows the EPA to refuse registration, a prerequisite to distribution or sale, only if there are “unreasonable adverse effects” on the environment.\(^{56}\) All four of these statutes provide some measure of control, but, absent any evidence of danger inherent in rDNA techniques or technology, the threshold for regulation is relatively high.

Because the ultimate aim of rDNA work is the production of a product, in most cases, the end products will fall within some aspect of regulation. In addition to the four statutes mentioned, other laws may also come into play. The laws include the Hazardous Materials Transportation Act,\(^{57}\) the Occupational Safety and Health Act of 1970,\(^{58}\) the Clean Water Act,\(^{59}\) the Marine Protection Research and Sanctuaries Act of 1972,\(^{60}\) the Resource Conservation and Recovery Act,\(^{61}\) the Safe Drinking Water Act,\(^{62}\) and the Federal Clean Air Act.\(^{63}\) In addition, the Department of Agriculture has jurisdiction through four acts: the Federal Meat Inspection Act,\(^{64}\) the Poultry Products Act,\(^{65}\) the Egg Products Inspection Act,\(^{66}\) and the Virus, Serum and Toxin Act.\(^{67}\)

The act with the most limited usage in terms of language has also had the biggest impact. The National Environmental Policy Act (NEPA),\(^{68}\) which requires only that an Environmental Impact Statement (EIS) be filed for federally funded research, was used successfully to prevent an experiment approved

\(^{59}\)33 U.S.C. § 466-466g (1983).
Two sidelights of these laws deserve passing mention. If any statute had real potential for application to rDNA work from a language standpoint, it would have been the Virus Serum and Toxin Act. Its language was almost tailor-made for rDNA vectors. The Act forbids the preparation or shipment of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product. In the realm of possibility is the idea that a court might agree that the splicing of a new gene into a virus vector constituted "contamination." "Analogous product" could also apply to vectors, since they are virus-like combinations. Unfortunately, the Act is limited in application since it applies only to interstate, not intrastate production and, in addition, is limited to the preparation of animal biologics (i.e. products intended for the treatment of domestic animals).

A second sidelight may be provided by the changes foreseeable in biotechnology. Advances may provide federal agencies with problems relating to the interpretation of statutory language. Federal meat inspection regulations provide for the condemnation of carcasses and edible tissues which have been rendered adulterated by the presence of biological residues. Advancing biotechnology may pose an interesting problem. In a past experiment, growth hormone in experimental mice reached a level eight hundred times greater than normal. Will the genetically designed animal capable of "naturally" or normally producing high levels of a substance be producing a "residue," and will the animal's carcass be considered adulterated in such a case?

TORT LAW

Because there has been no new catastrophe on the order of the "Black Death" as a result of rDNA work, the question of tort liability is largely academic. Were such a catastrophic plague unleashed, the laboratory personnel might find a tort remedy a remote likelihood. An initial legal problem might realistically involve a charge of murder. In terms of liability beyond that, the options would be based on either negligence or strict liability.

The doctrines of negligence and strict liability as applied to rDNA

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75 See RESTATEMENT (SECOND) OF TORTS § 520 (1976) (for a review of the factors considered in a strict liabi-

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technology have been covered by other articles and will not be discussed here. Since, at present they are "future risks," they serve only as a reminder of what may happen should something go wrong in the lab.

**INTENTIONAL RELEASE EXPERIMENTS**

On June 1, 1983, the NIH authorized the release of a form of genetically engineered frost-inhibiting bacteria into a potato field. The bacteria act in such a way as to prevent the formation of ice. A group of environmentalists, led by author Jeremy Rifkin, filed suit for an injunction prohibiting the experiment. Filed on September 14, 1983, in the District of Washington, D.C., the suit charged that the NIH had violated the National Environmental Policy Act of 1969 and the Administrative Procedure Act. The basis of the suit was that the NIH had failed to prepare an Environmental Impact Statement (EIS) and, in addition, had failed to hold hearings prior to approval of the experiment. On May 16, 1984, in a decision which stunned observers, Judge John Sirica granted the injunction.

When the NIH released its initial set of Guidelines in 1976, included in its list of "Forbidden Five" experiments, which were not to be performed at all, was a prohibition against the "deliberate release into the environment of any organism containing a recombinant DNA molecule." The prohibition on such experiments was still in place when a revised set of Guidelines was promulgated in 1978. However, just underneath the list of prohibited experiments was a new proviso: "[e]xperiments in these categories may be excepted from the prohibitions... provided that these experiments are expressly approved by the Director, NIH, with advice of the Recombinant DNA Advisory Committee. . ." Without the one-line addition to the NIH Guidelines, Jeremy Rifkin would have been unable to mount any significant challenge to the authority of the NIH. Key to an understanding of the importance of that wording change is

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*41* Fed. Reg. 27,914-27,915. The five types of experiments absolutely proscribed by the Guidelines were:

i) Cloning of rDNAs derived from certain pathogenic organisms, oncogenic viruses, or cells infected with such agents;

ii) Deliberate formation of rDNAs containing genes for the biosynthesis of potent toxins (the prohibition against botulinum or diphtheria);

iii) Deliberate creation from plant pathogens of rDNAs that were likely to increase virulence and range;

iv) Deliberate release into the environment of any organism containing a recombinant DNA molecule;

v) Transfer of a drug resistance trait to microorganisms not known to acquire such resistance naturally.

An additional classification, one with large-scale experiments, was prohibited unless it was of "direct societal benefit."

*See Guidelines for Research Involving Recombinant DNA Molecules, 43 Fed. Reg. 60,108 Section 1-D-6 (1978).*
that while it gives the NIH Director seemingly absolute power to deny permission for experimentation, the original language had not even conferred the power to deny experimentation. Prior to the change, the NIH had no authority whatsoever to oversee such experiments, no power to even consider such experiments, let alone grant or deny permission to conduct them.

Any student of constitutional law knows that the President cannot, without Congressional approval, simply declare and levy a tax. The Constitution confers on him no such authority. What the NIH did, by the addition of that single sentence, was as revolutionary a concept as allowing the President to singlehandedly levy a tax. One day the NIH had no control over deliberate release experiments, the next day it had such power, and could deny or allow experimentation on almost a whim.

In perspective the change was not spectacular. It did not, on a conceptual level, approach the dimensions of a Presidential directive to levy a tax. Because the Guidelines were based on contract law, a change in the Guidelines was no more earth-shattering, legally, than a decision by Ford or General Motors to change the terms of a contract by raising auto prices. Judge Sirica, in his decision to issue an injunction, did not even question the authority of the NIH to make such a change. The basis for the injunction was, instead, the failure of the NIH to prepare an Environmental Impact Statement assessing the impact of the change. However, as Jeremy Rifkin observed after the decision was handed down, whether the NIH was enjoined or not, private industry was not under the legal constraints which NIH-funded institutions were, and was thus, for the most part, unaffected by the ruling.80

The National Environmental Policy Act of 1969 (NEPA) requires that federal decision makers compile an Environmental Impact Statement (EIS) prior to final approval of all "major Federal actions significantly affecting the quality of the human environment."81 With that statutory command as a guide, Judge Sirica had to determine first, whether NIH actions were "major Federal actions" having a "significant effect" on the environment, thus requiring an EIS. Second, if an EIS was required, what steps had been taken to comply with that requirement.82 Under the first prong of the statutory command, Sirica determined that "major Federal action" was involved. On the question of whether that action might have a "significant effect," Sirica found the NIH had no information sufficient to make such a determination, either in the form of a formal EIS, or in the form of an alternative "hard look" analysis.83 Finally, since an EIS was necessary, Judge Sirica ruled that there were grounds for a

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80 15 Env't Rep. (BNA) 130 (May 25, 1984).
82 Heckler, 587 F. Supp. at 761.
83 Id. at 762.
finding of NEPA violations in the failure to prepare an EIS.\textsuperscript{84}

Judge Sirica determined that three allegations involving NEPA violations by the NIH warranted serious analysis.\textsuperscript{85} An initial challenge was to the specific potato-field experiment approved by the NIH.\textsuperscript{86} A second, spin-off argument related to the general issues involved in any intentional release experiment, or a broad, programmatic assessment of the environmental problems involved.\textsuperscript{87} A third area addressed was that of changes in the text of the Guidelines.\textsuperscript{88} Quite surprisingly, it was the seemingly innocuous language and text changes which provoked the most intense scrutiny and the lengthiest analysis.

Because of the NIH's actions Judge Sirica determined that language changes alone could place an agency within reach of NEPA's commands. When the NIH promulgated the first set of Guidelines, it actually compiled and adopted an Environmental Impact Statement, prompted by the belief that the Guidelines themselves were a "major Federal action" having a potentially significant effect on the environment. As stated by the Director of the NIH in October 1977: "[t]he issuance of Guidelines . . . with respect to recombinant DNA experiments is viewed by NIH as within the category of a Federal action that may significantly affect the quality of the human environment."\textsuperscript{89}

Although Judge Sirica determined that the Guidelines and the actual decision to allow the potato-field experiment met the criteria for a "major Federal action," Judge Sirica did not set out the specific criteria involved in a major action. Instead, he pointed to statements emanating from the NIH. Judge Sirica started with the premise that if the NIH in October 1977 had considered the issuance of the Guidelines to be a major Federal action, then a "major" change in the original Guidelines would also constitute a major Federal action.\textsuperscript{90} Judge Sirica reasoned further that if the NIH labeled an action or change as a "major" one, then he would hold the NIH to that determination.\textsuperscript{91} Judge Sirica thus pointed to a statement by the NIH characterizing a change in the Guidelines as a "major" revision.\textsuperscript{92} The NIH Director had stated that granting authority to permit deliberate release experiments was a "major" revision and the actual decision a "major" one.\textsuperscript{93} Such statements were determined sufficient to qualify the underlying action as a "major Federal action."

\textsuperscript{84} See Id. at 758 (emphasis added) (quoting National Institutes of Health, Environmental Impact Statement on NIH Guidelines for Research Involving Recombinant DNA Molecules of June 23, 1976).

\textsuperscript{85} Id. at 762.

\textsuperscript{86} Id.

\textsuperscript{87} Id. at 760.

\textsuperscript{88} Id. at 759.
Judge Sirica’s arguments sound quite plausible. At the same time it may be suggested that he is engaging in little more than a semantic game, because what may be a major change in the text of the Guidelines, may or may not be the equivalent of a “major Federal action.” On the other hand, the point may be well taken, that if the issuance of the original Guidelines did constitute a “major Federal action” as the NIH assumed it did, then major changes of a significant and substantive nature would quite appropriately be “major Federal actions.”

Having made a finding of major Federal action, Sirica then focused on the second issue, whether such action was one “significantly affecting” the environment. When the NIH did alter the Guidelines to permit intentional release experiments, it prepared one environmental document. Although it was not a full EIS, it was an environmental impact assessment (EA), which assessment concluded that the Guidelines change would have no significant effect on the human environment.

Despite this finding, Judge Sirica was apparently not reassured by the government’s analysis. What disturbed Judge Sirica about the EA was the fact that it was almost totally lacking in either substantive analysis or in factual data to analyze. There were, in fact, two EAs, although, as Judge Sirica notes, the second was merely a summary of the first one. Absent from both was any indication that the problems of intentional release had been addressed at all, instead, the first EA postponed such analysis and referred in general terms to NIH mechanisms for waiver decisions.

Judge Sirica’s analysis of the EAs provided him with no concrete evidence of any NIH deliberations. Nor was he reassured by the Director’s refusal “to articulate any standards, requirements, or values” to guide future decision making. Just as disturbing was the fact that, after the 1978 revisions, the only environmental documents which addressed intentional release experiments were the notices of approval for three experiments. Incredible as it seemed, experiments considered too dangerous to allow in 1976, were matter-of-factly given a go-ahead without any new data on their safety. “In 1978 . . . the record fails to reveal the Director of NIH, seeking, compiling, or addressing any specific or general data about the environmental hazards associated with the same type of experiments the Director had absolutely prohibited only two years before on the grounds of environmental risk.”

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84 Id. at 762.
85 Id. at 761.
86 Id.
87 Id. at 762.
88 Id. at 761.
89 Id. at 762.
90 Id. at 760.
There is an exception to NEPA’s EIS requirements which allows an agency to forego an EIS if it has analyzed environmental problems against a standard comparable to that required by NEPA. That comparable standard requires an in-depth substantive “hard look” at environmental problems. Unfortunately, the NIH’s review could not satisfy even one of the four “hard look” criteria. The criteria require a court to inquire:

1) whether an agency took a ‘hard look’ at a problem;
2) whether the agency identified the relevant areas of environmental concern;
3) as to the problems studied and identified, whether the agency made a convincing case that the impact was insignificant; and
4) if there was impact of true significance, whether the agency convincingly established that changes in the project sufficiently reduced it to a minimum.  

Since the NIH had barely looked at the problems, let alone taken a “hard look,” had overlooked rather than identified areas of concern, and had presented no case on the insignificance of the environmental impact, Judge Sirica’s decision was a relatively simple one.

There were other reasons to be concerned with the NIH decision-making process. It was as if the NIH had taken the attitude that it was in a position to thumb its nose, both at the scientific ideal of experimentation and at the legislative and judicial process.

Judge Sirica was no doubt surprised that the NIH could, on the one hand, not articulate any standard governing the authorization of intentional release experiments, while on the other hand, in effect, claim the benefit of the doubt, that approval by the NIH of the three experiments meant a satisfaction of all criteria under an unarticulated standard. It was not reassuring to hear the Director’s opinion that RAC review and public participation constituted an adequate “standard.” Failing to find any other evidence of the “standard” governing the review process, Judge Sirica finally determined that:

On the basis of the Director’s 1978 comments, therefore, the Court must conclude that the “standard” for granting a waiver can only be described as whatever it takes to win the confidence of, hopefully, at least a majority of the RAC and the subsequent approval of the Director of NIH.  

While the Director may have seemed eager to rely on the RAC in the matter of setting standards for actual experiments, there was a contrasting reluctance to delegate the decision on whether to prepare an EIS. Somewhat puzzling is the complete about-face of the Director. Where the Director had been keen on placing the burden for experimental release standards on the RAC, there was a jealous guarding of the Director’s asserted “case-by-case” decision-making.
making powers in relation to the preparation of an EIS. The Director took great pains to point out:

It is not the function of the RAC to determine what NEPA and the CEQ [Council on Environmental Quality] regulations require. The RAC is not constituted to interpret points of law and the requirements of NEPA. Specifically, it is not a function of RAC to determine when an environmental assessment is required by NEPA. 104

104 Id. at 760, citing 49 Fed. Reg. 697 (January 5, 1984). Judge Sirica interprets the Director’s remarks to mean that the Director distinguishes between the roles played by the Director and the RAC. The Director thus delegates the scientific analysis of the actual release determination to a “standard” to be set in part by the RAC. On the other hand, the Director reserves for his office a determination of when an EIS or EA must be prepared.

A reading of the Director’s comments in its full context suggests an alternative interpretation, namely that, when the Director asserts that “[i]t is not the function of the RAC to determine what NEPA and the CEQ regulations require, ” the Director does not mean to distinguish between the role assigned to RAC and the role assigned to the Director. In the beginning sentence of the same paragraph the statement is made that “[t]he NIH Recombinant DNA Advisory Committee [RAC] does not have the responsibility to determine, and it is not appropriate for the NIH Guidelines to state what is, or is not, required by the National Environmental Policy Act.” (emphasis added).

The statement is made in the context of a request by Jeremy Rifkin, Edward L. Rogers and Michael W. Fox that there be a more formal assessment of safety. The discussion does not distinguish between the role to be played by the RAC and that to be played by the Director.

Judge Sirica may not have wanted to draw the conclusion that, on the one hand, when addressing critics of NIH procedures, the Director would assert that the NIH, through the RAC, was not competent to make a legal determination on the need for an EIS, while, on the other hand, asserting that the NIH was quite competent to make such a determination in other situations on a case-by-case basis.

It would be the height of duplicity to even entertain such a notion, yet, based on the other actions of the NIH, there is a sense that it has attempted to make both arguments at the same time: When addressing Jeremy Rifkin, the RAC has no responsibility and is not constituted to interpret the law; when addressing Judge Sirica, the NIH suddenly is competent to make a case-by-case determination based on unarticulated standards.

The text of the NIH comments are presented here to give the full flavor of the context. The text is found at 49 Fed. Reg. 696-97 (1984).

SUPPLEMENTARY INFORMATION: The National Institutes of Health will consider the following actions under the Guidelines for Research Involving Recombinant DNA Molecules.

1. Proposed Amendments of the NIH Guidelines and Comments by the Director, NIAID.


1. Amendment of the Section III. The title of Section III of the Guidelines would be changed from “Containment Guidelines for Covered Experiments” to “Guidelines for Covered Experiments.”

Messrs. Rifkin and Rogers argue that the current title of Section III reflects an orientation towards experiments contained within a laboratory. However, the RAC is reviewing experiments involving the deliberate release into the environment of certain organisms containing recombinant DNA. Messrs. Rifkin and Rogers state that:

Accordingly, the focus should no longer be on the concept of containment alone, but rather on guidelines to assure safety for all experiments, whether through containment procedures or other techniques.

2. Amendment of Section III-A. Section III-A would be amended by adding at the end thereof the following paragraph:

A programmatic environmental impact statement (EIS) is required under the National Environmental Policy Act (NEPA), 42 U.S.C. § 4332, and the Council on Environmental Quality Regulations (CEQ Regs) implementing NEPA, 40 CFR §§ 1502.1-1520.25, for the program involving deliberate releases into the environment of recombinant DNA molecules.

Messrs. Rifkin and Rogers, in their submission, provide a detailed explanation for this proposed modification.

3. Additional Amendment of Section III-A. Section III-A would be further amended by adding after the material set forth in the prior amendment the following paragraph:

Individual experiments involving deliberate releases into the environment of an organism containing
Beginning with the claim that the NIH should make decisions regarding the need for an EIS on a "case-by-case" basis, there is a common thread running through NIH pronouncements. That common thread is "vagueness" and a sense that the NIH is being evasive: waiver standards were "deferred;" a decision by the RAC was to be endowed with a presumption that it was made in compliance with proper but unarticulated standards.

A glance at NIH pronouncements in the Federal Register suggests a certain laxness on the part of the NIH. A suggestion that NIH Guidelines be applied to NIH-supported research in foreign countries prompts the response that a certificate of compliance with host country rules may be submitted in lieu of compliance with NIH Guidelines, so long as safety practices of the two are "reasonably consistent." The NIH chooses to be diplomatic where it should be rigorous. And when Jeremy Rifkin and Edward Rogers make the suggestion that: "[w]here it is uncertain whether a particular experiment may or may not have a significant impact on the environment, then, at the least, an environmental assessment (EA) must be prepared . . . ." The Director responds by raising a legal, but inadequate, technicality that the RAC does not have the responsibility to determine NEPA requirements.

recombinant DNA require the preparation of either an environmental impact statement or an environmental assessment.

In explanation of this proposed change, Messrs. Rifkin and Rogers state:

Where it is uncertain whether a particular experiment may or may not have a significant impact on the environment, then, at the least, an environmental assessment (EA) must be prepared explaining the conclusion reached on the question of the significant impact, and the relevant environmental agencies must be involved in that assessment process. See CEQ Regs. §§ 1501.3, 1501.4, and 1508.9. At issue here are the great variety of deliberate-release experiments that have potential environmental impacts.

B. Comments by the Director, National Institute of Allergy and Infectious Diseases, on the Amendments Proposed by Messrs. Rifkin and Rogers.

The NIH Recombinant DNA Advisory Committee (RAC) does not have the responsibility to determine, and it is not appropriate for the NIH Guidelines for Recombinant DNA Research to state, what is, or is not, required by the National Environmental Policy Act (NEPA) (42 U.S.C. §§ 4321 et seq.) and the regulations (40 CFR Part 1500) promulgated by the Council on Environmental Quality (CEQ) to assure the uniform implementation of that Act. It is not the function of the RAC to determine what NEPA and the CEQ regulations require. The RAC is not constituted to interpret points of law and the requirements of NEPA. Specifically, it is not a function of RAC to determine when an environmental impact statement or an environmental assessment is required by NEPA. [In reading further, the Director, while stating that careful consideration will be given to the potential environmental impact of waiver decisions, makes no distinction between the role of the RAC and the role of the Director.]

It should also be noted that a proposal similar to that now proposed by Messrs. Rifkin and Rogers was considered and rejected by the Director, NIH, at the time of the revision of the NIH Guidelines in December 1978. NIH Director Donald Fredrickson wrote in the Federal Register (43 FR 60083, December 22, 1978), "Another commentator urged that for waiver of the prohibition of deliberate release into the environment, the guidelines explicitly require compliance with the National Environmental Policy Act (NEPA) and any additional safeguards to be stipulated by EPA. Others urged that full Environmental Impact Statements be filed on most exceptions to the prohibitions. As I noted in my decision accompanying the PRG on July 28, 1978, all waiver decisions will include a careful consideration of the potential environmental impact. Some decisions may be accompanied by a formal assessment or statement — a determination, however, that can only be made on case-by-case basis." (Emphasis added).

The arguments asserted on behalf of the NIH in Judge Sirica’s court are a little too pat and a little too convenient. An overly swift approval mechanism for experiments, a lackadaisical attitude toward the need for experimental data, and a general disregard for legal and administrative safeguards, make the NIH look like a Barnum & Bailey promoter for the field of genetic engineering. Insofar as the NIH was entrusted with the formulation of guidelines for research, its role was intended to be that of a watchdog guardian. The NIH understood that when it accepted that role. The fact is that society does not need a watchdog agency looking out for the perceived interests of the business and scientific communities. The business and scientific communities have shown themselves quite capable of looking after their own interests.

The NIH disregarded the language and intent of the environmental laws, approved an experiment in violation of those laws, and then attempted to defend its actions by looking for a legal loophole. Such action was a sad combination of laziness and arrogance. At its best it was an example of a careless inattention to detail and an inept disregard of procedural formalities. At its worst, it is a disgraceful attempt to evade moral, ethical, and legal responsibilities.

In the abstract, spraying a few ounces or gallons of an ice-inhibiting bacteria onto a potato field seems quite harmless. Based on the summary approval given the experiment by the NIH, it apparently agreed. But, there are some not-so-imaginary horror stories in the ecological field which should snap the scientific community back to reality. While it may seem trite, the local pet shop can provide some frightening examples of just what can happen when something new is introduced into the local ecological scene.

A trip to the local aquarium or pet shop will reveal any number of exotic birds, fish, and animals — hardly a frightening menagerie. In May 1967 a night watchman at a Florida construction site, on hearing his dog bark, discovered an albino catfish, which relentlessly marched toward the beam of light from his flashlight. The problem was that the nearest waterway was half a mile away. More perplexing, the native home of this walking catfish was southeast Asia and eastern India. Imported to Florida in 1961, the fish have a voracious appetite, will devour and eventually displace other fish in a pond, and are equipped with a tremendous capacity for survival. These traits allow the catfish to breathe directly with a lung if water disappears, and fast up to eight months if food is scarce. After their discovery in May of 1967, more than 2500 albinos were caught before August.109

The walking catfish is only one example of a species brought to a new land and moving into the wild by escaping from captivity or being dumped in a local river when the tourist went home. Also, South American piranha have


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been caught in Florida waterways.\footnote{110}

The introduction of the large Cuban tree frog may have contributed to a
decrease in populations of native but smaller Florida frogs.\footnote{111} Another threat
posed to a Florida native is from Central America, the caiman. Nearly indistinguishable from alligators, caimans have been sold as “alligator” pet
substitutes and thousands have been released. And while humans fear alligator
attacks, alligators, in turn, fear caimans. Caimans unfortunately will not maintain the deep alligator holes which the native reptiles provide as a side benefit
for fish and fisherman.\footnote{112}

There are some major ecological disasters which have developed from
seemingly minor occurrences. In 1957, 26 African queen bees escaped from a
Brazilian research station. Mating with native bees, they produced offspring
which were aggressive, nomadic, and fast-breeding. Labeled “killer bees” for
good reason, at one point they fought a seven hour battle in one town against
Brazilian troops armed with flame throwers, hand grenades, and tear gas. They
have killed farmers and livestock, dive-bombed a funeral procession and, advancing 200 miles a year, may reach the U.S. by 1988. Mexican authorities
fear that when they reach Mexico by the summer of 1985, they may destroy
Mexico’s honey industry.\footnote{113}

Eugene Scheifflin was a wealthy drug manufacturer who took an interest
in both Shakespeare and bird watching. Because he wished to see the birds
mentioned in Shakespeare’s plays established in the New World, he released
forty pairs of European starlings in New York’s Central park on March 6,
1890. Another forty pairs were released on April 25, 1891. All present starlings
in America are descendents of those released birds. The native American blue-
birds still left would not feel much gratitude toward Scheifflin since the aggressiveness of the starlings is focused on the nesting places of the smaller
bluebirds.\footnote{114}

The introduction of the mosquito to Hawaii was responsible for the near-
extermination of a bird called the Hawaiian honeycreeper. There were no mos-
quitoes of any kind in Hawaii until 1826. Their mode of entry was a barrel of
water on the deck of a ship arriving from Mexico. These mosquitoes, infected
with bird malaria and pox, in turn infected the native honeycreepers with these
diseases. Because the mosquitoes found cool temperatures uninviting, only
those birds dwelling above three thousand feet survived.\footnote{115}

The NIH and many research scientists perhaps cry foul at Jeremy Rifkin’s
\footnote{110}Id. at 47.
\footnote{111}Id. at 52-53.
\footnote{112}Id. at 238-39.
\footnote{114}MILNE, supra note 109, at 156, 220-21.
\footnote{115}Id. at 244-46.
suit. In perspective, the discussion surrounding the introduction of survivable species into new environments was long overdue. It takes very little to upset and destroy the fragile equilibrium of insulated biological worlds. The importation and release of threatening foreign animals and plants has, as often as not, provoked not even a whimper. Unfortunately, Judge Sirica's ruling can be neither expanded to cover such situations, nor made retroactive.

The arguments presented in the NIH lawsuit do not place the NIH in a favorable light. It appears not to have adequately studied the overall problem. A workshop on DNA problems by the EPA in December 1983 indicates that that agency, as well, may not be totally prepared to evaluate potential hazards. Commenting on reports submitted for the workshop, a senior scientist stated:

A concern I didn't see addressed in these papers, and one that I believe should be high on any list, is the potential for a genetically engineered organism to out-compete native organisms and take over some environmental niche. This has happened numerous times with species introduced from one part of the world to another.\(^{116}\)

At least the EPA can be commended for its efforts to develop expertise in the area. On the other hand, the NIH, as Judge Sirica infers in his opinion, seems to have made no real attempt to determine if any hazards are involved in new experiments.

**A Ten Year Perspective**

Some three thousand years ago the prophet Nathan confronted David, the King of Israel, over his actions in ordering the front-line death of a soldier to cover up David's wrongdoing.\(^{117}\) That confrontation was an example of what a constitutional law professor once called the indirect controls on governmental power. A king, for all practical purposes beyond the law, was still subject to a commonly understood standard of conduct and could be called to account by higher authority when the standard was violated.

When the United States Constitution was written, it was decided that direct controls were more effective at controlling the excesses of earthly rulers than the moral tongue-lashings which the occasional Nathans could provide. The newly independent colonists felt, as King George proved, that the potential excesses of a real king could in reality be quite excessive. For this reason, the Constitution incorporated a system of checks and balances and the separation of powers.

Jeremy Rifkin and his cohorts at the Foundation for Economic Trends could doubtless attest to the effectiveness of direct controls in comparison to

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\(^{117}\) Samuel 2:11-12.
that of indirect control, as shown by Rifkin's success in his suit with the NIH. Until a federal court stepped in, the NIH was largely ignoring the moral lectures which Rifkin unleashed from time to time.

What the law is and whether it was broken by the actions of the NIH, is a question for the courts. But whether the NIH violated the standard it should be adhering to is another matter. The medical community is revered because its sacrifices and goals are still considered to be in service to humanity, as opposed to other groups which incidentally provide services and are considered to be primarily out for profit. The medical community, in turn, holds the search for empirical truth in high esteem, requiring the truth of a given proposition to be proven by empirical evidence. What came out in the NIH suit points to an unsettling suspicion, namely that without empirical evidence to support its decision the NIH nevertheless chose to proceed with experimentation.

A decision to go forward, without supporting evidence, would seem a blatant violation of the scientist's code. There is, thus, a violation on the scientific side. On the legal side, the NIH chose to run interference directly over whatever rules stood in the way of its decision. In short, the NIH is displaying symptoms of a single-minded determination to proceed with rDNA experimentation at all costs, be those costs in ethical, scientific, or procedural terms.

Laws can be evaded and goals can be achieved by sheer political power. The question which needs to be addressed, however, is whether the ultimate goal is set high enough to justify any means employed in attaining it. Pressure to forge ahead with research is coming from companies who may not survive financially for much longer. Because laws are usually intended to serve a more lasting purpose and not some immediate very short-term goal, the question is whether the NIH should proceed, based on these immediate concerns.

What appears to be afflicting a part of the scientific community is a single-minded focus on curing disease, but a somewhat blurred or abstract perception of human life. Curing disease is not necessarily the same thing as saving a life. Many diseases can be cured, but with drugs which will exact a fatal price for their saving powers.

With fame and fortune riding on the discovery of a cancer cure, scientists at Asilomar, with a competitive intensity, were anxious to get on with the research. Curing cancer or disease became not a means of overcoming human tragedy, but simply a more complex puzzle to be solved, representing an interesting and overriding goal, or a trophy symbolizing success. Whether injury or death might result from a laboratory accident, and whether legislation or regulation might cut down on such chances, became of secondary importance to that all-consuming passion of curing cancer. James Watson no doubt expressed the feelings of many when he commented: "[w]e can just suffer the possibility that someone will sue us for a million dollars if things don't work."
out.” And while scientists have downgraded the assessment of risk associated with rDNA research, Watson’s statement is a rather understated euphemism for the results of an “experiment gone bad.” The estimated 17 to 28 million fatalities associated with a four year visitation by the Black Death in the fourteenth century demonstrates what happens “if things don’t work out,” as does the 15 to 25 million victims of the world flu epidemic of 1918-1919.

**ACADEMIC FREEDOM**

Sooner or later, in reading through the articles written on Asilomar and the rDNA debate, one is likely to come across references to Galileo. Government attempts to regulate research are compared to the Inquisition’s treatment of Galileo, who was forced by the Inquisition to recant his theory that the earth was not the center of the universe. The analogy appears so often as to be almost a knee-jerk response set off by a hair-trigger sensitivity. So often is it used that there is a temptation to ask, not when was it that the Church abolished the Inquisition, but how soon can the Inquisition be brought back?

It is not the purpose of this article to mount a full-scale philosophical attack or defense on academic freedom, save for a few comments on certain aspects of the debate. The concept of academic freedom was established because societies have learned that “advances in civilization” have come when ideas are given a free reign. Like freedom of religion, it has been felt that more good will come out of a situation in which government does not meddle. Nevertheless, academic freedom is society’s gift to the world of science, not the researcher’s private kingdom. It is not an absolute inviolate right granted to scientists at birth, nor is it the paramount goal of society.

Scientists are best equipped to develop arguments for scientific freedom, but it must be remembered that academic freedom is but one of a number of areas competing for the attention of the collective community we call society. Newsmen will contend that freedom of the press is just as important a “foundation” of freedom as academic inquiry. Civil libertarians will contend as strongly that the constitutional rights of accused persons are a similar cornerstone. In the end, when these competing interests confront each other, society will be the ultimate arbitrator. Courts have been willing to let reporters sit in jail when criminal defendants seek a witness buried in the reporter’s confidential notes. And those who contend that the tail of academic freedom should wag the dog, might take cognizance of the fact that political pressure to protect the “rights of law-abiding citizens” is forcing a retreat by those civil libertarians asserting the “rights of criminals.”

A second point about the debate is that there are places and times when

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10Rogers, supra note 4, at 64.
an argument is simply inappropriate. The actions of a control tower at a major airport in directing airplanes in when to take off and land can be labeled as a restriction on the individual freedom of a pilot to do as he pleases, however, such an argument lacks even the slightest degree of credibility. The use of Galileo as an example may not be a particularly appropriate one for the biological sciences. Galileo's writings involved highly theoretical interactions of distant planets, stars and galaxies, not the more immediate physical dangers of experimentation with thermonuclear detonators or the plague bacillus. From time immemorial, and long before academic freedom of inquiry gelled into a principle, governmental authorities have been responsible for the quarantine of disease-bearing ships and the control of the spread of contagion.

Those who choose to, in Robert Sinsheimer's words, "wave the flag of Galileo" at every opportunity, at the least appear to be crying wolf a little too often. While scientific writing demands putting one's best foot forward, exaggerated and untrue comparisons to Galileo seem out of place in the context of the scientific ideal of empirical truth. On a more concrete level the argument becomes almost obscene. American scientists are becoming millionaires on the strength of their expertise while Andrei Sakharov, the Russian physicist, is being tortured on the strength of his beliefs.

In perspective, the issue of academic freedom will largely remain a tempest in a teapot. The likelihood of governmental interference in scientific inquiry is remote, not so much because the scientific community opposes it, but simply because society does not demand it. A request to Congress endorsed by Jerry Falwell, asking for a ban on certain experiments, is unlikely to gain much support. At the same time, the reality is that a lay jury would find heavy liability by delicately, but decisively, cleaving the line which separates negligent experimentation from that of true academic inquiry. The parameters of the debate were summarized by Professor Capron — just as "the image of a broken Galileo recanting his 'heresies' haunts any discussion of controlling basic research," so also "direct risks of physical injury" have provided a "traditional basis for injunction and damages." In practical terms, the decision to go forward with research, as evidenced by Congress' refusal to legislatively control it, is a societal concession to those who hold the view that real risks are quite small, the potential dangers speculative and the benefits adequate on the risk/benefit scale.

In terms of the presentation of arguments, those who call on Galileo's im-

age at the slightest whisper do a great disservice to their cause. Galileo does not translate well when the debate turns to actual risks involved in experimentation. Galileo is most forceful when the argument is regulation of ideological inquiry, but is a very weak analogy on disease risks. In any debate, one has to watch proponents of academic inquiry, for they can subtly pull any argument concerning health regulations over to ideological ground, where Galileo’s reputation and persecution provide a stronger argument.

Perhaps the best presentation of the argument was made by Professor Carl Cohen of the University of Michigan. Professor Cohen, conceding that academic freedom is not totally immune from regulation, noted that “[t]hose who argue, as I do, that the commitment to free inquiry is critical to the placement of the burden of proof, do not contend that never, under any circumstances, may restrictions upon inquiry be imposed.” 124 Professor Cohen expanded on his perception of the freedom granted, claiming “[academic freedom] is not an enforceable claim against the assets of others. Freedom of inquiry is not a right in the strong sense that the scholar or scientist can demand the provision of means needed to pursue the particular line of research he thinks wise. . . .”125

While the scholar is expected to experiment and test:

This does not mean, obviously, that the professional investigator is free from all restraints, that academic freedom is an absolute. Institutions may and do formulate rules for the guidance of research within their precincts. Medical experimentation with human subjects, an invaluable instrument for the achievement of humane and scholarly objectives, is yet properly subject to carefully formulated restrictions.126

The development of legal and governmental systems has been a matter of trial and error. The jury system was instituted because it was felt that there were significant problems with the system of trial by ordeal. Similarly, the legislative branch of government and the procedural formalities incorporated into the judicial and administrative processes, whereby laws are made and interpreted, was a considered response to past defects.

If this article takes a critical view of the workings of the NIH decision-making process and a cautious approach to rDNA research, perhaps it is because of past history. Anyone who takes statements at face value in the business world will not survive long. And it is not always safe to rely solely on the expertise of experts. As some major accounting firms have discovered, escaping liability can depend on treating the assertions of corporate officials with some degree of skepticism.

125Id. at 1106.
126Id. at 1107.
The NIH was entrusted with the regulation of rDNA research because it was presumed to have the most expertise in the field. It was entrusted with the responsibility for decision making because its scientists can develop and interpret biological evidence, not because the NIH has a special ability to make decisions in the absence of supporting evidence. Anyone is capable of making a simple yes or no decision and any federal agency could have decided to go ahead with the potato patch experiment by flipping a coin. To analogize, the Securities and Exchange Commission might have required a more thorough environmental impact study through its financial disclosure requirements than the NIH undertook. Conferring an advanced degree is presumed to confer some level of competence in a field. However, officials at the NIH are not paid simply to rubber stamp a decision based on no more than the collective authority of a committee of degreed individuals. A basic mastery of a subject matter is no substitute for a specific study of a particular problem.

LESSONS FROM THE PAST AND DEJA VU

The medical field has made some of its greatest advances by a meticulous attention to detail and a careful study of medical case histories. If there is one thing missing in the rDNA debate, it is perhaps a sense of the past. So convinced were scientists and reporters of the potential dangers from a future doomsday bug that the enormity of past plagues and epidemics was largely lost. So certain were researchers of this new tool that a good deal of caution was thrown to the wind, not in terms of laboratory procedures or safety, but in terms of knowledge. If there is one lesson which should be taken to heart from the past, it is that it is dangerous to base assumptions and make pronouncements based on knowledge which is not complete. Of course it is somewhat difficult to know what one does not know. On the other hand there is a sense of overconfidence, even cockiness, of which the willingness of the NIH to dispense with experimental evidence is probably symptomatic. We know a good deal more than medical experts of a hundred years ago, but we are still only "on the verge of" a cancer cure. The ever present danger is in succumbing to a false belief that, through the illusion of certainty, this time we have an answer and this time we really are unique. The NIH was certain that it now knows enough to dispense with experiments, and on the legal side, to dispense with past procedure. The question which should be asked, however, is whether there is now any particularly pressing reason, experimentally or legally, to cut down all the laws simply to get at the Devil.

Deja vu is the phrase used when there is a sense that one is previewing a past event in the present. It may have more relevance than is at once apparent, for we have been here before.

Lung cancer is a disease familiar to nearly everyone. Mesothelioma, however, is a disease which is part of the vocabulary of a much smaller group of individuals, those familiar with the medical and legal aspects of asbestos.
thelioma is also a cancer, but of the lining surrounding the lungs. Unlike lung cancer, a diagnosis of mesothelioma is a certain death sentence, death often coming between six to eight weeks after diagnosis. Mesothelioma is one of several diseases which have caused the filing of 20,000 lawsuits against the Manville Corporation, with a potential total liability estimated to be $2.5 billion.127

The safe threshold level of exposure to asbestos while avoiding mesothelioma is not known. A summer’s work exposure can be sufficient. But the time between initial exposure and development of the disease can be as long as ten, fifteen, twenty, even forty years. It was not until 1964 that the evidence was considered strong enough to definitively state that there was a connection between asbestos exposure and the disease.128 It has been asserted that nothing has gone wrong in research involving rDNA and that it appears to be safe. Yet with the field barely ten years old, the question presented is how scientists can be certain. There are many “conventional” diseases with long latency periods besides mesothelioma. Although D.E.S. had been prescribed as early as 1947, cancer did not show up in children born to women who were given D.E.S. until 1971.129 Veterans exposed to Agent Orange in Viet Nam often did not develop symptoms until years later.130 Whether an accurate observation, the rabies virus has been recorded as having, in a few cases, an incubation period of a year.131

Fear of the release of a doomsday bug through rDNA research has largely subsided. Yet, as mentioned previously, the Black Death of 1347 through 1351 killed an estimated twenty-eight million. It began in October, 1347, when a Genoese fleet with its sick crew sailed into the Sicilian harbor of Messina.132 Another ‘doomsday bug’ was unleashed on the New World by the Spaniards in the early 1500s in the form of smallpox. Estimates of the number who died range from a low of two million to a high of fifteen million, and all in a period of less than six months.133

It was Cotton Mather who introduced smallpox inoculation to the New World in 1721. That inoculation was not without controversy. Indeed, it was opposed by some as shown by the fact that, although it failed to explode, someone had a homemade grenade thrown into Mather’s house.134 Smallpox vaccination no doubt saved many lives, but it could be dangerous in some cir-

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127 Manville: A drama with no end in sight. The Denver Post, August 26, 1984, at J12.
128 Selikoff, Churg & Hammond, Asbestos Exposure and Neoplasia. 188 J. AM. MED. ASSOC. 22 (1964).
132 Gottfried, supra note 119 at iii.
133 D.R. Hopkins, PRINCES AND PEASANTS — SMALLPOX IN HISTORY. 207 (1983).
134 Id. at 248-50.
cumstances. In the eighteen hundreds, sixty-three children at Rivalta, Italy were vaccinated from a faccinal pustule of an apparently healthy baby. Unfortunately the donor baby had syphilis, and forty-four of those vaccinated developed syphilis; several died and some infected their mothers and nurses.\textsuperscript{135} It was a rare hazard of inoculation, but was the result of the incomplete knowledge of disease transmission. In 1767, a London physician inoculated himself deliberately with gonorrhea, but unknowingly, with syphilis as well.\textsuperscript{136}

Those who led the way, like Koch and Pasteur, and those who followed, became known as microbe-hunters. They had some brilliant successes, received public accolades, government appointments, but also encountered failure. Then, as now, there were high expectations for the new medical discoveries. The theory was that fitting the pieces together in an understanding of the lowly germ was the solution to all medical problems. It is with those researchers of the late nineteenth century that one gets the sense of having been here before.

Robert Koch first came to the attention of the medical world in 1876 when he demonstrated the ability of the anthrax bacillus to form spores and still remain infectious. In 1880 Koch was made Extraordinary Associate of the Imperial Health Office. In 1882 Koch was made Extraordinary Associate of the Imperial Health Office. In 1882 Koch was made Extraordinary Associate of the Imperial Health Office.\textsuperscript{137} Louis Pasteur worked for years analyzing problems of the French breweries and distillers. In 1880 while experimenting with chickens he discovered that an injection of weakened chicken cholera conferred immunity. In June 1881 he demonstrated a successful anthrax vaccine and in July of 1885, he began injections of a rabies vaccine on a small boy bitten by a rabid dog.\textsuperscript{138} That vaccine was an astonishing achievement considering the fact that the agent of rabies was a virus much smaller than any of the microbes Pasteur had previously encountered.

There were other successes as well. Diptheria antitoxin was successfully tested in the 1890s. The discovery that the tsetse fly carried sleeping sickness and that mosquitoes carried malaria, led not to vaccines, but to preventive measures which effectively reduced contagion.

Just as twentieth century researchers would later refine disease-fighting techniques and discover important cures and preventive measures, researchers of the nineteenth century also made startling advances. But there were also some terrible failures. What is more than a little disturbing is that some of the symptoms displayed by the scientific community of today appeared a hundred years ago. Newspapers, then as now, trumpeted new triumphs, and the scientific community then as now, engaged in a fierce and nationalistic competition.
to discover, first, the microbe, then the cure. At stake were honors, positions, and national pride.

In an article entitled *Science as Technology*, L.F. Cavalieri recounts the story of the announcement of the synthesis of somatostatin. On November 2, 1977, Dr. Philip Handler, president of the National Academy of Sciences, was testifying before a Senate Subcommittee holding hearings on rDNA technology. During the course of that testimony, Dr. Handler announced that a team of researchers had succeeded in its efforts to synthesize the chemical somatostatin. According to Professor Cavalieri, one of the canons of scientific propriety in the medical research area is the scrutiny of works prior to publication. Therefore, Dr. Handler’s announcement, before submission of a manuscript on the research, was an unheard-of breach of the scientific canons. Compounding Dr. Handler’s breach was a decision by *Science* magazine not to call for or publish the collective letters critical of such conduct.139

Professor Cavalieri makes the point that technology does not really fall within the protection of academic freedom. “[T]he synthesis of somatostatin is a technological act that, unlike the practice of pure science, has no claim to freedom of inquiry.”140 Furthermore, incorporating the competitive spirit on the intense level of industrial rDNA work does not encourage the free exchange of ideas, and in fact fosters secrecy and noncommunication.141 These are undesirable traits in a field devoted to the expansion of human knowledge.

The article decries the use of science as a competitive game.

[Science is treated] . . . as a bona fide tournament. This is regrettable because it tends to legitimize this sort of fierce rivalry and makes it appear as simplistic competition which it is not; hasty results, cut-corners in safety procedures, excessive personnel, secrecy, and so forth are all part of this unseemly game . . . .142

On May 31, 1881, Louis Pasteur watched as a fatal dose of anthrax was administered to a group of sixty animals. Some two weeks before, Pasteur had injected twenty-four out of the group with his newly developed anthrax vaccine. On June 2, 1881, Pasteur watched triumphantly as the unvaccinated animals all died while not one of those vaccinated showed signs of disease.143 But it was a strange experiment, because it was not conducted in one of Pasteur’s laboratories. It was conducted on a farm, observed by reporters and crowds of Parisians. It was also not on Pasteur’s normal experimental agenda, for it had resulted from a challenge by other eminent medical experts. The intensity of the

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139Cavalieri, *supra* note 38, at 1155-56.
140*Id.* at 1155.
141*Id.* at 1155.
142*Id.* at 1156.
143DE KRUIF, *supra* note 137, at 150-54.
scientific debate between Pasteur and his opponents had gotten so high that Pasteur exchanged insults at one meeting with a Dr. Jules Guerin, resulting in a near fistfight and a challenge to a duel. But the vaccine test was a success and it got Pasteur worldwide headlines as "an unprecedented success."

But the height of success may not have prepared Pasteur for what was to come. A year later, because thousands of sheep had died of anthrax contracted from Pasteur's vaccines, angry farmers sent Pasteur letters. Robert Koch, conducting clinical tests with Pasteur's vaccine, found that some batches of the vaccine killed sheep.

In a letter Koch sent to Pasteur, Koch chided Pasteur for his showman-like passion for science and the truth, a passion which, Koch observed, did not go so far as to allow for the revelation of Pasteur's unsuccessful results. Also, in a finishing remark, as appropriate now as it was then, Koch admonished Pasteur: "Such goings-on are perhaps suitable for the advertising of a business house, but science should reject them vigorously . . . ."

Koch himself would later stumble over a prematurely disclosed report of his experiments with tuberculosis. Koch would announce the discovery of the tubercle bacillus in March 1882, but a cure was a good deal of work away. In 1885, Koch was made head of the Hygienic Institute in Berlin. It was while at that position in 1890 that Koch discovered the injection of a substance he called tuberculin, the solution of heat-killed tubercle bacteria which seemed to arrest tuberculosis in test animals. It was at a conference in 1890 that Koch made a tragic gaffe. Partly as a result of pressure from the German government, Koch decided to announce his preliminary findings. The Minister of Culture emphasized the new discovery in his introduction. Because Koch's injections could kill tubercle bacilli, the minister implied a cure. Koch only served to reinforce that inference with one sentence, stating that tuberculin had proved able to check the growth of the tubercle bacilli, not only in test tubes, but also in living animals. However, the animals were only guinea pigs and Koch's experiments were not over. Unfortunately, the transatlantic cable carried the news to America and presses rolled.

Patients at the Saranac Lake, N.Y. sanitarium traveled to New York City to obtain some of the new drug as soon as it would arrive from Europe. Unfortunately, tuberculin turned out not to be a cure. Because doctors overdosed patients, some patients died.

144 Id. at 147.
145 Id. at 157-58.
146 Id. at 159.
147 D.C. Knight, Robert Koch — Father Of Bacteriology, 88-90 (1961).
148 Id. at 106-07.
149 Id. at 108-10.
150 Id. at 111-12; See also A.L. Baron, Man Against Germs. 61-64 (1957).
The debacle which followed Koch’s announcement cannot be blamed entirely on Koch, for the press played up what they wanted to hear. But there are other indications that the research community was infected with the spirits of Barnum and Bailey. Dr. Max Pettenkofer, after making a public speech vowing to “look death quietly in the face” and “die in the service of science as a soldier perishes on the field of honor,” on October 7, 1892, deliberately swallowed a broth culture of comma-shaped cholera bacteria. Pettenkofer, not an opponent to the germ theory, nevertheless did not feel the bacteria isolated was the cause of cholera. Surprisingly, Pettenkofer did not die, he developed only mild flu-like symptoms, which apparently encouraged Pettenkofer’s assistant to repeat the experiment with more drastic, but still not fatal results. Still later in 1892, another researcher, Elie Metchnikoff, repeated the same experiment on himself and three of his assistants. One of the assistants developed a near-fatal infection; another recovered but died shortly after from unknown causes. Metchnikoff developed the theory of white-blood cells engulfing invading bacteria, but he had also accepted a position at the Pasteur Institute shortly after one of his anthrax vaccines had killed a few thousand sheep. Still another researcher, a student of Robert Koch’s, rubbed test tubes of staph on his arms, developing a serious case of boils, “proof,” he said, that the staph was the cause of boils and carbuncles. The question which needs to be asked is whether some of those researchers were interested in proving a theory or simply interested in grabbing early headlines with a more dramatic form of proof, though not a more scientific one.

In the March 31, 1980, issue of *Time* magazine, the cover story featured a newly synthesized drug called interferon. Within the article was an illustration similar to a Paul Revere rider, riding from one cell to another to warn of an impending viral attack. It was felt by many of the scientists interviewed that interferon showed early promise as a cancer fighter. It would later be discovered that interferon works not like a warning rider, but instead, like a giant freezer or ray-gun. Instead of initiating an active defense by the cell, interferon appears to temporarily stop the cell’s own functions, preventing a virus from utilizing those functions to take over the cell. During large-scale testing of interferon in 1982, four French cancer patients died and the French government suspended further testing.

... and the Bishops of Asilomar

One of the shortest, but most flamboyant attacks on the proceedings at

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131A. Chase, supra note 131, at 153-54.
132Id. at 155.
133DE Kruif, supra note 137, at 207.
134Id. at 132.
Asilomar was voiced by microbiologist Erwin Chargaff. In what has become a classic quote in rDNA literature, Chargaff likened Asilomar to the high councils of the Church by stating, “[a]t this Council of Asilomar there congregated the molecular bishops and church fathers from all over the world, in order to condemn the heresies of which they themselves had been the first and principal perpetrators.”

At the Tuesday session of Asilomar, James Watson observed that “[t]hese people have made up guidelines that don’t apply to their own experiments.” The comment succinctly states one of the stronger criticisms which can be leveled at both Asilomar and the later scientific meetings, namely that the level of risk and the corresponding degree of control on experimentation were assigned, not on the basis of hard empirical data, but on an almost ad hoc or arbitrary basis. It was as if to say — “but how can that work be dangerous, Dr. Smith is working with that.” James Watson asked point blank why frog DNA was considered safer than cow DNA — and received no answer. Also an observer of still another subsequent meeting wondered whether guidelines weren’t “tailored to fit particular experiments that are already on the drawing boards.”

A more general criticism which can be applied to Asilomar and subsequent proceedings is that what began as a sincere interest in safety was slowly turned into a legalistic and somewhat transparent shield, useful in the on-going fight against government regulation. Asilomar, it would be argued, was proof positive that the scientific community could regulate itself. From what transpired at the conference, it becomes apparent that the motivation for self-regulation was not always the fear that human tragedy might result from experimentation. Instead, a prime mover for self-regulation was the fear of and contempt for government involvement. To the extent NIH involvement was sought, it was an attempt to forestall a still deeper and more extensive government involvement. Therefore, the prospect of NIH involvement on the level of partner was preferable to the prospect of Congressional involvement as overseer.

LESSONS FROM GALILEO

Defenders of academic freedom, in using Galileo’s image, have drawn only one lesson from the Inquisition’s proceedings. In perspective, Galileo escaped with a relatively light sentence. It must be remembered that earlier popes had few qualms about launching the Crusades, which involved

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17Chargaff, A Slap at the Bishops of Asilomar, 190 Scl. 135 (1975).
18ROGERS, supra note 4 at 75.
19Id. at 75.
21See ROGERS, supra note 4, at 62, 76, 78.
thousands of deaths and that the Church, when faced with smaller but more direct threats, did not hesitate to dispatch, with equal ferocity, what it considered heretical challenges to its authority.

What the Church perhaps feared the most from Galileo was having to go back and decide already settled questions of doctrine on a case by case basis. Once an already established assumption was successfully challenged, a lot of cases could then be brought up for reexamination.

Expediency may answer the reverse side of such an argument. Why was Galileo, one of the day's leading thinkers, so easily sacrificed to the preservation of a philosophical worldview which, in reality, was nothing more than a bureaucratic convenience. A monk in some far-off northern country, by the suppression of Galileo's thought, was saved the embarrassment of having to re-think, re-evaluate, and ultimately defend some illogical aspects of Church doctrine.

Before we rush to condemn the medieval Church as a haven for dogmatic, but misguided zealots, it might be well to remember that we have incorporated and presently utilize similar, if not identical methods and systems of thought. We too, have areas in which we find it expedient to leave well enough alone; areas which we do not wish to continually examine on a case by case basis. A prime example is found in the rDNA debate itself. For all the intensity of the debate, few, in fact no scientists, have dared to question the academic credentials of scientists on the other side. In fact, society as a whole does not easily permit such challenges. Doctors or lawyers who have successfully gained admission to a profession by passing the necessary exams are deemed qualified to practice it. A similar example is found in the legal area. While an occasional innocent person is found guilty of a crime, appeals courts have found it expedient to leave the decisions of trial courts alone. While this can be criticized as providing a convenient out for the judicial system, any other course would leave individuals in a state of uncertainty for years, and would slowly bring society to a chaotic but certain standstill.

It is a distinct advantage to be able to place a cherished belief in the class or on the level of an established presumption. What happens when beliefs, cosmologies, or concepts of nature become sanctified or elevated into iron-clad or universal truths or universal principles of nature? They become immune from challenge. Therefore, their proponents must no longer lay a foundation for their actions and it becomes quite easy to move ahead.

It is possible to argue that what happened at Asilomar and what resulted was an attempt by the scientific community to place its profession and its activities on a high plane. A plane from which such activities would be immune from any challenges from below. Asilomar was to set an example, to prove

that the biomedical research community was unique among the professional organizations because the group possessed sufficient moral stamina to regulate itself. Asilomar was to be offered as proof absolute that there was at least one unique group whose moral standing was beyond reproach, whose pronouncements would be an unchallenged assumption, and whose activities would be beyond question. Asilomar was such an attempt. And while it can be argued that it was a success, it can as easily be argued that it was a failure.

Scientists certainly can make the argument that Asilomar was proof of the ability to self-regulate, just as they can assert that they are in danger of persecution from some twentieth century Inquisition. Whatever assertions scientists may make, the assertion that they, as a group, possess a superior moral authority, a greater intelligence, or a physical dexterity sufficient to carefully control dangerous organisms, simply does not accord with the facts.

Beginning with the legal side, scientists made a fundamental error. It is such a gross mistake that if called before a jury they would be found liable without doubt. They assumed that they could focus solely on the best aspects of an activity, without so much as giving a thought to the worst. They assumed that when the "best and brightest" are at their best, danger from the stupid has simply vanished. A fundamental tenet of the law of tort is that the best and brightest must not only be intelligent enough to eliminate their own mistakes, but must also be able to anticipate and prevent the mistakes, stupidity, and carelessness of others. The president of a grocery store chain is never called to testify on the question of whether he or she would be stupid enough or careless enough to leave a banana peel lying on the floor.

It would not be enough for the Asilomar participants to establish their own conduct or care. To support their argument they would have to account for the activities of all scientists, past, present and future. From the small sampling of past medical disasters already cited, their argument would be rather weak. Even putting aside as insane the conduct of the German medical corps during World War II, where German doctors transplanted human bones and organs and injected gangrene, tetanus or staph bacteria into human subjects, the Asilomar participants have a heavy burden to carry.

On the experimental side, the mistakes of Pasteur and Koch are less extreme than one or two other quite bizarre examples. H.T. Ricketts became famous for his studies into deficiency diseases. In 1917 he was studying the transmission of typhus by lice. He made the unfortunate and fatal mistake, not only of collecting lice in an envelope, but also of carrying the unsealed envelope in his pocket—from which the lice escaped and infected him. A


\[16^{4}\] SYLVESTER, supra note 156 at 143.
plumber working at Fort Detrick, the Army’s biological warfare research center, contracted a fatal case of anthrax when he entered an area posted with a sign reading “DO NOT ENTER WITH OPEN WOUND.” The plumber had recently had a tooth pulled.¹⁶⁵

Perhaps the most unsettling incident was one which occurred just two years prior to Asilomar. It is unsettling for two reasons; first, the relaxation of safety precautions rested on the assumption that modern immunization had eliminated risks to the population from the disease and second, although doctors knew of the place where the disease was contracted, they did not diagnose it until a week after it had run its course. The disease was smallpox. It must have been a close relation to the epidemic pox which decimated the Aztec population, for like that earlier version the 1973 disease proved fatal to a young couple.

The virus initially infected a laboratory worker who happened to be in a room where smallpox was being harvested from half-open eggs on an open laboratory bench. When the disease manifested itself two weeks later it was first thought to be influenza, which diagnosis was later changed to possible meningitis, then to an antibiotic reaction, next a possible fungal infection, and finally a glandular fever. Not until a week after release was the lab worker’s case recognized as smallpox. By that time the disease had been passed on to a young couple and within several weeks, both individuals had died. Public health officials had one body cremated, the other sealed in a disinfectant-saturated coffin and buried by gravediggers given fresh vaccinations.¹⁶⁶

If researchers were to assert the argument that Asilomar proved, if not the experimental, at least the moral superiority of their calling, they might have difficulties once more in squaring their argument with the facts. To begin with, James Watson’s book, The Double Helix¹⁶⁷ provides one strike against them on that score.

The Double Helix is nothing, if not interesting. But it does illustrate, on a lighter level, some of the excesses which the intense competition in research can bring out. Nobel prize winner Linus Pauling somehow inherited Louis Pasteur’s flair for the dramatic and, as the book states, Pauling was resented for that trait.¹⁶⁸ That resentment is not one of the excesses. The excesses one might point to are a failure to inform Pauling of a mistake in one of his papers and a refusal to share pictures and information with Pauling.¹⁶⁹ Two aspects of The Double Helix are unsettling. The first is that Pauling even made a mistake and that the mistake was in elementary college chemistry. The second unsettl-

¹⁶³ROGERS, supra note 4 at 125.
¹⁶⁴Id. at 107-09.
¹⁶⁶Id. at 30.
¹⁶⁷Id. at 104-107, 08.
ing aspect is that Watson and his colleagues were not particularly anxious to reveal that error to Pauling, just as they were not particularly eager to share some x-ray pictures which might help him.

The events described in *The Double Helix* provide a comic note since no lives were at stake in the contest; the theoretical side of a subject providing that type of leeway. More serious are the fights in applied science, where a refusal to share information or to cooperate can affect the course of research and ultimately the course of disease. What came out of Asilomar and subsequent proceedings reveals some shortcomings on the moral side of research. More serious is the inability of the NIH to account for its actions in the intentional release area.

One story, which came out at Asilomar, concerns a researcher named Andrew Lewis. In 1971 Lewis was associated with the Laboratory of Viral Diseases at the National Institute of Allergy and Infectious Disease (NIAID). As Lewis described his experiences on a Tuesday afternoon at Asilomar, his audience of scientists listened in what turned into a hostile silence. In the course of Lewis' work at NIAID, five strains of SV40 hybrids, with an unknown hazard level, were identified and entrusted to Lewis for distribution. Worried that distribution was not safe, Lewis had hesitated to send out cultures, until the strains were described at the Cold Spring Harbor Tumor Virus Workshop held in August 1971. If Lewis didn't distribute the viruses, there would, it was hinted, be congressional action, administrative pressure from NIH, and a letter to *Science*. Lewis, forced to act, felt that he should at least require some formal promise of safety in return for receiving the virus. But his Memorandum of Understanding, Lewis' prerequisite to distribution, requiring the assumption of full moral and legal responsibility, was not well received. As he told the attendees at Asilomar, several major laboratories would not support the memorandum, and more ominously, one or more of the laboratories seem to have ignored Lewis' request that the original virus hybrid cease to be distributed.¹⁷⁰

The reasons for the hostility toward government regulation result in part from personal experience by researchers with the paperwork and bureaucratic politics involved in research. One researcher probably spoke for many when he told Michael Rogers that "[a]lready we spend two months a year applying for grants; now we're afraid we'll spend another month filling out more forms. And the forms don't protect anybody; they just take more time."¹⁷¹

To assume something, is by one definition, to take for granted something that is not proved. In stating that forms don't protect anyone, the researcher stated an apparently widespread belief among those at Asilomar. But it is only assumption and it is further evidence that scientists, who are supposed to make

¹⁷⁰ *Rogers, supra* note 4, at 69-71.
¹⁷¹ *Id.* at 83.

https://ideaexchange.uakron.edu/akronlawreview/vol19/iss1/3
statements based only on experimentation and testing, make that advice more the exception than the rule. The assumption relating to paperwork is a false one.

The deaths which resulted from Koch's premature announcement of experimental results with tuberculin occurred because there was no watchdog organization to require experimental proof on paper. Dr. Edward Trudeau, at the time of Koch's announcement, had been only partially successful in protecting guinea pigs against tuberculosis.112 Pasteur's disappointments with his anthrax vaccine resulted, not so much from theoretical errors, but from the practice of attempting to mass-produce vaccine in his experimental laboratory rather than a factory.113

Perhaps some of that detested paperwork might have curtailed the damage done by therapeutic radiation use by the medical profession during the period from the late 1930s to the early 1960s. However the practice got started, it is testimony to the fact that the medical profession is as prone to rely on a tradition, once established, as it is to resort to empirical evidence. Radiation therapy was well accepted medical practice, prescribed to shrink tonsils and adenoids or to treat acne, fungal infection and dermatitis.114 Although reports on the correlation between radiation and cancer began circulating as early as 1950, the practice continued for another ten years.115

Just how important paperwork and regulation can be is most strongly presented by the actions surrounding the attempt by the William S. Merrell Co. to introduce the drug thalidomide into the United States.116 It is at once the most damning and conclusive proof that whatever high ideals Asilomar may have represented, such ideals and efforts are insufficient to overcome the real shortcomings of the research community and the very real dangers those shortcomings present to society. Because an administrative agency, the FDA, required paperwork, thalidomide did not become a greater American tragedy.

On September 12, 1960, the William S. Merrell Company submitted a New Drug Application (NDA) to the FDA, which assigned the NDA for review to Dr. Frances Oldham Kelsey, the newest medical officer on the FDA staff.117 The review should have been a routine one. Superficially, the drug had every appearance of being safe, having been test marketed in West Germany

111KNTGH. supra note 147 at 111.
112DE KRUIF. supra note 137, at 155-56.
113See Management of Patients with a History of Radiation Therapy to the Head and Neck During Childhood, 77 J. KANS MED. DOC. 212 (1976); Continuing Occurrence of Thyroid Carcinoma After Irradiation to the Neck in Infancy and Childhood, 292 NEW ENG. J. MED. 171-73 (1975).
114See B.J. Duffy, P.J. Fitzgerald, Cancer of the Thyroid in Children: A Report of 28 Cases, 10 J. CLIN. ENDOCRIN. & METAB. 1296 (1950); A.C. Schultz, M.D., Childhood Irradiation and the Incidence of Thyroid Cancer, 63 MINN. MED. 535-38 (July 1980).
115McFadyen, Thalidomide in America: A Brush with Tragedy, 11 CLIO MED. (2) 79-93 (July 1976).
116Id. at 80.
as early as November 1956. But Dr. Kelsey felt that Merrell's evidence, submitted to establish the drug's safety, was inadequate. The supporting clinical reports sounded more like testimonials than scientific studies. Dr. Kelsey drafted a letter to Merrell stating that chronic toxicity data was incomplete and no evaluation could be made. The letter served to delay approval for a 60-day period.

Merrell seemed, nevertheless, intent on getting the drug marketed. In what was described as one of the most "severe" applications of pressure, Merrell's representatives repeatedly made phone calls and personal visits in an effort to gain approval for the drug.

In an issue of the *British Medical Journal* read by Dr. Kelsey in February 1961, there was a report of possible side effects from thalidomide involving deterioration of nerves in the hands and feet. Merrell's medical staff felt the report was of no major consequence. After European meetings with English and German representatives for drug manufacturers, Merrell's staff assured the FDA that the incidence of side-effects was low and rapidly reversible. Merrell representatives suggested that any such toxic side-effects could be taken care of with a warning label. But proof of the drug's safety was never forthcoming. Stressing the lack of actual proof that thalidomide caused nerve deterioration, Merrell attempted to throw the burden of proof on the government.

In an attempt to gain approval for the 1961 Christmas market, in September Merrell brought in clinical investigators to talk to the FDA. Nevertheless, FDA officials remained unconvinced that Merrell had proved the safety of the drug. On November 30, 1961, Dr. Kelsey was informed by telephone that thalidomide had been withdrawn from the German market. Congenital abnormalities during pregnancy were reportedly now linked to the drug. Ironically, it was the Merrell official who had exerted pressure on Dr. Kelsey for approval of the drug, who telephoned Dr. Kelsey with the information.

The telephone call to Dr. Kelsey was not the end of the story. The FDA assumed that Merrell had intended to use a limited number of clinical investigators, some thirty-five to sixty. Yet when the FDA in April 1962 requested that Merrell provide information on steps being taken to warn physicians of the dangers, it learned that Merrell had sent the drug to over one thousand doctors. On July 20, 1962, an executive vice-president of Merrell met with
the commissioner of the FDA and assured him that a recall of the drug had been completed and that all clinical investigators had been contacted by phone, wire, or in person. Yet, when an FDA inspector visited Merrell’s offices on July 23 and 24, Merrell was still in the process of contacting the 1,126 physicians who had received the drug. In addition, while some 5 tons of thalidomide had been returned to Merrell, over two tons remained unaccounted for.187

An FDA survey showed that more than two million five hundred thousand tablets had been distributed and given to almost twenty thousand patients. Some 624 of the twenty thousand were reported as pregnant.188 West German figures show that, in all, there were four thousand cases of birth defects attributed to the use of the drug.189

Central to the rDNA debate is the fact that a pharmaceutical company, presumably an adherent to the same professional and ethical code as the researchers at Asilomar, chose to rely on the appearance of safety provided by the German field tests, rather than resorting to rigorous clinical testing of its own. While it might be convenient to concede that in this one instance government regulations actually worked, to imply, by the reverse argument, that in most cases they don’t work and are unnecessary, is a false and potentially dangerous assumption. In fact, they work all the time. Newspaper stories giving accounts of real tragedies, the exception rather than the rule, should serve as proof. Researchers, perhaps obsessed with the need for dramatic announcements, should not take their argument to its final conclusion, by requiring tragic headlines to convince themselves of the need for stringent controls on any undertaking.

Perhaps the most striking fallacy held by the participants of Asilomar was that freedom from societal controls could be purchased for the price of a meeting. Society imposes the greatest controls where it finds the greatest danger, not where it finds the greatest virtue. Assuming that good intentions are sufficient to avoid danger is like the story of the frog who reluctantly agreed to carry a scorpion across a waterway after exacting a promise from the scorpion that he would not sting him. Halfway across, the scorpion stung, and as the frog began to sink, the scorpion was asked why he had stung the frog, for now he would himself drown in the water. “Because,” said the scorpion, “it’s in my nature.” Viruses and bacteria are dangerous, regardless of the good intentions of the researcher.

Asilomar was rDNA’s answer to Pasteur’s crowd-pleasing “scientific experiment” with the anthrax vaccine. It was good public relations, but it fell far

187 Id. at 85.
188 Id. at 86.
short of scientific proof. Pasteur at least provided the trappings of a genuine experiment. Yet, while Asilomar provided good press, it lacked even the semblance of reality which Pasteur's anthrax cultures provided. For while Pasteur gambled his reputation against the hard evidence provided by animals that anthrax kills, scientists at Asilomar lifted a year-and-a-half moratorium, on nothing more than the speculative conclusions provided by what amounted to a four-day philosophizing session.

Disease hazards run the gamit from the mild discomfort of colds to the deadly symptoms of rabies. It is pure delusion to assume that Asilomar could be offered as proof against all danger from the deadliest microbes. For to eliminate the need for regulation, scientists would have to rule their domain so tightly that, like the Biblical falling sparrow, they could hear a test tube break in the most remote laboratory. The irony of the field in which they work is that in order to bring any credibility at all to their argument, they could only buy their freedom from regulation by a dictatorial control so extensive that government regulation would seem like a summer breeze in comparison to a hurricane. Asilomar proved only that scientists didn't wish to be regulated, it did not prove that they should be free of regulation.

THE PRINCIPLE UNQUESTIONED

There are sound reasons why, like every other societal group, the research community cannot be entrusted with any unquestioned privileges. First, even some of its best, like Koch, Pasteur, and Ricketts have committed the rather ordinary sins of being careless and possessing pride. Second, society is incapable, at times, of separating the true scientists from the snake-oil salesmen masquerading as true scientists. It is naive of some in the scientific community to expect the rest of us to run for cover, to grant unrestricted freedom, simply because we are afraid of being likened to the Grand Inquisitor. On the financial and budgetary side alone, we would be labeled as fools to simply grant carte blanche to anyone requesting funds for medical research. Not to impose restrictions to prevent cheating is as unfair to those conducting needed research as it is irritating to those who must submit their department to an audit.9

One might begin to suspect that what researchers cannot attain on the basis of moral authority, they would nevertheless like to attain on some other basis. The argument goes as follows: Even if research on a practical level is not unique in terms of nobility, it is still unique in terms of value and technical difficulty, and on that basis, should be granted an exemption from the case by case analysis applied to the endeavors of other groups.

What makes scientists uncomfortable is a comparison between their ideals

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9The Rocky Mountain News reported a UPI story concerning a Defense Department report that military doctors may have pocketed or given assistants $47,000 in research money provided by drug companies and research institutions. The Rocky Mountain News, Jan. 17, 1985, at 39.
and expectations and their true actions. They do not like to be reminded that while they preach academic freedom of inquiry and the open exchange of ideas, their business interests and the need for secrecy in the genetic engineering field have placed them at odds with those very ideals. And while they will bristle at the suggestion of any control being imposed on the areas they wish to research, there is a growing tendency, on their own initiative, to forego research in one area because another area may be of greater interest to industry. Censorship by neglect is, after all, not forbidden by canons of ethics. But the desire to be accorded the status and privileges which come with the coronation of a principle is strong. Being accorded the privileges, without the moral authority, still runs a strong second. The biomedical community, it may be argued, was still unique, even if not morally superior. A participant of Asilomar would be first to agree that biomedical researchers were among the first groups in history to succeed in self-imposing a moratorium. And biomedical researchers would like to believe that their field is not easily understood by the layman and that, whatever their faults, they are still among a diminishing number of groups whose goals are the service of mankind. Still another argument has made its appearance — an "I told you so," in the form of the assertion that the money spent on debate and regulation was simply a waste and could have been better spent on research. That may be so, but those who assert such an argument may not want it taken to its logical conclusion. If that were to happen researchers might have to begin explaining to auditors on a yearly basis why funds were "wasted" on a project which did not result in a cure for cancer.

Repeated references to Galileo may, in the end, do more harm than good. Such references only serve as a reminder that the scientific community can itself play the role of Grand Inquisitor as often as it enjoys the role of Galileo. The scientific threats aimed at Andrew Lewis, to compel him to distribute his viruses, the pressure placed on the FDA to approve thalidomide, and even the milder forms of intimidation applied to those who opposed rDNA work hardly comport with analogies to the broken man forced to recant before the inquisitors.

CONCLUSION

Whether the dangers from rDNA research are actually behind us remains to be seen. It may be that those questions involving the purely ethical areas may loom larger in the future than those from the technical side ever actually
do.

In 1945, scientists working on the Manhattan Project speculated that the detonation of a nuclear device in the atmosphere might generate such intense heat that it would start a chain reaction involving the entire earth's atmospheric oxygen, destroying the planet. They were quite relieved when no such chain reaction occurred on the detonation of the bomb at Alamogordo, New Mexico, proving the theory an imaginary one. They might not have been so quick to relax had it been realized that within forty years of that first explosion, the Doomsday Clock, a rough estimate of the world's nuclear arsenal, would be hovering between five and two minutes to midnight. Whether there are hidden dangers in biological research will only become apparent at some future date.

It should be apparent, however, that while we may keep a wary eye on the future, that future should not blind us to our past. As scientists, researchers would do well to focus on where empirical evidence leads, not on where they want it to take them, while ignoring standard procedures in favor of short-term goals, which has often proved a formula for disaster. So too, in the legal area, attempts to restructure long-standing safeguards to fit present goals has often proved no formula for success.