

tron Cancer Therapy facility (*Science*, 15 October, p. 329)—appears to have ended in victory for opponents. Conferees crafted language that says DOE should fund the project only if there is extra money in its budget, an unlikely prospect.

■ **NASA.** Space boosters would normally be breathing a sigh of relief over this year's moderate 6% increase (\$424 million) for NASA's research and development budget (*Science*, 8 October, p. 173). But the fate of the space station remains a question mark for

NASA, whose supporters are also worried about the sudden ability of Congress to kill large high-tech projects such as the SSC and the Advanced Solid Rocket Motor (*Science*, 22 October, p. 499).

"I don't think people realize how close we came to losing the space station this year," says Lori Garver, executive director of the National Space Society. The House this summer kept the international project alive, by one vote, after the Clinton Administration rolled out its big lobbying guns, but the ever-changing station is being redesigned

once again, this time with the Russians in mind. Garver predicts that the new partner will appeal to some wavering legislators, but any loss of U.S. jobs that results from the collaboration could make the space station even harder for Congress to swallow next year. And that leaves space scientists wondering about the impact of the station, which now consumes about one-seventh of NASA's budget, on future NASA appropriations.

—Jeffrey Mervis, Christopher Anderson  
and Eliot Marshall

## EPIDEMIOLOGY

### Women's Health Initiative Draws Flak

The Women's Health Initiative, the largest clinical study ever undertaken by the National Institutes of Health (NIH), began recruiting test subjects at 16 clinics this fall to participate in an ambitious attempt to explore the causes of disease among older women. But just as the long-planned study is finally getting off the ground, a panel of medical experts has concluded that it may never achieve its goals. The panel said it is highly unlikely that the \$625 million study will stay within budget or find solid evidence linking low-fat diets to a reduction in breast cancer rates—its primary concern. The panel urged that the study be changed to emphasize other health issues, and that its monitoring methods and informed consent procedures be improved.

The unusually critical review, requested by a cost-conscious House appropriations subcommittee, came out on 1 November. Authored by a special panel at the Institute of Medicine (IOM), the review stops short of calling on NIH to abandon the clinical trial at the center of the initiative. But panel members had harsh comments about the feasibility of the trial, designed to collect data on the diets and illnesses of 63,000 women between age 50 and 79. Lynn Rosenberg, an epidemiologist at Boston University and a member of the review panel, explains that "it's a very weak hypothesis that changing the diets of women in their fifties, sixties, or seventies will influence their risks" of getting breast cancer. Furthermore, the logistics of testing this hypothesis are "extremely difficult," according to Rosenberg, because it is hard to keep people on low-fat diets and collect accurate data over 10 years.

Similar criticisms have been leveled in the epidemiology community for months (*Science*, 7 May, p. 744), but the Women's Health Initiative has been popular since Bernadine Healy, former director of NIH, launched it in 1991 as part of a general effort to improve the status of women in medicine. One of her goals was to redress a bias in NIH-funded clinical studies, which have focused

on men. The project has three parts, the largest of which is the clinical trial. In addition to looking at diet and breast cancer, it is designed to test for a variety of dietary and drug effects, including the apparent benefits of hormone supplements in reducing heart disease. A related "observational study" is designed to collect unspecified data on a variety of topics, and the "community prevention trials" are meant to instruct low-income and ethnic groups in healthy lifestyles. The entire project is being designed and run by the NIH director's office and managed through contracts with 45 clinics around the country.

The IOM panel took issue with some of the basic goals of this network of projects. The panel urged NIH to:

■ De-emphasize research on fat as a cause of breast cancer and concentrate on other parts of the initiative that stand a better chance of producing scientifically valid results, such as the effect of diet on heart disease and colorectal cancer or the risks and benefits of hormone supplements. More women are likely to be affected by heart disease, and the statistics are likely to be stronger.

■ Write better consent forms. For example, volunteers who join the study section focused on hormone supplements should know that they could be given a placebo, and that this could result in bone loss.

■ Do better planning. Two parts of the initiative—the observational study and the community prevention trials—are still poorly defined, according to panel member Joanne Lynn, professor of medicine at the Dartmouth Medical School.

■ Develop a more rigorous monitoring system that would allow the agency to terminate the study early—after 7 or 8 of its planned 14 years—if the results on the diet elements of the project are not promising.

**"It is a very weak hypothesis that changing diets of [older] women will influence their risks."**

—Lynn Rosenberg

The panel appears to have been divided between those who felt these comments should be presented in an optimistic light and those who were in favor of using strong language. According to the chair, Marion Finkel, vice president for drug registration at the Sandoz Pharmaceuticals Corp., "There wasn't total agreement among members." In the end, the skeptics held the majority, though the final report, she says, represents a "consensus." One member of the team that wrote the report says a "sunny" draft was scrapped and replaced with a harsher version.

Healy is characteristically unconcerned by these attacks on one of her best-known legacies. In a phone interview from Ohio, where she's running for the Senate, Healy called the study

"magnificent." She argues that evidence is evenly balanced on the diet-cancer question, and it deserves a large trial. Furthermore, she says, this is just one of several facets of the study. It would be a "serious mistake" to back off now, just because "a handful" of skeptics don't like the study, she says.

NIH leaders are also putting a good face on the report. "We interpret it as a positive report," says William Harlan, associate NIH director for preventive health and director of the Women's Health Initiative. It could have been worse. He finds encouragement in the fact that the report "says the study should continue," and adds that "we are looking at their suggestions very carefully." Harlan says the investigators have already decided to improve the consent forms and provide for an interim review of the project in 2002.

Still, Harlan says that NIH has no intention to shift the main theme of the study away from diet and breast cancer. But that could change after the House appropriations subcommittee finishes digesting the report.

—Eliot Marshall