Statute: Regulation of Potentially Hazardous Biomedical Research

Health and Safety Code Section 25200

The Legislature recognizes that current and proposed research in biology, especially research which employs novel DNA recombinant organisms, poses potential hazards of grave and immediate public health concern. Such hazards include the risk of initially silent epidemics; exchange of potentially harmful genes with naturally occurring organisms; infection of research personnel and their families with pathogenic organisms, and environmental disturbances, including disruption of the normal relationships between animal hosts and their resident bacterial or other microflora; and, the disturbance of the critical relationship between plants and nitrogen-fixing bacteria.

The scientific community, recognizing the extreme urgency of these and other potential hazards, has issued regulations for recombinant DNA research (Federal Register; July 7, 1976; Part II; Recombinant DNA Guidelines; pp. 27902- 27943) which provide minimum safeguards for the public; such regulations do not encompass the private sector, nor afford legal redress or sanctions should breaches of the safety requirements occur. The present law specifies that researchers engaged in recombinant DNA or other potentially hazardous micro-biological research comply with these guidelines whether their work is in the private or public sectors.

Section 25210 Requirements for performance of hazardous biological research.

Hazardous biological research shall be conducted only in approved facilities in which adequate physical and biological containment procedures have been instituted; and shall be conducted by personnel who have received training in the handling and disposal of potentially hazardous infectious agents or materials.

(a) Hazardous biological research: Research or investigations which employ organisms (1) with existing or potential pathogenicity to humans; or (2) produce toxins, poisons or other pharmacologically active substances with potentially deleterious effects on health; or (3) possess or may acquire these properties through exchange of genetically active macromolecules; or (4) any other related research which produces a replicating organism or molecule which may disrupt the normal relationship between vectors or organisms and their hosts in a deleterious manner to human well-being or environmental stability, shall be considered hazardous biological research.

(b) Adequate facilities: Hazardous research shall be conducted only in those facilities which meet the specifications set forth by the Guidelines for Recombinant DNA Research which appeared in the Federal Register, July 7, 1976, pp. 27902-27943. Hazardous research areas in such facilities are to be designated by the official responsible for the conduct of the laboratory or research establishment and marked by the conspicuous display of the symbols for biohazardous research which appear on page 27927 of the Federal Register for July 7, 1976.

(c) Reporting requirements: The responsible official of any establishment conducting hazardous biological research shall report to the Director of Health within 15 days of the institution of such research. Said report shall contain (1) an identification of the nature of the hazard; (2) a research protocol specifying the organisms, agents or operations to be employed; and (3) the names and titles of all research personnel including laboratory workers, assistants, and other supporting personnel including janitorial staff and other persons who may be exposed to a hazardous condition. The contents of the report are confidential and are to be used only by the Director and his immediate staff.

(d) Consent requirements: Employees, including scientific and advisory staff; laboratory personnel and maintenance workers, shall be informed of the hazardous nature of the work and allowed to decline to perform one or more tasks which in the staff's estimation, pose hazards to their well-being. Refusal to participate shall be honored without regard to cause and without loss of employment, pay, pension, or other worker benefits. Specific instructions describing the risks involved and the precautions necessary in carrying out research activities shall be given in writing to each employee, as well as a form requesting consent. Consent forms shall indicate the responsible civil rights officer in the Department of Health to whom complaints may be directed.

(e) Biological containment and other safety measures: All research establishments performing hazardous biological research are to follow the requirements for containment, limited production and other precautions designated by the Guidelines for Recombinant DNA Research. These standards are to be regarded as minimum safeguards and do not contraindicate additional measures which may be taken to protect the health of personnel or the public.

Section 25220 Responsible Persons

(a) Public safety officer: Each research establishment laboratory or other facility which conducts or employs biologically hazardous agents or processes shall appoint a public safety

officer who will have responsibility for ensuring that the regulations are followed and that employees are protected.

(b) Reporting requirements: Any incident, accident or other unforeseen event which may be associated with the release of a potentially hazardous agent or agents, or its products, shall be reported by phone within 12 hours to the Director of Health or his designee. A description in writing of the steps taken to safeguard employees or the public is to be sent to the Director of Health within 30 calendar days of implementing any hazardous research protocol.

Section 25230 Additional safety requirements:

Promulgation of this statute shall not supervene existing reporting requirements, review procedures or committees or other codes in force within institutions in which hazardous research is conducted, providing such procedures comply with the law.

Section 25240 Penalties

Failure to comply with this statute shall be punishable by a fine of five hundred dollars for each count; institutions not in compliance with these provisions must do so within 30 days of notification in writing by the Department of Health. Institutions which fail to comply may be closed at any time on summary judgment by the Director of Health that their continued generation poses a health hazard to the personnel or community in which they operate.

Section 25250. Review and appeals procedure:

Individuals or institutions fined or penalized under this statute may appeal in writing to the civil rights officer of the Department of Health for a restraining order; if an appeal is denied, the offending party or parties may seek legal redress in the courts, but under no circumstances may a non-compliant institution operate without meeting the conditions of this law.

STATE OF CALIFORNIA—HEALTH AND WELFARE AGENCY EDMUND G. BROWN JR., Governor

DEPARTMENT OF HEALTH
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January 27, 1977

Cambridge City Council
Cambridge City Hall
Cambridge, Mass. 02139

To the Honorable Alfred Vellucci and Council Members:

I have been following the conscientious work which you and your colleagues have expended in assessing the risks involved in conducting Recombinant DNA research. I would like to share with you some of the involvement of my office and the State of California in this same area.

In October, 1976, the Office of Health Law and Values in the Department of Health initiated inquiries into Recombinant DNA research in the State of California. By February 3, the Assembly Subcommittee on Health, and the one on Land Use, Energy and Resources will have conducted three hearings on the issues imbedded in the controversy over the safe conduct of this research (January 21, 28 and February 3.) Participants will have included scientists, philosophers and public policy experts. Transcripts of these proceedings will be available to the public from Assemblyman Barry Keene's office in Sacramento.

I have drafted a provisional version of legislation which defines the conditions under which potentially hazardous research could be conducted in California. It makes the basic provisions of the NIH guidelines applicable to both the private and public sectors as well as providing reporting requirements and worker safety provisions.

An advance copy of this proposal is included for your perusal. At this time, the proposal has not been offered to any legislators for submission in bill form, but I expect this to occur in the next few weeks, as the Department of Health, Health and Welfare Agency and Governor's office have approved its general specifications in principle.

If I may be of further assistance to you and your efforts, please call on me. In turn, I would be extremely grateful for any materials which you may develop in the following few weeks. (I have in hand the summary of your recommendations).

Sincerely,

Marc Lappe

Marc Lappe, Ph.D., Chief
Office of Health Law and Values

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Comm. from Dr. Marc Lappe of the Dept. of Health, California forwarding a draft version of legislation which defines conditions under which potentially hazardous research could be conducted.

In City Council,
Jan. 31, 1977

1/31/77
To Ordinance Committee

Copies made CS
copy put into Committee folder. 2/2/77 dl