Recombinant DNA Bills Derailed: Congress Still Trying to Pass a Law

A year ago this month Congress began deliberations over legislation to govern research with recombinant DNA. There was then a sense of great urgency about the issue that is reflected in the language of a resolution, introduced in the House on 19 January, that called recombinant DNA research "potentially devastating to the health and safety of the American people. . . ." By spring a dozen measures were before Congress [the principal bills were introduced by Senator Edward M. Kennedy (D–Mass.) and Representative Paul G. Rogers (D–Fla.)], and some Hill staffers were predicting that a DNA law would be passed by the Fourth of July. Within the scientific community, there was growing concern that the law would be disastrous.

But forecasts of quick legislation turned out to be wrong; Congress has yet to pass a recombinant DNA bill. For the present, DNA legislation is in what one Senate staffer describes as a "state of suspended animation," waiting to be taken up again during the session of Congress that has just begun.

What happened? Why, when legislation seemed so certain, was neither house of Congress able to pass a bill? There are a number of answers. Some of them have to do with internal House and Senate politics. Others have to do with the actions of individual scientists and of scientists acting collectively as a lobby to protect their own interests, just as any lobby does. As the summer wore on, they helped turn the tide. In the Senate, Kennedy began to lose his early support as two other senators stepped into the picture with alternative proposals. Gaylord Nelson (D–Wis.) introduced competing legislation in August. And in September Adlai E. Stevenson III (D–Ill.), chairman of the subcommittee on science, technology, and space, announced that he would hold hearings to reassess whether legislation was appropriate at all. Late in September, Kennedy announced that he was temporarily backing off from his own bill and began talking about establishing a commission to study the issue anew. In the House, Rogers' bill fell victim to political infighting.

The debate over recombinant DNA research has set scientists against scientists, and congressmen against congressmen, as all sides struggle with contentious questions about how the research should be regulated and, if so, by whom.

Almost everyone agrees that inherent in recombinant DNA research is some potential for hazard or abuse. It was, after all, recombinant DNA workers themselves who first called this to public attention. Furthermore, almost no one in science or politics thinks recombinant DNA research should be banned altogether. But the path to a middle ground is rocky and full of pitfalls.

The past couple of years have witnessed the interesting phenomenon of a "public" debate on recombinant DNA that really amounts to a debate between two scientific camps slugging it out in public. On the one side are scientists—many of them active in recombinant DNA experimentation—who take the view that the risks are "vanishingly small," and that the research can be adequately contained by "voluntary compliance" with scientist-written National Institutes of Health (NIH) guidelines. On the other side are scientists—most of whom are not engaged in recombinant DNA work—who believe that the risks are "substantial" and that it makes little sense to rely on scientists to regulate themselves. This side has the support of public interest groups including the Boston-based Science for the People and the environmental lobby.

It is probably fair to say that in the beginning, Congress was impressed by assertions that recombinant DNA experimentation poses a substantial risk. Add to this circumstance the fact that the NIH guidelines are thought not to be applicable to research in industry or other areas of the private sector and it is easy to see why Congress was ready to step in with legislation. Nor is it difficult to understand why the majority of scientists find legislation distasteful, for each of the bills before Congress contains, in one form or another, provisions for federal licensing and inspection of laboratories, complex reporting systems, and fines in the thousands of dollars to be imposed on scientists who violate the rules.

To many scientists who had tried to seize the initiative by calling for self-regulation (thereby trying to preempt federal legislation), the turn of events holds a cruel irony. Nobel laureate David Baltimore of M.I.T. was one of the organizers of the landmark Asilomar conference which marked the scientists' first formal attempt to write guidelines for self-regulation (*Science*, 14 March 1975). Last May, he spoke for many of his colleagues when he said:

> The new biology has become the new politics in a very concrete manner: biologists are spending their time in the halls of Congress trying to prevent the establishment of the first commission to be appointed to control basic research. I believe that our success or failure will determine whether America continues to have a tradition of free inquiry into matters of science or falls under the fist of orthodoxy.*

The Kennedy Bill

In particular, Baltimore referred to the bill introduced by Senator Kennedy, which called for the creation of a new national commission, composed predominantly of nonscientists, that would have authority to regulate all research in recombinant DNA. Baltimore called the Kennedy bill "a clear invitation to begin the process of deciding what research shall be allowed and what research prevented." (In fact, in drafting the Kennedy bill, the Senator and his staff first considered a bill to regulate all potentially hazardous biological research before deciding to stay for the present with recombinant DNA.)

Kennedy's was by far the most controversial recombinant DNA bill before the Congress. In addition to establishing in the commission a brand new bureaucracy, the Kennedy bill provided that local communities could adopt regulations more stringent than those set by Washington or could even prohibit recombinant DNA research altogether. Some scientists foresaw a mass exodus of DNA researchers from conservative towns to places where citizens have what they regard as "more respect for the scientist's right to free inquiry." In the minds of many biologists, Kennedy's bill assumed the character of a monster as fearsome as any biological mutant one could fantasize as coming from a recombinant DNA laboratory.

In spite of strong criticism from the scientific community, the drafters of the Kennedy bill even now defend it as sound legislation. Kennedy aides report, for instance, that the Senator proposed a separate regulatory commission for two reasons. First, NIH itself was anxious not to be put in the awkward position of both sponsoring and regulating recombinant DNA research. By establishing a commission outside of HEW altogether, Kennedy would make sure NIH was not

*"The new biology becomes the new politics," delivered 6 May 1977 at the University of Missouri.

0036-8075/78/0120-0274$01.00/0

forced into a regulatory role. Second, Kennedy also saw in the commission a chance to make a philosophical statement about public participation in science, a cause he has championed for the past few years. His commission of 13 members was designed to include scientists and representatives of the public, inasmuch as the applications of recombinant DNA research and its risks, if any, would be borne by the public at large. Nevertheless, there is a chance he would have agreed to make it an advisory body in the end. Senate staffers hint that the tough regulatory stance might have been compromised away in House-Senate conference if the bills had gotten that far. As one staffer said, "The researchers who oppose this bill don't understand the give and take of the Hill, the fact that we have to go to conference with something we're willing to give away."

Kennedy's commitment to public participation is also the motive behind his refusal to go along with blanket federal preemption of local laws. The much publicized situation in Kennedy's own backyard in Cambridge, where a citizens' review board made its own assessment of safety and policy questions, merely reinforced his view. According to Kennedy aide Lawrence Horowitz, when the Senator looked at those actions local communities had taken, he concluded there was not a single case in which citizens acted irresponsibly. Still, he is not encouraging a profusion of local laws. His bill provides for them only when a community can prove some overriding need for a regulation that differs from a federal one.

The Rogers Bill

If the scientific community had to choose between the Rogers and the Kennedy bills, it would vote for Rogers hands down. For one thing, Rogers' bill goes about regulating recombinant DNA research in a basically familiar way, by giving clear authority to the Secretary of HEW (even over other federal agencies that have responsibilities for public health and safety) and by establishing an advisory committee rather than an autonomous commission. Scientists are not uncomfortable with advisory committees. On the matter of federal preemption, Rogers' bill also permits local variation from national policy only if some special need is demonstrated.

The Administration Bill

While Congress was drafting recombinant DNA legislation, the Executive Branch was at work on a bill of its own. The first crack at writing it was taken by the Federal Interagency Committee on Recombinant DNA Research, whose members, working under the implicit leadership of NIH, came up with a bill that seemed designed with the needs of the research community in mind.

By 15 March a bill had been drafted and was sent to the Office of Management and Budget (OMB), where all Administration proposals must be cleared. There, as one NIH partisan described it, "A whole new cast of players got into the act, demanding more federal control and more explicit authority for their own agencies. Months worth of careful negotiation and compromise were washed away." According to knowledgeable sources, representatives of the Veterans Administration, the National Institute of Occupational Safety and Health, and the Occupational Safety and Health Administration demanded their territorial rights, and the "designation of HEW as the lead agency was obscured." A provision for federal preemption of local laws also gave way.

The Events That Turned the Tide

No single event brought recombinant DNA legislation to a standstill. But several things happened during the spring and summer that, together, convinced relevant members of Congress that the potential dangers of the research are not nearly as great as they have been cracked up to be. Once the perception of hazard was muted, the sense of urgency that had been driving Congress diminished, and it became possible to argue that, for the moment, the most responsible thing to do would be to do nothing—legislatively.

Among the events that influenced Congress are these:

• The Curtiss letter. Roy Curtiss III of the University of Alabama medical school in Birmingham was from the first more convinced than many of his colleagues in the field that recombinant DNA could pose a real threat. Indeed, it was Curtiss who took great pains to develop the first strain of enfeebled bacteria that cannot live outside of the laboratory in order to provide a form of biological containment of recombinant DNA organisms. Then, early last year, after much experimental work, Curtiss changed his mind. In a 12 April 1977 letter to NIH director Donald S. Fredrickson, Curtiss spelled out in great detail why he had come to the conclusion that "the introduction of foreign DNA sequences into EK1 and EK2 host-vectors offers no danger whatsoever to any human being. . . . I do not believe that cloning foreign DNA into *E. coli* K-12 host-vectors poses any threat to nunhuman organisms in the biosphere." To be sure, Curtiss was not giving blanket endorsement to all possible forms of recombinant DNA research, but he was, in effect, saying that those experiments that are permitted under NIH guidelines are not risky. Curtiss's letter had considerable impact within the scientific community and among members of Congress, to whom it was widely distributed.

• The Falmouth Conference. A constant complaint about the nature of the "official" debate about recombinant DNA and about the process of writing the NIH guidelines was that they were dominated by molecular biologists to the exclusion of bacteriologists, virologists, infectious disease specialists, and others whose experience with virulent organisms was far greater than that of any scientist who spends most of the time thinking about DNA. Therefore, in June, a workshop was convened in Falmouth, Massachusetts, by an ad hoc NIH committee to bring together such a group of individuals to assess the potential risks associated with recombinant DNA. Chaired by Sherwood L. Gorbach, chief of the infectious disease unit at Tufts medical school, the workshop participants generally concluded that the speculative hazards of recombinant DNA research are unsubstantiated, although the group was not unanimous on all points. Gorbach summarized the majority view in a 14 July 1977 letter to Fredrickson, which, like the Curtiss letter, was widely circulated on Capitol Hill.

• Stanley Cohen. Stanford University scientist Stanley Cohen "invented" recombinant DNA research. Unlike Curtiss, he felt from the start that fears about the potential risks of such DNA experiments were overblown and was quick to tell Congress that in testimony in the spring of 1975, when Senator Kennedy held the first congressional hearing on the subject (*Science*, 20 June 1975). But at the time, Cohen's arguments were not terribly persuasive to either Kennedy or his staff, and Cohen came out of the hearing feeling somewhat abused.

But last year, Cohen and his co-workers succeeded in making their point when they completed experiments that demonstrated what a number of scientists believed but could not prove—namely that recombinant DNA occurs in nature and is not just a novel, laboratory-made "new form of life." Details of Cohen's experiment were published in the December issue of the *Proceedings of the National Academy of Sciences*, but preprints of the paper conveniently have been floating around Congress all fall.

During the past few years, biologists have gradually begun to reconsider their traditional and ingrained opinion that

OSTP Pursues Use of Existing Laws

Most observers consider the eventual passage of recombinant DNA legislation all but inevitable. Nevertheless, a small band of stalwart opponents continues to argue against it on grounds that it can be regulated under existing provisions in the public health law (*Science*, 6 January). The President's science advisers are taking this possibility quite seriously and Gilbert Omenn, a deputy director of the Office of Science and Technology Policy, says they are "looking diligently" into the matter. Because a number of federal agencies have responsibilities for the public health, any application of existing statutes would require considerable interagency cooperation, most likely with the Department of Health, Education, and Welfare as lead agency. Observers call use of present laws a "long shot" but one that should not yet be ruled out.—B.J.C.

politics is dirty. Last year, led by a microbiologist from Brandeis named Harlyn O. Halvorson, they broke with tradition in a surprisingly well organized and effective way when they formed a lobby that played a major role in stalling recombinant DNA legislation.

The Biologists' Lobby

Halvorson, an officer of the American Society of Microbiologists (ASM), had not been one of the stellar players in the recombinant DNA issue. In fact, he was not even invited to Asilomar, although he had asked to be. Keenly aware of the need for scientists other than molecular biologists to get into the act, for the past two years Halvorson and his society were involved in the DNA battle on the periphery. The society was asked by NIH to offer its opinion of the draft guidelines in 1976 and, as president of the ASM, Halvorson was asked by NIH director Fredickson to sit on an ad hoc advisory panel that met to review the guidelines in February 1977. In the spring of 1977, the Rogers subcommittee held hearings. The ASM was not invited to testify. Shortly thereafter, Kennedy held hearings. Halvorson called the Senate and asked that his society be included. He was turned down.

By that time, Halvorson recalled in an interview with *Science*, "I was really mad. So I called a scientist I know in Boston who had been a close adviser to Senator Kennedy on this thing and I threatened to call a press conference blasting Kennedy's position. An hour later, I got an invitation to testify."

Halvorson's involvement in the politics of recombinant DNA came partly as a product of his own personality and partly from his position last year as president of the microbiologists' society. In that capacity, for instance, he heard frequently from Harvard bacteriologist Bernard Davis, who urged the ASM to stand up and take a position on the issue. (From the start, Davis argued adamantly that the critics of recombinant DNA research were blowing talk of potential hazards out of all proportion.)

When Halvorson decided to engage himself fully in the cause of stopping what he saw as heavy-handed federal regulation of research, he decided to go about it with all the political savvy he could muster. First, he turned to experienced sources for advice about organizing a lobby. He consulted a lawyer from the American Civil Liberties Union and a veteran aide to a member of Congress.

Halvorson was advised to form a broad coalition within the scientific community. He was told to devise a plan—decide what it was he wanted from Congress—and to stick with it, not changing in mid-course. He was instructed not to be arrogant, and not to embarrass congressmen. If you're asking them to change their minds, he was urged, give them an "escape clause." (With that in mind, Halvorson and company leaned hard on the "new" information that now indicated the hazard of recombinant DNA research is vanishingly small.) And above all, whenever possible, enlist a scientist from a congressman's own district to be your spokesman.

The first decision Halvorson and his colleagues came to was that they would support some form of federal legislation, resisting what they thought the futile temptation to argue against any legislation whatever.

By this time, Halvorson had met Rogers' aide, Burke Zimmerman, who had recently joined the congressman's staff after working at the Environmental Defense Fund, a public interest lobby that has, at times, espoused the idea that recombinant DNA poses a substantive hazard. However, Zimmerman, a Ph.D., never took a hard line and on the Hill followed Rogers' style of contacting and listening to everyone. "We were commenting on the Rogers bill line by line," Halvorson recalls, "and though we and they did not always agree, we felt we were being heard in the House."

By the spring of 1977, the microbiologists' society was ready to take the stand Davis had been pushing for. The ASM drafted "nine principles relative to recombinant DNA legislation," most of which, it pointedly noted, were embodied in the Rogers bill that was described as one that "will permit free scientific inquiry while protecting the safety of the general public." When the society officially voted at its May meeting to adopt the principles, Halvorson says, "We cabled Rogers immediately to let him know he had our support." Among the nine principles was one embracing the idea of making the Secretary of HEW responsible for regulatory action and one calling for a sunset clause in any bill that might be passed.

All the while, Halvorson was working to form the broad coalition he needed. Twenty societies, including the huge Federation of American Societies for Experimental Biology, lent their support. In addition, ten "prominent individuals" speaking for themselves rather than their societies endorsed the nine principles. (The AAAS declined to endorse the principles, so AAAS president William D. McElroy signed in his capacity as chancellor of the University of California at San Diego.)

From the coalition's point of view, things then were going swimmingly in the House. But the Senate was still trouble. "The one thing we had been advised against," Halvorson remembers, "was taking our lobby to the Senate because we were told that Kennedy would win. But we needed the Senate, so by midsummer we decided to go for broke."

Nelson and Stevenson Enter

Halvorson found a particularly sympathetic senator in Gaylord Nelson, the only member of the Committee on Human Resources who voted against sending the Kennedy bill, which he called "unnecessarily burdensome and detrimental to the future of this important research," to the Senate floor. Nelson had heard from University of Wisconsin geneticist Oliver Smithies and from other individuals who opposed Kennedy's bill. Halvorson and his coalition, which as one congressional aide put it, "finally got rolling like a lobby rolls," contributed a lot to Nelson's decision to write his own bill. By the end of summer, dozens of scientists

had written hundreds of letters and made innumerable phone calls to encourage members of the Senate to go along with Nelson.

Nelson's bill seemed like a recombinant DNA researchers' dream. In introducing it in the form of a substitute to Kennedy's bill, Nelson said his proposal "reflects new information"—namely, a reduced concern about risk. Nelson's bill makes HEW the lead agency in recombinant DNA regulation, provides for federal preemption of state and local laws, and contains a sunset clause. The act would expire 5 years after being enacted. Nelson introduced his substitute amendment in August, and during the late summer recess, when most of the senators had gone home, Halvorson and his troops set about contacting every member of the Senate they could find.

They discovered that there were a lot of senators who did not know much, if anything, about recombinant DNA, but who could be persuaded that a regulatory commission would be a needless new bureaucracy. According to an informal head count by Senate staffers, Kennedy was fast losing support for his own bill, even from members of his own committee who previously had favored it.

While Nelson was joining the issue with the introduction of a substitute bill, Senator Stevenson assumed an important role on another front. Stevenson is chairman of the subcommittee on science, technology, and space whose jurisdiction was somewhat diminished when responsibility for the NIH and the National Science Foundation was given to the Kennedy subcommittee on health and scientific research. Stevenson reportedly wants to expand his subcommittee's activities but opted to stay out of the recombinant DNA issue at first—partly, staffers say, because he did not know very much about it. But during the summer, Stevenson was drawn in.

For one thing, he was urged to take an interest by one of his subcommittee members—Senator Harrison H. Schmitt (R-N.M.), a former astronaut and Ph.D. geologist from Harvard, who has shown an interest in science policy since his election last year. In addition, Stevenson is said to have been very impressed with a meeting he had with a group of scientists organized through the AAAS.

Stevenson was persuaded that Congress was rushing headlong into dangerous territory with the pending recombinant DNA bills. Furthermore, he saw an opportunity for his subcommittee to become involved by holding hearings on the issue from the standpoint of overall science policy, even though he had no intention overstepping jurisdictional bounds by introducing a bill of his own.

On 22 September, Stevenson delivered what the scientists have called a "masterful" and statesmanlike" address on the floor of the Senate. He noted approvingly that scientists had called attention to the problem inherent in recombinant DNA research and, that the risk was not only hypothetical but seemed, with "new" data, to be very, very small. Then, Stevenson struck the most responsive chord of all when he called on the Senate to put off any legislative action on the matter until next session lest, in haste, it enact a bill that would compromise "freedom of scientific inquiry."

Stevenson, who now was regarded by the scientific community as clearly being on the side of the angels, held three days of hearings in November—hearings, he said, intended to provide the most thorough record of the recombinant DNA debate.

Stevenson went into the hearings on the side of the scientific establishment. Some observers bet he might even conclude no regulation is needed at all. But he came out with mixed feelings. Shortly before the hearings began, News and Comment writer Nicholas Wade reported that there had been a technical violation of the NIH guidelines at the University of California at San Francisco (*Science*, 30 September). Stevenson called the California scientists and NIH director Fredrickson to answer in the affair. The lawyer in Stevenson was plainly evident during his questioning, which was tough and legalistic. There is no doubt that the California incident affected Stevenson's thinking on the subject of recombinant DNA legislation, but how it will influence his final judgment remains to be seen. A subcommittee report on the November hearings should be released any day.

Kennedy's Change of Mind

A week after Stevenson announced he would hold hearings, Kennedy made a surprise announcement that he was temporarily withdrawing support for his own bill (though he has not withdrawn it from the Senate calendar). He could see the mood of the Congress changing and knew he was losing the votes he would need for passage of his own bill. Furthermore, Kennedy, like other members of the House and Senate, was being converted to the belief that recombinant DNA research is not as hazardous as Science for the People and other public interest groups have claimed. As early as April, Kennedy had been meeting personally with scientists who kept telling him he was overreacting to the notion of hypothetical risk. By summer, he was persuaded. Kennedy was particularly impressed by Stanley Cohen's paper. (Kennedy heard a lot about Cohen's recent work from subcommittee staff director Horowitz, an M.D., who last year was on leave from the Senate to complete a residency at Stanford. Cohen's office was across the hall from Horowitz's.)

Kennedy has not abandoned his belief in a national commission nor reversed his commitment to the idea of local option. However, his intention now is to establish a special commission to review what has occurred up to now, and to establish as clearly as possible the available "facts" about the nature and potential hazards and benefits of the research. Although he hopes to have the support of HEW Secretary Califano and Representative Rogers in naming a study commission, Kennedy is prepared to do so on his own if no support is forthcoming.

Meanwhile in the Senate, Jacob Javits (R-N.Y.), ranking minority senator on the health and scientific research subcommittee, is preparing yet another bill—one that he hopes will be an acceptable compromise between the Kennedy and Nelson positions, and one that is not likely to contain a provision for a new, autonomous recombinant DNA regulatory commission.

Rogers' Bill Still in Committee

In the House, Rogers' bill remains tied up in committee where Representative Harley O. Staggers (D-W. Va.), chairman of the Committee on Interstate and Foreign Commerce has refused to report it to the floor. Rogers and Staggers are known to have no great love for one another, and during the fall, Staggers dragged his heels whenever Rogers brought his bill up for full committee discussion. Then, at the eleventh hour, Staggers got a letter from Stanley Cohen, calling on the House to reconsider the question of legislation. Staggers seized the opportunity to block Rogers' bill, leading to acrimonious debate and continued ill will. Rogers will try again this session of Congress.

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The course of controversial legislation seldom runs smoothly, but few would have predicted 12 months ago that a year would pass with no recombinant DNA legislation at all. The sense of Congress and the biological research community now is that legislation will surely be enacted this year. But who can say?

—BARBARA J. CULLITON