THE NIH RECOMBINANT DNA GUIDELINES: BRIEF HISTORY AND CURRENT STATUS

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ISSUE DEFINITION

In June 1976, the National Institutes of Health issued the initial version of the Recombinant DNA guidelines. The guidelines were developed in response to concern from both scientists and the general public about the potential hazards of genetic engineering. Other Federal agencies which support recombinant DNA research have adopted the guidelines, and most industries have decided to comply with them voluntarily The techniques associated with genetic engineering enable the researcher to recombine DNA (the hereditary material of the cell) in a very precise manner. The recombinant DNA can be used to manufacture products which have never been produced before by bacteria and to manufacture products at a higher rate and yield than previously possible.

After 10 years of experience with recombinant DNA, many believe that earlier estimates of risk were exaggerated. This change in perception is reflected in the successive modifications of the guidelines over the past 6 years. Recombinant DNA and the NIH guidelines remain topics of continuing concern to the Congress and have been the subject of legislation in previous sessions.

BACKGROUND AND POLICY ANALYSIS

During a 1968 Senate Subcommittee hearing on a Joint Resolution (S.J. Res. 145) to establish a new health science commission, Dr. Arthur Kornberg directed the subcommittee's attention toward the rapidly progressing field of molecular biology. He noted that important developments were near fruition and that the potential social impact of these advances could be far-reaching. Dr. Kornberg was referring to discoveries which would provide the technical framework for the specialty commonly known as genetic engineering. New techniques have been developed in this field which enable a researcher to recombine DNA (the hereditary material of the cell) in a very precise manner. The recombinant DNA can provide a cell with the ability to manufacture products (for example, insulin) which were previously not part of the cell's make-up.

In 1973, a group of scientists attending a Gordon Conference Session chaired by Drs. Maxine Singer and Dieter Soll discussed the possibility of public health risk associated with genetic engineering. Their concern was based upon the conjecture that the new techniques could accidently produce a recombinant molecule with hazardous characteristics. For example, it has been speculated that an inadvertant modification of DNA in a previously harmless organism might enhance its capability of producing a highly infectious disease. The session's participants voted in favor of sending a letter to the National Academy of Sciences (NAS) suggesting that the academy consider the risks associated with genetic engineering and "recommend specific actions or guidelines" (Science, July 1973). In response to the Gordon Conference letter, NAS appointed a panel of experts to study the risk question. After a year of discussion, the panel issued the following three recommendations:

1. Scientists should temporarily postpone certain experiments until the risk associated with genetic engineering could be

adequately assessed;

2. The National Institutes of Health (NIH) should establish an Advisory Committee which would devise guidelines for investigators working with recombinant DNA; and

3. An international conference of experts should be organized to discuss the risk questions associated with recombinant DNA.

The international conference was held in February 1975 at Asilomar, California, and was attended by a group of 150 eminent scientists. The final report recommended that biological and physical containment standards should be assigned to experiments based on their perceived hypothetical risk.

The original Asilomar report was formalized into the guidelines by the newly formed NIH Recombinant DNA Advisory Committee (RAC, which was formed in response to the NAS panel's recommendations). After an analysis of the RAC's proposed guidelines and public comments, the Director of NIH, Dr. Donald S. Fredrickson, issued the initial version of the guidelines in June 1976 (Federal Register, v. 41: 27902-27943). This original version of the guidelines was only binding on research supported by NIH.

A special interagency advisory committee was later formed with representatives from all Federal agencies which perform, fund, or regulate recombinant DNA research. The committee succeeded in gaining agreement among its member agencies to adopt the NIH guidelines and to require compliance by federally funded researchers in work involving recombinant DNA. While the guidelines are not promulgated by law, an agency can enforce the compliance of researchers who receive Federal funds. Even though the guidelines do not cover non-federally supported research, most industries have decided to comply voluntarily with the guidelines.

By 1978 it was found that the original guidelines were unnecessarily restrictive and that a mechanism for the revision of the guidelines needed to be incorporated directly into the document. A series of scientific and public meetings were held to discuss the matter, and subsequently a new version of the guidelines was published for public comment in July 1978 (Federal Register, v. 43: 60080-601005). Following a public hearing in September 1978, the guidelines were reissued and became effective on Dec. 22, 1978 (Federal Register, v. 43: 60108-60131). The 1978 version contains a mechanism for the future revision of the document. Proposals which would modify any section or introduce a new section into the guidelines must be published in the Federal Register at least 30 days prior to a RAC meeting. The proposal and any public comments are discussed by the RAC in an open public session. The NIH Director then reviews the RAC's recommendations and makes a final decision upon the proposal.

On Dec. 29, 1978, 14 new members were added to the RAC, including six non-biologists. This broadening of the committee's composition was in compliance with a new provision contained within the 1978 version of the guidelines.

There have been many modifications of the guidelines since the implementation of the revision procedures. Three complete republications have been issued since 1978:

1. January 1980 -- This modification lowered the physical containment requirements for some, but not all, recombinant DNA experiments which use a particular strain of bacterium (E. coli K-12). Approximately 80% of all studies use this laboratory strain of bacteria as a host cell for recombinant DNA. In addition, a large percentage of principal investigators using this particular strain of bacteria were no longer required to notify NIH of the details of their experiments. Notification of a local review board (the Institutional Biosafety Committee or IBC) was all that was required (Federal Register, v. 45: 6724-6749, 1980).

2. November 1980 -- The physical containment requirements were lowered and more changes were made in the notification procedures required of principal investigators (Federal Register, v. 45: 77384-77408).

3. July 1981 -- In response to a letter from representatives of the Institutional Biosafety Committees (IBCs), the RAC voted to exempt research with E. coli K-12 (and a few other host systems) from the guideline regulations (Federal Register, v. 46: 34462-34487).

Several attempts were made in previous Congresses to focus attention on recombinant DNA issues through hearings, proposed legislation, and reports. Congressional committees have identified the evolution of this issue as a matter of vital public policy concern and have suggested the need to monitor research continuously in order to be prepared for further legislative action if necessary. Legislation which would regulate and study the implications of research involving recombinant DNA was introduced during the 95th Congress. Several bills proposed the establishment of new Federal regulatory powers, ranging from declaring a total moratorium on the research until a risk assessment could be completed to setting up licensing and certification procedures for researchers and laboratories. Four congressional committees (2 House, 2 Senate) held extensive hearings on the DNA issues in 1977, with some continued legislative hearings in 1978. Two major bills (S. 1217 and H.R. 11192) each received final full committee action in their respective houses, but none of the legislation reached the floor during the 95th Congress. In the 96th Congress, one major bill was introduced, S. 2234. This bill would have required persons not covered by the NIH guidelines to notify the Secretary of the U.S. Department of Health, Education, and Welfare (HEW -- now the Department of Health and Human Services (HHS)) of their activities in the area of genetic engineering research and applications. Non-federally supported institutions and industry would have been affected by this bill, but there was no congressional action on S. 2234.

While the Federal Government has not passed any legislation directly regulating recombinant DNA research, several States and local governments have adopted ordinances regulating this type of research. In addition, bills were introduced on this subject in a number of States in recent years.

On Apr. 23, 1981, the RAC discussed a proposal, introduced by Drs. Allen Campbell and David Baltimore, which would transform the guidelines into a voluntary code of laboratory practice. The Baltimore-Campbell proposal would have reduced the physical containment levels for most recombinant DNA experiments with the exception of prohibited experiments. The proposal also would have eliminated all punishments for failing to follow the guidelines. The committee voted to have a special panel review the guidelines and make

recommendations. The Working Group on Revision of the Guidelines was appointed at the April meeting and met on June 1 and July 9, 1981. The group did not agree that the NIH guidelines should be made voluntary. However, it did suggest that detailed rules for the composition of the local IBCs be removed from the guidelines.

At the RAC's September 10-11 meeting, Dr. David Baltimore offered a new proposal which mixed portions of the original Baltimore-Campbell proposal with the working group's recommendations. The RAC developed its own proposal for publication in the Federal Register, (v. 46: 59368-59425, Dec. 4, 1981) by modifying Dr. Baltimore's proposal. The new RAC proposal differed from the Baltimore-Campbell proposal in that it eliminated the prohibition of experiments, but instead retained admonishments against the cloning of toxin genes and drug resistance traits in organisms which do not already have these characteristics.

An alternative proposal appeared in the Federal Register, on Dec. 7, 1981 (v. 46: 59734-59737) at the request of Dr. Susan Gottesman, Chairman of the Working Group. The Gottesman proposal differs from the previously discussed proposals in that the guidelines would remain mandatory for institutions receiving NIH funding. In addition, certain experiments would require prior review by either NIH or an IBC. At the Feb. 8, 1982, meeting of the RAC, the committee voted in favor of the Gottesman proposal, 17 for and 3 against.

The Gottesman proposal was accepted by the Acting Director of NIH and published in the April 21, 1982, Federal Register. At the June 28, 1982, RAC meeting, the committee decided not to include within the guidelines a prohibition against the use of recombinant DNA for the development of biological warfare agents. An existing international convention, adopted in 1972 by many countries including the U.S. and the Soviet Union, prohibits development of biological weapons. The committee concluded that the convention's prohibitions were broad enough to cover work involving the use of recombinant DNA techniques.

HEARINGS

U.S. Congress. House. Committee on Interstate and Foreign Commerce. Subcommittee on Health and the Environment. Recombinant DNA Research Act of 1977. Hearings, 95th Congress, 1st session, on H.R. 4759, H.R. 4849, H.R. 3191, H.R. 3591, H.R. 3592, H.R. 5020, H.R. 4232, and H.Res. 131. Mar. 15-17, 1977. Washington, U.S. Govt. Print. Off., 1977. 480 p.
"Serial no. 95-18"

U.S. Congress. House. Committee on Science and Astronautics. International science policy. Panel on Science and Technology (twelfth meeting), 92d Congress, 1st session. Jan. 26-28, 1971. Washington, U.S. Govt. Print. Off., 1971. p. 336-366.

U.S. Congress. House. Committee on Science and Technology. Subcommittee on Science, Research, and Technology. Science Policy Implications of DNA Recombinant Molcule Research. Hearings, 95th Congress, 1st session. Mar. 29-31, Apr. 27-28, May 3-5, 25, 26, Sept. 7-8, 1977. Washington, U.S. Govt. Print. Off., 1977. 1293 p.

----- Recombinant DNA Act. Hearings on H.R. 11192, 95th

Congress, 2d session. Apr. 11, 1978. Washington, U.S. Govt. Print. Off., 1978. 182 p.

U.S. Congress. House. Committee on Science and Technology. Subcommittee on Investigations and Oversight and Subcommittee on Science, Research and Technology. Commercialization of academic biomedical research. Hearings, 97th Congress, 1st session. June 8-9, 1981. Washington, U.S. Govt. Print. Off., 1981. 166 p.

U.S. Congress. Senate. Committee on Commerce, Science, and Transportation. Subcommittee on Science, Technology, and Space. Regulation of recombinant DNA research. Hearings, 95th Congress, 1st session. Nov. 2, 8, and 10, 1977. Washington, U.S. Govt. Print. Off., 1978. 432 p.

U.S. Congress. Senate. Committee on Commerce, Science, and Transportation. Subcommittee on Science, Technology, and Space. Industrial applications of recombinant DNA techniques. Hearing, 96th Congress, 2d session. May 20, 1980. Washington, U.S. Govt. Print. Off., 1980. 90 p.

U.S. Congress. Senate. Committee on Human Resources. Subcommittee on Health and Scientific Research. Biomedical research and the public. Edited transcript of a conference on the relationship between biomedical research and the public, held at Airlie House, Airlie, Va., Apr. 1-3, 1976; sponsored by the Hastings Institute of Society, Ethics, and the Life Sciences, and by the Case Western Reserve University Medical School. Washington, May 1977. 154 p.
At head of title: 95th Congress, 1st session. Committee print.

----- Recombinant DNA Regulation Act, 1977. Hearings, 95th Congress, 1st session, on S. 1217 and related bills. Apr. 6, 1977. Washington, U.S. Govt. Print. Off., 1977. 472 p.

U.S. Congress. Senate. Committee on Labor and Public Welfare. Subcommittee on Health. Genetic engineering, 1975. Hearings, 94th Congress, 1st session. Apr. 22, 1975. Washington, U.S. Govt. Print. Off., 1975. 35 p.

U.S. Congress. Senate. Committee on Labor and Public Welfare. Subcommittee on Health./ Committee on the Judiciary. Subcommittee on Administrative Practice and Procedure. Implementation of NIH guidelines governing recombinant DNA research. Oversight hearing, 94th Congress, 2d session. Sept. 22, 1976. Washington, U.S. Govt. Print. Off., 1976. 159 p.

REPORTS AND CONGRESSIONAL DOCUMENTS

U.S. Congress. House. Committee on Interstate and Foreign Commerce. Recombinant DNA Act. Report (together with dissenting and separate views and including the Congressional Budget Office cost estimate) to accompany H.R. 11192. Mar. 24, 1978. Washington, U.S. Govt. Print. Off., 1978. 44 p. (95th

Congress, 2d session. House. Report no. 95-1005, Part I.)

U.S. Congress. House. Committee on Science and Astronautics. Subcommittee on Science, Research, and Technology. Genetic engineering: evolution of a technological issue. 92d Congress, 2d session. Prepared by the Science Policy Research Division, Congressional Research Service, Library of Congress. Washington, U.S. Govt. Print. Off., 1972. 119 p.

----- Genetic engineering: evolution of a technological issue; Supplemental Report I. 93d Congress, 2d session. Prepared by the Science Policy Research Division, Congressional Research Service, Library of Congress. Washington, U.S. govt. Print. Off., December 1974. 215 p.

U.S. Congress. House. Committee on Science and Technology. Recombinant DNA Act. Report (together with dissenting views and including a Congressional Budget Office cost estimate) to accompany H.R. 11192. Apr. 21, 1978. Washington, U.S. Govt. Print. Off., 1978. 32 p. (95th Congress, 2d session. House. Report no. 95-1005, Part II)

----- Subcommittee on Science, Research, and Technology. Genetic engineering, human genetics, and cell biology: evolution of technological issues -- DNA recombinant molecule research; Supplemental Report II. 94th Congress, 2d session. Prepared by the Science Policy Research Division, Congressional Research Service, Library of Congress. Washington, U.S. Govt. Print. Off., December 1976. 259 p.
At head of title: 94th Congress, 2d session. Committee print.
(See appendixes for a selected bibliography, selected articles on DNA recombinant research, and copies of the NIH Guidelines and Draft Environmental Impact Statement.)

----- Biotechnology (Supplemental Report III). 96th Congress, 2d session. Prepared by the Science Policy Research Division, Congressional Research Service, Library of Congress. Washington, U.S. Govt. Print. Off., August 1980. 144 p.

----- Science policy implications of DNA recombinant molecule research. Prepared by the Subcommittee on Science, Research, and Technology. March 1978. Washington, U.S. Govt. Print. Off., 1978. 78 p. (95th Congress, 2d session. House. Serial X)

U.S. Congress. Senate. Committee on Commerce, Science, and Transportation. Subcommittee on Science, Technology, and Space. Recombinant DNA research and its applications. Oversight report. August 1978. Washington, U.S. Govt. Print. Off., 1978. 106 p.

U.S. Congress. Senate. Committee on Human Resources. Recombinant DNA Safety Regulation Act; report together with supplemental views to accompany S. 1217. July 22, 1977. Washington, U.S. Govt. Print. Off., 1977. 63 p. (95th Congress, 1st session. Senate. Report no. 95-359)

CHRONOLOGY OF EVENTS

06/28/82 -- RAC voted against including within the guidelines prohibitions against the use of recombinant DNA in developing biological warfare agents.

04/21/82 -- Republication of NIH Guidelines in Federal Register, Gottesman revision. (v. 47: 17180-17198)

02/09/82 -- RAC voted in favor of Gottesman proposal 17 to 3.

12/07/81 -- Gottesman Proposal published in the Federal Register (v. 46: 59734-59737).

12/04/81 -- RAC's Guideline revision published in Federal Register (v. 46: 59368-59425).

09/10/81 -- David Baltimore proposed a compromise between Baltimore Campbell proposal and the Working Group proposal. RAC modified the Baltimore proposal.

07/09/81 -- Working Group on the Revision of the NIH Guidelines met for second time.

07/01/81 -- Republication of NIH Guidelines in Federal Register exempting all research with E coli K-12 from the Guidelines (v. 46: 34462-34487).

06/01/81 -- Working Group on the Revision of the NIH Guidelines, met for first time.

04/23/81 -- Baltimore-Campbell proposal discussed by RAC.

11/21/80 -- Republication of NIH Guidelines in Federal Register lowering physical containment requirements for additional host cells. Change notification procedures required of principal investigators (v. 45: 77384-77408).

06/16/80 -- Supreme Court rules 5-4 that life forms created in the laboratory by genetic engineering may be patented like any other invention.

01/29/80 -- S. 2234 introduced by Senator Stevenson and referred to Committee on Labor and Human Resources.

01/29/80 -- Republication of the NIH Guidelines in Federal Register lowering physical containment requirements for experiments using E. coli K-12 (v. 45: 6724-6749).

11/30/79 -- NIH recombinant DNA research proposed guidelines published in the Federal Register (v. 44: 69210-69251).

04/02/79 -- NIH proposed plan for a program to assess the risks of recombinant DNA research. Federal Register, (v. 44: 19301-19304).

12/29/78 -- Fourteen new members were named to the NIH Recombinant DNA Advisory Committee.

12/22/78 -- FDA announced intent to propose regulations for recombinant DNA (Federal Register, Dec. 22, 1978: 60134-60135).

-- NIH Revised Guidelines regarding the conduct of research involving recombinant DNA were published (Federal Register, Dec. 22, 1978: 60080-60105; 60108-60131).

07/28/78 -- Proposed revised guidelines for the conduct of recombinant DNA research published Federal Register, v. 43: 33041-33178.
Also includes an Environmental Impact Assessment).

02/28/78 -- H.R. 11192 introduced in House.

12/15/77 - 12/16/77 -- NIH Public Meeting on the Recombinant DNA Guidelines.

11/28/77 -- The availability of the NIH Environmental Impact Statement on Guidelines for Research Involving Recombinant DNA Molecules (October 1977) was noted in the Federal Register.

10/26/77 -- S. 1217 (Recombinant DNA Regulation Act) was placed on the Senate calendar under "Subject on the Table" at the request of Senator Robert Byrd.

09/27/77 -- Proposed revised NIH guidelines for the conduct of recombinant DNA research were published (Federal Register v. 42, no. 187, part III: 49595-49609).

06/22/77-06/23/77 -- The NIH Advisory Committee met again (see May 14-15, 1977 entry) to continue consideration of the DNA research guidelines revision.

05/14/77-05/15/77 -- The NIH Recombinant DNA Molecule Program Advisory Committee met to consider revision of the recombinant DNA research guidelines.

03/15/77 - 03/17/77 -- Subcommittee on Health and Environment, House Interstate and Foreign Commerce Committee, held hearings on H.R. 4759 (and other bills): recombinant DNA.

03/06/77 -- House Science and Technology Committee released report "Genetic Engineering, Human Genetics, and Cell Biology" (see REPORTS).

09/06/76 -- DHEW-NIH Recombinant DNA Research Guidelines -- Draft Environmental Impact Statement, was

published (Federal Register: 38426-38438).

07/07/6 -- DHEW-NIH Recombinant DNA Research Guidelines were published (Federal Register: 27942-27943).

02/09/76 - 02/10/76 -- First meeting of the NIH Director's Advisory Committee was held to review the proposed guidelines concerning recombinant DNA research.

04/22/75 -- Genetic Engineering was the subject of hearings before the Subcommittee on Health, Senate Committee on Labor and Public Welfare.

02/24/75 -- NAS-NSF-NIH supported Conference on Recombinant DNA Research, held in Asilomar, Calif.

10/07/74 -- NIH Recombinant DNA Advisory Committee was established.

06/11/73 -- Gordon Conference on Nucleic Acids was held in New Hampton, N.H.

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----- Recombinant DNA guidelines wear thin. Nature, May 7, 1981. p. 3.

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Recombinant DNA research: Government regulation. Science, July 15, 1977: p. 208.
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Regulation of recombinant DNA research. Chemtech. July 1980. p. 447-456.

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Stockton, William. On the brink of altering life. New York Times magazine. Feb. 17, 1980. p.16-19, 62-64, 76-80.

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----- Recombinant DNA research. Volume 2. Documents

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----- Recombinant DNA research. Volume 3. Documents relating to "NIH guidelines for research involving recombinant DNA molecules." November 1977 - Sept. 1978. (Published Sept. 1978) DHEW publication no. (NIH) 78-1843 and (NIH) 78-1844. 608 p. Plus appendices.

----- Recombinant DNA research. Volume 4. Documents relating to "NIH guidelines for research involving recombinant DNA molecules." August-December 1978. (Published December 1978) DHEW publication no. (NIH) 79-1875 and (NIH) 79-1876. 449 p. Plus appendices.

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