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House of RepresentativesSubcommittee on Health and the Environment
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THE RECOMBINANT DNA ACTSummary and Discussion
by Burke ZimmermanBackground

This bill is a two year interim control measure to extend the appropriate safety requirements of the NIH Guidelines to all public and privately supported recombinant DNA activities. This proposal is based upon several informal discussions held in early December with appropriate congressional staff members and representatives of the Administration, including Donald Frederickson, Director of NIH, in order to find a common point of agreement and a way out of the legislative morass that existed last fall. Although there was considerable misunderstanding of the purpose of legislation last year, particularly among some scientists who feared that Federal involvement would necessarily mean some form of repression, there has always been agreement between the appropriate subcommittees of Congress, the White House and the National Institutes of Health, as well as the clear majority of scientists, that (1) the NIH Guidelines represent a sound policy regarding the conduct of recombinant DNA research and (2) they should apply to and be enforceable for all activities outside the current boundaries of NIH supported research.

Clearly, there is no unique solution to this problem. Most of the legislative proposals of 1977 would have accomplished this task effectively, although the degree of administrative detail was generally so great as to provide many focal points for controversy and protracted debate. There was never, however, disagreement that the actual safety standards would be anything other than the NIH Guidelines. Most of the objections to these bills from outside of Congress stemmed from a failure of understanding of administrative law on the part of many scientists, at least the most vocal. Within Congress, the deluge of

amendments respecting minute procedural details and administrative provisions slowed the progress through committee mark ups and halted, perhaps, through sheer inertia, the progress of these bills to the floor.

A possible non-legislative solution, first proposed by the Environmental Defense Fund in 1976, and discussed from time to time within the Administration, involved extension of the Guidelines through existing statutes, the most workable being section 361 of the U.S. Public Health Service Act. This provision allows the Secretary of HEW to promulgate and enforce regulations to control the spread of communicable disease. Adequate enforcement authority is contained in section 368.

This solution was reviewed extensively by the administration during the past two months. While it would work legally, the authority is generally not considered appropriate for the regulation of recombinant DNA activities. Including recombinant DNA under such a general provision of the USPHSA as section 361 is considered by many to be an undesirable precedent, which might lead to regulation of a variety of other activities.

It was generally agreed that an interim control bill to extend and enforce the appropriate parts of the NIH Guidelines, without the administrative specificity of earlier bills, would represent a simple, workable solution to the problem at hand. There was generally agreement that section 472 of H.R. 7897, later also included in the Nelson amendment in the Senate, would provide a reasonable legal structure upon which to base such a measure.

Contrary to some opinions, there is no such thing as a "simple" extension of the Guidelines. Section IV of the Guidelines, Roles and Responsibilities, is the administrative portion of the Guidelines and is intimately involved with the NIH grant application and review process. It is thus an inappropriate administrative mechanism for the extension of the guidelines. Inspection and enforcement authority must also be added to make any set of requirements legally enforceable. The bill, to be introduced in the near future, co-sponsored by Representatives Staggers and Rogers, was drafted in consultation with experts in administrative law to have both the legal soundness and flexibility needed in a two year interim measure.

General Considerations

This is a two year interim control bill which would:

- (1) Make the sections of the NIH Guidelines, as

currently amended, on Containment (Section II) and Experimental Guidelines (Section III) apply to all parties conducting recombinant DNA activities,

(2) Empower the Secretary of Health, Education and Welfare to promulgate administrative regulations, revise the Guidelines to reflect new scientific data, and exempt from the Guidelines activities determined to present no significant risk to health or the environment or for specific risk assessment studies,

(3) Give inspection authority to the Secretary of HEW, and empower him to enforce the Guidelines, as appropriate, by (a) suspension of research grant funds, (b) a civil penalty (\$5000) or (c) seeking an injunction through the courts, and

(4) Establish a ~~study commission~~ to evaluate Federal Policy on activities involving genetic manipulation as well as the long term applications of gene splicing technology.

The interim controls and the study commission are created for two years. It is the intent of the legislation that after approximately one to one and a half years after enactment, the appropriate Congressional subcommittees would exercise their oversight responsibilities to assess the current need for uniform standards and the performance of DHEW in administering the NIH standards to all parties. Based upon the performance of the department and the current state of the art, appropriate legislation will be developed as needed.

Dr. Donald Frederickson, Director of NIH, has personally endorsed the bill, calling it "the most promising solution yet proposed for establishing national standards for the use of recombinant DNA techniques". This should not yet be construed as the official position of the Administration, which still has the bill under review.

Summary of Provisions

Findings

The "findings" section of previous bills have probably been the most misunderstood of any part of last year's DNA bills. Findings set forth a general justification for legislation and establish the Constitutional basis for the

provisions of the bill. They are not, however, to be considered the editorial position of Congress, nor do they appear in the final statute.

The findings have been somewhat simplified from earlier bills, and the uncertain nature of risk emphasized for the purpose of an interim bill. This section should not, however, become a major focus of those critiquing legislation.

Definition of Recombinant DNA

Recombinant DNA is defined explicitly and operationally as it is done in the current NIH Guidelines. No artificial exclusions to the definition have been included, as they were in earlier bills. There are two reasons for going back to the older definition. First, this definition does not mandate that guidelines be written to cover everything technically included. NIH is considering exempting certain classes of recombinant DNA activities from the Guidelines and may do so. The standards in effect are cited as those currently specified in Sections II and III of the Guidelines. Any exclusions written into these sections therefore apply.

✓ The second, and probably a more important reason to define recombinant DNA in this way, is because anything excluded by the statutory definition could then be regulated by State or local governments. The preemption section would not apply to exclusions in the definition, but would govern exclusions or exemptions in Sections II or III of the Guidelines.

Proposals which would merely cite the definition of recombinant DNA in the NIH Guidelines suffer not only from the above drawback, but, in effect, grant a department of the Administration complete discretion to define the scope of legislation. There are many obvious reasons for not writing a bill in this way, not the least of which would be the precedent it would set.

Extension of the Safety Requirements of the NIH Guidelines to All Public and Private Entities

Whatever is currently in Section II (Containment) and Section III (Experimental Guidelines) of the NIH Guidelines would now apply to all public and private recombinant DNA activities. Section IV (Roles and Responsibilities) is intimately tied to the NIH granting process and is thus inappropriate as a general provision.

The Secretary of Health, Education and Welfare may

promulgate administrative regulations within 90 days of enactment, and without regard to the provisions of the Administrative Procedure Act. The latter requirements could delay the promulgation of even administrative and procedural regulations by more than a year and would generally be sufficiently non-controversial as not to require a lengthy public comment period.

Revisions and Exemptions

The bill permits revisions by regulation but also requires that they be in accord with a legislative standard--that is, the final requirements must always be sufficient to protect health or the environment.

Exemptions may be granted by order of the Secretary (and therefore not subject to the Administrative Procedure Act) for activities determined to pose no significant risk to health or the environment, or for specific risk assessment studies supported by the Secretary, but according to any conditions the Secretary may prescribe.

Thus revisions, considered to be major changes in the standards, must be done by regulation, with a public comment period. The Secretary may act quickly by order to exempt activities where the lack of significant risk is well established, or in order to conduct needed risk assessment experiments which may require going outside the Guidelines.

Inspection

The Secretary is given broad inspection authority, similar to that in H.R. 7897. He may, however, delegate most of this responsibility to local (biohazard or biosafety) committees at his discretion. Inspection authority is a legal necessity for this bill to be enforceable.

Enforcement

The interim bill spells out what constitutes a "prohibited act" and allows the Secretary to suspend HEW grant funds for violations, to impose a civil fine of \$5000, which is intended for violations for activities not supported by federal grants, or to seek an injunction in the courts to restrain or enjoin activities done in violation of the requirements. U.S. District courts shall have jurisdiction over civil action, including that brought for the seizure or destruction of material involved in a violation of the

law. Civil penalties are considered essential for enforcement in private industry.

The Secretary does not have the authority to suspend non-HEW grant funds. Because of the jurisdictional problems in writing legislation which would allow discretionary withdrawal of funding from other Federal agencies, the cooperation of the other Federal granting agencies is urged.

Preemption of State and Local Regulations

✓ The bill uses preemption language nearly identical to that in H.R. 7897. That is, a local requirement must be not only more stringent than the comparable Federal provision, but necessary to protect health or the environment.

This provision of the bill appears to be the one section of the bill which will receive intense debate and may well be amended before finally being voted out of Congress. The lobbying for strong preemption by University administrations and against it by the environmental and public interest groups has been considerable.

Study Commission

A study commission would be established which would evaluate Federal policy on recombinant DNA activities and look at the long-term applications of gene splicing technology. The scope of the commission includes all aspects of genetic manipulation to be considered in its deliberations, rather than being narrowly limited to recombinant DNA activities. It is to be purely a study commission and has absolutely no regulatory role whatsoever.

NEPA Exemption

All action to be taken by the Secretary is exempted from the provisions of the National Environmental Policy Act. Thus, the time consuming preparation of Environmental Impact Statements would not have to be carried out each time there were revisions or exemptions made, nor for the promulgation of administrative regulations. An EIS has already been prepared by DHEW concerning the possible environmental and health effects of using the recombinant DNA technique. NEPA is not intended to apply to regulations or safety requirements, as some have contended, and to require its application in this Act would be inappropriate.