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

THURSDAY, MARCH 17, 1977

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:)

Dr. Fredrickson. I would like to give an abbreviated version of the statement which you have suggested be incorporated in the record.

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

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

We are pleased to appear before you today to discuss particularly Federal policies concerning Recombinant DNA Research. I would like to specifically tell you about the research activities of two organizations -- those of the National Institutes of Health and those of the Federal Interagency Committee.

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

These techniques certainly offer promise for better understanding and improved treatment of human diseases but there may be risks in this new research area as well as anticipated benefits.

Until the potential risks are better delineated and evaluated in light of developing scientific knowledge, the public should expect such research to be conducted under strict conditions, insuring safety.

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

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

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

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

At the conference held in Asilomar in February 1975, temporary guidelines were issued calling for a moratorium on some experiments but allowing others to proceed with appropriate

biological and physical safeguards, pending issuance of NIH guidelines.

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

In December 1975, the Committee, after several open meetings, and half a dozen working drafts, recommended proposed guidelines to the NIH director for his review and decision.

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

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

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

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

The NIH Guidelines established strict conditions for the conduct of this research, prohibiting certain types of experiments and requiring special safety conditions for other types. The provisions were designed to afford protection -- with a wide margin of safety -- to workers and the public and the environment.

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

Over 40,000 copies of the guidelines were widely distributed to foreign embassies, medical and scientific journals, NIH grantees and contractors, and major professional research societies, and to others who requested them.

To facilitate implementation of the Guidelines, the NIH, in June, established the Office of Recombinant DNA Activities; to administer and coordinate intramural and extramural activities at the NIH; to review the institutional biohazards committees and certification statements; and to monitor reports and information concerning accidents, containment, and safety research innovation.

In August, the NIH published a volume containing the

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

A second volume is planned for publication in late Spring documenting the correspondence that the NIH received on the guidelines, the Environmental Impact Statement, and the Departmental patent policy.

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

The NIH Guidelines were released prior to the completion of the assessment because they're release provided greater protection for the public and the environment than the Asilomar Guidelines which they replaced.

For example, in a number of instances, the NIH Guidelines require more stringent safety and containment measures, extension of the list of prohibited experiments, and a specific ban on the release of recombinant molecules into the environment.

A Draft Environmental Impact Statement was filed and published in the Federal Register on September 9, 1976, to afford additional public review and comment. The statement is currently being analyzed and comments received will be responded

to in the final Environmental Impact Snatement to be published in late March.

In June, shortly before the release of the Guidelines, Stanford University and the University of California asked NIH to review DHEW policies relating to the patenting of recombinant DNA research inventions developed under NIH grants or contracts.

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

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

For those institutions that have not entered into a patent agreement with the Department, determination of ownership is deferred until an invention has been made, at which time an institution may petition the Department for ownership of the invention.

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

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

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

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

The Committee is advisory to the Secretary of Health, Education and Welfare. It includes representatives of Federal Departments and Agencies that support and conduct recombinant DNA research, or may do so in the future, and representatives of Federal Departments and Agencies that have present or potential regulatory activity in this area.

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

Two meetings of the Committee were held in November 1976. The first of these, on November 4, was devoted to a review of the development of the NIH Guidelines. The Committee also reviewed activities in other countries on the development of

guidelines for this research.

I will reserve, since you may have questions, Mr. Chairman, a review of those activities abroad which I have reviewed first hand on a continuing basis, both in numerous countries, including Britain and Europe and here with conversations with scientists and administrators from those countries and from behind the Iron Curtain and Japan.

At the meeting, the Interagency Committee held in November 23, the Federal Research agencies discussed their activities and possible roles in the implementation of the NIH guidelines. All research agencies endorsed the Guidelines to govern recombinant DNA research.

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

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

All regulatory agencies were represented on the Subcommittee, assisted by attorneys from their offices of general counsel.

The Subcommittee was charged to determine whether existing legislative authority would permit the regulation of all recombinant DNA research in the United States, whether or not

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

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

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

The Subcommittee, in reaching this conclusion, reviewed the following laws that were deemed to warrant detailed consideration:

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

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

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

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

The Committee also noted the resolution introduced by Representative Ottinger on January 19, 1977, H. Res. 131, requesting DHEw to regulate recombinant DNA research under Section 361 of the PHS Act.

Hearings held by State and local governments, including State legislatures, were among State and local activities reviewed. Recommendations by the New York State Attorney General's Environmental Health Bureau for State regulation, and by the Cambridge, Massachusetts City Council for city regulation, were also considered.

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

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

The Pharmaceutical Manufacturers Association has adopted

the NIH Guidelines as standards for safe conduct of this research.

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

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

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

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

The Secretary added that the Department will begin immediately to draft legislation in the light of the recommendations made by the committee.

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

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

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

(COMMITTEE INSERT)

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

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

The committee also had before it the petition by the Environmental Defense Fund requesting the HEW to issue regulations for recombinant DNA research under 361 of the Public Health Service Act.

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

There was general committee agreement that present legislation should be restricted, not only to recombinant DNA techniques, allowing for sound administrative and scientific expertise in developing safety standards in other area.

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

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

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

Regulation of just the research aspects of recombinant techniques, DNA techniques, presents a problem because of the difficulty in determining the border between research and pilot plant production.

Therefore, the Interagency Committee has recommended that regulations covering the production or use of recombinant DNA molecules, such language would clearly include research activity, bit it makes immaterial possible concerns whether a given activity constitutes research, pilot production or manufacture.

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

There was general agreement by the committee that registration of projects and other activities involving the use or production of recombinant DNA molecules was necessary. The committee also recommends the license share of facilities and

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

The committee concluded that licensure of the facility and registration of products would meet the needs for safety monitoring without extension of licensure to the projects themselves.

The committee urges full disclosure to the appropriate regulatory body of all relevant safety and scientific information on the use and production of recombinant DNA molecules. However, the committee recognizes the important worldwide commercial potential of recombinant DNA molecules in medicine, agriculture and other areas, and in science and technology.

It believes that the potential commercial users of recombinant DNA techniques require that information of a proprietary nature and patent rights be given an appropriate protection from disclosure by the regulatory agency receiving such information.

Because the potential hazards posed by the use of recombinant DNA techniques extends beyond the local to the national and beyond that to international levels, the committee recommends that a single set of national standards must govern and accordingly state and local laws should be preempted to insure national standards and regulations.

The committee, however, took into account the activities

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

It was agreed that if the state passes a law imposing requirements identical to that in the Federal statute, then the Secretary may enter into an agreement with the state to utilize its resources to assist the Secretary in carrying out his duties.

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

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

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

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

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

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

The question being debated now is not that but how is this to be accomplished? Here in this Chamber today we begin to discuss how it should be accomplished within the United States? This is a matter by no means now confined to only our country but to almost all of the developed countries of the world, where parliment and parlimentary committees, committees established by states in both private and public manner have considered extensively whether this research should go on.

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

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

It is necessary to bear in mind, Mr. Chairman, the changes in DNA, the nucleic acid that is present in all living organisms and which determines their inheritative characteristics, also occurs spontaneously in nature.

They have made possible the never ending process of

evolution. Research on recumbant DNA holds great promise. It may become a powerful tool in advancing our knowledge, knowledge which conceivably can be used to further the conquest of disease.

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

NIH has responded to this concern by the requirement of formation of review boards to oversee human experimentation, animal care, and now the use of recumbant DNA techniques. Similar bodies may soon have to be established in many institutions to over see other hazardous laboratory work.

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

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

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

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your testimony you would not share that approach?

Dr. Frederickson. I do not share that approach, Mr. Chairman, for several reasons. I suppose one of them is a practical or pragmatic view that this research will clearly continue and in many places in the world.

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

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

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

If you could point out in one article for us, or one development, the difference between our proposed guidelines and

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

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

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

Dr. Frederickson. The Defense Department representatives on the Interagency Committee expressed to the committee a concern that it might be necessary to impose some moratorium on exchange of information, or to exempt from the guidelines certain aspects because of national security considerations.

I should then tell you, Mr. Chairman, that the committee decided that it did not have the mandate or authority to determine those questions and did not take action on it.

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

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

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

Dr. Frederickson. No.

Mr. Rogers. Did it participate?

Dr. Frederickson. It did not participate.

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

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

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

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

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

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

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

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

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

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

Mr. Rogers. Thank you. Dr. Carter?

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

Dr. Frederickson. Well, by cell fusion, Dr. Carter; I can supply to you for the records some answers to these questions but I cannot answer them with any expertise this afternoon.

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

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

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

Dr. Carter. Yes, sir.

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

Dr. Carter. In this method?

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

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

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

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

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

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

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

Dr. Frederickson. By definition, they are.

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

Dr. Frederickson. I am not certain about pseudomonis.

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

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

Dr. Carter. I believe we have it. What about animal implantation of recombinant genes in animals, how far has that gone, Doctor?

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

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

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

Dr. Carter. Are you sure of that?

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

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

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

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

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

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

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

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

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

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

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

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

Dr. Frederickson. That is very true.

Dr. Carter. It is a long process but by process of elimination, we could determine which gene has certain effects?

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

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

Dr. Frederickson. Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

experiments should be done in each one of these?

Dr. Frederickson. We will get the guidelines out. We can briefly summarize it for you, if you like, but it will not take us long to provide the material for the record. It is a portion of the guidelines.

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

Dr. Frederickson. No, I donot.

Dr. Carter. Thank you, sir.

Mr, Rogers. Mr. Ottinger?

Mr. Ottinger. No.

Mr. Rogers. Mr. Waxman?

Mr. Waxman. Dr. Frederickson, I was interested, in glancing at your testimony regarding other countries that are involved in recombinant DNA research. You mentioned a number of western countries that were following the guidelines set up by the United Kingdom.

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

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

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

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

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

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

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

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

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

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

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

There they are sharing their views on what decisions they are making, what projects they have reviewed and other common problems relative to conforming to a common set of standards.

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

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

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

Mr. Waxman. You mentioned that the interagency level or the NIH guidelines were adopted and the CIA was not involved?

Dr. Frederickson. It was not, sir.

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

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

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

Dr. Frederickson. Yes.

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

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

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

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

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

Mr. Ottinger. Will the gentleman yield?

Mr. Waxman. Will be pleased to.

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

which make grants for such research or contracts for such research?

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

Mr. Ottinger. Thank you.

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

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

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

Dr. Frederickson. No, I do not.

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

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

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

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

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

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

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

Dr. Carter. I yield.

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

Mr. Rogers. Mr. Maguire?

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

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

What was the rationale for not broadening it?

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

For purposes of making that analysis, we have established at NIH a committee on other aspects of genetic recombination and laboratory safety which has had several meetings. It now has three subcommittees, one on cell fusion, another on mutogenesis and another on recombination experiments other than

recombinant DNA techniques as defined by the NIH guidelines.

This committee is examining and attempting to develop recommendations to the NIH with respect to possible need for other guidelines to govern this type of research.

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

Dr. Frederickson. Yes, I do.

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

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

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

However, it recognized that there are already at least

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Dr. Frederickson. Yes.

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

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

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

Indeed, these are not single experiments which have a long time scale necessarily. The matter of using recombinant DNA techniques is comparable in many ways outside of its uncertainties with regard to hazard and benefit, to the use of an extraordinary number of techniques that are used in experimentation.

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

guidelines that have been referred to today.

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

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

Mr. Maguire. I would like to ask some additional questions rather than submit them for the record because I think they are important for this discussion, Mr. Chairman.

Mr. Rogers. I want everyone to but we do have nine additional witnesses to finish this afternoon, if possible.

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

Mr.Rogers. Sure.

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

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

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

Dr. Frederickson. We think we should.

Mr. Maguire. That was not clear.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Mr. Rogers. Mr. Ottinger?

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

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

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

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

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

Dr. Frederickson. My view of the problem, and of the current state of regulation and of the activities of the government and public sector, my views are derived from an extraordinary exposure and experience in the last three years or the last two years, derived from my position as Director of NIH and responsible for listening to all of the scientific and public testimony, to which I have been exposed and an attempt to determine from listening to all of the arguments that I can, whether I think this work ought to proceed.

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

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

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

Dr. Frederickson. Yes, I have.

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

Dr. Frederickson. Yes. I have been briefed on the hearing testimony here. It represents attitudes and opinions from a variety of people that I have heard from extensively over this entire period of review.

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

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

These guidelines, when I received them, had been extensively revised and strengthened since the time they were handed to

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

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

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

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

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

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

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

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

major, beneficial breakthroughs derived from this experimentation?

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

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

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

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

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

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

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

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

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

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

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

they must reduce tremendously the risk of an organism that is a recombinant product actually getting out and into the environment in the first instance and surviving, should it escape in the second instance.

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

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

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

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

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

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

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

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

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

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

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

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

contest that.

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

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

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

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

It was concerned that the inclusions of standards for strict liability as proposed in the measure submitted by Senator Bumpers and yourself could place a very severe constraint on the ability of institutions to obtain liability insurance.

It felt, after lengthy discussion with a number of institutions, that it was very possible they might have to terminate all of their research activities unless some national

legislation were passed to indemnify them against this possibility.

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

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

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

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

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

Dr. Carter. I have one question.

Mr. Rogers. All right.

Dr. Carter. Are you acquainted with Dr. _____at the

Cancer Institute in Philadelphia?

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

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

Dr. Frederickson. I am not familiar with --

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

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

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

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

Dr. Frederickson. I know that.

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

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