

swayed the agency is protest from right-to-life groups such as the American Life Lobby and National Right to Life Committee. The conservatives' objections are based on the belief that Depo-Provera is a dangerous medication and also that Upjohn sells products that cause abortion. An AID official denies that the right-to-lifers were influential.

Upjohn's Gordon Duncan says the company has persisted in seeking FDA approval because it believes Depo-Provera is "a good drug. There is a reason-

able population of women who want Depo-Provera." Upjohn insists that the drug's market potential is modest.

But information about the contraceptive market suggests that the economic stakes are tantalizingly large. The international market for oral contraceptives alone totals roughly \$700 million annually. Population groups estimate that a significant percentage of women who use the Pill will switch if FDA approves Depo-Provera. The drug will also attract first-time users of contraceptives. About

1.5 million women outside the United States now receive the injectable contraceptive and the figure could shoot up by as much as 50 percent within 5 years after FDA approval, according to the Population Crisis Committee.

The value of Depo-Provera sales has already reached approximately \$25 million, according to market analyst Arnold Snider of Kidder, Peabody and Company in New York. He adds that contraceptives are very lucrative. Oral and injectable methods "have an incredible profit margin." They are "among the most profitable of all pharmaceuticals."

Whether the FDA will approve Depo-Provera is unclear. Commissioner Hayes may be willing to accept a greater margin of risk than his predecessors, given his voting record on aspartame. Although a Board of Inquiry advised him not to approve the sweetener, Hayes ruled in favor of the drug. He said at the time, "It is wrong, and I'm not just singling out aspartame here, to say well let's just wait further and further for more evidence or a unanimous opinion. The question is, are you really trying to assure a zero risk? . . . I do not think most people expect zero risk" (*Science*, 28 August 1981, p. 986). But Hayes' aspartame ruling may or may not be a clue to his verdict on Depo-Provera. Wolfe and others are hoping Hayes concludes the drug presents an unacceptable cancer risk.

The agency is charged with weighing the risk-benefit ratio only for American women, a fact that provides little comfort to developing countries clamoring for the drug. Kennedy, during his FDA tenure, stated that other countries must take into account their individual needs despite his verdict not to approve the contraceptive. In addition, he suggested that AID modify its export policy or that Congress initiate export reforms. He argued that if other nations request the drug and AID clearly explains FDA's reservations, AID could then be of assistance. Such a policy should help shield the United States from accusations of adopting a double standard on drug safety.

But AID continues to be faced with a delicate political situation. Cynthia Green of the Population Crisis Committee says that the Reagan Administration most likely does not want to risk raising the ire of the right-to-life groups. Kennedy perhaps put his finger on the solution when he said, "The right way to solve this policy dilemma is by an export policy that recognizes national differences, and allows national autonomy in the making of decisions about health."

—MARJORIE SUN

## ISABELLE Spending Questioned

The Department of Energy's (DOE's) inspector general has raised questions about some \$25 to \$30 million that is being spent on the ISABELLE accelerator at Brookhaven National Laboratory. Although work on ISABELLE will be halted in fiscal year (FY) 1983, pending a decision on whether to complete the project, Brookhaven has been spending its FY 1982 money as if the accelerator were going to be completed as originally designed, the inspector general claims.

Chiding DOE's Office of High Energy and Nuclear Physics more than Brookhaven, the inspector general's report calls for a plan to guide ISABELLE activities through the rest of FY 1982 and 1983. Brookhaven provided DOE with such a plan in May, and it was approved last month. The inspector general's office says it is mollified.

There are two main issues. The first is the alleged improper guidance by DOE's high energy office to Brookhaven. DOE's FY 1983 budget submission, prepared last October, contained nothing earmarked specifically for ISABELLE. Some \$23 million was included for R & D on superconducting magnets for a future accelerator. DOE should have informed Brookhaven last fall of the budget situation and to ensure that no FY 1982 money was spent on items that were so ISABELLE-specific as to be wasted if the accelerator was terminated, argued the report.

In fact, the situation was somewhat less clear-cut because the controversial ISABELLE project was not definitely excluded from FY 1983 funding until mid-January. One of the items holding up a decision was a study by the subpanel of the High Energy Physics Advisory Panel. The physicists reported in November that ISABELLE should be completed only if the high energy budget was raised dramatically. Although the proposed FY 1983 level of spending was \$59 million below the amount recommended, the physicists had indicated a willingness to accept a partial budget increase as a sign of good faith toward the full amount in 1984.

The second issue is what constitutes appropriate superconducting magnet R & D? DOE's high energy office and Brookhaven had agreed that the laboratory should assemble and test a section of the full accelerator ring, specifically a sextant comprising some 100 magnets. Among other things, this would require the purchase of the full ISABELLE liquid helium refrigeration system for cooling the magnets.

The inspector general's office suggested that testing of a shorter string of magnets would be more in line with the intent of the FY 1983 Brookhaven budget, in part because making and testing too many ISABELLE magnets would commit the laboratory to a particular design that might not be suitable for an altered ISABELLE or other accelerator. The inspector general's report identified an estimated \$25 to \$30 million of Brookhaven expenditures that seemed to be more specific to ISABELLE than generic to superconducting magnet R & D, or that were not immediately needed.

With a management plan in hand, the affair seems to be over. The director of DOE's Office of Energy Research was "generally responsive" says the report.—ARTHUR L. ROBINSON