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THE REGULATION OF RECOMBINANT DNA RESEARCH

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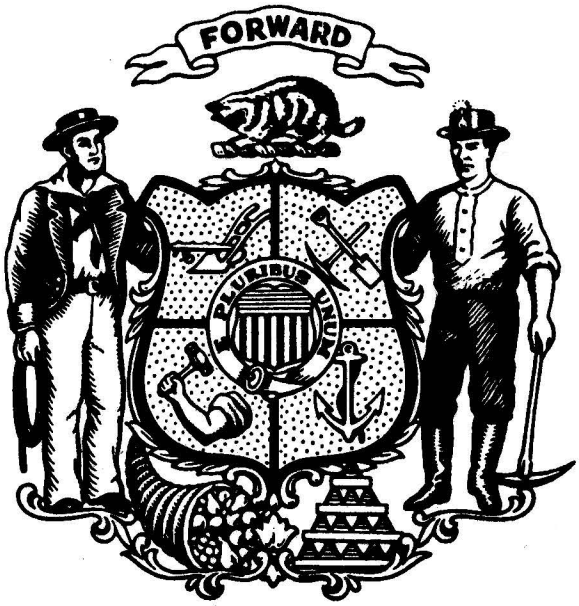

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Table of Contents

Page

I. INTRODUCTION: THE NATURE OF RECOMBINANT DNA RESEARCH 1
- Dimensions of the Problem 1
- Definition of Recombinant DNA 1
- Some Potential Benefits and Risks 2
- Major Issues Raised by Recombinant DNA Research 3

II. FEDERAL REGULATION OF RECOMBINANT DNA RESEARCH 3
- The Origin of Federal Guidelines 3
- National Institutes of Health Guidelines 4
- Federal Legislation 4
- Prospects for Further Regulation 5

III. THE STATUS OF RECOMBINANT DNA RESEARCH IN WISCONSIN 5
- Nature and Extent of Research 5
- Regulation of Research 6
- Reaction to Federal Proposals to Regulate Recombinant DNA Research 6
- Wisconsin Legislation 7

IV. STATE AND LOCAL REGULATION OF RECOMBINANT DNA RESEARCH 8
- Maryland 8
- New York 8
- California 9
- Other States 9
- Local Ordinances 10

V. SOURCES 11

THE REGULATION OF RECOMBINANT DNA RESEARCH

I. INTRODUCTION: THE NATURE OF RECOMBINANT DNA RESEARCH

Dimensions of the Problem

In 1953 the nature of modern biology was radically transformed when scientists succeeded in recreating the molecular structure of deoxyribonucleic acid (DNA) — the fundamental building block of life. This discovery was heralded as a great advance in man's knowledge of genetics since it gave scientists a new understanding of the biological and chemical functions of life. Twenty years later, in 1973, another breakthrough occurred when scientists developed a technique which permitted DNA molecules from totally different organisms to be combined to create a new organism. The implications of this discovery are immense: man now has the capacity to manufacture and alter genetic information, thereby creating new forms of life.

The discovery of recombinant DNA techniques immediately created a controversy concerning the potential benefits and risks inherent in genetic engineering. The potential for far-reaching advances in science, medicine and agriculture has been contrasted with possible hazards to human health and the environment and moral concerns regarding genetic manipulation. The ensuing debate on the scientific and ethical implications of recombinant DNA research has involved both the scientific community and the general public and has raised questions about the role of the public and government in regulating science and the responsibility of scientists to society. The central issue has been one of achieving a balance between protecting the public health and safety without unduly restricting scientific inquiry.

Beginning in 1974 when a group of scientists requested the scientific community to voluntarily halt recombinant DNA experimentation until adequate safeguards could be instituted, the Federal Government and a number of state and local governments have grappled with the problem of devising appropriate regulations. Although interim guidelines regulating DNA research have been in effect since 1976, they apply only to federally funded research. Congress has been unable to agree on comprehensive legislation covering all forms and aspects of recombinant DNA research. In the absence of federal legislation, several states and local governments have considered adopting laws regulating DNA research conducted in their respective jurisdictions. At the present time, Maryland has been the only state to enact regulatory legislation.

The regulation of recombinant DNA research has also received a great deal of attention in Wisconsin, partially due to the University of Wisconsin's status as one of the leading research centers using this technology. Both the city of Madison and the Wisconsin Legislature have considered legislation to regulate biomedical research.

Definition of Recombinant DNA

Deoxyribonucleic acid, more commonly referred to by the acronym DNA, is the fundamental genetic material for all known forms of life. The DNA molecule is the repository for stored genetic information including inheritable traits, which all living organism transmit from generation to generation. It contains the biological information which organisms use to reproduce, to manufacture their vital products, and to perform the functions necessary for survival.

Recent advances have enabled scientists using new biochemical techniques to "cut" the DNA molecule and insert the cut segment into another organism, thereby recreating a "recombinant" DNA molecule. The resultant recombinant DNA molecules are comprised of genetic information derived from two or more different species. The recipient organism also has the capacity to replicate the foreign DNA during the cell division process, providing a means of synthesizing large amounts of DNA

Prepared by Lawrence S. Barish, Research Analyst

containing identical laboratory-induced traits. The significance of this process has been described as follows:

> "The exchange and rearrangement of genetic information is a routine phenomenon in nature, resulting in the appearance of offspring of traits that were not found together in either parent, but which occur together on the chromosomes of the offspring because of an exchange of DNA between two chromosomes. The crucial feature of such natural recombination of genetic information is that it almost always occurs only between individuals of the same species, and although it results in the rearrangement and continued mixing of genetic information within the species, it does not provide for the introduction of new genetic information from other species. Even the bacterial viruses, many of which can carry pieces of genetic information from one bacterial cell to another, are usually quite restricted in the range of bacterial species which they can infect.
>
> "This ability to join together genetic material from two different sources and to propagate these hybrid elements in bacterial and animal cells has resulted in a profound change in the field of genetics. Now, for the first time, there is a methodology for crossing very large evoluntionary boundaries, and for moving genes between organisms that are believed to have previously had little genetic contact."

Some Potential Benefits and Risks

Most observers agree that recombinant DNA research can have both positive and negative effects. However, since this is a new biochemical tool which has been relatively untested, most assessments of potential benefits and risks have been necessarily speculative. The major area of disagreement, dividing both the scientific community and the public, has been the balance between risks and benefits.

It is clear that recombinant DNA technology provides the tool for increasing man's understanding of genetics. It is anticipated that this research will make significant contributions to medicine, agriculture and industry. Dr. Stanley Cohen, a scientist who helped develop recombinant DNA technology, has offered the following possible applications:

> "On a more practical level, recombinant DNA techniques may enable the construction of bacterial strains that produce biologically important substances such as insulin and other hormones, or antibodies and vaccines to treat presently uncontrollable viral diseases. We also can expect recombinant DNA techniques to revolutionize the production of antibiotics, vitamins, and medically and industrially useful chemicals. And we can anticipate the development of antimicrobial agents that are not inactivated by drug-resistant bacteria.
>
> "Other benefits from this research in the areas of food and energy production are more speculative. However, even in these areas there is a scientific basis for expecting that the benefits will someday be realized. The limited availability of fertilizers and the potential hazards associated with excessive use of nitrogen fertilizers now limits the yields of grain and other crops. It would be possible, agricultural experts suggest, to use the techniques of gene transplantation to modify grains and other food crop plants so that they will not require nitrogen fertilizers. For many years, scientists have modified the heredity of plants by comparatively primitive techniques. Now there is a means of doing this with greater precision."

The vast potential that recombinant DNA holds has led government and industry to establish what one commentator calls "a technical boom town set up to mine the new genetic motherlode". Numerous pharmaceutical, chemical and agricultural companies are currently performing recombinant DNA research. It has been reported that one major corporation has already developed a recombinant "oil-eating" bacteria that may be useful in cleaning up oil spills.

The hazards associated with recombinant DNA research have raised wide public concern, and have generally been focused on two types of potential risks. The first pertains to the possibility of environmental contamination, while the second involves the ethical implications of man-made genetic recombinations.

Some of the potential hazards inherent in recombinant DNA research were summarized in a petition filed by the Environmental Defense Fund and the Natural Resources Defense Council with the Secretary of Health, Education and Welfare, during hearings on the need for federal regulatory legislation:

> "Recombinant DNA technology permits the creation of organisms or viruses with an unprecedented genetic make-up which may have the potential of causing grave and irreversible harm to humans and the environment. The extent of our current knowledge does

not allow us to predict all of the possible results of experiments involving the manipulation of genes. Because most of the present and proposed recombinant DNA research and technology involves the genetic modification of bacteria or viruses, there exists the potential danger of creating a highly deleterious communicable infectious agent that could be introduced into and spread among laboratory workers and/or the general population."

A frequently mentioned scenario involves the escape of recombinant DNA organisms from the laboratory into an environment which may have no natural defenses against such agents. Possible effects cited include the creation of new incurable diseases or the rendering of existing diseases resistant to antibiotic treatment.

Perhaps the potential hazard which has elicited the most concern is the fear that recombinant DNA research will damage the evolutionary process by creating new, self-replicating life forms which upset our finely-tuned ecological balance. Scientist Dr. Robert Sinsheimer states this concern as follows:

> "As science pursues this synthetic biology, we will be leaving the secure web of evolutionary nature that, blindly and strangely, has supported all living creatures for some 3 billion years. With each step we will be increasingly on our own. How do we prevent grievous, inherently irreversible, errors? Can we in truth foresee the ultimate consequences of intervention into this ancient process?"

Major Issues Raised by Recombinant DNA Research

Apart from questions about the safety and morality of recombinant DNA research are fundamental questions concerning the relationship between science and society. These questions involve the balance between the "right" of free scientific inquiry and the "right" of the public to be informed about scientific research and to have a role in influencing the course of such research. Although there is a general consensus that scientists have an overriding responsibility to society, the nature and shape of this responsibility is not clearly defined. At the same time, the public's role in the policy formulation process has not been clearly described.

Dr. Key Dismukes, a Massachusetts Institute of Technology biophysicist, has offered a rational perspective with which to view the problem:

> "Who will control this research? Who will determine what is an acceptable level of risk and enforce restrictions? These are not scientific questions, but issues of social policy. The public must have a choice in their resolution, because the public shares the risks.
>
> "In the furor of debate, the two issues have become confused. Scientists are legitimately concerned that controversy may distort and exaggerate hazards, but that is not an excuse for neglecting public involvement. It seems clear that this research will go on, and that it must be regulated. Scientists must join public representatives to develop a coherent, rational, and widely acceptable social policy."

II. FEDERAL REGULATION OF RECOMBINANT DNA RESEARCH

The Origin of Federal Guidelines

Concern over the implications of genetic research, particularly recombinant DNA research, surfaced in 1973 during a meeting of some 140 molecular scientists at the Gordon Conference on Nucleic Acids. The scientists present at the meeting voiced their concern about the potential public health hazard posed by certain types of genetic research involving recombinant DNA. This concern was based on the realization that the new technology might accidently produce a recombinant molecule with unforeseen, and possible hazardous, characteristics. As a result of the issues raised at this meeting, an open letter was sent to SCIENCE Magazine in which the National Academy of Sciences was asked to establish a committee to study the attendant problems of recombinant DNA research and make appropriate recommendations in light of potential safety hazards.

The outgrowth of this action was the convening of an international group of scientists at Asilomar, California, in 1975 to discuss the issues raised at the Gordon Conference. From this meeting, the so-called "Asilomar Guidelines" for the safe conduct of recombinant DNA research emerged. These guidelines later provided the basis for more detailed regulations developed by the National Institutes of Health (NIH).

National Institutes of Health Guidelines

In 1976 the National Institutes of Health established comprehensive safety guidelines for federally funded recombinant DNA research. The NIH, an agency of the U.S. Department of Health, Education and Welfare, is primarily concerned with biomedical research. In addition to promulgating rules regulating research, the agency conducts research in its own laboratories, provides grants to other institutions, and offers education and training programs in the field of biomedicine.

The NIH guidelines for DNA research were the product of a special study committee which adopted and modified the informal rules that had been in effect since 1975. The NIH rules adopted were more stringent than the previous regulations and were officially promulgated in the Federal Register in July 1976. Safety precautions for all DNA experiments were established and certain high-risk experiments involving highly toxic substances were banned completely.

The guidelines establish various safety controls designed to prevent the escape of recombinant organisms into the outside environment. Experiments utilizing recombinant DNA technology are assigned to specific containment levels based upon the potential hazards associated with the host and donor organisms. The assignment of containment levels relies on the assumption that the less the evolutionary distance between the donor organism and man, the greater the potential hazard.

Both physical and biological containment precautions are specified. The guidelines establish four physical containment levels matched to the potential risk of a particular experiment. These levels range from P1, the minimal category, requiring standard laboratory safety procedures, to P4, the highest risk level, requiring sealed rooms, double doors, and protective clothes. Workers in P4 laboratories are required to shower and change clothing before entering and after leaving the laboratory.

The guidelines also recommend biological containment measures. The rules suggest the use of the E. coli K-12 bacteria and its variants as the principal recombinant host organism. This new strain developed specifically for use in genetic experimentation is a variation of the common E. coli bacteria found in the human intestine. To further reduce the chance of survival and propagation outside the laboratory, the host bacterium is disabled. Three levels of biological containment are recommended ranging from EK1, the first level, to EK3, the highest level. Experiments are placed in a particular containment level depending on the degree of potential hazard.

All recombinant DNA research which receives funding from the NIH must conform to the requirements contained in the guidelines. However, compliance is not required of nonfederally funded research and research done by private industry. The guidelines have been criticized by some scientists and nonscientists because of the lack of enforcement and compliance mechanisms. Others have argued that the safety measures recommended in the guidelines are too loosely drawn to be effective.

As a result of this criticism the Recombinant Advisory Committee, established by the original guidelines to recommend modifications, is currently studying revisions to the rules. The revised guidelines will take into account the effectiveness of existing containment procedures and the applicability of the rules to privately funded research. Another group established to examine the implications of recombinant DNA research, the Federal Interagency Committee on Recombinant DNA Research, has also recommended that legislation be enacted to extend the NIH guidelines to all recombinant DNA activities in the public and private sectors.

In addition, more stringent and inclusive legislation is currently being considered in Congress and at the state and local level.

Federal Legislation

There have been at least twelve bills introduced in the 95th Congress which would have some impact on recombinant DNA research. Two major bills currently before Congress, S. 1217 and H.R. 7897, would establish comprehensive controls over genetic research by requiring the licensing of both public and private research facilities. Both bills would permit state and local governments to establish their own, stricter standards on such research. However, the regulatory mechanisms proposed by each bill differ substantially.

S. 1217, introduced by Senator Edward M. Kennedy, would establish a National Recombinant DNA Safety Regulatory Commission to oversee both public and private research. The commission would be composed of 11 members appointed by the President, with the majority of members selected from the general public. The primary responsibility of the commission would be the development of rules and procedures to be followed by all laboratories conducting recombinant DNA research. Under the terms of the bill, these regulations would have to be at least as stringent as the physical and biological containment requirements contained in the National Institutes of Health guidelines. The Commission would also be authorized to conduct on-site inspections of research facilities.

H.R. 7897, sponsored by Representative Paul G. Rogers of Florida, employs an alternate approach towards regulating recombinant DNA research. This bill utilizes the existing governmental framework and places responsibility for promulgating regulations with the Secretary of the Department of Health, Education and Welfare. The bill contains no requirements regarding the safety standards to be set and authorizes the Secretary to exempt from regulation any recombinant DNA research found not to present "a significant risk to health or the environment." The bill also provides for the licensing of research facilities by HEW or local committees composed of government officials, scientists and representatives from the general public.

Representative Rogers has introduced several other bills which would regulate genetic research. One such bill sponsored by Representative Rogers, H.R. 11192, was approved by the House Interstate and Foreign Commerce Committee by a vote of 17-6 in March 1978. The bill, described as an interim measure, would extend the NIH guidelines to include research conducted by private industry for a period of two years. During this time, a 13-member commission appointed by the Secretary of Health, Education and Welfare would be responsible for examining the possible hazards and benefits of recombinant DNA research and recommending appropriate standards.

The bill would also prevent state and local governments from adopting safety standards which are more restrictive than the federal guidelines without first receiving approval from HEW. Observers have noted that the ordinance adopted by the city of Cambridge, Massachusetts imposing strict safety standards on genetic research conducted at Harvard University would probably be preempted by federal guidelines if H.R. 11192 became law.

Prospects for Further Regulation

At the present time, Congress appears to have adopted a "wait and see" attitude with regard to enacting legislation that would extend or strengthen controls over recombinant DNA research. Although numerous bills have been introduced in Congress and several committees have held hearings on the subject, a definitive legislative solution to the problems surrounding genetic research does not appear imminent. The dilemma facing Congress in enacting legislation was voiced by Senator Adlai Stevenson, chairman of the Subcommittee on Science, Technology and Space, during hearings held by that subcommittee in November 1977:

> "...(W)e are further from a legislative answer today than last spring when most persons believed an act would be on Presidents Carter's desk before the July Fourth recess. New findings related to the degree of hazard associated with certain recombinant DNA experiments have been published. The National Institutes of Health proposed revising its recombinant DNA guidelines. The Carter administration is reexamining its position. A growing number of States and localities are considering or have adopted their own regulations."

Much of Congress's indecision is due to the lack of firm evidence available to base a decision regarding the possible hazards of recombinant DNA research. This is understandable since there has been no consensus among scientists regarding the need and extent of formal DNA research safeguards.

In an effort to provide meaningful data concerning the possible risks of DNA research, the National Institutes of Health is planning to begin experiments with recombinant DNA procedures at two specially modified high containment laboratories in Maryland. The experiments were originally scheduled to begin in the summer of 1977 but, due to criticism that the experiments may pose potential hazards, testing has been delayed for almost one year. The NIH currently intends to begin risk assessment experiments in April 1978. It is hoped that the results will provide needed data on several key issues including whether organisms altered by recombinant DNA methods can infect other organisms and survive outside laboratory conditions.

III. THE STATUS OF RECOMBINANT DNA RESEARCH IN WISCONSIN

Nature and Extent of Research

The University of Wisconsin is one of the leading recombinant DNA research centers in the nation. This status is partially due to the fact that the University has received over three and one-half million dollars in federal funds to perform recombinant DNA research. By comparison, Stanford University, the institution receiving the second largest amount of federal funds, collected one and one-half million dollars.

At the present time, the UW-Madison campus is the only location in Wisconsin utilizing recombinant DNA technology. It has been reported however, that the Medical College of Wisconsin will soon begin research programs using similar techniques.

On the UW-Madison campus there are currently over 20 laboratories engaged in some form of research employing recombinant DNA techniques. Research is being conducted in a number of fields including biochemistry, genetics, molecular biology, physiological chemstry, bacteriology, pharmacology and plant pathology. Most of these research programs pose minimal safety threats and are thus subject to the least restrictive physical and biological containment levels specified by the National Institutes of Health guidelines.

According to information contained in a newspaper interview of UW scientist William Reznikoff (Madison *Capital Times*, December 5, 1977), 16 of the 23 laboratories conducting recombinant DNA research on the Madison campus are engaged in P1 level research requiring minimum safety precautions. Six laboratores are subject to P2 safeguards, requiring moderate precautions, while one laboratory is certified for P3 safeguards, subject to more stringent limitations. No laboratories in the state are performing P4 level research, considered to be the most hazardous by the NIH.

Regulation of Research

UW Biological Safety Committee

The NIH guidelines require institutions engaged in recombinant DNA research to establish a biohazards committee responsible for insuring the safety of all research performed. At the University of Wisconsin-Madison, a Biological Safety Committee has been in operation since 1972. The committee is comprised primarily of faculty members representing expertise in various scientific disciplines. The committee screens all grant applications for research projects involving recombinant DNA and approves such projects only after determining that no potential hazards exist. Ongoing research is also monitored to insure that federal safety guidelines are complied with. The University requires all projects to meet the NIH guidelines regardless of funding source.

The University of Wisconsin is currently in the process of hiring a full-time biological safety officer. The individual filling this position will be responsible for developing and implementing research safeguards and serving as safety coordinator for all scientific research performed on the Madison campus.

City of Madison Recombinant DNA Research Committee

In February 1977 the Madison City Council established a committee to study the potential effects of DNA research on the Madison community. Nine committee members were appointed, including 2 citizens-at-large, 2 representatives appointed by the Dane County Board, one designee of the U.W. Faculty Senate, one member of the City-University Coordinating Committee and several representatives of various city agencies. The charge given the Recombinant DNA Study Committee was to:

> "seek the best available testimony on the controversy surrounding Recombinant DNA experiments and to hold regular meetings for presentations of said testimony which will be incorporated in a final report of findings and recommendations to the Mayor and Council."

It was determined at the initial meeting that the committee would focus on seeking answers to such questions as whether recombinant DNA research poses a threat to the health and safety of both research personnel and Madison residents and whether there is sufficient public input and oversight over University research and research priorities.

Although the Madison Recombinant DNA Research Committee was given no formal statutory authority, the committee was expected to assume a role in working for state legislation to regulate DNA research.

Reaction to Federal Proposals to Regulate Recombinant DNA Research

In July 1977, twelve UW-Madison faculty members sent an open letter to the Wisconsin congressional delegation opposing the enactment of federal legislation to control recombinant DNA research. The letter claimed that federal legislation was unnecessary since DNA research is already subject both to the National Institutes of Health guidelines and to monitoring by local biohazard committees. The UW scientists also raised some broader issues regarding the proper relationship between scientific inquiry and governmental regulation:

> "What we fear is unprecedented and unwarranted intrusion of federal inspectors, red tape and additional unnecessary bureaucracy into the university setting. It seems difficult to

justify the expenditure of thirty million dollars annually (the current estimate of the cost of the regulatory mechanisms being proposed) to regulate a research activity which costs only 3 or 4 million to perform. This is particularly true when we bear in mind that the dangers are hypothetical...

"...(W)e feel it is unwarranted to impose prior restraints on research in the absence of a clear and present danger. American scientists have acted responsibly in openly discussing the hypothetical hazards. Legislation so ill-advised as the current bill will certainly discourage U.S. scientists from being so open and forthright in the future."

The legislation referred to by the UW researchers, H.R. 7897 and S. 1217, would establish more stringent controls on biomedical research. H.R. 7897 would assign responsibility for regulating DNA research to the Department of Health, Education and Welfare, while S. 1217 would establish a new national commission with authority to license and oversee all recombinant DNA research. The signers of the letter expressed the most concern with the regulatory commission proposed by S. 1217, which they perceived to be a "threat to freedom of inquiry":

"This bill proposes creation of a regulatory commission outside of NIH composed primarily of non-scientists who will be political appointees with blanket authority over all recombinant DNA activities and with sweeping powers...The potential for abuse of such a commission calls to mind the Lysenko era in Russian Science which led to a purge in that country of scientists who did not agree with Dr. Lysenko's views. We doubt that such a blatant event could occur here, but any regulation of free inquiry should be approached with great caution."

Some of those signing the letter to the Wisconsin congressional delegation later joined a group of scientists who went to Washington to voice their objections directly.

However, opposition to more stringent federal regulation is not unanimous in the University science community. During discussion of the issue of DNA research at the UW Faculty Senate meeting, support for additional safeguards was voiced by some scientists and nonscientists. The dialogue regarding the regulation of biomedical research taking place in Madison is reflective of the debate occurring nationally. There is a general consensus that if recombinant DNA research is permitted to continue, it must be subject to regulations which adequately ensure the safety of such research.

Wisconsin Legislation

During the 1977 session of the Wisconsin Legislature, one bill and one joint resolution dealing with recombinant DNA were introduced, but not passed.

1977 Assembly Joint Resolution 58, introduced by Representative Richard Matty and 15 others, directed the Legislative Council to undertake a study of the implications of genetic research including the issues of genetic engineering, embryo transplants, cloning and recombinant DNA. The resolution directed the Council to report its findings and recommendations to the 1979 Legislature. AJR-58 was referred to the Committee on Health and Social Services, where it received no further attention.

1977 Assembly Bill 1059 would have required that all recombinant DNA research in Wisconsin be conducted in accordance with the NIH guidelines. The bill was introduced by the Committee on Health and Social Services and was unanimously recommended for passage (10-0) by that committee. Under terms of the bill, a "memorandum of understanding and agreement" must be filed by the researcher and sponsoring organization and approved by the State Laboratory of Hygiene before any recombinant DNA experimentation can take place. The memorandum must contain information regarding the location of the research, the biological species from which DNA molecules will be obtained, the physical and biological containment levels required, and other information relating to the safety measures employed. The bill also empowered the director of the State Laboratory of Hygiene to inspect research facilities to ensure that appropriate safety measures are being used. Researchers found to be not in compliance with the requirements established by the bill are subject to injunction or restraining order to prevent continuation of their reeearch.

The fiscal estimate to Assembly Bill 1059, prepared by the University of Wisconsin System, noted that the UW-Madison currently requires all recombinant DNA research projects to meet NIH guidelines, regardless of funding source. Should additional research programs not subject to federal regulation be initiated, it was estimated that the director of the State Laboratory of Hygiene would need approximately $10,800 per year to pay the cost of a biological safety officer functioning about one-quarter time.

After being recommended for passage by the Committee on Health and Social Services, Assembly Bill 1059 was referred to the Joint Committee on Finance, where it was recommended for passage by 10-

3 vote on March 16, 1978. The bill subsequently died, however, when the Legislature adjourned two weeks later.

IV. STATE AND LOCAL REGULATION OF RECOMBINANT DNA RESEARCH

Maryland

In May 1977, Maryland became the first state to enact legislation regulating DNA research. Chapter 847, Laws of 1977 (HB 1887), established various procedures, effective July 1, 1977, to ensure that DNA research will not have any adverse effects on researchers, the public, and the environment. Under terms of the act, those engaged in DNA research in nonfederally funded laboratories are required to comply with the same National Institutes of Health (NIH) guidelines applicable to federally funded researchers. The latter are required to submit evidence of compliance with federal guidelines.

A major aspect of the Maryland law involves the licensing of DNA-related research. No recombinant DNA research may be carried out unless a license is first obtained from the Secretary of Health and Mental Hygiene. The secretary is empowered to issue a one-year license, renewable annually, based upon evidence that the proposed research will be conducted in accordance with the NIH guidelines. Although the law does not establish research standards in addition to the federal requirements, the state is given the authority to revoke, limit, or suspend a license if it is determined that the research poses a "significant hazard to the public health". Section 899 of the act enumerates seven grounds for terminating a license:

> "A license issued by the secretary may be revoked, suspended, or limited if the secretary finds after reasonable notice and opportunity for a hearing to the licensee, that such licensee:
>
> (1) Has been guilty of misrepresentation in obtaining a license;
>
> (2) Has engaged or attempted to engage or represented himself as entitled to perform any research or procedure or category of procedures not authorized by the license;
>
> (3) Has failed to comply with NIH guidelines with respect to research facilities or personnel;
>
> (4) Has wilfully failed to comply with reasonable requests of the secretary for any information or materials the secretary deems necessary to determine continued eligibility for its license or continued compliance with the NIH guidelines;
>
> (5) Has refused a request from the secretary or agent of the secretary for permission to inspect the research facility and its operations and pertinent records at any reasonable time;
>
> (6) Has wilfully violated or aided and abetted any violation of any provision of this section or of any guideline; or
>
> (7) Has failed to correct any violations of this act within 30 days after written notice of such violation as set forth in section 901 (b) of this act."

The act also establishes a seven-member Biohazards Committee responsible for evaluating all recombinant DNA research project license requests and monitoring all licensed DNA research. The committee is comprised of the Secretary of Health and Mental Hygiene and "experts in the fields of microbiology, virology, epidemiology, nursing, medicine, environmental health, and at least two community members." The responsibilities of the Biohazards Committee include reviewing all proposals for DNA research, scheduling periodic site visits to research facilities, recommending and promulgating administrative rules, and holding public informational meetings in areas where research is being performed.

New York

During the 1977 session, the New York Legislature passed a bill to require the certification of recombinant DNA experiments. However, the bill, 1977 Senate Bill 4009-D, was vetoed by Governor Hugh Carey in August 1977 on the grounds that such regulation should be the responsibility of the Federal Government rather than the state government.

The bill was introduced with a recommendation by the New York Attorney General, who had conducted hearings on the need for regulating recombinant DNA research in October 1976. As a result of the hearings, the Attorney General issued a report which concluded that unregulated recombinant DNA research "posed a unique threat to the public health and to the environment" and should be permitted to continue only if adequate safeguards were adopted.

Under terms of the bill, the state health commissioner, assisted by an advisory panel comprised of representatives from both the public and the scientific community, would have the authority to establish regulations controlling DNA experimentation. The bill also would have directed the commissioner to

establish certification procedures and training programs for researchers, determine the types of organisms which could be used for experimentation, set standards of the kinds of equipment and facilities necessary to prevent the escape of potentially harmful organisms, and conduct both scheduled and unannounced inspections of laboratories where research is being conducted. Violation of any provision of the bill would have resulted in the revocation or suspension of certification and a fine of up to $5,000.

In his veto message, Governor Carey noted two basic problems with the bill:

> "First, there is a real question as to whether any legislation of this kind is appropriate at the State level. The National Institutes of Health has issued guidelines applicable to all federally funded DNA research, and the question of uniform, federal legislation in this area is now being considered. Thus, any externally imposed safeguards or restrictions, if they are ultimately found to be appropriate, should be national in application, and not imposed in random fashion from state to state. Second, even assuming State legislation would ever be appropriate, several deficiencies have been noted in this bill. Its language is vague and often disturbingly broad. The limits of the Commissioner's powers are not precisely expressed, nor is the nature of the scientific inquiry to be regulated clearly set forth. These deficiencies are especially critical in legislation of this type, which intrudes into an area where freedom of inquiry and exploration should be maximized and regulations, if any, should be narrowly and strictly defined."

During the 1978 session, Senate Bill 8019, similar to the 1977 bill, has been introduced. As of March 16, 1978, the bill had not been reported out by the Committee on Health.

California

During the 1977-78 session, the California Legislature considered, but did not enact, a bill to regulate recombinant DNA research. 1977 Assembly Bill 757, as amended, would have created a California Recombinant DNA Research Safety Commission, responsible for regulating and licensing those engaged in biomedical research involving recombinant DNA methodology. The commission was to be composed of 11 members, with backgrounds in such fields as molecular biology, agriculture, medicine, law and the social sciences, including ethics and human rights. The governor would have appointed 7 members, with the Speaker of the Assembly and the President pro tempore of the Senate appointing 2 members each.

The bill required the commission to adopt permanent regulations "no less stringent than the National Institutes of Health guidelines" by May 1, 1978. The commission was given the authority to issue certificates to conduct recombinant DNA research after determining that such research is in compliance with established regulations.

Other provisions of the bill directed the Recombinant DNA Research Safety Commission to develop an inspection program in cooperation with the State Departments of Health and Consumer Affairs. The commission would also have been responsible for establishing plans for seizing or destroying recombinant DNA supplies in the event of a disaster which jeopardized public health, safety or the natural environment.

Other States

Several other states have also been examining the problems related to recombinant DNA research. The Illinois Legislature adopted a resolution in March 1977 directing the House Committee on Environment, Energy and Natural Resources to undertake a study of the implications of biomedical research. In response to this directive, the committee organized a Subcommittee on Recombinant DNA Research. After holding several public hearings attended by both industry and university representatives, the subcommittee considered regulatory legislation patterned on the Maryland law. However, no consensus was reached, and the bill was not recommended for passage. According to a committee staff member, it is probable that similar legislation will be introduced during the 1979 legislative session.

In New Jersey, the Attorney General ruled in April 1977 that the state has the authority to regulate or prohibit certain recombinant DNA research in the interest of protecting the public health. In Formal Opinion No. 6-1977, Attorney General William Hyland concluded that the Public Health Council has rule-making power to adopt regulations regarding P3 and P4 level research, based upon a legislative mandate to protect the public from significant risks to health and safety.

Local Ordinances

The controversy surrounding genetic research has also involved a number of municipalities concerned with the potential biohazards of recombinant DNA experiments performed in the community. University communities where research activities are concentrated, such as Madison, Wisconsin; Ann Arbor, Michigan; Palo Alto and Berkley, California; and Bloomington, Indiana, have debated the question of whether such research should continue and, if so, with what level of local control. The delay in enacting comprehensive federal or state laws controlling recombinant DNA research has led some communities where such research is taking place to seek local regulatory legislation.

Perhaps the most national attention has been focused on the situation in Cambridge, Massachusetts, where the city council and Harvard University engaged in a heated debate over the University's plans to construct a high containment level DNA research laboratory. The dispute began in July 1976 when Harvard's plans to construct the laboratory became known and the Cambridge City Council responded by imposing a moratorium on recombinant DNA research. An eight-member citizens' committee was formed to study the issue and make recommendations to the council. After an eight-month period, the moratorium was lifted when the committee agreed that research could continue if certain guidelines were complied with. These guidelines were written into an ordinance approved by the Cambridge City Council in February 1977. The ordinance requires all recombinant DNA research performed in Cambridge, both publicly and privately funded, to comply with the NIH guidelines and additional safeguards recommended by the citizens' committee. These additional locally imposed rules require the preparation of a safety manual governing all genetic research and the establishment of a biohazards committee composed of local citizens responsible for monitoring DNA research and reporting violations.

Since it represents the first instance of a local government enacting controls on scientific research conducted within the community, the Cambridge ordinance regulating recombinant DNA research has already been accorded "landmark" status by some observers.

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Additional information regarding recombinant DNA research activities at the University of Wisconsin-Madison was provided by Dr. William S. Reznikoff of the College of Agricultural and Life Sciences in an interview conducted during February 1978.