FUSION RESEARCH

European Report Champions ITER

While the scientific underpinnings of the International Thermonuclear Experimental Reactor (ITER) program are under attack in the United States (see previous story), the $10 billion project continues to gather momentum in Europe. A panel of scientists and industrialists has given the European arm of the effort a resounding pat on the back.

"We have really been very much impressed by progress that has been achieved in the last 5 years," says Sergio Barabaschi, science adviser to the Italian government and chair of the panel. The European Commission, the executive arm of the European Union (EU), last year appointed the eight-strong panel to assess both scientific progress and ITER's management. According to the panel's report, expected to be published soon, its members were impressed by research progress since the previous evaluation in 1990.

The report endorses the ITER concept as it stands now, stating that a smaller reactor than currently planned—a strategy favored by some scientists—would be a poor choice because the aim is to build a reactor as close to a commercial, power-generating machine as possible. The board also believed that the demonstration reactor should be based in Europe, which would require an increase of at least 50% in EU funding for its fusion programs, now at $285 million a year, in the first decade of the next century. Italy is the only European country that has expressed a desire to host ITER.

On the technical side, the board suggests that the collaboration investigate stellarator technology as a possible alternative to the currently favored magnetic-confinement option, as scientists cannot be certain which will work best in a large reactor. Both techniques confine the plasma in a toroid-shaped vessel with magnetic fields, but in the current ITER design, the fields are pulsed and the confinement aided by a current circulating within the plasma. A stellarator operates in a steady state, and all the heating and confinement comes from outside.

On the management side, the board was impressed at how well the EU's fusion program has coordinated research in different member states, says Barabaschi. But the board admits that ITER has an image problem: Because of its huge cost and technical complexity, the project constitutes a "democratic dilemma." The board suggested that some money be spent on research on the economic and political aspects of fusion and public awareness.

–Alexander Hellemans

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FDA SCIENCE

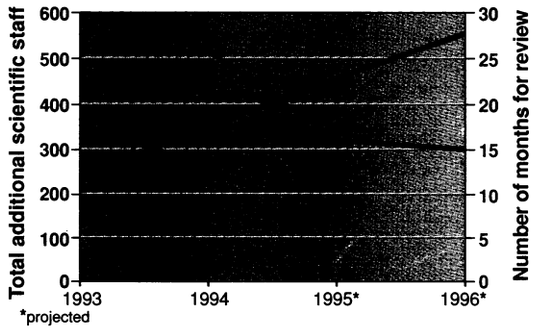
Kessler's Legacy: Unfinished Reform

At first blush, this month's third annual conference on in-house research at the Food and Drug Administration (FDA) will look like a typical scientific gathering. But accompanying the presentations and posters will be a new slate of awards for innovative research—an attempt to raise the spirits of a group that some critics in Congress and elsewhere say shouldn't exist, and which FDA Commissioner David Kessler has fought hard to strengthen. Now, the issue is one that Kessler's successor will have to face: Last week, Kessler announced that he would step down after six hectic years as FDA commissioner as soon as his replacement is chosen and confirmed.

Kessler, who will probably be remembered most for his campaigns to regulate nicotine as an addictive drug and to improve food labeling, admits that the job of improving the agency's science remains unfinished. Indeed, the agency has just embarked on a 5-year plan that would consolidate research at its 19 labs scattered across the country into as few as five. Still, his colleagues praise his efforts to define and elevate agency research. "He has had more impact on science than any of his predecessors," says Philip Noguchi, a 16-year veteran of the agency and current director of the cellular and gene-therapies division at FDA's Center for Biologics Evaluation and Research.

Kessler's departure comes at a time when FDA's $190 million research portfolio is under scrutiny by a Congress intent on reforming the entire agency. "It's a basic question of whether research is really FDA's role," says Carl Feldbaum, president of the Biotechnology Industry Organization (BIO). Feldbaum maintains that many of FDA's activities, including research, should be contracted out. Kessler argues, however, that FDA scientists will be better regulators if they also conduct cutting-edge research.

When Kessler arrived at FDA during the Bush Administration, he faced widespread criticism that neither FDA's science nor its regulatory machinery were working well and that the agency was too slow in approving new drugs. After lengthy talks between industry groups and FDA, Congress authorized the agency to collect fees from companies that file new drug applications. These "user fees" have been spent on hiring more than 500 new scientific staff—from microbiologists to statisticians—to review applications.



SOURCE: FDA/BIO

Helping hands. User fees have allowed FDA to hire more scientists and speed up the drug approval process.

The additional staff have helped lower the time needed to act on a new drug application from an average of 30 months in 1992 to 17 months in 1995. This is a "major accomplishment," says Louis Lasagna, dean of the Sackler School of Graduate Biomedical Sciences at Tufts University. For anti-cancer and AIDS drugs, it's a brisk 6 months.

Another key issue confronting Kessler was how to bring research at the agency's National Center for Toxicological Research (NCTR) in Jefferson, Arkansas, in line with agency needs. "It used to be out there doing its own work that wasn't relevant to the agency," Kessler says. His response: Every proposed project at NCTR must contain a statement justifying its relevance to FDA's mission. He also brought in toxicologist Bernard Schwetz from the National Institutes of Health as NCTR director and, later, also named him to the new position of associate commissioner for science. Schwetz helped to forge scientific collaborations across FDA's five product centers in suburban Maryland on subjects ranging from tissue engineering to emerging infectious diseases. "We have a lot of very good scientists, but what we haven't had is a common framework to work from," says Noguchi. Last year, Kessler lured Michael Friedman from the National Cancer Institute to become deputy commissioner for operations and to revive the agency's moribund science board, which coordinates the agency's in-house research.

Kessler has had less success in improving communication between agency reviewers and drug-company representatives. Although approval times have shrunk, companies see the FDA as part of the reason for the increasing cost and time spent on R&D, now estimated at 10 years and $500 million per drug. Company officials complain of poor commu-