DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

OFFICE OF THE SECRETARY

WASHINGTON, D.C. 20201

OFFICE OF THE
GENERAL COUNSEL

To: Holders of HEW Institutional Patent Agreements and Members of the Society of University Patent Administrators

Subject: Information Item No. 51

I am attaching herewith a copy of the proposed administration bill on regulation of recombinant DNA research. The proposed Senate bill is precedent setting in that it requires registration of research projects prior to their commencement, whether publicly or privately funded. This was deemed necessary in order to attempt to ascertain future risks in performance of recombinant DNA research. Presuming the necessity for such registration for the purpose of assuring public safety, a number of other issues emerge which your institution may wish to address. One is discussed in the Washington Post article attached.

From the point of view of patent administrators, the 6th question raised by Senator Kennedy in introducing the bill seems most important;

> "What information should be required to be submitted to the Government, and what information should be disclosed to the public?"

The way the proposed bill is now drafted, no special provision is provided on the handling of information disclosed to the Government. In essence, this means that information in the hands of the Government will be governed by the Freedom of Information and the Federal Advisory Committee Acts. It seems conclusive that advisory committees will be involved in assessing the information provided to the Government under the proposed legislation. Accordingly, questions posed by Congress to the President's Biomedical Research Panel and the National Commission on Human Subjects on the adequacy of the Freedom of Information and Federal Advisory Committee Acts in protecting proprietary information are again raised by this proposed legislation. As you may know, both the above groups concluded that the 4th Exemption of these Acts provides unpredictable protection for submitters of scientific information to the Government, and both groups have recommended a legislative change to the Public Health Service Act requiring closed peer review and increased protection of proprietary information in the hands of the Government. The proposed legislation's silence on this matter, accordingly, may be considered a rejection of these recommendations.

It would appear that the question of protecting information in the hands of the Government in this legislation is even more serious than the question as addressed by the Panel and Commission, since all research plans in this area will be affected even though no Federal funding is involved.

I understand that a subcommittee of the Committee on Science and Technology chaired by Congressman Thornton of Arkansas will continue hearings on recombinant DNA on April 27 and 28. However, due to the presumed urgency for legislation in this area, it appears now that the first time that your institution may be able to speak to the issues involved is when a bill equivalent to the Senate bill arises on the floor of the House of Representatives.

Sincerely yours,

N. J. Latker

Norman J. Latker
Patent Counsel

Enclosures

or adoptive home so licensed or designated may accept Indian child placements by a non-tribal government agency and State funds in support of Indian children, and shall have a preference in child placements in accordance with subsection 103(b) of the Act.

Section 203 describes some of the major features which may be included in off-reservation Indian family development programs.

Section 204 directs the Secretary of the Interior to undertake a study of past child placements and, if he has good cause to believe on the basis of this investigation that the placement may be invalid or legally defective, and if the child's family so requests, to institute appropriate legal proceedings challenging the placement. The Secretary is further directed to operate, or to make grants or contracts with Indian tribes or Indian organizations to operate, an Indian family defense program which shall provide representation by an attorney for every Indian child, or its parents, who is the subject of a child placement proceeding.

Section 205 establishes procedures for promulgating rules and regulations necessary to carry out the Act.

By Mr. KENNEDY:

S. 1217. A bill to regulate activities involving recombinant deoxyribonucleic acid; to the Committee on Hum. Resources.

Mr. KENNEDY. Mr. President, today I am pleased to introduce the administration's legislation regarding the urgent necessity to regulate and control recombinant DNA research. This legislation grows out of the recommendation of a broadly based interagency committee, which was chaired by the Director of the National Institutes of Health, Donald Frederickson. The need for such legislation is aslo recognized by the scientific community both here and abroad.

Mr. President, as chairman of the Senate Subcommittee on Health and Scientific Research, I have scheduled hearings on this and related legislation next Wednesday, April 6, 1977. These hearings are specifically designed to elucidate the relevant issues regarding this kind of genetic research so that it will be possible to promptly report a comprehensive bill from the committee to the Senate.

Recombinant DNA research has captured the attention and raised the anxiety of the Nation more than any other area of biomedical research in history. The potential to purposefully transform the nature of living organisms, for good or ill, is both an exhilarating and frightening prospect. The concern is not over current benefits or current risks—but over uncertain future benefits and uncertain future risks.

The questions of potential benefits and hazards of this research extend beyond the walls of the laboratory and the realm of freedom of scientific inquiry. These questions involve every citizen, scientist and layman alike. The assessment of risk and the judgment of how to balance risk against benefit of recombinant DNA research are responsibilities that clearly rest in the public domain. And it follows that these issues must be decided through public processes. The vigorous discussion and debate amongst both the scientific community and the general public over this issue is very beneficial to the policymaking process. However, as the dialog unfolds throughout the Nation, I believe that there is a growing concensus throughout the country that regulatory legislation is necessary.

The legislation that I am introducing today presents the administration's views on regulating recombinant DNA research. I believe that the approach taken by the administration leaves several unresolved issues. First, I think that there is need for an alternative definition of recombinant DNA research to that given in the administration's proposal. I suggest that we define recombinant DNA research as any research, study, investigation, experiment, or act in which molecules or segments of molecules of deoxyriboneculeic acid—DNA—that are not known to be otherwise capable of being propagated in a particular species of living cell are rendered capable of propagation in that species by joining them by any method outside of living cells to another DNA molecule or segment of DNA molecules. I would like the witnesses at the hearing to comment on this definition.

Second, I strongly feel that the public has a right to participate in the decisions concerning this area of research. I would like the witnesses at the hearing to consider whether a commission within the Department of Health, Education and Welfare, should be established and be composed of a majority of individuals who are not involved in biomedical research.

Third, I have concern about the scope and nature of the standards to be promugated under the administration's bill. Why should the thrust of the standards be limited to the production or possession of recombinant DNA? Why not include recombinant DNA research and include standards for the responsibilities and qualifications of those who both own research facilities and those who actually do the research.

In this regard, I take exception with the apparent limitation under the administration's approach. Should not the failure to comply with the standards be a ground for revoking a license. Is it not the main purpose of licensure to assure that the standards are met?

I believe that there must be a legislative standard under which the decision to grant a license is made. Therefore, I would like those who will be before my subcommittee next week to consider if a license should only be granted when the Government is satisfied that the research to be authorized by a license will be conducted in a manner as to assure the health and welfare of the persons to engage in the research, the environment, and the population of the surrounding community.

Finally, I would like to raise the following questions for consideration at the hearing:

First. Should there not be a comprehensive, thoughtful study which will consider and evaluate the ethical, societal, and legal implications of recombinant DNA research. I think that a group such as a subcommitee of the Naitonal Commission for the Protection of Human Subjects could be formed with the charge to study these long-range implications and make periodic reports to the Nation.

Second. Does the public not have a right to know who is conducting this type of research, where it is being conducted, and under what conditions?

Third. How much funding will this entire effort require and how many positions?

Fourth. Should there be a limit on how many facilities are to exist at the highest level of physical containment?

Fifth. Why should this research be exempt from environmental impact requirements?

Sixth. What information should be required to be submitted to the Government and what information should be disclosed to the public?

These are some of the concerns I have and I encourage the witnesses at the hearing next Tuesday to comment on the administration's proposal, the issues I have raised and to express their own concerns.

I ask unanimous consent that the bill be printed at this point in the RECORD.

There being no objection, the bill was ordered to be printed in the RECORD, as follows:

S. 1217

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Recombinant DNA Regulation Act".

FINDINGS

SEC. 2. The Congress finds that—

(1) work with recombinant DNA will improve the understanding of basic biological processes and offers many potential benefits,

(2) there exists, however, a possible risk that microorganisms containing recombinant DNA may cause disease or alter the environment,

(3) microorganisms containing recombinant DNA could spread throughout the United States and to other countries, adversely affecting human health, the environment, industry, and agriculture.

(4) the only effective way to minimize the risk to health, the environment, industry, and agriculture is by regulating activities involving recombinant DNA, whether or not those activities are in interstate commerce, and therefore,

(5) all activities involving recombinant DNA either affect or are in interstate commerce.

GENERAL REQUIREMENTS

SEC. 3. (a) Except as provided in subsection (b), no person may possess or engage in the production of recombinant DNA unless—

(1) the production or possession complies with the standards promulgated under section 4,

(2) the production or possession occurs in a facility licensed under section 5, or the possession occurs while transporting recombinant DNA from one such facility to another and

(3) the production or possession occurs as part of a project that has been registered under section 6.

(b) The Secretary may exempt from some or all of the requirements of subsection (a) any category of activities he finds poses no significant risk to health or the environment (1) because of the nature of those activi-

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(A)

ties, or (2) because the category is adequately regulated under other Federal law.

STANDARDS

SEC. 4. (a) For purposes of protecting the health and safety of individuals who work with recombinant DNA, the health and safety of the public at large, and the integrity of the environment, the Secretary—

(1) shall, no later than 90 days after the enactment of this Act, promulgate (without regard to section 102(2)(C) of the National Environmental Policy Act of 1969 or 5 U.S.C. 553) as interim standards applying to the production or possession of recombinant DNA the Recombinant DNA Research Guidelines (41 Fed. Reg. 27901 (1976)), with such modifications as he finds are needed,

(2) shall, no later than 180 days after the promulgation of interim standards under clause (1), initiate procedures to promulgate final standards applying to the production or possession of recombinant DNA,

(3) shall, no later than one year after the promulgation of interim standards under clause (1), promulgate final standards applying to the production or possession of recombinant DNA, and

(4) may, from time to time, promulgate (A) new standards applying to the production or possession of recombinant DNA, and (B) amendments to standards promulgated under this section.

(b)(1) Any person adversely affected by an action of the Secretary under this section may obtain review of the action in the United States Court of Appeals for the District of Columbia. The petition for review must be filed within sixty days of the action. Review shall conform to chapter 7 of title 5 of the United States Code.

(2) An action with respect to which review could have been obtained under paragraph (1) shall not be subject to judicial review in any other proceeding.

LICENSING OF FACILITIES

SEC. 5. (a) The Secretary may issue or renew a license for a facility to permit the production or possession (or certain categories of production or possession) of recombinant DNA at that facility only if (1) the facility submits an application therefor containing or accompanied by such information concerning recombinant DNA activities at that facility as the Secretary may prescribe, (2) the facility agrees and the Secretary determines that such production or possession (including the transportation of recombinant DNA to or from that facility) will comply with the standards promulgated under section 4 and such ancillary conditions as he may prescribe, and (3) the facility agrees and the Secretary determines that such production or possession will occur only as part of a project registered under section 6.

(b) The Secretary may require payment of a fee from a facility for the issuance or renewal of a license under this section to cover all or part of the costs of administering this Act in respect to that facility.

(c) A license issued or renewed by the Secretary under this section is valid for the period prescribed by the Secretary, not to exceed three years.

(d) The Secretary may permit an appropriate State or local agency or a licensing or accrediting body to issue and renew licenses for facilities to permit the production or possession (or certain categories of production or possession) of recombinant DNA at those facilities if and for so long as the Secretary determines that the agency or body—

(1) requires a facility to comply with the standards promulgated under section 4 and such ancillary conditions as the Secretary may prescribe,

(2) requires a facility to permit the production or possession of recombinant DNA only as part of a project registered under section 6, and

(3) has the capacity to and does make provision for assuring that the requirements of clauses (1) and (2) continue to be met.

(e) The Secretary may revoke, suspend, or limit a license issued under this section if he finds, after notice and opportunity for a hearing to the facility, that the facility—

(1) has misrepresented any material fact in obtaining the license,

(2) has engaged or attempted to engage or represented itself as entitled to perform any activities involving recombinant DNA not authorized by its license,

(3) has failed to comply with any of the terms or conditions of the license,

(4) has failed to comply with a request of the Secretary for any information or materials the Secretary finds necessary to determine the facility's continued eligibility for its license or to evaluate the possible effects on health or the environment of activities involving recombinant DNA,

(5) has failed to comply with a request of the Secretary to inspect any portion of the facility, its operations, or its records, which are related to activities involving recombinant DNA, or

(6) has violated or aided and abetted in the violation of any requirement established under this Act.

REGISTRATION

SEC. 6. The Secretary shall register any project involving recombinant DNA if the request for registration is accompanied by such information as the Secretary may prescribe concerning recombinant DNA activities which are part of that project.

INSPECTIONS

SEC. 7. An individual designated as an inspector by the Secretary, upon presenting appropriate credentials to the owner, operator, or agent (if any of these be present) in charge of a facility at which the inspector has reasonable grounds to believe that recombinant DNA is present or is being produced may enter that facility at reasonable times, and inspect, at reasonable times and in a reasonable manner, the facility and all things at (or being transported to or from) that facility which he has reasonable grounds to believe are involved with recombinant DNA and obtain appropriate samples of such things. When an inspector has completed such an inspection he shall, before he leaves the facility, inform the owner, operator, or agent in charge of the facility of any conditions or practices which in the inspector's judgment constitute a violation of any of the requirements of this Act. The inspector shall also prepare a written report of his findings and send it to the owner, operator, or agent in charge of the facility within a reasonable time.

RECORDS AND SAMPLES

SEC. 8. Each facility at which recombinant DNA is produced or located shall keep and make available to the Secretary such records (including medical records of personnel) and samples involving recombinant DNA at (or being transported to or from) that facility as the Secretary may prescribe.

REPORTS

SEC. 9. Each facility at which recombinant DNA is produced or located shall submit to the Secretary such reports concerning recombinant DNA at (or being transported to or from) that facility as the Secretary may prescribe.

EFFECT ON STATE AND LOCAL REQUIREMENTS

SEC. 10. (a) Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to recombinant DNA activities any requirement which is different from, or in addition to, any requirement applicable under this Act to such activities.

(b) Upon application of a State or political subdivision of a State, the Secretary shall exempt from subsection (a) a requirement of that State or political subdivision applicable to recombinant DNA activities if he determines that the requirement is, and will be administered so as to be, as stringent as, or more stringent than, a requirement under this Act. The Secretary may not withdraw any such exemption for so long as he finds that such requirement remains unchanged and continues to be so administered.

EMPLOYEE PROTECTION

SEC. 11. (a) No employer may discharge any employee or otherwise discriminate against any employee with respect to the employee's compensation, terms, conditions, or privileges of employment because the employee (or any person acting pursuant to a request of the employee) has—

(1) commenced, caused to be commenced, or is about to commence or cause to be commenced a proceeding under this Act,

(2) testified or is about to testify in any such proceeding, or

(3) assisted or participated or is about to assist or participate in any manner in such a proceeding or in any other action to carry out the purposes of this Act.

(b)(1) Any employee who believes that the employee has been discharged or otherwise discriminated against by any person in violation of subsection (a) of this section may, within 30 days after such alleged violation occurs, file (or have any person file on the employee's behalf) a complaint with the Secretary of Labor (hereinafter in this section referred to as the "Secretary") alleging such discharge or discrimination. Upon receipt of such a complaint, the Secretary shall notify the person named in the complaint of the filing of the complaint.

(2)(A) Upon receipt of a complaint filed under paragraph (1), the Secretary shall conduct an investigation of the violation alleged in the complaint. Within 30 days of the receipt of such complaint, the Secretary shall complete such investigation and shall notify in writing the complainant (and any person acting on behalf of the complainant) and the person alleged to have committed such violation of the results of the investigation conducted pursuant to this paragraph. Within ninety days of the receipt of such complaint the Secretary shall, unless the proceeding on the complaint is terminated by the Secretary on the basis of a settlement entered into by the Secretary and the person alleged to have committed such violation, issue an order either providing the relief prescribed by subparagraph (B) or denying the complaint. An order of the Secretary shall be made on the record after notice and opportunity for agency hearing. The Secretary may not enter into a settlement terminating a proceeding on a complaint without the participation and consent of the complainant.

(B) If in response to a complaint filed under paragraph (1) the Secretary determines that a violation of subsection (a) of this section has occurred, the Secretary shall order (i) the person who committed such violation to take affirmative action to abate the violation, (ii) such person to reinstate the complainant to the complainant's former position together with the compensation (including back pay), terms, conditions, and privileges of the complainant's employment, (iii) compensatory damages, and (iv) where appropriate, exemplary damages. If such an

order is issued, the Secretary, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorney's fees) reasonably incurred, as determined by the Secretary, by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

(c)(1) Any employee or employer adversely affected or aggrieved by an order issued under subsection (b) may obtain review of the order in the United States Court of Appeals for the circuit in which the violation, with respect to which the order was issued, allegedly occurred. The petition for review must be filed within sixty days from the issuance of the Secretary's order. Review shall conform to chapter 7 of title 5 of the United States Code.

(2) An order of the Secretary, with respect to which review could have been obtained under paragraph (1), shall not be subject to judicial review in any criminal or other civil proceeding.

(d) Whenever a person has failed to comply with an order issued under subsection (b)(2), the Secretary shall file a civil action in the United States district court for the district in which the violation was found to occur to enforce such order. In actions brought under this subsection, the district courts shall have jurisdiction to grant all appropriate relief, including injunctive relief and compensatory and exemplary damages. Civil actions brought under this subsection shall be heard and decided expeditiously.

(e) Subsection (a) of this section shall not apply with respect to any employee who, acting without direction from the employee's employer (or any agent of the employer), deliberately causes a violation of any requirement of this Act.

CONSULTATION

SEC. 12. In administering this Act, the Secretary shall consult with the Secretaries of Agriculture, Commerce, Defense, Labor, and Transportation, the Administrators of the Environmental Protection Agency and Veterans' Affairs, the Director of the National Science Foundation, other appropriate officials, and such interagency committees and other advisory bodies as the Secretary may establish, concerning the promulgation of standards and of amendments to standards, the avoidance of duplicative requirements, and such other matters which may be of mutual interest.

ENFORCEMENT

SEC. 13. (a) Upon petition by the Secretary, the district courts of the United States may restrain violations of this Act.

(b)(1) Any person who violates a provision of this Act (other than in section 11) may be assessed a civil penalty by the Secretary of not more than $5,000 for each violation.

(2) No civil penalty shall be assessed unless the person charged shall have been given notice and opportunity for a hearing on such charge. In determining the amount of the penalty the Secretary shall consider the appropriateness of such penalty to the gravity of the violation.

(3) In case of inability to collect such civil penalty or failure of any person to pay all or such portion of such civil penalty as the Secretary may determine, the Secretary shall refer the matter to the Attorney General, who shall recover such amount by action in the district court of the United States for the district in which that person resides or has his principal place of business.

(c) Any person who knowingly or willfully violates any provision of this Act (other than in section 11) shall be subject, upon conviction, to a fine of not more than $5,000, or to imprisonment for not more than one year (and not more than ten years for a related series of violations), or both.

(d) Each day a violation of this Act continues shall constitute a separate violation for purposes of this section.

EMERGENCY PROCEDURE FOR HAZARDOUS RECOMBINANT DNA

SEC. 14. The Secretary may commence a civil action, by process of libel or otherwise, in an appropriate district court of the United States for the seizure or destruction of hazardous recombinant DNA or for other appropriate relief to prevent its production, movement, or spread.

ADMINISTRATIVE RESTRAINT OR SEIZURE

SEC. 15. If during an inspection under section 7 an inspector finds material he has reasonable grounds to believe is hazardous recombinant DNA, he may order the material not to be moved or may seize the material. Within twenty days after such action by an inspector the Secretary must commence a civil action under section 14 with respect to the inspector's action, unless the owner of the material has agreed otherwise.

TRAINING

SEC. 16. The Secretary may conduct and support training in the safe handling of recombinant DNA.

REPRESENTATION BY ATTORNEY GENERAL

SEC. 17. The Attorney General shall appear and represent the Secretary or the Secretary of Labor at any civil or criminal action initiated under this Act.

DEFINITIONS

SEC. 18. For purposes of this Act—

(1) "Secretary" (except as used in section 11) means the Secretary of Health, Education, and Welfare.

(2) "DNA" means deoxyribonucleic acid.

(3) "recombinant DNA" means DNA that consists of different segments of DNA which have been joined together in a cell-free system and that has the capacity to infect and replicate in some host cell either autonomously or as an integrated part of the host's genome.

(4) "hazardous recombinant DNA" means recombinant DNA which either—

(A) poses a significant risk to health or the environment, or

(B)(i)(I) is neither located at a facility licensed under section 5 nor being transported from one such facility to another, or

(II) is likely to be moved or to spread from such a facility or transportation to a location not at such a facility or part of such transportation, and

(ii) is not known not to pose a significant risk to health or the environment.

(5) "person" means any individual, partnership, corporation, association, or any Federal, State, or local governmental entity.

(6) "district court of the United States" includes the District Court of Guam, the District Court of the Virgin Islands, the highest court of American Samoa, and a similar or equivalent court in any other United States territory or possession or in the Trust Territory of the Pacific Islands, and

(7) in relation to transportation to or from a facility, a suitable facility in a foreign country shall be treated as a facility licensed under section 5.

GEOGRAPHIC APPLICABILITY OF ACT

SEC. 19. This Act applies to the United States, its territories and possessions, and the Trust Territory of the Pacific Islands.

RELATIONSHIP TO OTHER FEDERAL LAWS

SEC. 20. (a) This Act shall not affect the authority of any Federal agency to regulate under any other Act activities involving recombinant DNA.

(b) In exercising any authority under this Act, the Secretary, or any person acting on his behalf or pursuant to the provisions of this Act, shall not, for purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970, be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health.

(c)(1) Upon request by the Secretary, each Federal agency is authorized—

(A) to make its services, personnel, and facilities available (with or without reimbursement) to the Secretary to assist the Secretary in the administration of this Act, and

(B) to furnish to the Secretary such information, data, estimates, and statistics, and to allow the Secretary access to all information in its possession, as the Secretary may reasonably determine to be necessary for the administration of this Act.

(2) Upon request by any Federal agency, the Secretary is authorized—

(A) to make the services, personnel, and facilities of the Department of Health, Education, and Welfare available (with or without reimbursement) to that agency to assist the agency in the administration of any Act with respect to activities involving recombinant DNA, and

(B) to furnish to that agency such information, data, estimates, and statistics, and to allow that agency access to all information in the Secretary's possession, as the agency may reasonably determine to be necessary for the administration of any Act with respect to activities involving recombinant DNA.

SEPARABILITY

SEC. 21. If any provision of this Act is held invalid by reason of being inconsistent with the Constitution, all provisions of this Act which are separable from that invalid provision shall remain in effect.

EFFECTIVE DATE AND EXPIRATION DATE OF ACT

SEC. 22. (a)(1) This Act is effective upon enactment, except that sections 3(a), 10(a), and 18(4)(B) are effective 180 days after enactment.

(2) Upon promulgation of standards under section 4, no person may possess or engage in the production of recombinant DNA unless the production or possession complies with those standards.

(b) This Act shall expire five years after its enactment except with respect to records made within that period.

By Mr. BAYH:

S. 1218. A bill to amend the Juvenile and Delinquency Prevention Act of 1974, and for other purposes; to the Committee on the Judiciary.

CARTER ADMINISTRATION URGES EXTENSION OF 1974 JUVENILE JUSTICE AND DELINQUENCY PREVENTION ACT

Mr. BAYH. Mr. President, today I am pleased to introduce by request, President Carter's proposal to extend the Juvenile Justice and Delinquency Prevention Act of 1974 through fiscal year 1980. Like my own bill, S. 1021, introduced last month, the President's bill, which incidentally has been thoughtfully shepherded by Attorney General Bell, would provide the stability and revitalization so essential to the implementation of the 1974 Act which passed this body by a vote of 88 to 1 and the House of Representatives by a vote of 329–20.

I am proud that this bipartisan congressional initiative was strongly endorsed in my party's national platform in the following unequivocable manner:

A Democratic Congress in 1974 passed the Juvenile Justice and Delinquency Prevention Act to come to grips with the fact that

Wash. Post 4/12/77

How To Regulate Basic Research (B)

THE FEDERAL government is in the process of writing legislation to control research on DNA molecules—the material that determines the hereditary characteristics of all known cells. This is a particularly delicate undertaking, because Congress has no experience with regulating basic scientific research and because the kind of research under scrutiny has the potential not only of bringing great good to mankind but also of threatening it with untold harm. So we would like to underline the plea of Dr. Norton Zinder of Rockefeller University to the Senate Health Subcommittee last week that "this be done with extreme care and without haste."

With that in mind, it seems to us that the licensing proposal presented by Secretary of Health, Education and Welfare Califano is a useful starting point. Mr. Califano has followed the general outline proposed by an inter-agency committee which urged that federal safety standards be set for the laboratories in which this research is conducted. But he rejected the committee's key recommendation that the federal standards override state and local safety legislation in this field. This, it seems to us, is a serious mistake.

It is not good enough for the federal government to say, as Mr. Califano recommends, that it is setting *minimum* standards and letting states and local governments set higher ones, if they want to. The federal standards must be sufficiently high to provide adequate safety for all the country if anything should go wrong in the experimental process; the potential for harm is that great. But if federal standards are that high, there is no sound reason for local governments to drive them higher. When the federal government talks about minimum standards, it almost invites additional regulation by local governments.

There are, as we see it, several dangers in such an invitation. One is that some local governments would create unrealistic standards; the expertise available to the federal government in drafting regulations of this kind is not so readily available to state and local governments. Another is that local governments might erect standards so stringent that scientists could not meet them. Either possibility would drive this kind of research out of institutions located in certain communities and cause a reshuffling of scientists between institutions as they sought more congenial regulations. Indeed, it is conceivable that fear of DNA research could produce a series of local regulations that would drive this research out of the institutions best equipped to conduct it and force this work into less qualified institutions or, in the worst possible case, underground.

It seems quite remarkable that the federal government would consider giving local governments so much leeway in handling so delicate a subject when it has denied local option in such matters as regulating the amount of meat in a package of bacon. This is one area where Congress must exercise that "extreme care" of which Dr. Zinder spoke—extreme care that citizens not only are protected against the harm that DNA research might do but are also assured that this research can continue under the best possible conditions.

DNA Bill