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BILLS H.R. 4759, H.R. 3191  
AND H.R. 4232

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THURSDAY, MARCH 17, 1977

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House of Representatives

Subcommittee on Health and the  
Environment of the Committee  
on Interstate and Foreign  
Commerce

Washington, D. C.

The subcommittee met pursuant to notice at 2:00 p.m. in  
Room 2123, House Rayburn Office Building, Hon. Paul G. Rogers,  
Chairman of the subcommittee, presiding.

Present: Representatives Rogers, Waxman, Maguire, Ottinger,  
and Carter.

Mr. Rogers. The subcommittee will come to order. Our  
first witness is Dr. Donald B. Frederickson, Director, National  
Institutes of Health. We will incorporate in the record, the  
statement in its entirety.

If you wish to summarize it or in any other way proceed,  
we will certainly appreciate hearing from you any way you would  
like to have the material.

(The statement follows:)

*We need to 3-1  
get final print  
of this -  
may have it  
here*

1 Dr. Fredrickson. I would like to give an abbreviated ver-  
2 sion of the statement which you have suggested be incorporated  
3 in the record.

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1 STATEMENT OF DR. DONALD B. FREDERICKSON,  
2 DIRECTOR, NATIONAL INSTITUTES OF HEALTH, ACCOMPANIED BY:  
3 JOSEPH G. PERPICH, M.D., ASSOCIATE DIRECTOR, PROGRAM  
4 PLANNING AND EVALUATION, RICHARD RISEBERG, OFFICE OF  
5 GENERAL COUNSEL

6 Dr. Frederickson. I should say that it is a pleasure for  
7 me to appear before the committee today. I have with me, on  
8 my left, Dr. Joseph Perpich and on my right, Mr. Richard Riseberg,  
9 of the NIH staff.

10 We are pleased to appear before you today to discuss par-  
11 ticularly Federal policies concerning Recombinant DNA Research.  
12 I would like to specifically tell you about the research ac-  
13 tivities of two organizations -- those of the National Institutes  
14 of Health and those of the Federal Interagency Committee.

15 As you are well aware, from testimony that you have already  
16 heard, the techniques for creating recombinant DNA molecules  
17 is a new and powerful tool of science that has generated both  
18 great hope and excitement on the one hand, and many expressions  
19 of concern on the other.

20 These techniques certainly offer promise for better under-  
21 standing and improved treatment of human diseases but there may  
22 be risks in this new research area as well as anticipated bene-  
23 fits.

24 Until the potential risks are better delineated and evalu-  
25 ated in light of developing scientific knowledge, the public  
should expect such research to be conducted under strict con-  
ditions, insuring safety.

1 This was the fundamental principle that guided the NIH and  
2 the Federal Interagency Committee in their deliberations on  
3 recombinant DNA Research.

4 I would like to review with the committee the activities of  
5 NIH in developing guidelines to cover this research and devote  
6 the rest of my remarks to the activities of the Interagency  
7 Committee.

8 As I am sure has already been covered in testimony before  
9 the committee during this hearing, you are aware that the  
10 scientists engaged in the use of these techniques were the  
11 first to express concern about potential biohazards, a concern  
12 which grew and came to a manifestation in July of 1973 at which  
13 time a request was made to the National Academy of Sciences  
14 to create a committee that might outline restrictions for these  
15 types of experiments, and to organize an international confer-  
16 ence to consider the problem further.

17 The committee also called on the NIH to establish an ad-  
18 visory committee to study containment procedures and draft  
19 guidelines for the conduct of this research. This was the first  
20 entry of government, in general, and the Federal Government in  
21 particular, into the matter relative to the use of recombinant  
22 DNA techniques.

23 At the conference held in Asilomar in February 1975, tem-  
24 porary guidelines were issued calling for a moratorium on some  
25 experiments but allowing others to proceed with appropriate

1 biological and physical safeguards, pending issuance of NIH  
2 guidelines.

3 In response to the National Academy of Sciences, the NIH  
4 Recombinant DNA Molecule Program Advisory Committee, hereafter  
5 the NIH Recombinant Advisory Committee, was established in  
6 October 1974 to advise the Secretary of HEW, the Assistant  
7 Secretary of Health, and the Director of NIH in accomplishing  
8 their tasks.

9 In December 1975, the Committee, after several open meetings,  
10 and half a dozen working drafts, recommended proposed guide-  
11 lines to the NIH director for his review and decision.

12 To assist my review of the proposed guidelines, a special  
13 meeting of the Advisory Committee to the Director, NIH, was con-  
14 vened in February of 1976. Members of the Committee represented  
15 not only science but such other disciplines as law, ethics,  
16 and consumer affairs.

17 Comments received from committee members and a number of  
18 public witnesses represented a wide range of views. Follow-up  
19 written comments were also solicited. In April, the NIH Re-  
20 combinant Advisory Committee considered these comments from the  
21 February meeting, and a number of changes to the guidelines  
22 were made.

23 Concurrently, meetings for information exchange were held  
24 with representatives from other Federal agencies and private  
25 industry as well as with Congressional staffs. Finally, on

1 June 23, 1976, with the approval of the Secretary of HEW and the  
2 Assistant Secretary of Health, the NIH issued guidelines to  
3 govern the research it supports on recombinant DNA molecules.

4 The NIH Guidelines established strict conditions for the  
5 conduct of this research, prohibiting certain types of experi-  
6 ments and requiring special safety conditions for other types.  
7 The provisions were designed to afford protection -- with a  
8 wide margin of safety -- to workers and the public and the en-  
9 vironment.

10 Two weeks later, on July 7, 1976, the NIH Guidelines -- to-  
11 gether with a document indicating the basis of decisions, my  
12 decisions, NIH, on principal issues -- were published in the  
13 Federal Register for public comment.

14 Over 40,000 copies of the guidelines were widely distri-  
15 buted to foreign embassies, medical and scientific journals,  
16 NIH grantees and contractors, and major professional research  
17 societies, and to others who requested them.

18 To facilitate implementation of the Guidelines, the NIH,  
19 in June, established the Office of Recombinant DNA Activities;  
20 to administer and coordinate intramural and extramural activ-  
21 ities at the NIH; to review the institutional biohazards  
22 committees and certification statements; and to monitor reports  
23 and information concerning accidents, containment, and safety  
24 research innovation.

25 In August, the NIH published a volume containing the

1 transcript of the February public hearing on the proposed  
2 guidelines as well as related correspondence received by the  
3 Director and the results of relevant data sought prior to the  
4 release of guidelines in June.

5 A second volume is planned for publication in late Spring  
6 documenting the correspondence that the NIH received on the  
7 guidelines, the Environmental Impact Statement, and the Depart-  
8 mental patent policy.

9 The NIH, in accordance with the National Environmental  
10 Policy Act of 1969, undertook an environment impact assessment  
11 to review environmental effects, if any, of research that may be  
12 conducted under the guidelines.

13 The NIH Guidelines were released prior to the completion of  
14 the assessment because they're release provided greater pro-  
15 tection for the public and the environment than the Asilomar  
16 Guidelines which they replaced.

17 For example, in a number of instances, the NIH Guidelines  
18 require more stringent safety and containment measures, ex-  
19 tension of the list of prohibited experiments, and a specific  
20 ban on the release of recombinant molecules into the environ-  
21 ment.

22 A Draft Environmental Impact Statement was filed and pub-  
23 lished in the Federal Register on September 9, 1976, to afford  
24 additional public review and comment. The statement is cur-  
25 rently being analyzed and comments received will be responded

1 to in the final Environmental Impact Statement to be published  
2 in late March.

3 In June, shortly before the release of the Guidelines, Stan-  
4 ford University and the University of California asked NIH to  
5 review DHEW policies relating to the patenting of recombinant  
6 DNA research inventions developed under NIH grants or contracts.

7 Under current DHEW patent regulations, invention rights to  
8 discoveries developed under the Department's research support  
9 are normally allocated in either of two ways:

10 One, the Department may enter into an Institutional Patent  
11 Agreement with a university or other nonprofit institution that  
12 has adequate mechanisms for administering patents on inventions.  
13 The IPA provides the institution the first option to own all  
14 inventions made in performance of the Department grants or con-  
15 tracts, subject to a number of conditions deemed necessary to  
16 protect the public interest.

17 For those institutions that have not entered into a patent  
18 agreement with the Department, determination of ownership is  
19 deferred until an invention has been made, at which time an in-  
20 stitution may petition the Department for ownership of the  
21 invention.

22 The NIH solicited opinions from a number of different  
23 groups in the scientific community and the public and private  
24 sectors concerning those departmental patent policies, with  
25 respect to recombinant DNA research inventions.



1 An analysis of the issues raised by the commentators is  
2 under review by the Federal Interagency Committee.

3 I would now like to devote the remainder of my testimony to  
4 the activities of the Interagency Committee on Recombinant DNA  
5 Research. This Committee was created, with the approval of the  
6 President, to address extension of the NIH Guidelines beyond  
7 the NIH, to the public and private sectors.

8 The specific mandate of the Interagency Committee is as  
9 follows: to review the nature and scope of all recombinant  
10 DNA research conducted in the United States, to determine the  
11 applicability of NIH standards to the government of this  
12 research nationally, and to recommend mechanisms to ensure that  
13 the standards are being complied with.

14 The Committee is advisory to the Secretary of Health,  
15 Education and Welfare. It includes representatives of Federal  
16 Departments and Agencies that support and conduct recombinant  
17 DNA research, or may do so in the future, and representatives  
18 of Federal Departments and Agencies that have present or po-  
19 tential regulatory activity in this area.

20 At the Secretary's request, I serve as Chairman of the  
21 Committee.

22 Two meetings of the Committee were held in November 1976.  
23 The first of these, on November 4, was devoted to a review of  
24 the development of the NIH Guidelines. The Committee also re-  
25 viewed activities in other countries on the development of

1 guidelines for this research.

2 I will reserve, since you may have questions, Mr. Chairman,  
3 a review of those activities abroad which I have reviewed first  
4 hand on a continuing basis, both in numerous countries, includ-  
5 ing Britain and Europe and here with conversations with scien-  
6 tists and administrators from those countries and from behind  
7 the Iron Curtain and Japan.

8 At the meeting, the Interagency Committee held in November  
9 23, the Federal Research agencies discussed their activities and  
10 possible roles in the implementation of the NIH guidelines.  
11 All research agencies endorsed the Guidelines to govern recom-  
12 binant DNA research.

13 At present, the NIH, the National Science Foundation, the  
14 Veterans Administration, and the U.S. Department of Agriculture.

15 At the November 23 meeting, the Federal regulatory agencies  
16 reported on their regulatory functions. Following that review,  
17 a special Subcommittee was formed to analyze the relevant  
18 statutory authorities for the possible regulation of recombinant  
19 DNA research.

20 All regulatory agencies were represented on the Subcom-  
21 mittee, assisted by attorneys from their offices of general  
22 counsel.

23 The Subcommittee was charged to determine whether existing  
24 legislative authority would permit the regulation of all re-  
25 combinant DNA research in the United States, whether or not

1 federally funded, and would include at least the following  
2 regulatory requirements.

3 It was the conclusion of this Subcommittee that present  
4 laws could permit imposition of some of the above requirements  
5 on much recombinant DNA laboratory research, but no single  
6 legal authority or combination of authorities currently existed  
7 that would clearly reach all research and other uses of re-  
8 combinant DNA techniques.

9 Although there is existing authority that might be inter-  
10 preted broadly to cover most of the research at the present  
11 time, it was generally agreed that regulatory actions taken on  
12 the basis of any such interpretation would probably be subject  
13 to legal challenge.

14 The Subcommittee, in reaching this conclusion, reviewed  
15 the following laws that were deemed to warrant detailed con-  
16 sideration:

17 The Occupational Safety and Health Act of 1970, Public Law  
18 91-596; the Toxic Substances Control Act, Public Law 94-469;  
19 The Hazardous Materials Transportation Act, Public Law 93-633;  
20 and Section 361 of the Public Health Service Act, 42 U.S.C.264

21 The full Committee adopted the report of its Subcommittee  
22 and agreed that new legislation was required.

23 In considering the elements for legislation, the committee  
24 reviewed federal, state and local activities bearing on the  
25 regulation of recombinant DNA research. Among Congressional

1 proposals reviewed were Senate Bill 621, "The DNA Research Act  
2 of 1977", introduced by Senator Dale Bumpers, and the companion  
3 measure introduced by Representative Richard L. Ottinger in the  
4 House, H.R. 3591.

5 The Committee also noted the resolution introduced by  
6 Representative Ottinger on January 19, 1977, H. Res. 131, re-  
7 questing DHEW to regulate recombinant DNA research under Section  
8 361 of the PHS Act.

9 Hearings held by State and local governments, including  
10 State legislatures, were among State and local activities re-  
11 viewed. Recommendations by the New York State Attorney General's  
12 Environmental Health Bureau for State regulation, and by the  
13 Cambridge, Massachusetts City Council for city regulation,  
14 were also considered.

15 Several committee representatives also reported on meetings  
16 with other interested parties, which they had held soliciting  
17 views on legislation, to regulate recombinant DNA research.  
18 Those who were contacted included agricultural scientists,  
19 biomedical scientists, environmentalists, labor unions, and  
20 private industry.

21 At my request, the Industrial Research Institute and the  
22 Pharmaceutical Manufacturers Association are surveying their  
23 member firms to determine the scope of the research efforts in  
24 the private sector.

25 The Pharmaceutical Manufacturers Association has adopted

1 the NIH Guidelines as standards for safe conduct of this re-  
2 search.

3 In considering elements of proposed legislation, a number  
4 of issues were raised and discussed fully by the Committee.  
5 After detailed deliberations at meetings on March 10 and 14,  
6 1977, the Committee agreed on a set of elements for proposed  
7 legislation.

8 The elements agreed upon and the various alternatives  
9 reviewed by the Committee were presented in an Interim Report  
10 transmitted to HEW Secretary Califano on March 15, 1977.

11 Secretary Califano, in releasing the report on March 16,  
12 stated that "legislation in this area would represent an un-  
13 usual regulation of activities affecting basic science but the  
14 potential hazards posed by recombinant DNA techniques warrant  
15 such a step at this time."

16 We are not saying that research should be all the more  
17 urgent that it should proceed under safe guards unless until  
18 we have a better understanding of the risks and benefits posed  
19 by use of recombinant DNA techniques without government regu-  
20 lation.

21 The Secretary added that the Department will begin im-  
22 mediately to draft legislation in the light of the recommend-  
23 ations made by the committee.

24 Mr. Chairman, I would like to submit for the record, this  
25 "Interim Report of the Federal Interagency Committee on

1 Recombinant DNA Research on Suggested Elements for Legislation,  
2 along with a copy of the Secretary's remarks, accompanying its  
3 release.

4 Mr. Rogers. Without objection, we will commit that as part  
5 of the record at this point.

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(COMMITTEE INSERT)

1 Dr. Frederickson. I would like to review very briefly some  
2 of the major elements of legislation which were considered by  
3 the committee. The committee determined that, in its view, the  
4 Department of Health, Education and Welfare is the appropriate  
5 locus in the government for the regulation of use and production  
6 of DNA molecules.

7 In reaching this determination, the committee took into  
8 account existing roles of certain agencies within the HEW, for  
9 example, that of the NIH in developing the guidelines and the  
10 Center for Disease Control and Bureau of Biologics of the Food  
11 and Drug Administration in regulating infectious agents and  
12 other biological products.

13 The committee also had before it the petition by the En-  
14 vironmental Defense Fund requesting the HEW to issue regulations  
15 for recombinant DNA research under 361 of the Public Health  
16 Service Act.

17 The committee reviewed, at great length, the nature and  
18 scope of regulations. Consideration was given to regulation of  
19 laboratory research where hazardous and potentially hazardous  
20 substances were employed.

21 There was general committee agreement that present legis-  
22 lation should be restricted, not only to recombinant DNA  
23 techniques, allowing for sound administrative and scientific  
24 expertise in developing safety standards in other area.

25 In this regard, Mr. Chairman, I have established a committee

1 at NIH Chaired by Richard DeCause (ph), the Director of the  
2 National Institute for Allergy and Infectious Diseases to study  
3 and recommend if necessary, safety standards for other research  
4 involving actual or potential biohazards.

5 A preliminary report is expected shortly from this commit-  
6 tee and I will keep your committee informed of the progress of  
7 this NIH review. I just thought that would be helpful.

8 Regulation of just the research aspects of recombinant tech-  
9 niques, DNA techniques, presents a problem because of the diffi-  
10 culty in determining the border between research and pilot  
11 plant production.

12 Therefore, the Interagency Committee has recommended that  
13 regulations covering the production or use of recombinant DNA  
14 molecules, such language would clearly include research activity,  
15 but it makes immaterial possible concerns whether a given ac-  
16 tivity constitutes research, pilot production or manufacture.

17 The committee recommends that the Secretary, in consultation  
18 with appropriate regulatory agencies, be allowed to determine  
19 the nature of the activity and should defer to a national  
20 regulatory body he determines is better empowered and equipped  
21 to deal with that specific activity.

22 There was general agreement by the committee that regis-  
23 tration of projects and other activities involving the use or  
24 production of recombinant DNA molecules was necessary. The  
25 committee also recommends the license share of facilities and



1 that the facility would, under the terms of its license, accept  
2 responsibility for the particular activities and the individuals  
3 at the facility.

4 The committee concluded that licensure of the facility and  
5 registration of products would meet the needs for safety mon-  
6 itoring without extension of licensure to the projects them-  
7 selves.

8 The committee urges full disclosure to the appropriate  
9 regulatory body of all relevant safety and scientific infor-  
10 mation on the use and production of recombinant DNA molecules.  
11 However, the committee recognizes the important worldwide  
12 commercial potential of recombinant DNA molecules in medicine,  
13 agriculture and other areas, and in science and technology.

14 It believes that the potential commercial users of recom-  
15 binant DNA techniques require that information of a proprietary  
16 nature and patent rights be given an appropriate protection  
17 from disclosure by the regulatory agency receiving such infor-  
18 mation.

19 Because the potential hazards posed by the use of recombin-  
20 ant DNA techniques extends beyond the local to the national and  
21 beyond that to international levels, the committee recommends  
22 that a single set of national standards must govern and ac-  
23 cordingly state and local laws should be preempted to insure  
24 national standards and regulations.

25 The committee, however, took into account the activities

1 at state and local levels on regulation of recombinant DNA  
2 research.

3 It was agreed that if the state passes a law imposing re-  
4 quirements identical to that in the Federal statute, then the  
5 Secretary may enter into an agreement with the state to  
6 utilize its resources to assist the Secretary in carrying out  
7 his duties.

8 A number of other recommendations were made that I can dis-  
9 cuss further with you, Mr. Chairman, if you have questions. I  
10 would like to emphasize the work of the Interagency Committee  
11 and how it has been done in an extraordinarily cooperative  
12 and effective fashion.

13 It is most unusual, I think, for servants of some 16 to  
14 20 federal agencies whose territory crisscrosses a difficult  
15 and complicated area and yet to achieve gradually through full  
16 and frank discussion a consensus which was complete on the  
17 recommendations that I have described before you.

18 Mr. Rogers. I would share that feeling. That is unusual.

19 Dr. Frederickson. The Department will continue to cooperate  
20 and work with other relevant federal agencies and departments  
21 in this important matter.

22 In conclusion, Mr. Chairman, I think this much is clear.  
23 The international, as well as the national scientific community  
24 is in substantial agreement concerning the potential hazards  
25 of recombinant DNA techniques until they are better understood,

1 a common set of standards must exist everywhere throughout the  
2 world.

3 The question being debated now is not that but how is this  
4 to be accomplished? Here in this Chamber today we begin to dis-  
5 cuss how it should be accomplished within the United States?  
6 This is a matter by no means now confined to only our country  
7 ~~but to almost all of the~~ developed countries of the world, where  
8 ~~parliament~~ and parliamentary committees, committees established  
9 by states in both private and public manner have considered ex-  
10 tensively whether this research should go on.

11 Numerous bodies such as these and the WHO, International  
12 Council of Scientific Unions, have determined that this research  
13 should proceed but proceed under care and prudence until we  
14 have more knowledge of both its potential and its benefits.

15 Indeed now in many countries we find a disagreement having  
16 been reached, either the NIH or the guidelines established by  
17 the United Kingdom of Canada, all of which have a common ground  
18 ~~in the Asilomar meeting~~ are being used for the purpose of  
19 gradually extending that commonality of standards for these  
20 activities.

21 It is necessary to bear in mind, Mr. Chairman, the changes  
22 ~~in DNA~~, the nucleic acid that is present in all living organ-  
23 isms and which determines their inheritative characteristics,  
24 also occurs spontaneously in nature.

25 They have made possible the never ending process of

1 evolution. Research on recumbant DNA holds great promise. It  
2 may become a powerful tool in advancing our knowledge, knowledge  
3 which conceivably can be used to further the conquest of dis-  
4 ease.

5 In conclusion, I have to note that biomedical research is  
6 opening a new era in relationship to society, at least passing  
7 from an extended period of relative privacy and autonomy to  
8 engagement with some new ethical, legal and social imperatives  
9 under increasingly concerned public scrutiny.

10 NIH has responded to this concern by the requirement of  
11 formation of review boards to oversee human experimentation,  
12 animal care, and now the use of recumbant DNA techniques. Sim-  
13 ilar bodies may soon have to be established in many institu-  
14 tions to over see other hazardous laboratory work.

15 I think these responsibilities are an inescapable adjustment  
16 to the rising demand for public governing of science. I think,  
17 however, this need not and should not go beyond what is clearly  
18 required for public safety for it is the possibility that we  
19 can harm the effectiveness of a creative and responsible  
20 scientific apparatus of which this country at the present time  
21 is in possession and which has no peer throughout the world.

22 Thank you, Mr. Chairman. I will be glad to answer any  
23 questions you might have.

24 Mr. Rogers. Thank you. It has been proposed by some that  
25 we effect a ban for a certain period of time. I take it from

1 your testimony you would not share that approach?

2 Dr. Frederickson. I do not share that approach, Mr. Chair-  
3 man, for several reasons. I suppose one of them is a practical  
4 or prgmatic view that this research will clearly continue and  
5 in many places in the world.

6 Even if it were wise, as I think it is not, to attempt a  
7 complete moratorium on this research, I see no way in which it  
8 could be achieved, with the positions taken now by many other  
9 countries capable of doing the same.

10 I also think, Mr. Chairman, that banning this research or  
11 halting it will not answer the very questions that we need to  
12 know. We must have more knowledge in order to proceed and until  
13 we get that, we have to proceed with utmost prudence and  
14 caution, and under a rather inhibited pace which the guidelines  
15 in effect pose upon all of those who are subject to them.

16 Mr. Rogers. I think it would be helpful if you could,  
17 for the record, perhaps list for us possible benefits that are  
18 envisioned, that could be developed from this type of research,  
19 also a list of possible dangers that you see could develop, al-  
20 so, if you could, for the record, let us have a comparison of  
21 the various guidelines that have been issued or the various  
22 regulations that may have been issued in other countries in  
23 regard to recumbinant DNA research or similar research.

24 If you could point out in one article for us, or one de-  
25 velopment, the difference between our proposed guidelines and

1 those of say, England and Canada which would seem to be similar  
2 or any others that are significant.

3 Dr. Frederickson. We will be very glad to do that, Mr.  
4 Chairman.

5 Mr. Rogers. Thank you; it would be helpful to the committee.  
6 Let me just ask this. What was the nature of the Defense De-  
7 partment's request for a waiver on certain types of recombinant  
8 DNA research restrictions in time of national emergency?

9 Dr. Frederickson. The Defense Department representatives  
10 on the Interagency Committee expressed to the committee a con-  
11 cern that it might be necessary to impose some moratorium on  
12 exchange of information, or to exempt from the guidelines cer-  
13 tain aspects because of national security considerations.

14 I should then tell you, Mr. Chairman, that the committee  
15 decided that it did not have the mandate or authority to deter-  
16 mine those questions and did not take action on it.

17 Mr. Rogers. Should the President be given that authority?

18 Dr. Frederickson. I should think so, that the authority  
19 should be at a very high level, perhaps the Cabinet, National  
20 Security Council or --

21 Mr. Rogers. Was the Central Intelligence Agency invited  
22 to participate in the Interagency Committee meeting?

23 Dr. Frederickson. No.

24 Mr. Rogers. Did it participate?

25 Dr. Frederickson. It did not participate.

1 Mr. Rogers. Has there been any interest indicated by the  
2 CIA?

3 Dr. Frederickson. There has been no inquiry made to the  
4 committee or to NIH from the CIA with respect to this matter.

5 Mr. Rogers. I think it would be well for the record, and I  
6 would not ask you to document this now, but for the record,  
7 would you give us a discussion of the nature of gene transplan-  
8 tation, the regulation, but what is actually going on that we  
9 know of in the way of experiments in Great Britain, Continental  
10 Europe and other countries?

11 Are there any countries in which such research is being  
12 conducted where they have no guidelines for safety?

13 Dr. Frederickson. I will be glad to supply that for the  
14 record. I might call to the attention of the committee an  
15 article in the March 3rd issue of "Nature" in which Mr. Colin  
16 Norman (ph) describes the up to date occurrence of events rela-  
17 tive to this.

18 Mr. Rogers. We will ask staff to acquire that for the  
19 committee. We had a copy, I understand. What about the possi-  
20 bility of U.S. companies going abroad if we did put on very  
21 strict regulations?

22 Dr. Frederickson. I think it is essential for the pro-  
23 tection of all of us on this globe that there be uniformity.  
24 One finds in the scientific community no question about this  
25 and a great determination to achieve it.

1           Of course there would be transmigration of people from one  
2 area to another, I would say not only industrialists but  
3 scientists in the academic world to other areas if they felt  
4 this were possible and that they might conduct research there.

5           I do not imply, however, irresponsibility on the part of  
6 either groups because I think, as I emphasized, it was the  
7 scientists who raised these questions and it is they who have  
8 been extremely responsible in recognizing the dangers and  
9 seeking by all means to have a common set of standards.

10          I do think that we must attempt to achieve uniformity and  
11 conformity throughout the world. I think the way to do that  
12 is to have common standards within national jurisdictions which  
13 must not be confusing or pluralistic because by then we can  
14 use other devices to get that, create the fabric or the blanket  
15 that will go out throughout the whole world, capable of doing  
16 this research.

17          Mr. Rogers. Thank you. Dr. Carter?

18          Dr. Carter. Thank you, Mr. Chairman. How far have we  
19 gone with -- in implanting genes or nuclei into plant ova or  
20 cells? or uniting cells in some cases by dissolving the ecto-  
21 derm?

22          Dr. Frederickson. Well, by cell fusion, Dr. Carter; I  
23 can supply to you for the records some answers to these ques-  
24 tions but I cannot answer them with any expertise this after-  
25 noon.



1       There may be some witnesses on your list today who could  
2 answer those questions.

3       Dr. Carter. You do not know if this -- whether you have  
4 had vegetables formed in this manner?

5       Dr. Frederickson. In terms of the hybridization of the  
6 plants by such techniques?

7       Dr. Carter. Yes, sir.

8       Dr. Frederickson. They have been going on for many years,  
9 Dr. Carter.

10       Dr. Carter. In this method?

11       Dr. Frederickson. They have been going on by a variety of  
12 grafting.

13       Dr. Carter. I do not mean by grafting, I mean by this  
14 method of transplantation of genes?

15       Dr. Frederickson. No, I must defer to witness such as  
16 Dr. Lewis who may follow me later this afternoon, Dr. Carter,  
17 and have him answer the question.

18       Dr. Carter. What about in bacteria, do we have new strains  
19 of bacteria formed by implantation of nuclei in those genes, in  
20 those bacteria?

21       Dr. Frederickson. We have had transformation of bacteria  
22 to be created by recombinant DNA techniques in the sense that  
23 some new properties have been transposed from one species to  
24 another by more or less a replication of the natural process  
25 that produces antibiotics resistance in many strains, not by

1 nuclei but by single genes, implantation through recombinant  
2 DNA techniques.

3 Dr. Carter. We have developed entirely new strains in some  
4 cases, is that not true?

5 Dr. Frederickson. By definition, they are.

6 Dr. Carter. In the case of pseudomonis (ph), particularly?

7 Dr. Frederickson. I am not certain about pseudomonis.

8 Dr. Carter. I think it was Texaco or Standard Oil that  
9 developed that technique, one of them, it is an oil eating  
10 organism.

11 Dr. Frederickson. That is the General Electric Company,  
12 Dr. Carter, which has been working on that problem.

13 Dr. Carter. I believe we have it. What about animal im-  
14 olantation of recombinant genes in animals, how far has that  
15 gone, Doctor?

16 Dr. Frederickson. Genes have been introduced -- foreign  
17 genes have been introduced into tissue culture from animal  
18 cells lines as that kind of recombination has occurred.

19 Dr. Carter. Have we been able to clone frogs?

20 Dr. Frederickson. No, sir, we have not been able to  
21 clone frogs.

22 Dr. Carter. Are you sure of that?

23 Dr. Frederickson. I will certainly have to check on that,

24 Dr. Carter.

25 Dr. Carter. I believe that has been done. I believe they

1 have taken genes from a tadpole, destroyed the nucleus of a  
2 cell of a frog and then by implementation of this -- well, a new  
3 cell entirely in this case, clone of the frog grew. I believe  
4 that is being done at the present time.

5 Doctor, do you think that cloning of humans is possible in  
6 the next 15 or 25 years?

7 Dr. Frederickson. I think it highly unlikely, Dr. Carter.

8 Dr. Carter. You see, some people project that this is  
9 possible, do they not, some say 15 to 40 years?

10 Dr. Frederickson. There are people who have made public  
11 utterances to this effect.

12 Dr. Carter. Then in your opinion, we will not have alpha,  
13 beta, delta, gamma man in the foreseeable future, is that  
14 correct?

15 Dr. Frederickson. I think that the confusion of recombinant  
16 DNA techniques with so-called genetic engineering is a dangerous  
17 distortion.

18 Dr. Carter. It is dangerous but you do not say if it is  
19 possible or not.

20 Dr. Frederickson. I really do not know, Dr. Carter, nor  
21 do I think anybody knows; that is certainly not yet in these  
22 things.

23 Dr. Carter. We can define by elimination which gene has  
24 what effect, we can do that at the present time, is that not  
25 true?

1 Dr. Frederickson. That is very true.

2 Dr. Carter. It is a long process but by process of elimin-  
3 ation, we could determine which gene has certain effects?

4 Dr. Frederickson. I think eventually over a long period  
5 of time.

6 Dr. Carter. That is being done now, Doctor?

7 Dr. Frederickson. Yes.

8 Dr. Carter. All right, sir. Now should a researcher who  
9 uses recombinant genes be licensed if he is engaged in this  
10 work?

11 Dr. Frederickson. It was the view of the committee which  
12 considered this at great length that facilities should be  
13 licensed and that those who used them should be subject to  
14 registration of the project, but not licensing of individuals.

15 Dr. Carter. Not licensure of the individuals, I see. The  
16 laboratory, of course, should be one of four types, I believe  
17 you said; is that correct?

18 Dr. Frederickson. Yes, in terms of physical containment.

19 Dr. Carter. What about the projects? When they attempt a  
20 project, should they be registered with some agency to determine  
21 just what they are going to do, if they are going to clone  
22 bacteria or attempt to do so or attempt to implant genes and  
23 vegetable or whatever?

24 Should this project be licensed or should it be registered  
25 and approved before it can be done?

1 Dr. Frederickson. On the current implementation of the NIH  
2 guidelines, all of our projects are first approved by study  
3 sections and registered.

4 Dr. Carter. Under the NIH guidelines, but what if some  
5 independent laboratory wants to do this?

6 Dr. Frederickson. I think that is the whole purpose of  
7 the legislation that we are discussing, to extend that same  
8 registration requirement.

9 Dr. Carter. At this present time, there are no rules or  
10 regulations concerning them are there?

11 Dr. Frederickson. At the present time, there are no rules  
12 that cover private.

13 Dr. Carter. Now, sir, the Class I, 2-B, 1-B, 2-B, B-3 and  
14 B-4, would you tell me what experiments could be done in each  
15 one?

16 Dr. Frederickson. That is an extensive answer, Dr. Carter.  
17 We can supply you --

18 Dr. Carter. As briefly as possible, would you include it  
19 for the record?

20 Dr. Frederickson. If we could insert that for the record,  
21 we could do so.

22 Mr. Rogers. Without objection, it will be received for  
23 the record.

24 Dr. Carter. Do you think that would take quite a long  
25 time, that you could not give us any rough idea of what

1 experiments should be done in each one of these?

2 Dr. Frederickson. We will get the guidelines out. We can  
3 briefly summarize it for you, if you like, but it will not take  
4 us long to provide the material for the record. It is a por-  
5 tion of the guidelines.

6 Dr. Carter. You do not foresee any brave new world in the  
7 immediate future then, is that correct?

8 Dr. Frederickson. No, I donot.

9 Dr. Carter. Thank you, sir.

10 Mr. Rogers. Mr. Ottinger?

11 Mr. Ottinger. No.

12 Mr. Rogers. Mr. Waxman?

13 Mr. Waxman. Dr. Frederickson, I was interested, in glanc-  
14 ing at your testimony regarding other countries that are in-  
15 volved in recombinant DNA research. You mentioned a number of  
16 western countries that were following the guidelines set up by  
17 the United Kingdom.

18 To your knowledge, what guidelines are being followed in  
19 -- by the Eastern European Bloc countries, including the Soviet  
20 Union?

21 Dr. Frederickson. The Soviet Union has a committee of  
22 the Academy of Sciences which is still developing guidelines  
23 for conduct or use of these techniques. We have discussed  
24 with the Chairman of that committee, its general direction and  
25 it is considering an amalgamation of both the United States and

1 the UK guidelines but it has not published those or made them  
2 available to us at the present time.

3 Mr. Waxman. Do you feel that there will be full coop-  
4 eration internationally including the Soviet Union Eastern Bloc  
5 countries in working out guidelines of the -- will cross national  
6 boundaries?

7 Dr. Frederickson. My opinion is that will occur. That  
8 arises because of the excellent exchange and demonstration of  
9 interest on the part of the Eastern European countries and the  
10 International Council for Scientific Union meetings in which  
11 there is an opportunity for western and eastern people to --  
12 scientists to exchange views.

13 Mr. Waxman. How advanced is the recombinant research  
14 in other countries, particularly eastern bloc countries?

15 Dr. Frederickson. I would say, as a matter, that it is  
16 not as advanced in eastern bloc countries as it is in the  
17 Western World at the present time.

18 Mr. Waxman. In the international scientific community,  
19 is there a full exchange of information about the projects  
20 that are undertaken and how advanced they are so that there is  
21 some learning from each other.

22 Dr. Frederickson. There is what I would have to  
23 characterize as quite full exchange. We are certainly learning  
24 from each other and the connections between the European eco-  
25 nomic community countries and the United States is excellent,

1 both at the administrative and scientific level in regard to  
2 this.

3 We just had our own NIH representative and liaison to  
4 the meeting of the European Science Foundation last week of the  
5 Genetic Manipulation Advisory Groups, the so-called G-mags, a  
6 new word for the acronym for the future, which operate now in  
7 each of the 16 member countries of the European Science Foun-  
8 dation.

9 There they are sharing their views on what decisions  
10 they are making, what projects they have reviewed and other  
11 common problems relative to conforming to a common set of stan-  
12 dards.

13 Mr. Waxman. Is there a risk of contamination from abroad  
14 given your knowledge of the research projects that are now being  
15 undertaken?

16 Dr. Frederickson. I think that we cannot say there is  
17 no risk of contamination. There is a hypothetical, speculative  
18 risk to recombinant DNA research which is the very basis for  
19 the matter being here discussed.

20 I know of no experimentation going on, however, which  
21 proposes any serious or even topical hazard to us at the  
22 present time.

23 Mr. Waxman. You mentioned that the interagency level  
24 or the NIH guidelines were adopted and the CIA was not involv-  
25 ed?



1 Dr. Frederickson. It was not, sir.

2 Mr. Waxman. Do you know whether the CIA is involved in  
3 research with DNA recombinant combinations and experimentation?

4 Dr. Frederickson. We have no knowledge, Mr. Waxman,  
5 whether they might or might not be so involved.

6 Mr. Waxman. You are under the Secretary of HEW?

7 Dr. Frederickson. Yes.

8 Mr. Waxman. At the Cabinet level. Do you know whether  
9 there has been any discussion of exchange of information about  
10 DNA recombinant research?

11 Dr. Frederickson. I am not aware whether that has  
12 occurred or not.

13 Mr. Waxman. We heard testimony yesterday indicating  
14 that the Department of Agriculture has not yet adopted the NIH  
15 guidelines. Have you attempted to get other federal departments  
16 to comply and why are they resisting compliance?

17 Dr. Frederickson. The Department of Agriculture has  
18 formally adopted the NIH guidelines and so have all federal  
19 agencies that are conducting or say they may ever conduct  
20 recombinant DNA research.

21 That includes the Department of Defense which is not  
22 conducting such experiments at the present time.

23 Mr. Ottinger. Will the gentleman yield?

24 Mr. Waxman. Will be pleased to.

25 Mr. Ottinger. Does that include all grants, all agencies

1 which make grants for such research or contracts for such re-  
2 search?

3 Dr. Frederickson. Yes, it does, Mr. Ottinger.

4 Mr. Ottinger. Thank you.

5 Mr. Waxman. How about the National Security Agency, are  
6 they in adherence to the NIH guidelines?

7 Dr. Frederickson. They were not represented on the  
8 committee; we have no communication from the National Security  
9 Agency.

10 Mr. Waxman. Do you know whether they are involved in  
11 DNA recombinant research?

12 Dr. Frederickson. No, I do not.

13 Mr. Waxman. How about the Arms Control Disarmament  
14 Agency?

15 Dr. Frederickson. They are represented on the Inter-  
16 Agency Committee.

17 Mr. Waxman. They have subscribed to the NIH guidelines?

18 Dr. Frederickson. I think they have formally not done  
19 so because they conduct no research or support no such research,  
20 Mr. Waxman, but they are on the committee and represented.

21 Mr. Waxman. I would be pleased to yield to Mr. Carter.

22 Dr. Carter. There are, I believe, just three federal  
23 agencies or groups in this National Science Foundation, Vet-  
24 erans Administration and U.S. Department of Agriculture are  
25 now doing some experimentation, is that correct?

1 Dr. Frederickson. Yes, they are doing it or supporting  
2 it.

3 Dr. Carter. I yield.

4 Mr. Waxman. I thank you very much for your testimony  
5 and your answers to these questions have been very helpful.

6 Mr. Rogers. Mr. Maguire?

7 Mr. Maguire. Thank you, Mr. Chairman. Dr. Frederickson,  
8 you have indicated that the committee decided not to attempt  
9 to address the question of other research involving biohazards,  
10 that is other research than recombinant DNA.

11 I understand that there are techniques for cell hybrid-  
12 ization, bacterial transformation and transduction and plasmic  
13 engineering, among others. Was it your feeling that those did  
14 not pose the same kind of hazards or that you simply could not  
15 deal with more than one thing at a time?

16 What was the rationale for not broadening it?

17 Dr. Frederickson. The committee clearly recognizes  
18 as do we at NIH individually that there are other hazards, other  
19 techniques for genetic recombination which we do think need  
20 evaluation.

21 For purposes of making that analysis, we have estab-  
22 lished at NIH a committee on other aspects of genetic recom-  
23 bination and laboratory safety which has had several meetings.  
24 It now has three subcommittees, one on cell fusion, another on  
25 mutogenesis and another on recombination experiments other than

1 recombinant DNA techniques as defined by the NIH guidelines.

2 This committee is examining and attempting to develop recom-  
3 mendations to the NIH with respect to possible need for other  
4 guidelines to govern this type of research.

5 Mr. Maguire. I am looking now, not at your statement, but  
6 the interim report of the committee which I assume you also have  
7 a copy of. I will be referring to various pages of that.

8 Dr. Frederickson. Yes, I do.

9 Mr. Maguire. On page 17, you indicate that the Secretary,  
10 in consultation with appropriate regulatory agencies, should be  
11 allowed to determine the nature of the activity and should  
12 defer to a regulatory body he determines is better empowered and  
13 equipped to deal with it.

14 I take it that you have fallen short of saying that he  
15 should be required to defer to that regulatory body? Do I  
16 read that correctly and are you reserving then to him the right  
17 not to defer if he should choose not to, if he felt, for example,  
18 a lack of confidence in what some other regulatory body might  
19 do in a given instance?

20 Dr. Frederickson. The choice of verb form there is de-  
21 liberate and one that the committee debated and considered at  
22 great length. It felt that it was necessary to embody in one  
23 person the first discretionary responsibility that someone  
24 would have to make that determination.

25 However, it recognized that there are already at least

1 two other regulatory agencies, EPA for example and FDA in the  
2 commercial area and that these authorities, when clearly ap-  
3 plicable to a given activity, might very well mean that those  
4 agencies should be the one to take over regulation of that  
5 activity.

6 Mr. Maguire. But the discretion should remain with the  
7 Secretary?

8 Dr. Frederickson. We felt that the discretion had to be  
9 placed within the Secretary.

10 Mr. Maguire. I agree with that; I just wanted to clarify  
11 that. On page 18, you indicate that the Secretary should have  
12 the authority to exempt certain classes of projects from this  
13 requirement, namely the registration requirement.

14 In view of the fact that you are simply asking for regis-  
15 tration other than licensure or prior approval or what have  
16 you, I am finding it difficult to envisage what classes of  
17 projects might require or need the benefit of that exemption.

18 I am wondering why that exemption is there if all we are  
19 asking for is simply registration. It would seem simple enough  
20 to register.

21 Dr. Frederickson. You are also referring, I believe, Mr.  
22 Maguire, to the suggested elements of legislation which also  
23 appear on page 12?

24 Mr. Maguire. I am really reading from page 18, although  
25 there may be some --

1 Dr. Frederickson. That is an extension or comments on the  
2 more specific element; that is on page 12 in the second paragraph  
3 if I might call your attention to it there.

4 Mr. Maguire. I see. Then let us deal -- I see. In other  
5 words, if there were a specific commercial purpose or where  
6 there was no unreasonable risk.

7 Dr. Frederickson. No, Mr. Maguire. I think that I have  
8 just referred you to page 12 and the other element relevant to  
9 registration is the third paragraph on page 13. Let me clarify  
10 the intent, what the committee had in mind here.

11 It is envisioned that as more knowledge is acquired, it  
12 will be possible to determine with a high degree of accuracy  
13 that certain kinds of experiments may no longer pose any hazard  
14 and that then it will be possible with appropriate justification  
15 for the Secretary to place an exemption on those but it is not  
16 meant to exempt commercial or other activities.

17 Mr. Maguire. Then the reference to page 12 was not a  
18 correct reference. We are talking about --

19 Dr. Frederickson. Page 13 is the reference with respect  
20 to registration.

21 Mr. Maguire. On page 13 though, you see I am worried  
22 about loopholes. I am wondering, registration would seem to be  
23 such a simple matter, I am just wondering why we just cannot  
24 simply ask anybody concerned in any way with this to register  
25 and why we would want to introduce an exemption which could be

1 exploited either by people seeking exemptions or people who are  
2 granting them, in a way that might be consistent with the public  
3 interest.

4 I am not saying that would happen; I am saying why permit  
5 that exemption, particularly when I think we would agree there  
6 might be some difficulty, in some cases, in defining the test  
7 for unreasonable risk.

8 Dr. Frederickson. I understand that. The committee, too,  
9 was concerned about loopholes and sought to create none and to  
10 avoid all, however, it was a major aspect of our consideration  
11 and it remains a great concern that it is certain that our  
12 knowledge of the meaning of these techniques, their potential  
13 for either benefit or harm, must vastly increase in the new  
14 few years.

15 It is very probable, it seems to me, that some experiments  
16 between now, placed under sanctions or regulation, may prove  
17 to be completely harmless or have either no benefit or any  
18 hazard so that there will be a change in these standards.

19 I think that is one of the extraordinary problems we face  
20 here in this kind of regulation with which we are dealing, a  
21 field in which knowledge is going to advance rapidly, where  
22 resynthesis will indicate that we will have to be able to  
23 change a view which cannot be fixed in an inflexible fashion.

24 Mr. Maguire. Then you feel the exemption is important?

25 Dr. Frederickson. Yes.

1 Mr. Maguire. What about those that you choose not to  
2 exempt, why would you not ask for the right to approve projects  
3 before they commence or is it your feeling that would be equi-  
4 valent to licensure and you are trying to avoid licensure?

5 Why, if you are going to insist on registration for those  
6 that you do not exempt, why would you not also insist on project  
7 approval?

8 Dr. Frederickson. I think that the ability to examine  
9 in extraordinary detail each use of a recombinant DNA technique  
10 maybe an impossible regulatory task, that is to require prior  
11 approval of every small change in protocol or utilization of  
12 these techniques.

13 Indeed, these are not single experiments which have a long  
14 time scale necessarily. The matter of using recombinant DNA  
15 techniques is comparable in many ways outside of its uncertain-  
16 ties with regard to hazard and benefit, to the use of an extra-  
17 ordinary number of techniques that are used in experimentation.

18 We felt this would impose an intolerable burden on any  
19 regulatory group if it had to approve each change in the  
20 project. It must know, however, the nature of the general  
21 activities and that by proximal determination, the NIH guide-  
22 lines which are very explicit in regard to how each individual  
23 project shall be carried out, that they should be followed be-  
24 cause we do have codified in those guidelines an explicit set  
25 of directions which far exceeds that of the other existing



1 guidelines that have been referred to today.

2 Mr. Maguire. Thank you, Mr. Chairman. I have additional  
3 questions if we can come back.

4 Mr. Rogers. If we could get them answered in the record,  
5 would that be satisfactory? You could submit them and they  
6 will --

7 Mr. Maguire. I would like to ask some additional ques-  
8 tions rather than submit them for the record because I think  
9 they are important for this discussion, Mr. Chairman.

10 Mr. Rogers. I want everyone to but we do have nine ad-  
11 ditional witnesses to finish this afternoon, if possible.

12 Mr. Maguire. May I submit some of them for answering in  
13 the record and ask one or two more, Mr. Chairman?

14 Mr. Rogers. Sure.

15 Mr. Maguire. Would you like for me to do that now?

16 Mr. Rogers. If you could do that rapidly, it would help  
17 us.

18 Mr. Maguire. You said you did not want to license indi-  
19 viduals in answer to Dr. Carter, why not register individuals?

20 Dr. Frederickson. We think we should.

21 Mr. Maguire. That was not clear.

22 Dr. Frederickson. I am sorry; we did not clarify that, we  
23 should know who they are.

24 Mr. Maguire. On page 18, midway down the page, there is  
25 a very interesting sentence which says, "There was concern

1 expressed unattributed that revocation was a very punitive  
2 measure but it was agreed that the Secretary may wish to consider  
3 it for serious violations of the standards."

4 While I would emphatically agree that the Secretary ought  
5 to be able to consider sanctions in the event that things are  
6 seriously wrong, I just wondered why it was necessary in this  
7 document to back into what I would assume was a minimum position  
8 with respect to that matter or what ought to be a minimum  
9 position in relation to the public interest.

10 It looks as if there were a lot of people here who were  
11 saying in effect, let us do all of this but let us not punish  
12 anybody if they get out of line. I found this a very troubling  
13 wording on that point. I wonder if you could comment on that?

14 Dr. Frederickson. I would be glad to. There are two  
15 reasons why the committee took this position. One, it felt that  
16 it would be extremely difficult that the qualifer's serious  
17 and willful, are not to easy to deal with in many situations.

18 Second, it felt that given that, that an infraction of  
19 the rules by a single investigator, that might penalize an  
20 entire institution would indeed in many instances be punitive  
21 and certainly very serious.

22 It did not want to exclude the fact that there might be  
23 circumstances that would clearly warrant that action but it  
24 did not want to go on record as indicating that this would be  
25 an extreme action in regard to an institution or whole facility

1 or could be and that it often may very difficult to determine  
2 what was willful or not.

3 Mr. Maguire. From the public's point of view, willfulness  
4 is less important than the fact about what is happening if there  
5 are serious violations, it would seem to me we do not have to  
6 make a lot of apologies to anyone to revoke.

7 I would hope we would not get ourselves into an apologetic  
8 framework from out outside on that point.

9 Dr. Frederickson. Yes, the committee did not intend to be  
10 apologetic but it felt that the Secretary here should have  
11 discretion. It may be a very difficult problem.

12 Mr. Maguire. At one point in this document you talk about  
13 giving the Secretary the authority to enjoin use for production  
14 on page 20; at another point, page 13, you talk about giving  
15 him authority to sue to enjoin use or production.

16 Those, I think, are very different matters. One requires  
17 that he go to court first before he can enjoin and the other  
18 says that he can simply enjoin; which is it you are suggesting  
19 and why?

20 Dr. Frederickson. I think that what happened here is  
21 there may have been some general language that could imply the  
22 remedies that he might seek to bring action. I would like to  
23 answer that question for the record, however, after studying  
24 its appearance here and in what places.

25 Mr. Maguire. You cannot tell the committee right at this

1 moment which of those two you intend? If you cannot, submit  
2 it for the record, but I think --

3 Dr. Frederickson. I am advised by my counsel that we  
4 intended to sue in court but I should like to reserve for a  
5 clarification.

6 Mr. Maguire. If that is the case, I should also like to  
7 ask you to review that point and see if you might want to take  
8 another position on it. Thank you, Mr. Chairman.

9 Mr. Rogers. Mr. Ottinger?

10 Mr. Ottinger. Thank you, Mr. Chairman. I think this is  
11 one of the most concerning issues that we have had raised con-  
12 cerning our obligations to public health and safety in the  
13 Congress, perhaps ever since we had to deal with the splitting  
14 of the atom.

15 I wonder what makes you so confident that the risks that  
16 have been outlined for us by some very responsible and well  
17 qualified scientists in the course of this hearing are not  
18 going to actually happen?

19 Why is there any great rush to promote this research in  
20 view of the tremendous risk that seem to be attendant. I am  
21 seriously contemplating legislation which would call for a  
22 moratorium and get the international scientific community to-  
23 gether and see if we cannot come to better consensus on this  
24 before we expose society to this kind of risk.

25 In view of the experiences such as were had at Ft. Detrich,

1 as has been described to us as happened at other research  
2 laboratories, and in view of the dangers and the cost to society  
3 that have been caused by our rushing headlong into other  
4 scientific developments throughout the country, I wonder if we  
5 would be much wiser to say well, let us stop, let us take a  
6 look both at the dangers involved in this research and in the  
7 degree of controls and let us have those controls if we are  
8 to go ahead with this in place before we have to encounter a  
9 catastrophe of the kind that is predicted, is at least possible  
10 through recombinant DNA research.

11 Dr. Frederickson. My view of the problem, and of the  
12 current state of regulation and of the activities of the govern-  
13 ment and public sector, my views are derived from an extra-  
14 ordinary exposure and experience in the last three years or  
15 the last two years, derived from my position as Director of  
16 NIH and responsible for listening to all of the scientific and  
17 public testimony, to which I have been exposed and an attempt  
18 to determine from listening to all of the arguments that I  
19 can, whether I think this work ought to proceed.

20 I have come to the conclusion that this set of guidelines  
21 and the actions taken are very conservative indeed. I have  
22 not been exposed to any argumentation outside the arguments  
23 that were posed in the course of the development of the guide-  
24 lines at Asilomar and at my own scientific advisory committee  
25 which have represented any increment of scientific information

1 that indicated these guidelines might not be as conservative  
2 and as prudent as possible.

3 Mr. Ottinger. Have you followed our hearings or have you  
4 had somebody follow our hearings?

5 Dr. Frederickson. Yes, I have.

6 Mr. Ottinger. Because we have had a whole parade of  
7 scientific and some public witnesses who have said, including  
8 an imminent scientist at MIT, that is working in this kind of  
9 biological research, as a matter of fact, two of them; it was  
10 said they should not go forward at all.

11 Dr. Frederickson. Yes. I have been briefed on the hear-  
12 ing testimony here. It represents attitudes and opinions from  
13 a variety of people that I have heard from extensively over  
14 this entire period of review.

15 Mr. Ottinger. You told me just then that you had heard  
16 nobody that has said that the guidelines that were adopted  
17 were not adequate.

18 Dr. Frederickson. No, that is not what I said, sir. What  
19 I said was that I heard many opinions, concerns and anxieties  
20 that they were not adequate but I have not heard, in the course  
21 of this, substantial scientific arguments that allowed one to  
22 conclude that was a correct view or that they altered my  
23 opinions about the guidelines, once revised.

24 These guidelines, when I received them, had been extensive-  
25 ly revised and strengthened since the time they were handed to

1 me by the Recombinant DNA Committee. In the course of that, I  
2 benefitted greatly by reading testimony and talking personally,  
3 listening to the statements of a variety of people, many of  
4 whom had legitimate concerns.

5 I sent these back to the committee and I came to a final  
6 decision on each element, each criticism, each point of sub-  
7 stantive nature that was raised about those guidelines so I  
8 have attempted to examine them at great length.

9 Mr. Ottinger. Give us some odds as roughly as you can,  
10 because I guess that really is the calculation that we have  
11 to make, what are the odds on their being developed, some strain  
12 that would be damaging to either human beings or the plant life  
13 on which human beings depend?

14 Dr. Frederickson. I cannot give you accurate odds; I  
15 can only give you some yes' and some explanation which is  
16 spelled out further in the environmental impact statement  
17 which we have developed.

18 My own opinion is that the odds are very small indeed.

19 Mr. Ottinger. What range are we talking about; are we  
20 talking about one in 1,000, one in 100,000, one in 1,000,000,  
21 one in 10,000,000?

22 Dr. Frederickson. I would have to say, giving you my  
23 own personal opinion, derived from the sources I have described  
24 to you that they might be one in 1,000,000.

25 Mr. Ottinger. What kind of odds do you put on their being

1 major, beneficial breakthroughs derived from this experimen-  
2 tation?

3 Dr. Frederickson. Again, that is a qualified statement as  
4 to what is major or beneficial but the odds are already one to  
5 one or one because the use of these techniques in the development  
6 of pure gene material to a degree of purity that cannot be  
7 achieved by any other known technique has already been exploit-  
8 ed and used.

9 Mr. Ottinger. The kinds of things we have been hearing as  
10 possibilities on the beneficial side range from I suppose the  
11 most spectacular, the possibility of cancer cure, to the possi-  
12 bility of using this technology to clean up oil spills, cure  
13 diabetes.

14 In terms of the actual applied benefits that could be  
15 achieved, are those speculative benefits or are those things  
16 that you can see as likely to happen within the next three,  
17 five, ten years?

18 Dr. Frederickson. I think a number of the benefits  
19 that have been mentioned for the use of these techniques are  
20 also highly speculative, although I think it is extremely  
21 likely, the probability is very high they will allow us to  
22 advance knowledge of the nature of genes but much more, par-  
23 ticularly their control, the control of their expression in  
24 organisms and that fundamental knowledge will prove someday to  
25 be extremely valuable.



1 I think it has a potential for developing eventually some  
2 knowledge which will be practical and perhaps very useful.

3 Mr. Ottinger. On what do you base your one in a million  
4 guess on the risk side? Is it on the kind of logic given to us  
5 by Dr. Davis from Harvard of an extremely small likelihood that  
6 the recombinant can survive in the environment in view of the  
7 basic genetic nature of survival of the fittest?

8 Is it that you think these guidelines are so strong that  
9 nothing is going to get out?

10 Dr. Frederickson. Certainly all of us realize that the  
11 strongest guidelines in the world can be -- if human error  
12 occurs. I would base that opinion on several points.

13 One, actually these guidelines are very stringent, too  
14 restrictive in the view of many scientists. They clearly are  
15 retarding the utilization of these techniques and I think that  
16 is the appropriate intent at the present time.

17 Not only do they retard the use of the techniques in  
18 certain ways, but they actually prohibit a number of experiments.  
19 Those experiments, as best one can judge, might be the most  
20 potentially harmful derivatives of this kind of activity.

21 Furthermore, the containment that is used to scale down,  
22 based on rationale which is developed in the guidelines in such  
23 ways that all and all the guidelines do provide through their  
24 attempts to contain all of these molecules in satisfactory,  
25 either physically or by so-called biological containment, that

1 they must reduce tremendously the risk of an organism that is a  
2 recombinant product actually getting out and into the environ-  
3 ment in the first instance and surviving, should it escape in  
4 the second instance.

5 Mr. Ottinger. I do not quiet understand. I would like  
6 to get a little clearer in my own mind. Are you saying that  
7 the risk is in fact great, but the guidelines will prevent it  
8 getting out into the environment or are you saying that the  
9 risk itself is not great and the risk not being great, combined  
10 with the guidelines give --

11 Dr. Frederickson. My personal belief is that the risk is  
12 not very great but that I do not know that for sure, and to  
13 allow the possibility that I and others are wrong, I think the  
14 guidelines are, in a sense, an overkill and I think a deliberate  
15 and appropriate overkill in this situation.

16 Mr. Ottinger. Let me ask a specific question; I know we  
17 do have time constraints. Under the legislation which Senator  
18 Bumpers and I put through, you have indicated that you were  
19 against licensure, I take it.

20 I have not seen the interagency agreement. Where do you  
21 come out with respect to the patent and liability provisions  
22 of our legislation?

23 Dr. Frederickson. You will note that in the report of  
24 the committee, which is on page 13,--

25 Mr. Ottinger. I only have your testimony before me, sir.

1 Dr. Frederickson. I am sorry, this is the report of the  
2 Interagency Committee, page 18, Mr. Ottinger.

3 Mr. Ottinger. I have a copy before me now, where you refer  
4 to disclosure of information on page pages 14 and 18, basically  
5 the line of thought of the committee ran like this. It feels  
6 that there is potential commercial use of recombinant DNA  
7 techniques and it felt that appropriate measures should be  
8 taken to protect the nature of proprietary information but it  
9 was very clear in making, in attempting to indicate that it  
10 felt that the public safety must eventually override, of  
11 course, the protection of any proprietary information that  
12 it describes in certain language. It would hope that this  
13 could come about.

14 Do you provide for disclosure to some select group of  
15 people, everything which is of a proprietary nature?

16 Dr. Frederickson. We think that all relevant to safety  
17 and scientific information must be provided to the regulatory  
18 group.

19 Mr. Ottinger. But not to the public at large?

20 Dr. Frederickson. No, except under certain provisions,  
21 if there is an overriding need for the public to know on an  
22 issue of safety, then the committee clearly has its own record  
23 as indicating the Secretary must indicate that and discuss it,  
24 how he might take such steps in informing the submitter and  
25 giving the submitter some administrative or judicial right to

1 contest that.

2 Mr. Ottinger. Do you reserve to yourselves the decision  
3 as to what is proprietary?

4 Dr. Frederickson. No, not in the sense that the Secretary  
5 can first make a determination that he may want to reveal some-  
6 thing which the submitter thinks is proprietary but I think  
7 ultimately we recognize that this might have to be settled in  
8 the courts.

9 Mr. Ottinger. Where do you come out on liability? We  
10 call for absolute liability without fault on the theory that  
11 if there was that kind of liability, then there would be much  
12 greater care exercised by private groups engaged in this re-  
13 search.

14 Dr. Frederickson. On page 20, Mr. Ottinger, the committee  
15 discusses its views and it considers -- it is unlike the  
16 question of civil liability. The committee believed that  
17 actions or damages should be left to state and local law.

18 It was concerned that the inclusions of standards for  
19 strict liability as proposed in the measure submitted by  
20 Senator Bumpers and yourself could place a very severe con-  
21 straint on the ability of institutions to obtain liability  
22 insurance.

23 It felt, after lengthy discussion with a number of in-  
24 stitutions, that it was very possible they might have to ter-  
25minate all of their research activities unless some national

1 legislation were passed to indemnify them against this possi-  
2 bility.

3 Mr. Ottinger. One last question which you may submit for  
4 the record. I would like to know what efforts -- you can answer  
5 this -- are there any efforts at the present time by the United  
6 States as to trying to get international agreement; are there  
7 negotiations going on for an international agreement to adopt  
8 guidelines similar to those which you have put forward?

9 Dr. Frederickson. Yes, there are informal activities at  
10 the level of scientific organizations and the federal govern-  
11 ment in this direction. The committee knows in its future  
12 agenda that it will deal with the State Department to see if we  
13 can more formally begin, through State Departments, WHO and  
14 the International Scientific Council.

15 Mr. Ottinger. I hope you will do that urgently and in a  
16 formal manner because it is going to do us little good to put  
17 restrictions on this ourselves if there are not restrictions on  
18 the knowledge elsewhere in the world.

19 I must say that I have grave concerns, that the degree of  
20 protection provided here may not be great enough. Thank you,  
21 Mr. Chairman.

22 Mr. Rogers. Thank you, Mr. Ottinger. Yes, Dr. Carter?

23 Dr. Carter. I have one question.

24 Mr. Rogers. All right.

25 Dr. Carter. Are you acquainted with Dr. \_\_\_\_\_ at the

1 Cancer Institute in Philadelphia?

2 Dr. Frederickson. I do not believe I am, Dr. Carter.

3 Dr. Carter. Did you know that actually she has developed  
4 a mouse which has four parents? She has been able to take an  
5 embryo, two embryos, place them together, dissolves the ecto-  
6 derma, outer covering and plant some in the uterus of another  
7 mouse, female mouse, and she has produced mice by this method?

8 Dr. Frederickson. I am not familiar with --

9 Dr. Carter. I was just reading an article about the lady.  
10 I think I have a copy or a picture of the mice here. This is  
11 not fiction; it has actually happened. Thank you.

12 Mr. Rogers. We appreciate your being here. We will be in  
13 touch with you. I think it will be helpful and I presume we  
14 can expect the proposed legislation to be presented to this  
15 committee in what period of time?

16 Dr. Frederickson. The Secretary hopes that it can be  
17 prepared and past review by the OMB within 30 days.

18 Mr. Rogers. I hope that is fast enough. We may have to  
19 move more rapidly.

20 Dr. Frederickson. I know that.

21 Mr. Rogers. We will be in touch with him too but you  
22 might encourage him to try to let us have a rough draft, maybe  
23 even before OMB.

24 Dr. Frederickson. I am sure he would accede to your  
25 request.