STATE OF NEW YORK
DEPARTMENT OF HEALTH

→ Dr. Jesaitis

MAR 19 1979

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MEMORANDUM

March 12, 1979

To: Addressees

From: David Axelrod, Commissioner of Health

Subject: Regulation of Recombinant DNA Activity

Article 32-A of the Public Health Law, enacted by Chapter 488 of the Laws of 1978, provides for the regulation of all recombinant DNA activity conducted in this State. The law serves the dual legislative purpose of permitting research with great potential value to go forward while requiring adequate safeguards for the health of the public and the research workers themselves.

The law prohibits any recombinant DNA activity which is not conducted pursuant to a certificate issued by the Commissioner of Health. As required by the statute, the Commissioner has promulgated implementing regulations which are contained in Subpart 61-1 of the Department's Administrative Rules and Regulations. The regulations, effective February 22, 1979, follow closely the recombinant DNA research guidelines issued by NIH December 22, 1978. One important difference between the State law and regulations and the NIH Guidelines is that the latter apply only to recombinant DNA research at institutions receiving Federal support for such research, whereas the New York law applies to all recombinant DNA activity without regard to funding. This includes activity by industries and scientific and educational institutions which are not recipients of Federal funding for recombinant DNA research or activity.

One other important difference concerns experiments in categories which the NIH Guidelines list as exempt from their requirements. Public Health Law Article 32-A does not make provision for exempt activities. Until an amendment of the statute can be effected, the regulations contain authority for the issuance of a certificate limited to exempt-type activity without requiring compliance with provisions applicable to other recombinant DNA activity, including the necessity of establishing an IBC.

The following administrative guidance is provided to facilitate compliance with requirements of the Law and Subpart 61-1, a copy of which is enclosed:

1. The application of an institution which has registered one or more recombinant DNA projects with NIH or another Federal funding agency for a certificate to engage in recombinant DNA activity shall consist of (1) a copy of the registration document(s) received from NIH or the

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Federal funding agency with respect to one or more of the recombinant DNA projects submitted to NIH or the Federal agency, and (2) a list of the members of the IBC with their curricula vitae.

2. An institution will be issued a certificate to engage in recombinant DNA activity limited to the recombinant DNA molecules specified in Section 61-1.3 (c) of the Regulations upon submission of a statement certified by the chief executive officer of the institution that the institution will so limit its recombinant DNA activity.

3. (a) An institution which has not registered any recombinant DNA research project with NIH or another Federal funding agency may qualify for a certificate to engage in recombinant DNA activity if it registers one or more of its projects with NIH under the Voluntary Registration provisions (IV-F-3) of the NIH Guidelines as revised in December, 1978 and submits a copy of the NIH registration document(s).

   (b) If NIH advises an institution that its voluntary registration will be delayed because of logistical problems, the institution should apply for certification by the Commissioner of Health. The application shall consist of a photocopy of the Memorandum of Understanding and Agreement (MUA) submitted to NIH with respect to the recombinant DNA activity, a copy of NIH's notification that voluntary registration will be delayed for other than substantive reasons, and a list of the proposed IBC members with their curricula vitae.

4. An institution may not undertake any recombinant DNA activity which would require prior approval by NIH, or another funding agency designated by NIH for the purpose, if the institution were an applicant for or the recipient of Federal funding for recombinant DNA activity until the activity is approved and registered by NIH or the designated funding agency and the Commissioner receives satisfactory evidence thereof, or in accordance with 3 (b) above. Section 61-1.3 (d) also contains provisions respecting new host-vector systems.

Article 32-A of the Public Health Law provides that, if the NIH Guidelines are revised, the Commissioner of Health shall make corresponding revisions in his regulations. Accordingly, pending completion of administrative steps required for amendment of state regulations, recombinant DNA activity which is in conformity at a given time with the NIH Guidelines and supplements thereto as most recently revised will be considered in State compliance.

Applications for certification should be filed with Roger C. Herdman, M. D., Director of Public Health, New York State Department of Health, Tower Building, Governor Nelson A. Rockefeller Empire State Plaza, Albany, N.Y. 12237.

(b) An activity in a category specified in paragraph (a) may be excepted by the commissioner and conducted in accordance with an express approval given for the experiment by the Director, NIH.

61-1.3 Certification. (a) An institution may be issued a certificate by the commissioner to engage in recombinant DNA activity if it:

(1) establishes an institutional biosafety committee (IBC) composed of members approved by the commissioner as satisfying the requirements of section 61-1.31;

(2) adopts a statement of policy, approved by the commissioner, assuring compliance with the requirements of article 32-A of the Public Health Law and this Subpart.

(b) An institution engaged in recombinant DNA activity subject to, and in compliance with, policies and regulations or guidelines promulgated by any agency of the federal government for the regulation of recombinant DNA activity may submit to the commissioner copies of the documentation approved by the federal agency, including information relating to the institutional biosafety committee of the institution. Such documentation may be accepted by the commissioner as authority for issuance of a certificate to engage in recombinant DNA activity upon the same conditions and limitations, if any, as imposed by the federal agency.

(c) Unless the activity is prohibited by section 61-1.2, an institution may be issued a certificate by the commissioner to engage in recombinant DNA activity limited to the following recombinant DNA molecules and for such certificate shall not be required to comply with the provisions of section 61-1.30:

(1) Those that are not in organisms or viruses.

(2) Those that consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.

(3) Those that consist entirely of DNA from a prokaryotic host, including its indigenous plasmids or viruses, when propagated only in that host (or a closely related strain of the same species) or when transferred to another host by well-established physiological means; also those that consist entirely of DNA from a eukaryotic host, including its chloroplasts, mitochondria, or plasmids (but excluding viruses), when propagated only in that host (or a closely related strain of the same species).

(4) Certain recombinant DNA molecules that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent, as specified in a list of such exchangers prepared and periodically revised by the Director, NIH.

(5) Other recombinant DNA molecules and procedures listed in the NIH guidelines as exempt therefrom.

(6) Other classes of recombinant DNA molecules if the Director, NIH, finds that they do not present a significant risk to health or the environment and the commissioner is furnished satisfactory evidence of such finding.

(d) The commissioner will not certify or will suspend or revoke the certification of an institution which proposes to conduct or conducts a recombinant DNA activity which would require prior approval by NIH if the institution were required to comply with the NIH guidelines, unless the institution registers the recombinant DNA activity with NIH and provides the commissioner with satisfactory evidence thereof.