

posture from FDA. Miller subscribes to the view that, except for its political sensitivity, somatic-cell gene therapy is not qualitatively unique. (This view was spelled out articulately in a background paper issued in December 1984 by the congressional Office of Technology Assessment.) Therefore Miller, who has publicly criticized the composition of the NIH working group for being heavy on ethicists and lawyers and light on basic scientists and clinicians, takes the position that physicians planning to initiate human gene therapy should simply have to file an investigational new drug (IND) application covering the experimental gene and vector. The IND would then be handled by the drug agency in a routine manner.

It is not likely that gene therapy will escape special review by some body other than the FDA but it is clear that if the proposal outlined in the 1 August memo takes shape, NIH will have to share authority with both FDA and the BSB. Meanwhile, as the result of a compromise worked out between Wyngaarden and Young, NIH will be permitted to publish the second draft of the gene therapy guidelines by adding a sentence

that states the obvious: "These 'Points to Consider' apply only to research conducted or supported by the NIH."

It is here that the issue of the continued authority and clout of the NIH RAC comes sharply into focus. NIH never has had the legal authority to regulate genetic engineering experimentation in gene therapy or any other subset of recombinant DNA research if it were done without NIH funding. Nonetheless, the RAC has been widely looked to as a source of expertise on both technical and policy questions and its moral authority and influence have gone well beyond its literal mandate. What is feared is that if the new Biotechnology Science Board is given broad authority, the RAC will be effectively reduced to a science advisory body for NIH alone and that the complex issues of ethics and policy that it has grappled with in the past may no longer fall within its scope.

The proposed BSB would look very much like the RAC. Like the RAC, it would have 25 members. Ten would be drawn from the agency-based genetic engineering advisory committees in the five agencies under BSB jurisdiction. Initially, "ten present or former mem-

bers of the NIH RAC will be selected . . . to ensure continuity with the experience and exemplary past performance of the RAC." Later, agencies would submit a list of candidates in addition to those that officially represent them on the BSB. Final selection would then be made by the assistant secretary for health who, under this plan, would assume substantial consolidated authority over recombinant DNA research.

The plan, which will be published for comment in the *Federal Register* before it is a fait accompli, has its advantages. Clearly some coordination is needed within the government as opportunities to use genetic engineering in a host of areas mount. Clearly NIH eschews a government-wide role in any but an unofficial, advisory capacity. And yet, with the BSB existing as a clone of RAC and vested with full authority to oversee the decisions of the RAC, it is inevitable that the influence of the RAC will yield to that of the BSB, long before it is demonstrated that the BSB will work effectively as a supreme court rather than being reduced to an arena where interagency turf battles will dominate. It is something of a gamble.—BARBARA J. CULLITON

Congress to Review Chinese Nuclear Trade

The White House has found the China pact to be in compliance with weapons control laws; some congressmen spot loopholes

After aging 15 months in the State Department's files, an agreement allowing nuclear trade between the United States and China has been endorsed by the President and sent to Congress for approval. If it is cleared after a 90-day review (the clock runs only when Congress is in session), it will open the gate to trade said to be worth between \$500 million and \$8 billion for hungry U.S. manufacturers. The lower estimate may be closer to the mark, skeptics on Capitol Hill say, partly because European competitors had early access to the market and got the first commitments.

On 24 July the President sent the text of the U.S. agreement to Congress for approval, and on 31 July the House Foreign Affairs Committee held a preliminary hearing. The Senate Foreign Relations Committee will take it up after the August recess.

As the agreement aged, it gained favor. Some in the Administration found it unpalatable in April 1984 when it was drawn up, for explicit reports were circu-

lating that China had helped and possibly was still helping Pakistan develop nuclear weapons. The Nuclear Non-Proliferation Act (1978) bans nuclear trade with countries that help others join the nuclear club. Pending a "clarification" from China, the Administration set the agreement aside.

Since then, China has brought its policy into line with U.S. norms, according to Richard T. Kennedy, the State Department's ambassador-at-large for non-proliferation policy and negotiator of the agreement. In the last year China also seemed to step up the pace at which it signed nuclear cooperation pacts with the Europeans and Japanese, which may have goaded the Administration as well. Among those who have signed or are negotiating agreements with China are Argentina, Belgium, Brazil, Britain, France, Japan, and West Germany.

Not a word of the document has been changed since President Reagan and Chinese Prime Minister Zhao Ziyang initialed it in April 1984. Nor have the

Chinese offered to put in writing their pledge to adhere to U.S. standards. This has caused modest trouble in Congress. Ambassador Kennedy is now trying to persuade doubters that Chinese officials have shown by word and deed in the last year that they will be responsible nuclear partners.

Opposition is expected to come in two forms: ideological and legalistic. According to congressional staffers, Senator Jesse Helms (R-N.C.) will lead the ideological charge, carrying the banner of the Republican right wing. Here the complaint is not with details but with the perceived strategic folly of lending aid to a communist power. Helms sits on the Senate Foreign Relations Committee and will coordinate the assault from there. The conservative opponents will be few but vocal.

Ironically, the Administration may find it harder to deal with these fellow travelers than with liberals from the Democratic party who fault the agreement on legal grounds. The second group

is upset by what it considers a bad precedent in this agreement, another in a series of policy retreats by the Reagan Administration that weakens the credibility of the international nonproliferation program.

The Democratic critics are led by Senators Alan Cranston (California), John Glenn (Ohio), and William Proxmire (Wisconsin). Cranston and Glenn have specialized in nonproliferation issues, and Proxmire is the sponsor of an amendment passed this year that will complicate Congress's role. This 1985 amendment to the Export Administration Act requires that the foreign affairs committees vet nuclear agreements for compliance with export legislation. In this case, the President has said the China document does not require a waiver of any item in U.S. law. If the foreign affairs committees disagree, the Administration is allowed several options, including resubmitting the document with a waiver attached. With no waiver, the President prevails unless Congress raises a two-thirds vote in both houses. With a waiver, majority approval is needed.

The first congressman to level his guns on the agreement was Representative Edward Markey (D-Mass.), an adversary of nuclear power in all forms and chairman of the House subcommittee on energy, conservation, and power. Speaking before the House Foreign Affairs Committee, he criticized the "fuzzy" language of the agreement and the lack of a firm commitment by China to cooperate in nuclear material controls. He said President Reagan should apply to Congress for a waiver.

The agreement does not ask China to submit to inspection and monitoring "safeguards" by the International Atomic Energy Agency. The IAEA system is designed to track reactor fuel and keep it from being diverted to military uses. Instead, the Chinese promise to engage in "mutually acceptable arrangements for exchanges of information and visits . . ." with the United States. Nor does the agreement ask China to seek prior consent from the United States before reprocessing or exporting U.S.-controlled material, as is normally required. On this point, the text says that neither signatory intends to do any reprocessing of fuel covered by the agreement, but that if either should change its mind, "the parties will promptly hold consultations to agree on a mutually acceptable arrangement."

An aide to Ambassador Kennedy, Allan Labowitz, stresses a point the State Department has made throughout: that China is a nuclear weapons state and by

law not bound to accept IAEA safeguards. Other major weapons states have offered to submit to some IAEA inspections, however. So China's acquiescence to "visits" and "exchanges of information" is described as a similar gesture of goodwill. The package of materials sent to Congress also concedes that the "text of the provision" dealing with America's prior consent rights on reprocessing is "different from the formulations in previous agreements," but asserts that "the effect of the provision is that none of the activities may be under-

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taken unilaterally; prior approval of the United States is required." Some doubt this assertion.

The State Department cites extralegal documents to bolster the case for China. Some but not all are on the public record. A few legislators are skittish about passing on China's compliance when the Chinese have been accused of violating U.S. standards in the past, and, as an aide put it, "they have been noticeably reluctant to disclaim prior actions." Furthermore, there are specific answers to some of Congress's questions in secret annexes and memos submitted by the State Department, but Congress has been forbidden to quote them publicly. These include a memo by Kennedy describing Chinese nuclear policy in favorable terms, but including no written endorsement by the Chinese. And there is a classified letter of approval from the U.S. Nuclear Regulatory Commission, which—according to a staffer there—clears China for adhering to the letter but not the spirit of the law.

China has taken some notable public steps to reassure the West that it does not intend to help the Third World gain nuclear weapons. In January 1984, China became a member of the IAEA. Also that month, Prime Minister Zhao gave a toast at the White House to the effect that "China does not advocate nor encourage proliferation. We do not engage in proliferation ourselves, nor do we help other countries develop nuclear weapons." He repeated the statement to the Sixth Peoples Congress, and it was endorsed and published later in 1984. In

addition, in 1985 China accepted IAEA safeguards in nuclear agreements signed or in negotiation with Argentina, Brazil, Japan, and West Germany.

An aide to Markey says, "There is no denying that there has been a significant change in China's historic perspective" on nuclear power, and that the United States has brought about an improvement. China has moved away from its policy of the 1960's, which described nuclear weapons as a tool for liberating the Third World. In the last 2 years China has also disavowed the policy of the 1970's, which was to give selective nuclear assistance to allies. Nevertheless, several congressional aides express an uneasy feeling that these changes, which have yet to be tested fully, may have come at a high price for the United States. The cost is measured, they say, in the erosion of the legal principles on which the nonproliferation laws are built.

Ambassador Kennedy told Congress on 31 July that "There are very substantial benefits to be derived from this agreement." The economic benefits have deflated with the passage of time. The first reports noted that China wanted to build eight or ten big reactors by the end of the century and predicted that the trade would be worth \$20 billion. Now, as it turns out, the Chinese would like to buy two to five complete reactors from foreigners and build the rest themselves as copies. The optimistic trade estimate has slipped down to between \$6 and \$8 billion. Warren Donnelly, a nonproliferation specialist at the Congressional Research Service, points out that the true nuclear component of this trade could be as low as 20 percent, not enough to transform the sagging American nuclear industry.

One of the unanswered questions is, how will China pay for its nuclear equipment? The United States and China are already quarreling over the level of Chinese textile exports to America, but at the moment China produces few commodities with which to earn U.S. cash. Private financiers are likely to be skittish about investing in Chinese construction projects. And while France and West Germany may be willing to provide direct government loans to finance nuclear exports, the Reagan Administration would have difficulty justifying such subsidies.

At this writing, the agreement's economic outlook seems cloudier than its political future. While Congress may ask some probing questions along the way, there is little doubt that it will eventually give its approval.—ELIOT MARSHALL