

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

RECOMBINANT DNA ADVISORY COMMITTEE

MINUTES OF MEETING

JUNE 28, 1982

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The Recombinant DNA Advisory Committee (RAC) was convened for its twenty-fifth meeting at 9:00 a.m. on June 28, 1982, in Wilson Hall, Building 1, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20205. Mr. Ray Thornton (Chairman), President, Arkansas State University, presided. In accordance with Public Law 92-463, the meeting was open to the public.

Committee members present for all or part of the meeting were:

Abdul Karim Ahmed; David Baltimore; Kenneth Berns; Winston Brill; L. Albert Daloz; David Friedman; Richard Goldstein; Jean Harris; King Holmes; Myron Levine; David Martin; James Mason; Gerard McGarrity; Robert McKinney; Robert Mitchell; Elena Nightingale; Ramon Pinon; Mark Saginor; John Scandalios; Pieter Wensink; and William J. Gartland, Jr., Executive Secretary.

A Committee roster is attached. (Attachment I)

The following non-voting members and liaison representatives were present:

George Duda, Department of Energy; Herman Lewis, National Science Foundation; Henry Miller, National Center for Drugs and Biologics, FDA; and Sue Tolin, U.S. Department of Agriculture.

Other National Institutes of Health staff present were:

Stanley Barban, NIAID; Manuel Barbeito, OD; W. Emmett Barkley, OD; Becky Connors, NIAID; Irving Delappe, NIAID; Susan Gottesman, NCI; John Irwin, OD; Elizabeth Milewski, NIAID; John Nutter, NIAID; Robert Schreiber, NIAID; Bernard Talbot, NIAID; and Charles Wise, NIAID.

¹The RAC is advisory to the NIH, and its recommendations should not be considered as final and accepted. The Office of Recombinant DNA Activities should be consulted for NIH policy on specific issues.

Others in attendance for all or part of the meeting were:

William Beisel, Department of Defense; Irene Brandt, Eli Lilly & Company; Robert Brey, Genex Corporation; Steve Budiansky, Nature Magazine; Chia T. Chen, OSHA, U.S. Department of Labor; Scott Coleridge, Millipore Corporation; Paula Dwyer, McGraw Hill; Gershon Fishbein, Genetic Engineering Letter; John Galet, Schering-Plough Corporation; Richard Geoghegan, E. I. Du Pont De Nemours and Company; Tom M. Helscher, Monsanto Company; Timothy Henry, Health Industry Manufacturing Association; Philip Hilts, Washington Post; Evelyn Hurlburt, Johns Hopkins University; Dorothy Jessop, U.S. Department of Agriculture; Judith A. Johnson, Library of Congress; Mary Jane Johnson, Pall Corporation; Attila Kader, Food and Drug Administration; Geoffrey Karny, Office of Technology Assessment; Michael Larsen, Occupational Safety & Health Administration; Carter Leonard, Blue Sheet; D. S. Mabry, Pfizer, Inc.; James McCullough, Library of Congress; James Mikulak, State Department; Mary Moore, Millipore Corporation; Harvey Price, Industrial Biotechnology Association; Rich Ring, Genentech, Inc.; Marvin Rogul, Environmental Protection Agency; Sandra Ronspies, Genentech, Inc.; Harold Schmeck, New York Times; Marjory Sun, Science Magazine; Charles Turbyville, NIH Week; Dave Wareheim, SmithKline Beckman Corporation; and Charles Weiner, Massachusetts Institute of Technology.

I. CALL TO ORDER

The Chairman, Mr. Ray Thornton, called the meeting to order at 9:00 a.m. on June 28, 1982. He asked Dr. Ahmed to review the minutes of the February 8-9, 1982, RAC meeting.

II. MINUTES OF THE FEBRUARY 8-9, 1982 MEETING

Dr. Ahmed said the draft minutes (tab 1073) of the February 8-9, 1982, RAC meeting accurately conveyed the sense of that meeting. Dr. McGarrity moved that the minutes be accepted. Dr. Ahmed seconded the motion. By a voice vote, the motion to accept the minutes of the February 8-9, 1982, meeting was unanimously carried.

III. PROPOSED PROHIBITION

Dr. Baltimore noted that the proposal (tabs 1066, 1067, 1068, 1075, 1076) advanced by Dr. Richard Goldstein of Harvard Medical School and Dr. Richard Novick of the Public Health Research Institute of New York, would amend the Guidelines to prohibit "the construction of biological weapons by molecular cloning." He said the proposal generated tremendous initial sympathy because the concept of biological warfare is horrible.

Dr. Baltimore said he felt the proposal is based on Drs. Novick and Goldstein's perception that use of recombinant DNA technology for biological warfare is not covered by the Biological Weapons Convention.² The Convention, which prohibits biological warfare, was signed by the United States in 1972. Dr. Baltimore said he had questioned the United States Arms Control and Disarmament Agency in 1975 as to whether the Biological Weapons Convention prohibits production of recombinant DNA molecules for the construction of biological weapons. The Arms Control and Disarmament Agency, in reply (tab 1067) to his inquiry, stated that "the use of recombinant DNA molecules for such purposes clearly falls within the scope of the Convention's provisions."

Dr. Baltimore felt it was extremely important that any action taken by RAC bolster the Biological Weapons Convention and raise no suggestion that the treaty is insufficient. He said he wished to be recorded as stating the Biological Weapons Convention prohibits the use of recombinant DNA technology to produce biological weapons. He also wished recorded his sentiment that any RAC action should support the treaty language.

²The formal name of this Convention is: Convention on the Prohibition of Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction.

Dr. Baltimore noted that Mr. James George of the United States Arms Control and Disarmament Agency, in a letter of June 8, 1982 (tab 1075), had suggested alternative language to the Goldstein-Novick proposal, as follows:

"The use of recombinant DNAs for development of microbial or other biological agents, or toxins, of types or in quantities that have no justification for prophylactic, protective or other peaceful purposes, is prohibited."

Dr. Baltimore said this suggested language, which is taken largely from the treaty, would reinforce the Biological Weapons Convention. He moved acceptance of the language proposed by Mr. George. Mr. Mitchell seconded. Dr. Harris concurred with Dr. Baltimore's opinion; she added that the discussion served a useful purpose by permitting a public expression of concern.

Dr. Baltimore then suggested an amendment to his motion: he proposed that the phrase "the use of recombinant DNA methodology for development" replace the phrase "the use of recombinant DNAs for development." Mr. Mitchell agreed.

Dr. Goldstein said he would not support Dr. Baltimore's proposal. He said he had suggested the proposed prohibition on the broadest moral and ethical grounds. He said that RAC was responsible for overseeing recombinant DNA research and, therefore, of overseeing Department of Defense (DOD) endeavors in this area. He said that in 1980 DOD spent about \$16 million on their biological research program. He said that the bulk of the money was spent on defensive systems. He said that a very thin line exists between offensive and defensive studies in biological warfare.

Dr. Goldstein said the Biological Weapons Convention has no mechanism by which to monitor or enforce compliance. He recounted some alleged incidents in the Soviet Union and Cuba which, because no means of verification exist, could be interpreted as violations of the treaty. He argued that the world situation, which requires DOD to spend substantial funds on defensive systems, requires that RAC issue some firm statement prohibiting the development of biological weapons using recombinant technology.

Dr. Mason said the idea of deliberate construction and release of agents which cause disease and death is absolutely appalling. He feared, however, that the Goldstein-Novick amendment might create the presumption that the 1972 Biological Weapons Convention does not apply to recombinant DNA research. He felt, in addition, that the material submitted by Drs. Goldstein and Novick almost by innuendo suggests that the United States is violating the treaty. He said that RAC endorsement of the Goldstein-Novick amendment might be interpreted as RAC agreement with these innuendos. Dr. Mason said that if the Guidelines were to be amended to include some prohibition, he would prefer the George-Baltimore language to the Goldstein-Novick proposal. However, he did not feel the Guidelines should be used to attempt to resolve this issue. He warned that incorporating language prohibiting biological warfare into the Guidelines could inhibit possible future moves to make the Guidelines voluntary or abolish the Guidelines. He said that if it is

felt that RAC should do anything, a RAC resolution on the topic, independent and separate from the Guidelines would be more appropriate. Dr. McKinney agreed; he opposed both the Goldstein-Novick proposal and the Baltimore motion. Mr. Daloz said that he supported the language in Mr. George's letter.

Dr. Ahmed quoted from Article I of the Convention:

"Each...Party...undertakes never in any circumstance to develop, produce, stockpile, or otherwise acquire or retain:

- (1) Microbial or other biological agents or toxins, whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;
- (2) Weapons, equipment, or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict."

Dr. Ahmed said that a key word, "research," was missing from the phrase "to develop, produce, stockpile, or otherwise acquire or retain." He suggested that while the word "develop" might encompass research, "develop" may also be strictly interpreted as an industrial activity or as a large development program. He said that the George language, consistent with the Convention, may not cover research; therefore, the Baltimore motion would not encompass the total concern. Dr. Ahmed then asked the DOD representative whether the Biological Weapons Convention applies to research activities.

Mr. Thornton recognized Dr. Robert Mikulak of the Arms Control and Disarmament Agency. Dr. Mikulak said he wished to make several points. He said the Arms Control and Disarmament Agency had no objection to the NIH incorporating language dealing with biological weapons into the Guidelines for Research Involving Recombinant DNA Molecules. The Convention includes provisions under which governments may pass additional legislation or regulations to implement the Convention in their own territory. The Arms Control and Disarmament Agency had, however, suggested language which the agency feels is more similar to the language of the Convention. Fewer problems of interpretation will arise with language similar to the Biological Weapons Convention than might arise from substantially different language. He noted that the language proposed by the Agency had been moved by Dr. Baltimore.

Dr. Mikulak said that the Arms Control and Disarmament Agency does not distinguish between offensive and defensive biological weapons. Both are biological weapons and, thus, prohibited by the treaty. The negotiated history of the Biological Weapons Convention makes absolutely clear that possession of biological weapons, even for defensive purposes, is prohibited; a party state is not permitted these weapons regardless of the stated intent. Dr. Mikulak said that concern had been expressed by Dr. Ahmed that Article I of the Convention might not prohibit research on biological weapons. He said that in his interpretation, the first Article of the

Convention is extremely broad; it prohibits not only developing, producing, and stockpiling, but uses the formulation "or otherwise acquire or retain." In his interpretation of that formulation, any activity for biological weapons purposes, including research, would be prohibited.

Mr. Thornton then recognized Dr. William Beisel of the Department of Defense, Department of the Army. Dr. Beisel said DOD currently is not involved in research on biological weapons. When the United States signed the Biological Weapons Convention, the entire research structure for the creation of such weapons was dismantled. Any weapons in storage at the Pine Bluff Arsenal in Arkansas were destroyed. The manufacturing plant at the Arsenal in Pine Bluff was turned over to the FDA to become the National Center for Toxicological Research. The large laboratory at Fort Detrick, in Frederick, Maryland, was turned over to the National Cancer Institute to become the Frederick Cancer Research Facility.

Dr. Beisel said the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) at Fort Detrick is currently engaged in medical defensive research. The program is entirely unclassified and any individual can come and visit. The program focuses on diseases that could threaten U.S. troops or, secondarily, the U.S. population. He said the Centers for Disease Control (CDC) is officially responsible for defending the civilian population from a biological warfare attack. USAMRIID collaborates very closely with the CDC in that endeavor. Dr. Beisel said the USAMRIID program is attempting to develop vaccines or other prophylactic measures, and to develop methods for better, earlier, diagnosis. All of the research is of a public health nature. Dr. Beisel said vaccines developed by the USAMRIID program have on occasion been transmitted around the world and given to other governments.

Dr. McKinney noted that there are no prohibited experiments in the current Guidelines and said he opposed both the Goldstein-Novick proposal and Dr. Baltimore's motion.

Dr. Baltimore said that perhaps a resolution of the RAC would be adequate. He said that it could be misread as a lack of concern for the RAC to do nothing.

Dr. Nightingale thought it was necessary for RAC to issue some statement concerning biological weapons and recombinant DNA technology. What the statement is and how to make it needs to be discussed. One purpose of the Guidelines is to permit public participation in the formulation of policy. In this case, the policy exists so a statement from RAC would be an affirmation or endorsement of existing public policy. Such a statement within the content of the Guidelines would be appropriate. She said that a second function of the Guidelines is to protect the public; and, thus, insertion of a statement on biological weapons in the Guidelines is appropriate. She preferred that language be introduced into the Guidelines; language in the Guidelines would constitute a permanent record rather than a one time resolution. If such language were to be included in the Guidelines, she did not think the Guidelines would necessarily become hostage

to "permanency" as suggested by Dr. Mason. She said she would prefer RAC issue a broad statement which avoided ambiguities about who is being defended or how. She suggested, in addition, that the section of the Guidelines dealing with the Federal Interagency Advisory Committee on Recombinant DNA Research be expanded; that Section should list the Interagency Committee membership (including DOD) and explicitly indicate that DOD, as well as the other members of the Committee, have agreed to abide by the NIH Guidelines for Research Involving Recombinant DNA Molecules.

Dr. Nightingale also noted that the Commission on Life Sciences of the National Academy of Sciences (NAS) has refused to conduct a study requested by the DOD via the Board on Army Science and Technology of the Commission on Engineering and Technical Systems. Most of the work in that study was to be classified and the NAS Commission on Life Sciences has established the principle that it will not do classified work.

Dr. Nightingale said the NAS Commission on Life Sciences was unwilling to conduct studies on biological warfare defense but agreed to cooperate with the Board of Army Science and Technology on a mycotoxin study. Mycotoxins were classified as chemicals. She asked Dr. Beisel to clarify his previous statement that they did no classified work. Dr. Baltimore asked Dr. Beisel to clarify how the medical defense program relates to classified work funded by DOD. Dr. Beisel explained that DOD funds three separate research areas: physical defense, medical defense, and intelligence gathering. The physical defense aspects involve protective clothing, decontamination, early warning devices, air sampling, etc. Some of these materials and processes are classified.

Dr. Berns, referring to the letter (tab 1076) of Dr. Krinsky, asked if DOD has more than one Institutional Biosafety Committee (IBC) registered with ORDA. Dr. Gartland replied that several IBCs at military installations are registered with ORDA: the Walter Reed Army Institute of Research and U.S. Army Medical Research Institute of Infectious Diseases, the Naval Medical Research Institute, and the Uniformed Services University of the Health Sciences. The Naval Biological Laboratories in California uses the IBC at the University of California, Berkeley.

Dr. Berns said that one person whom he greatly respected pointed out that RAC action could lead to the erroneous distinction that biological warfare employing recombinant DNA is worse than other biological warfare, and therefore, opposed the amendment.

Dr. Holmes agreed it was important to avoid statements conflicting with the Biological Weapons Convention. However, he viewed language added to the Guidelines concerning biological warfare as potentially clarifying the Biological Weapons Convention. He agreed that some of the Biological Weapons Convention language is vague. He suggested that any language developed by RAC should be clearer. He said he favors the language proposed by Mr. George, but suggested addition of the phrase "as potential biological weapons" after the word "toxins."

Dr. Gottesman said she was concerned with the question of how a biological weapon is distinguished from a chemical weapon. Some items, which would be defined by biologists as biological weapons, might be defined by others as chemical weapons. She suggested that any language added to the Guidelines might include some definitions of biological weapons. Dr. Gottesman suggested that language on biological weapons could logically be added at the very beginning of the Guidelines or at the beginning of Section III. Dr. Nightingale agreed; she suggested that the Guidelines might refer to the Biological Weapons Convention and endorse it in principle and then indicate that the NIH Guidelines deal only with recombinant DNA research.

Dr. Baltimore said that after listening to the discussion, he had concluded that RAC should not add language on biological weapons to the Guidelines. The treaty has been ratified by Congress and signed by the President. It is the law of the land. He suggested that RAC pass a resolution endorsing the treaty and indicating that recombinant DNA technology is covered by the Convention.

Dr. Mason called the question on Dr. Baltimore's previous motion as amended. Dr. Berns seconded the motion. Dr. McKinney said that before the vote was taken, Dr. Baltimore should indicate where in the Guidelines the language would be inserted. Mr. Thornton ruled that if Dr. Baltimore's motion was passed by the RAC, NIH staff would be given the responsibility for determining the appropriate place in the Guidelines to insert the language.

Mr. Thornton said that his ruling was subject to appeal by the RAC. No appeal was made. By a vote of thirteen in favor, six opposed, and one abstention, the question was called. Mr. Thornton then called the vote on Dr. Baltimore's motion, i.e., insertion into the Guidelines of the following language:

"The use of recombinant DNA methodology for development of microbial or other biological agents, or toxins, of types or in quantities that have no justification for prophylactic, protective or other peaceful purposes, is prohibited."

By a vote of six in favor, twelve opposed, and two abstentions, the motion was defeated.

Dr. Holmes said he wished to present an alternative proposal. He said his opposition to Dr. Baltimore's motion was not so much against the intent as against the language which was phrased in a negative way. He moved adoption of the following language, either as a resolution to the Director or an amendment to the Guidelines:

"Use of recombinant DNA methodology for development of microbial or other biological agents or toxins as biological or chemical weapons is prohibited, as specified by the 1972 Biological Weapons Convention."

Mr. Thornton said that Dr. Holmes should indicate whether the statement would be included in the Guidelines or sent as advice to the NIH Director. Dr. Holmes replied that he moved the language as an amendment to the Guidelines. Dr. McGarrity seconded the motion.

Dr. Martin then proposed a substitute motion in the form of a resolution not to be included in the Guidelines:

"The Recombinant DNA Advisory Committee advises the Director, NIH, that the existing treaty of 1972 [Convention on the Prohibition of Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction] includes the prohibition on the use of recombinant DNA methodology for development of microbial or other biological agents, or toxins, of types or in quantities that have no justification for prophylactic, protective or peaceful purposes."

Dr. Scandalios seconded the motion.

Dr. Ahmed moved to amend Dr. Martin's substitute motion by eliminating all of Dr. Martin's proposal and adding the following language as originally proposed by Drs. Novick and Goldstein to Section I of the Guidelines:

"Construction of biological weapons by molecular cloning is prohibited."

The motion was seconded by Dr. Goldstein.

Dr. Baltimore characterized Dr. Ahmed's motion as dangerous in its assumptions. He felt Dr. Ahmed's motion implies that the Biological Weapons Convention is ambiguous. Dr. Baltimore felt that the treaty was very precisely written, with no indication of loopholes or ambiguities through which the methodologies of recombinant DNA can be used for the development of biological weaponry. He felt including the Goldstein-Novick language in the Guidelines could undermine the treaty obligations of the United States and raise the presumption that the use of recombinant DNA technology in developing biological weapons is permissible. Dr. McKinney called the question. Dr. Berns seconded. By a vote of nineteen in favor, one opposed, and no abstentions, the question was called.

The vote then occurred on the amendment to the substitute as offered by Dr. Ahmed. By a vote of two in favor, seventeen opposed, and one abstention, the RAC refused Dr. Ahmed's proposed amendment.

Mr. Thornton then called for discussion on Dr. Martin's substitute motion. Dr. Holmes said the major difference between Dr. Baltimore's earlier motion which the RAC had defeated and Dr. Martin's motion is that Dr. Baltimore's motion had involved insertion of text into the Guidelines and Dr. Martin's motion is a resolution to the Director. Dr. Holmes opposed Dr. Martin's motion; he said the language is vague and a RAC recommendation advisory to

the Director is weaker than language added to the Guidelines. Mr. Mitchell supported Dr. Martin's proposal. He said the statement reveals the concern of the RAC, is an expression in the nature of a resolution, has impact, and is consistent with the Biological Weapons Convention.

Mr. Thornton then called the vote on Dr. Martin's substitute motion. By a vote of fourteen in favor, six opposed, and no abstentions, the substitute motion was adopted as the motion before the committee. Mr. Thornton then called the vote on the motion, as follows:

"The Recombinant DNA Advisory Committee advises the Director, NIH, that the existing treaty of 1972 [Convention on the Prohibition of Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction] includes the prohibition on the use of recombinant DNA methodology for development of microbial or other biological agents, or toxins, of types or in quantities that have no justification for prophylactic, protective or peaceful purposes."

By a vote of fifteen in favor, five opposed, and no abstentions, the RAC adopted the motion.

Dr. Ahmed requested that his vote against the motion be recorded. He said he voted against Dr. Martin's motion as he felt there were problems with it; nonetheless, he felt it is important to address the issue. He suggested that RAC address the question at future meetings. Dr. Goldstein also requested that his vote against the motion be recorded. He said he opposed the motion for the reasons stated by Dr. Ahmed and also because Dr. Martin's motion does not change the status quo.

Dr. Nightingale suggested that the Director might have the resolution printed as part of the Guidelines. Mr. Thornton said any decision to publish the resolution was at the discretion of the Director.

Dr. Goldstein asked if it was possible to vote on Dr. Holmes' motion. Mr. Thornton said that procedurally a motion to reconsider the vote on Dr. Martin's motion would be in order until the meeting is adjourned. No motion to reconsider was offered at that time.

IV. PROPOSED REVISION OF APPENDIX A, SUBLIST F

Dr. Friedman introduced the proposal (tab 1069) from Dr. Gary M. Dunny of the New York State College of Veterinary Medicine. Dr. Dunny requested that Streptococcus agalactiae be added to Appendix A, Sublist F. Dr. Dunny argued that S. agalactiae should be added to this sublist as it exchanges genetic information with other Streptococcus species included in Sublist F.

Dr. Gottesman noted that the current Guidelines specify P1 containment for Dr. Dunny's proposed experiments. She said that the data submitted by Dr. Dunny in support of this request are marginal; there is no evidence of

chromosomal exchange. Dr. Friedman added that Dr. Dunny's data show only that an antibiotic resistance gene carried by a plasmid is expressed by the recipient species. Dr. Friedman then moved that Dr. Dunny's request to include S. agalactiae in Appendix A, Sublist F, be denied; he suggested that Dr. Dunny be informed that PI conditions are indicated under the current Guidelines. Dr. Wensink seconded the motion. By a vote of twenty in favor, none opposed, and no abstentions, the motion to deny Dr. Dunny's request was carried.

V. PROPOSED REVISION OF THE GUIDELINES

Dr. Nightingale began discussion of the modifications (tabs 1071, 1072, 1074) to the Guidelines proposed by the Working Group on Revision of the Guidelines. She recalled to the committee that the RAC at its February 8-9, 1982, meeting recommended that NIH accept a proposed modification of the NIH Guidelines for Research Involving Recombinant DNA Molecules.

In recommending this modification to the NIH, the committee recommended that a working group be formed to further simply and modify the document. The NIH, following this recommendation, promulgated the Revised Guidelines on April 21, 1982. An ad hoc Working Group on Revision of the Guidelines was formed and convened for a meeting on April 19, 1982, to further modify the document promulgated on April 21, 1982. Dr. Nightingale said the working group attempted to clarify and simplify, wherever possible, the structure and language of the Guidelines, to suggest changes appropriate in light of available data, and to recommend future activities in the area of guideline review and revision.

Dr. Nightingale then indicated four major proposed modifications offered by this working group. First, the working group had suggested the presentation of the Guidelines be rearranged primarily by placing the description of physical and biological containment into appendices. Second, the working group recommended that the RAC and NIH adopt for the Guidelines a revised version of the 1974 CDC Classification of Etiologic Agents on the Basis of Hazard. The working group also suggested that the RAC assume responsibility for regularly updating the listing. Dr. Nightingale explained that the original 1976 Guidelines used the Classification of Etiologic Agents on the Basis of Hazard, 4th Edition, July 1974, U.S. Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control (CDC), as the reference source for classification of microorganisms for the purposes of the Guidelines. At the present time, the CDC and the NIH are engaged in an effort to revise this classification. The working group, however, felt that this revised version might not serve the purposes of the Guidelines as well as the original 1974 version as revised. Dr. Nightingale said this is the only proposal of the working group that received a letter of comment. Dr. Berns said he wished to reply to an issue raised by Dr. John Richardson of the CDC in a letter of June 10, 1982 (tab 1074), concerning the proposed revision of Appendix B for the purposes of the NIH Guidelines. Dr. Berns said the proposed revised classification would classify Rabies street virus as a Class 3 agent for all procedures.

Dr. Richardson suggested that a Class 2 designation was adequate. Dr. Berns said he had discussed the issue with Dr. Richardson, and they had agreed that a Class 3 specification for Rabies street virus was more appropriate for the purposes of the NIH Guidelines; investigators following the NIH Guidelines would more probably be using quantities of viruses greater than the quantities needed for diagnostic purposes. The CDC classification is based on use of diagnostic quantities.

Third, Dr. Nightingale said the working group had discussed at length the role and responsibilities of the IBCs. They noted that a greater burden had been placed on the IBCs by the April 21, 1982, revision of the Guidelines. The working group discussed whether RAC should collect information about IBC functions. One suggestion was that a questionnaire be sent to all IBCs. Mr. Mitchell commented that the IBCs have been delegated a great deal of responsibility, but RAC has little data on the actual functioning and effectiveness of the IBCs. He suggested that some mechanism of specific communication between RAC and the IBCs should be developed.

Fourth, Dr. Nightingale noted that the working group suggested an ongoing process of review and revision of the Guidelines; such a process should occur with some regular periodicity, perhaps once a year.

Mr. Thornton suggested that RAC proceed through the proposed revisions of the Guidelines section by section; amendments could then be offered in an orderly fashion. He requested a formal motion to adopt the proposed revised Guidelines as they appeared in the Federal Register of May 26, 1982 (tab 1072). Dr. Ahmed so moved, and Dr. Berns seconded the motion. Dr. Mason offered an amendment to commend the working group for its outstanding efforts in generating the proposed document. Dr. Ahmed accepted the amendment as did Dr. Berns.

Beginning with Section I of the Guidelines, Dr. Baltimore questioned the words "potentially harmful polynucleotide" in the second paragraph of Section I-B, Definition of Recombinant DNA Molecules. He asked how synthetic DNA segments could yield "potentially harmful polynucleotides" other than being translated to "potentially harmful polypeptides". Dr. Wensink suggested it might be a transposable element. It was agreed to leave the language as proposed.

Dr. Baltimore said that a "pharmacologically active agent" is equated with a toxin in Section I-B. He questioned that language. It was pointed out that the text says "e.g., a toxin or a pharmacologically active agent" and does not necessarily equate the two. Also, the text is identical with that in the current April 21, 1982, version of the Guidelines. Dr. Berns said the working group determined that proposals to clone genes for certain biologically active polypeptides should be carefully evaluated, as were proposals involving toxins. The language of Section III-A-1 and Appendix F have been modified to reflect this intent. Dr. Berns said these sections specify the LD50s that define "biologically active polypeptides." It was agreed to leave the language as proposed.

Dr. Nightingale then reviewed the proposed changes in Section III. She noted that a "caution" had been added to Section III-B-3. That caution is as follows:

"CAUTION: Special care should be used in the evaluation of containment levels for experiments which are likely to either enhance the pathogenicity (e.g., insertion of a host oncogene) or to extend the host range (e.g., introduction of novel control elements) of viral vectors under conditions which permit a productive infection. In such cases, serious consideration should be given to raising physical containment by at least one level."

Dr. Nightingale said this is one instance where new information suggested that a caution be added. Dr. Ahmed asked to whom the caution was addressed. Dr. Berns replied that the caution is addressed primarily to the IBC. Dr. Ahmed asked if the phrase "consideration by the IBC" should be added. He felt the caution as proposed appeared parenthetical; the IBC should be cited more explicitly. Dr. Berns did not accept Dr. Ahmed's suggestion as he felt responsibility should be incumbent on both the investigator and the IBC. Dr. Ahmed withdrew the proposal.

Dr. Nightingale asked if Dr. Ahmed, as the maker of the motion, would agree to strike the word "viral" in Section III-B-2-a. The language reads in part:

"Recombinant DNA experiments in which DNA from Class 4 agents is transferred into nonpathogenic prokaryotes or lower eukaryotes can be performed at P2 containment after demonstration that only a totally and irreversibly defective fraction of the agent's viral genome is present in a given recombinant."

Dr. Berns explained that currently all Class 4 agents classified in Appendix B are viruses. That situation might, however, change in the future, and deleting the word "viral" in Section III-B-2-a would provide greater flexibility. Dr. Ahmed agreed to delete the word "viral."

Dr. Gottesman noted that language from Sections III-B-2-a and III-B-2-b of the April 21, 1982, Guidelines had been combined by the working group into a new Section III-B-2-a. In so doing, the working group had moved experiments involving a totally and irreversibly defective fraction of Class 4 agents into Section III-B-2-a and delegated authority to the IBC to lower containment on experiments involving these agents.

Dr. Nightingale mentioned the inadvertent omission in Section III-B-4-a of language dealing with USDA permits for working with Class 5 agents and suggested suitable language be inserted analogous to that found at the end of Section III-B-2-b. Mr. Thornton asked if Dr. Ahmed would agree to insertion of such language in Section III-B-4-a. Dr. Ahmed agreed as did Dr. Berns.

Dr. Nightingale then referred to Section III-C, Experiments that Require IBC Notice Simultaneously with Initiation of Experiments. The first sentence of this section reads as follows:

"Experiments not included in Section III-A, III-B, III-D, and subsections of these sections are to be considered in Section III-C."

She said the working group was concerned with the language of this section. They noted that non-exempt experiments which might merit more stringent review by RAC or by the IBC prior to initiation of the experiment might not be adequately described in Sections III-A and III-B and, thus, would automatically fall into Section III-C. Dr. Nightingale suggested that a reference be added at the end of the first paragraph of Section III-C drawing the reader's attention to the first two paragraphs of Section IV-A, which emphasizes the responsibility of the institution and those associated with it. Dr. Nightingale said the clause emphasizing institutional responsibility in Section IV-A ought to read:

"Therefore, it is the responsibility of the Institution and those associated with it to adhere to the intent of the Guidelines as well as to their specifics."

The RAC agreed that the word "intent" should be substituted for the word "purpose" which was used in the version proposed by the working group. Dr. Ahmed agreed to add a reference to Section IV-A in Section III-C and to substitute the word "intent" for the word "purpose" in the language of Section IV-A. Dr. Berns agreed.

Dr. Baltimore questioned why low-risk oncogenic viruses had been classified in proposed Appendix B as Class 2 agents. He said most are not human pathogens at all, and many are innocuous. He felt that classifying low-risk oncogenic viruses as Class 1 agents and moderate-risk oncogenic viruses as Class 2 agents would be more reasonable. Dr. Berns did not agree completely; he felt some of the moderate-risk oncogenic viruses, such as Herpesvirus saimiri or EB virus, should be classified as Class 3 agents. Dr. Baltimore agreed that Herpesvirus saimiri might be classified as a Class 3 agent but felt Rous sarcoma virus should be classified as Class 1. Dr. Berns agreed that the list warranted closer looking at, but he did not feel that this RAC meeting was the appropriate time for such a virus by virus review. Dr. McKinney pointed out that P2 provides the investigator with physical protection that is desirable and necessary for working with these agents. He suggested low-risk oncogenic viruses should be used under Class 2 containment conditions. Dr. Baltimore noted that in the current Guidelines a listing is given in Appendix B of low-risk and moderate-risk oncogenic viruses, but no containment relative to the Guidelines is specified. The proposed revised Guidelines include the statements that low-risk oncogenic viruses "should be treated as Class 2 agents" and moderate-risk oncogenic viruses "should be treated as Class 3 agents." Therefore, this involves an increased stringency of the proposed revised Guidelines for these agents.

Dr. Brill questioned the inclusion of all Klebsiella strains as Class 2 agents in Appendix B. He said Klebsiella species are ubiquitous. Dr. Berns pointed out that Klebsiella was classified as Class 2 in the original 1974 edition of the Classification of Etiologic Agents; the working group had not changed its classification. Dr. Holmes said he could suggest several modifications to Appendix B: he agreed with Dr. Richardson that Schistosoma mansoni should be Class 2; the Psittacosis-Ornithosis-Trachoma group needs to be revised; consideration should be given to grouping Mycobacterium leprae with Mycobacterium tuberculosis. Mr. Thornton suggested that a working group review the Appendix B list and report to the RAC at its next meeting. The committee agreed.

Dr. Nightingale reviewed the proposed changes in Section IV, Roles and Responsibilities. These modifications include:

- (1) in Section IV-B-2, language was inserted to the effect that the IBC's "responsibilities need not be restricted to recombinant DNA,"
- (2) in Section IV-B-2-a, the requirement was deleted that 20 percent of the IBC membership not be affiliated with the institution (although the requirement was retained that at least two IBC members not be affiliated with the institution), and
- (3) in Section IV-B-2-b, language recommending that "at least one member be a nondoctoral person from a laboratory technical staff" was modified to read "at least one member be from the laboratory technical staff."

Dr. Berns commented on the proposal to delete the word "nondoctoral". He said some members of the working group felt a "nondoctoral" technician with actual "hands-on" experience was most appropriate for this "slot" on the IBC.

Other members felt that anyone who had "hands on" experience and who was not a principal investigator (including technician, research associate, or post-doctoral fellow) was an appropriate representative of the laboratory technical staff. Following much discussion, the term "nondoctoral" had been deleted from the proposed revised Guidelines by the working group.

Dr. Ahmed questioned why the requirement was deleted that 20 percent of the IBC membership be non-affiliated with the Institution. Dr. Berns offered the example of an IBC just fulfilling the 20 percent specification, but wishing to add an additional specialist affiliated with the university. When this specialist was appointed, non-affiliated representation would fall below 20 percent, and the university would have to appoint another non-affiliated member. Dr. Berns said the working group felt the percentage of non-affiliated members was not critical as long as two non-affiliated members were present on the IBC. Dr. Ahmed pointed out that on an IBC

composed of 20 members, with two non-affiliated members, non-affiliated representation would be 10 percent or half of the non-affiliated composition mandated under the current Guidelines. He said the failure to maintain this requirement troubled him. Dr. Mason pointed out that a five-membered IBC would have at least 40 percent of its membership non-affiliated. Dr. McKinney said he believed that the institution, which appoints members to the IBC, will respond to the intent of the Guidelines and appoint IBCs of an appropriate composition.

Moving to the next section, Dr. Nightingale called the attention of the RAC to Section IV-B-2-f. Section IV-B-2-f reads:

"Institutions are encouraged to open IBC meetings to the public, whenever possible, consistent with protection of privacy and proprietary interests."

Dr. Nightingale said no modifications were suggested for this section but noted that one member of the working group, Ms. King, felt the issue of open meetings should be evaluated at some point in the future and that open meetings probably should eventually be required.

Dr. Nightingale finally noted the addition of proposed language to Section IV-D-4. The proposed language reads:

"Note: Other Federal agencies which have adopted the NIH Guidelines may have the authority to terminate funding to their grantees should these grantees not comply with the NIH Guidelines."

She felt this statement is not sufficient and that the section should be expanded to include a description of the Federal Interagency Advisory Committee on Recombinant DNA Research and of its membership. Dr. Goldstein felt that some description of the Interagency Committee would be desirable. In particular, a statement that its members have agreed to abide by the NIH Guidelines should be included. Dr. Gottesman suggested that an Appendix, describing the Interagency Committee, its agency members, and a statement that these agencies have agreed to abide by the Guidelines, be added to the Guidelines. References would be made to this new Appendix at (1) Section IV-C-1-a-(4) which describes the Director's responsibility for maintaining this committee, and (2) under Section IV-D-4 in place of the "Note". Dr. Ahmed suggested the proposed Appendix should also describe how the Interagency Committee was formed, who it reports to, and what responsibilities member agencies have assumed with respect to the NIH Guidelines. Dr. Ahmed agreed to accept this amendment, as did Dr. Berns.

Dr. Goldstein said he still had concerns on the potential use of recombinant DNA technology for biological warfare. He noted that the Department of Defense (DOD) is a member of the Interagency Committee. He said that earlier in the meeting RAC heard of classified research conducted by DOD. However, several questions on this research had not been answered to Dr. Goldstein's satisfaction by the DOD representative. Dr. McCullough

said that many DOD biomedical research projects are unclassified, but there are projects in defensive biological warfare techniques and processes that are classified. These projects might include aerosol detection devices, antibody identification devices, or air sampling processes. These are not weapons.

Dr. Goldstein asked if the motion made earlier in the meeting concerning the use of recombinant DNA technology for biological warfare might be reconsidered. Dr. Ahmed seconded. By a vote of five in favor, thirteen opposed, and no abstentions the RAC refused to reconsider the earlier motion.

Mr. Thornton called the attention of the RAC to Part D of tab 1072 which includes certain sections of the current Guidelines which the working group suggested deleting but which NIH staff felt should be retained. He said the version which Dr. Ahmed had moved includes these sections. If any member does not approve of the retention of any section, a specific motion to delete should be made. The sections to be retained are: (1) Section I-D-5 of Section I-D, General Definitions, which defines "Director, NIH," (2) Section IV-B-5-b and its subsections of IV-B-5, Principal Investigator, which deals with submissions by the principal investigator to the NIH, (3) Section IV-C-1-b-(1)-(a) and Section IV-C-1-b-(1)-(b) of Section IV-C-1-b, Specific Responsibilities of the Director, and (4) Section IV-C-1-b-(2) and its subsections which detail certain lesser actions which are the responsibility of the Director. No motion to delete any of these sections was made.

Dr. Brill returned to the issue of the classification of Klebsiella as a Class 2 agent in Appendix B. He suggested that the language in Appendix B which reads "Klebsiella - all species and all serotypes" be modified to read "Klebsiella - all strains known to originate from human and animal sources." Dr. Gottesman asked what an investigator would assume if he did not know the source of a strain. Dr. Brill replied that an investigator would assume that particular Klebsiella strain was a Class 1 agent. Dr. Gottesman pointed out that no new restrictions were being imposed on investigators working with Klebsiella by the proposed revised Guidelines. She questioned the appropriateness of modifying this language at this RAC meeting without data sufficient to formulate a reasonable motion. She felt a working group could examine the issue in greater detail. Dr. Ahmed agreed the issue should be referred to a working group; he felt insufficient information was available at the moment. Dr. McKinney said the Classification of Etiologic Agents states that "human etiologic agents" have been classified. Presumably, those strains of Klebsiella classified in proposed Appendix B are only the human pathogens. Dr. Tolin pointed out that Klebsiella appears in Sublist A of Appendix A and, therefore, many experiments involving Klebsiella will be totally exempt from the Guidelines.

Dr. Holmes suggested that the RAC might follow either of two options: (1) recommend Appendix B as proposed by the working group, or (2) retain Appendix B as it appears in the current Guidelines. He said he would suggest, as an amendment, that RAC retain Appendix B as it currently appears in the Guidelines. Dr. Berns disagreed; he said few substantive changes had been made in proposed Appendix B, and he would not accept Dr. Holmes' amendment. Dr. Holmes withdrew his amendment.

Mr. Thornton called the question on Dr. Ahmed's motion to recommend the proposed revised Guidelines, as amended. By a vote of eighteen in favor, none opposed, and no abstentions, the motion was accepted.

Dr. Nightingale moved that, as suggested by the Working Group on Revision of the Guidelines, a RAC Working Group be appointed to periodically review the Guidelines. By a vote of eighteen in favor, none opposed, and no abstentions, the motion was accepted.

Dr. Gottesman said that one issue discussed by the Working Group on Revision of the Guidelines was IBC functioning under the revised Guidelines. She suggested that a letter might be sent to the IBCs covering the following issues: are the IBCs experiencing problems with the revised Guidelines, do the IBCs disagree with RAC in terms of containment, are the Guidelines too stringent or too relaxed, does the IBC spend inappropriate amounts of time on any problem, how frequently do the committees meet, and does the committee fill other functions for the university, e.g., is the committee a general biosafety committee? If the committee is not a general biosafety committee, why not?

Dr. Gottesman said the effort would obviously be voluntary and the responses, therefore, would probably be somewhat biased; but the survey will at the minimum raise issues for discussion.

VI. FUTURE MEETING DATES

Dr. Gartland said the next meeting was scheduled for October 25, 1982. He assumed it would be a one day meeting.

VII. PRESENTATION OF CERTIFICATES OF SERVICE AND ADJOURNMENT

Mr. Thornton said that the June 28, 1982, meeting would be the last meeting for six RAC members as their terms of service would expire on June 30. The retiring members are Drs. Ahmed, Goldstein, Baltimore, Pinon, and Ms. King. Mr. Thornton said this meeting also was the last session of his term. He expressed his deep sense of friendship with many members of the Recombinant DNA Advisory Committee. He said he had learned much from the members of the committee. He expressed his thanks to the NIH staff for the invaluable support they had given. He also thanked Dr. Jim McCullough of the Congressional Research Service for his assistance over many years.

Certificates of service were then awarded to the retiring members. The meeting was adjourned at 4:40 p.m. on June 28, 1982.

Respectively submitted,

Elizabeth A. Milewski
Elizabeth A. Milewski, Ph.D.
Rapporteur

William J. Gartland, Jr.
William J. Gartland, Jr., Ph.D.
Executive Secretary

I hereby certify that, to the best of my knowledge, the foregoing Minutes and Attachments are accurate and complete.

11-22-82

Date

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Ray Thornton, J.D.
Chairman
Recombinant DNA Advisory Committee

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