USA

After the carrot, the stick

Colin Norman reports from Washington on the moves to introduce legislation to control recombinant DNA research in the United States

JUST two years ago, at the now famous Asilomar Conference, a group of scientists was discussing a set of proposed guidelines for experiments involving the powerful new recombinant DNA genetic engineering technology. Joshua Lederberg, a Nobel Prizewinner from Stanford who had been sounding ominous warnings about threats to free scientific inquiry, gloomily told his colleagues that there was "a graver likelihood of (these proposals) crystallising into legislation than some of us would like to think". That likelihood is now a virtual certainty.

Last week, the health subcommittee of the House of Representatives held three days of intense public hearings to examine a number of bills, including one proposed by the subcommittee chairman Paul Rogers, which seek to regulate all recombinant DNA experiments in the United States. Next week, the House subcommittee on Science, Research and Technology will begin its own set of hearings. On April 6, the Senate health subcommittee, chaired by Senator Edward Kennedy, will hold a hearing to discuss various legislative proposals already introduced into the Senate, and Kennedy will probably subsequently offer a bill of his own. And legislation which will soon be proposed by the Carter Administration is now taking shape (see below).

Thus, what Lederberg correctly perceived as an inexorable march toward federal legislation is now entering the home stretch. It will take several weeks, perhaps months, for a final bill to emerge from Congress, however, and the debate is likely to turn on a relatively small number of issues.

First, it should be noted that Congress is unlikely to try to rewrite the guidelines issued last year by the National Institutes of Health (NIH). Though it is possible that some legislators will offer proposals to ban the research entirely—Representative Richard Ottinger said at last week's hearings, for example, that he is considering offering a bill declaring a moratorium and calling for an international meeting to develop a better understanding of the hazards—it is unlikely that such a move would succeed.

The most probable outcome is that Congress will direct the Secretary of Health, Education and Welfare (HEW) to develop regulations based on the NIH guidelines. Both the Rogers bill and the Administration's draft bill take that approach, and Kennedy said in a statement last week that "we must assure sufficient and meaningful involvement of laymen and the general public in the formulation of regulations by the Secretary", thus indicating that he is likely to support that approach as well.

A second point to note is that the final regulations will apply equally to research supported by public and private funds, and that the legislation will establish a mechanism by which the controls can be enforced. Those two elements are missing from the NIH guidelines, and the need to extend and enforce the guidelines is largely responsible for the momentum now behind the development of federal legislation.

The coming Congressional debate is thus likely to centre on four areas:

● **The extent to which the federal regulations will override state and local controls.** Many scientists who were once opposed to federal legislation now support it because several state and local governments, led by the City of Cambridge, are developing their own controls on recombinant DNA experiments, thus raising the possibility that a patchwork of regulations of varying strictness will be adopted throughout the United States. Most scientists are consequently hoping that federal regulations will specifically prohibit local governments from setting their own controls on the research.

The Administration's draft bill would

A committee of government officials, representing 16 federal agencies, last week urged the Carter Administration to draft legislation to control all recombinant DNA research in the United States, and the committee sketched out the chief elements which it believes should be included in such a bill. As soon as the committee's report landed on his desk, the Secretary of Health, Education and Welfare (HEW), Joseph A. Califano, announced that his department would promptly transcribe the recommendations into formal legislation, noting that "such a measure is necessary not just to safeguard the public but also to assure the continuation of basic research in this vital scientific area".

The bill is expected to be ready early in April, when it will be submitted to Congress with an endorsement from the White House. It is likely to be particularly influential as Congress grapples during the next few weeks with the complex problem of how recombinant DNA research should be regulated.

The inte-agency committee, chaired by Donald Fredrickson, Director of the National Institutes of Health (NIH), began last November to seek ways to extend NIH's own recombinant DNA guidelines to cover experiments supported by other government agencies and by private industry. Though other agencies have since adopted the NIH guidelines, the committee decided that new legislation is needed to ensure compliance by everybody conducting recombinant DNA experiments in the USA.

The committee consequently recommended that the Administration's bill should contain the following provisions. The Secretary of HEW should issue regulations based on the NIH guidelines, "with such clarifications and modifications as the Secretary determines to be necessary". All recombinant DNA experiments should be conducted at facilities licenced by HEW, the licence being issued only when the Secretary is satisfied that the facility will be operated in accordance with the regulations. Researchers would have to register their experiments with HEW. The committee suggests, however, that the Secretary could exempt from licencing and registration requirements "categories of activities which he determines pose no unreasonable risk to health or the environment".

To ensure that the regulations are being followed, HEW would have the authority to inspect facilities, conduct environmental and health monitoring, and require that reports and records be kept. The Secretary would have power to halt experiments if necessary, and violations of the regulations could incur loss of a facility's licence. In the event of injury to people or the environment, actions and damages would fall under state and local laws.

The committee suggests that all reports submitted to HEW by experimenters and officials in research facilities should be made available to the public on request, except for information likely to cause loss of prorietary rights. Before information is released, researchers would be able to identify material which they believe should be kept confidential, but the final decision on disclosure should rest with the Secretary of HEW.

In what may turn out to be one of its most controversial recommendations, the committee suggests that federal legislation should specifically pre-empt all state and local regulations regarding recombinant DNA research. The only exception would be if a state passes a law imposing requirements identical to those contained in the federal legislation, the Secretary of HEW could enter into an agreement with the state to carry out the inspection, monitoring and enforcement responsibilities. In other words, such a clause would rule out the setting of state and local controls of varying stringency.

Finally, the committee recommends that the legislation should contain provisions protecting the rights of employees who blow the whistle on their superiors, and it also suggests that the legislation should lapse after five years unless further action is taken by the Congress.

indeed pre-empt local moves, though it would allow the Secretary of HEW to enter into agreements with state governments under which local agencies would enforce the federal regulations. The Rogers bill, however, would allow the Secretary of HEW to approve state regulations which are at least as strict as the federal controls, and Kennedy said last week that "we must carefully assess the wisdom of totally pre-empting state and local laws regulating the recombinant DNA research and applications given our concern to assure the involvement of the general public in these issues".

The crux of the issue is how the federal government can ensure the adoption of uniform regulations without throttling public debate and without cutting off legitimate community interest in what universities are up to.

● **The nature of registration and licencing schemes.** It is likely that the final version of the legislation will establish a mechanism through which researchers or research facilities would be licenced and research projects would be registered with the federal government. There is a significant difference in approach between the Administration's draft bill and the Rogers bill, however, and it is not clear which approach will prevail.

The Administration's draft bill, in short, would require that facilities housing recombinant DNA experiments be licenced by HEW and that individual research projects would simply have to be registered with HEW. The Rogers bill, on the other hand, would require researchers themselves to obtain licences from HEW before embarking on any recombinant DNA project, and the licence application would specify the nature of the project and the safeguards to be employed. The difference between the two approaches represents a very significant difference in the focus of control and the complexity of the licencing process. Kennedy has so far made no statement on that aspect of the legislation.

● **The extent to which proprietary information can be protected from public disclosure.** There is a clash of interests between the need on the one hand to provide full public information on recombinant DNA experiments and the need on the other hand to protect proprietary information from public disclosure. That dichotomy is sure to generate a good deal of Congressional debate. The Administration's draft bill and the Rogers bill deal with public disclosure in slightly different ways, though both leave to the Secretary of HEW the ultimate decision on what information should be made public. The Rogers bill essentially requires the Secretary of HEW to publish in the *Federal Register* details of research projects for which he has issued licences, though he would simply exempt from disclosure proprietary information. The bill under consideration by the Administration, however, would require the Secretary of HEW to make information public only on request and after the researcher involved is given a chance to object if he believes that disclosure would jeopardise commercial interests.

● **The nature of sanctions if violations are discovered.** It is likely that the legislation which will eventually emerge from Congress will empower HEW to inspect facilities, and require reports, health monitoring and so on. The legislation is likely to give the Secretary of HEW the power to revoke licences if violations of the regulations are discovered, and he would also be able to halt projects deemed to present an imminent hazard. As for the question of liability, the Administration's draft bill would leave that up to state and local laws, while the Rogers bill would allow imposition of a $1,000-per-day fine for each violation.

Those areas are likely to be the chief focus of discussion in the next few weeks as Congress goes through the unprecedented process of setting federal regulations on an area of basic science. One thing is already clear from the public debate so far, however. As NIH Director Donald Fredrickson put it during last week's hearing "biomedical research is entering a new era in its relationship to society. It is passing from an extended period of relative privacy and autonomy to an engagement with new ethical, legal, and social imperatives under concerned public scrutiny". □

NIH grants: OK, but . . .

AFTER a two-year study of the system used by the National Institutes of Health (NIH) to parcel out more than $1,400 million a year in research grants, an internal NIH committee has concluded that the system is working well, but would benefit from a few changes.

NIH now handles about 15,000 grant applications a year, and funds less than a third of them. They are reviewed first by a study group consisting of a number of scientists working in related fields, which rates the proposal according to its scientific merit and which takes into account such considerations as the track record of the applicant. The proposal, together with the study group's rating, is then passed along to the advisory council of the Institute to which the application has been referred. The council goes into such matters as whether the proposal fits in with the priorities of the Institute, and it recommends whether or not the grant proposal should be funded. The final decision is made by NIH officials. Clearly, the most influential stage of the review is the initial evaluation of the study group.

At present, study groups meet behind closed doors and their recommendations are exempt from general public disclosure. The committee has recommended that the groups continue to deliberate in private, but it has suggested that the groups' conclusions and recommendations routinely be communicated to grant applicants as soon as the Institute's Advisory Committee has completed its review.

On the question of confidentiality, the committee has also expressed concern about the fact that grant proposals, once they are funded, must be made available to the public, on request, under the Freedom of Information Act. The committee urges passage of legislation protecting grant proposals from public disclosure.

As for the support of unorthodox research, some concern has been expressed that the peer review system favours traditional, conservative research at the expense of creative, unorthodox research. The committee therefore suggests that applicants identify innovative aspects of their research proposals. It also suggests that the study groups prepare a statement pointing out the innovative aspects of a grant application.

Finally, the committee recommends that a formal appeals system be established in NIH through which applicants can appeal the assignment of their proposals. It suggests that an ombudsman be appointed to adjudicate disputes over the handling of grant proposals, and that a Permanent Grants Peer Review Appeals Board be established under the chairmanship of the ombudsman.

The committee's recommendations are now being considered by the NIH Director, Donald Fredrickson. He is expected to endorse most of them.

Colin Norman