DNA Rules Kept to Head Off New Laws

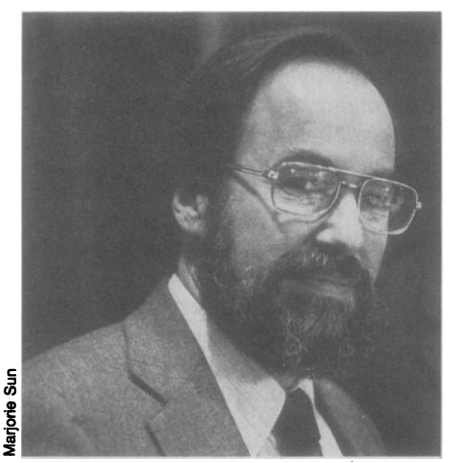
NIH advisory panel decides public not yet ready for clean sweep

A National Institutes of Health advisory panel voted this month to relax somewhat the regulations that govern federally funded recombinant DNA research, but at the same time approved keeping the guidelines compulsory. In doing so, the Recombinant DNA Advisory Committee (RAC) continued steering a conservative course on gene-splicing research, strongly rejecting another proposal that would have made the guidelines completely voluntary. For a combination of scientific and societal reasons, most committee members were not ready to forgo all the restrictions and oversight that NIH has exercised over this research since 1976.

The NIH committee chose to keep the rules mandatory for two principal reasons. Some members were clearly worried about public backlash and the possibility that the removal of federal regulation would invite local and state legislators to enact their own laws to restrict recombinant DNA research. Others had lingering concerns about the safety of some experiments regulated by guidelines. About 90 percent of gene-splicing research is exempt from the current regulations.

The committee considered two proposals, both of which would relax current mandatory guidelines, but to different degrees. One was a voluntary proposal that the committee voted in September to put out for public comment that was based largely on recommendations made by David Baltimore of the Massachusetts Institute of Technology and Allan Campbell of Stanford. The other is the mandatory plan which loosens present experimental restrictions, but not to the extent of the RAC's September proposal. These regulations were proposed by Susan Gottesman, who is a senior investigator in molecular biology at the National Cancer Institute and is a former RAC committee member. Her proposal passed 16 to 5 and is subject to the approval of the acting NIH director. (The proposals were published in the *Federal Register* on 4 and 7 December.)

Many committee members were uncomfortable with the prospect that the public would take matters into its own hands if the guidelines were made voluntary. "Although I believe the guidelines should be voluntary, the public is not yet ready for them to become voluntary," said James Mason, executive director of Utah's state health department, and panel member. In a letter to the committee, William N. Lipscomb, chairman of Harvard's biosafety committee, warned that public concern "should not be underestimated" and urged a careful relaxation of the rules.



Marjorie Sun

David Baltimore

In fact, others predicted that a patchwork of regulations might spring up across the country at the local and state level if NIH abandoned the mandatory guidelines. California state legislators, for example, have already discussed possible regulations in case NIH eliminated its regulations. Such legislation "will hamper research and that will be unjustifiable," said Richard Goldstein, an associate professor at Harvard Medical School.

Many biotechnology companies share the same concern about state and local regulation, fearing that haphazard regulation would impede a burgeoning industry. Federal regulations are "more compatible with commercial development . . . than would be a system of varying local requirements," wrote Harvey Price, director of a biotechnology trade group, to the committee.

During the discussion, Baltimore responded to charges of conflict of interest by some scientists who wrote to the panel. Baltimore is a board member and chairman of a scientific advisory committee at a biotechnology company called Collaborative Research. Baltimore retains his faculty post while serving the company as well. "If I was representing Collaborative Research, I wouldn't be putting up this proposal for voluntary guidelines because no one at the company wants to deal with the city council. I believe the voluntary plan is the right thing to do," he declared.

He said that the RAC proposal "tries to reflect the judgement of a vast majority of scientists who believe that recombinant DNA research is no more hazardous than the mainstream of research." Those who do not agree with him, Baltimore said, "represent, at best, a small fraction of the scientific community."

Indeed, committee members seemed to agree that the risk of hazards in this

Marjorie Sun

Susan Gottesman

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research is small given the track record of scientists so far. But this modicum of uncertainty elicited a different response from others. The reason Gottesman proposed her version of mandatory guidelines is that a few types of experiments, in her opinion, still warrant oversight. "If they are to be watched, then it makes sense to make the guidelines mandatory," she said. Others concurred, arguing that until more data become available on risks associated with the small number of experiments, it is better to err on the side of caution. Elena Nightingale of the Institute of Medicine said, "We should keep in mind that the probability of something going wrong is small, but . . . [if something goes wrong] the consequences are large. A powerful technology has powerful consequences."

Although the committee voted in favor of Gottesman's proposal primarily because of its mandatory requirement, it also found other provisions attractive. The proposal retains institutional biosafety committees, which the RAC proposal eliminated. The members seemed to agree that the groups have provided a useful forum for discussion between scientists and the community.

The proposal eases restrictions on the special handling of organisms—or containment rules. In particular, experiments involving nonpathogenic, one-celled organisms would be carried out at the least restrictive category. It does not lower containment levels as much as the RAC proposal.

In addition, the voluntary plan would drop prohibitions on three types of experiments but would require prior approval by the committee, NIH, and the local biosafety group. Experiments that would now be permitted under Gottesman's proposal are those that deliberately release into the environment organisms containing recombinant DNA, such as organisms to be used as agricultural pesticides; those that deliberately form material containing genes that translate into certain lethal toxins; and those that deliberately transfer a drug resistance trait to microorganisms if it could jeopardize the use of a drug that currently controls disease.

The committee plans further refinements of the Gottesman proposal at the next meeting in April. For now, the committee has decided a fundamental issue that has been discussed for 2 years. It is not to everyone's liking in the research community but the more moderate proposal they chose is likely to gain public acceptance more easily than a clean sweep of regulations for now.

—MARJORIE SUN

Final Draft of Classification Order

The third and final draft of the Reagan Administration's Executive Order on Security Classification came out on 4 February, little changed from the second draft. If Reagan signs the order, a 30-year trend toward reducing classified information will be reversed. For example, basic scientific research will be classifiable, as will research funded by grants, whether or not the funding agency itself has the power to classify (*Science*, 5 February, p. 636).

Congress has been given until 22 February to consider the final draft of the executive order—a time frame that a number of congressmen find too brief. Congress recessed on 10 February and will not return until 22 February. On 10 February, Glenn English, chairman of the House subcommittee on government information and individual rights of the Government Operations Committee, wrote to national security adviser William Clark asking that the deadline be extended. "No change should be made in the executive order without allowing for thorough review," he wrote. Seven other subcommittee chairman signed English's letter. A spokesman for English's subcommittee says that his and a number of other subcommittees would like to hold hearings on the executive order.—***Gina Kolata***

DOD and University Presidents to Meet

A newly formed committee consisting of seven university presidents, Defense Science Board members, and Defense Department administrators will have its first meeting this month to discuss a broad range of issues relating to the mutual concerns. Donald Kennedy, president of Stanford University, and Richard DeLauer, under secretary for research and engineering at the Department of Defense (DOD), are cochairmen of the committee.

Among the issues to be discussed are technology transfer and export controls, research support for universities, graduate education in the physical sciences and engineering, the universities' needs for new laboratory instruments, and the nation's needs for more students trained to know foreign languages and as experts on other countries. The committee was set up at the Defense Department's request by the Association of American Universities (AAU), the American Council on Education, and the National Association of State Universities and Land Grant Colleges.

Richard D. DeLauer

Donald Kennedy

According to John Crowley, executive assistant to the AAU president, the idea for such a committee came from two sources. One was the AAU, which was asked last year by DeLauer to prepare a report on major issues in research training that would be of concern to the Defense Department. The AAU presented its report in October, including the recommendation that it would be useful to establish a forum for the DOD and universities to talk to each other. In the meantime, the Defense Science Board came out with the same recommendation.

The establishment of the committee, says Crowley, "is a reflection of the seriousness of the situation and a recognition generally shared across DOD, universities, and Congressional committees that if the administration's fundamental objective is to rebuild our

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