portant to reduce health care costs with new materials," Bonfield says.

Richmond is believed to be concerned about the long-term commitment to IRCs, which receive funds for 6 years, with a review after four. A molecular biologist, he is less wedded to the idea of big science than some of his predecessors at SERC have been. Some research groups have become IRCs when they might have been better supported by smaller grants, Richmond says. He is enthusiastic about shifting money from big projects to small grants and studentships. "I think that's the way in which really bright young scientists emerge," he told reporters.

The budget crunch and the emphasis on small grants may endanger some collaborative projects that the U.K. has a current or planned role in. Participation in the efforts to build a new 8-meter telescope, for example, may go down the tubes. Two schemes are under consideration, one involving the U.S. and Canada, the other Spain. But while Britain's tab for either project is likely to be around £20 million, the immediate savings if it is scrapped are minimal—around £1 million. Likewise a planned Anglo-German gravity wave detector, pencilled in at £5 million, offers no savings now, because the money was not due to be spent for a couple of years.

Other ventures that might wind up being axed are collaboration in Lyman-FUSE, the U.S.-Canadian far-ultraviolet telescope, and Spectrum-X, a joint Soviet-European x-ray astronomy mission; Britain's part in the European Space Agency program; and the neutron source at the Institut Laue-Langevin (ILL) in Grenoble, France. ILL costs SERC £8.5 million a year, and the collaborative agreement with France and Germany is due for review next year. SERC already has a neutron source, Isis, at its Rutherford Laboratory, and Richmond wants SERC to take a hard look at its participation in ILL.

None of these dire scenarios, however, will come to pass immediately. SERC has set up "mini-policy groups" in each of its five subject boards to find savings now and examine future options. The policy groups will then put their suggestions to the full council. A meeting is scheduled for 19 December, but sources say it looks "increasingly unlikely" that any review will be available then. SERC's council is not due to meet again until February. ■ JEREMY CHERFAS

Parallel Track: Where Should It Intersect Science?

Boston—By now, most scientists are aware of the heartrending conflicts involved in AIDS drug testing—the tension between the need for solid clinical information and the desire to provide hope for dying patients. Many biomedical researchers hoped mechanisms such as "parallel tracking" would resolve the tension—scientific data would be collected as usual in clinical trials while promising therapies were made available through simultaneous release in exchange for an agreement by physicians that some data would be collected on that track as well. But, as a novel conference called "Expedited Access to Unproven Pharmaceuticals: Risk, Regulation, and Personal Autonomy" revealed last month, parallel tracking raises as many questions as it answers.

In particular, there was sharp debate at the meeting between AIDS activists and researchers over how much data should be collected on the parallel track. Activists, it turns out, fear innovative programs may grind to a halt as physicians struggle to cope with the paperwork required by data collection. Furthermore, clinicians at the conference were told that parallel tracking represents a fundamental shift in the accepted model of drug testing—a shift in which patients assume far more of the risk of unproved drugs.

Developments like these could turn traditional drug trials into anachronisms in the case of life-threatening diseases. The standard model for drug testing includes small phase I studies to evaluate safety and dosage; randomized phase II clinical studies of effectiveness; and large phase III trials to compare the drug to others. Rigid adherence to that system is a "sacred cow needing to be knocked down," says Thomas Chalmers, associate director of the Technology Assessment Group at the Harvard School of Public Health.

In fact, the sacred cow is already on its knees, as has been apparent since AZT was given free of charge to thousands of AIDS patients, largely through the efforts of AIDS activists, while clinical trials of the drug continued. The first such release was carried out under an existing FDA mechanism for expanded release called a treatment IND. Parallel tracking will expand the FDA exception and institutionalize it by making new drugs available to people with HIV-related disease who can't participate in a clinical study because they don't meet eligibility requirements or don't live near a trial center.

> ***"If I had malignant melanoma. . .I would want access to [an experimental] drug, even though it might kill me."***
>
> —LOUIS LASAGNA

But despite all the publicity it has received, the parallel tracking system has not yet been formally instituted. Instead, the surgeon general's office published a draft report on it last May. That report, Assistant Surgeon General James Allen said at the conference, has elicited more than 1200 comments, the majority amounting to "Sounds good. Go ahead." For the moment, however, Allen said, "The closest thing around to parallel track" is the program of expanded access to the anti-AIDS drug dideoxyinosine (ddI). And that program is seen differently by activists and researchers.

Since expanded access is aimed at treatment—not research—little data should be collected, Mark Harrington, an activist with ACT-UP, argued at the Boston meeting. Harrington claimed that physicians administering ddI under the current expanded access program had been overwhelmed by efforts to collect the data they had been asked to gather.

Researchers had a different concern. "It would be a shame," says Susan Ellenberg, "to waste the opportunity to collect some simple data on adverse drug reactions, safety and simple efficacy." Ellenberg, who heads the National Institute of Allergy and Infectious Disease's AIDS biostatistics research board, notes that before ddI went into expanded access, fewer than 100 patients had been taking it in clinical trials—a sample so small that fatal toxicities might have been missed. In expanded access almost 14,000 people have received the drug.

One solution to some of these problems might be to come up with a third track—a parallel track version of clinical trials that is compatible with expanded access. Such an effort was recently made by Ellenberg and 21 of her colleagues, led by David Byar, director of clinical trials at the National Cancer Institute (NCI). In a recent paper in *The New England Journal of Medicine*, that group called for large, simple trials of

AIDS drugs that would enroll almost anyone who wanted to participate. Such trials, focusing on straightforward questions of effectiveness and safety, might be better for the patient community and provide more generalizable results, Ellenberg told the conference.

One example is a trial planned by the Community-Based Clinical Trials Network to test the effectiveness of the drug pyrimethamine against toxoplasmosis, a parasitic disease characteristic of AIDS. Anyone who is HIV positive, has been exposed to toxoplasmosis, and has a T-cell count below 200 will be accepted, according to Cal Cohen, medical director of Community Research Initiative New England.

Whatever method is finally adopted for testing AIDS drugs, all systems that allow expanded access to drugs before they are finally approved have this in common: They increase the risk of toxicity or unexpected side effects in the patient population. Until now, the FDA philosophy was to minimize risk to all patients absolutely, but AIDS patients have taken the lead in saying that they want the option of taking some increased risk if the payoff is access to a potentially effective agent.

Louis Lasagna, director of the Center for Drug Development at Tufts University, recounted the story of interleukin-2, a growth factor that the FDA recently denied approval to as a treatment for two types of cancer that don't respond to other drugs. Although treatment with IL-2 could kill some patients, in others it caused a "magical melting away" of lesions, Lasagna said. "I can say," he added, "that if I had malignant melanoma all through my body, I would want access to that drug, even though it might kill me."

In the end what the conference made clear was that although expanded access was a significant victory for AIDS activists and a fundamental change in the usual way of doing business in clinical research, it is by no means a simple solution. And, the consequences might ultimately change clinical trials not only in AIDS and cancer but in many diseases. ■ **P. J. SKERRETT**

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NIH Panel: Bovine Hormone Gets the Nod

No drug has ever been subjected to as much scrutiny before being approved by the Food and Drug Administration as bovine growth hormone. And few drugs have generated as much controversy. In an effort to still the debate, Congress earlier this year called on NIH to appoint an independent panel to examine the available data and pronounce on the safety of a genetically engineered version of the hormone, known as recombinant bovine somatotropin (rBST), which is intended to increase milk production in cows. Last week, the 12-member blue-ribbon panel did just that. Its verdict: safe as milk.

"The evidence clearly indicates that the overall composition and nutritional quality of milk and meat from rBST-treated cows is equal to that from untreated cows," said panel chairman Melvin Grumbach, chairman emeritus of pediatrics at the University of California at San Francisco."

But the critics still aren't satisfied. Even as Grumbach announced the panel's findings at a press conference last week, rBST opponents in the audience interrupted him to say that the panel's conclusion was based on incomplete information because the companies that make the hormone won't release raw data from their studies. "Essentially, the panel has examined sanitized data of industry scientists and their indentured academics," charged Samuel S. Epstein, a physician and professor of occupational and environmental medicine at the Illinois College of Medicine, who has been carrying on a vocal crusade against FDA approval of the hormone along with a handful of other scientists and environmentalists, including Jeremy Rifkin.

The NIH consensus conference at which the panel announced its findings was an unusual affair. Although similar consensus development conferences have been held on medical techniques and drugs, they are almost always held after FDA approval, a move not expected for several months in the case of rBST. But at the behest of Congress, NIH put together a group of scientists, veterinarians—and a lone dairy farmer with no vested interest in the hormone.

This group met for three days last week at the NIH campus in Bethesda, where they listened to scientists, consumer activists, and drug company officials testify about the effects of rBST on the health of human beings and cattle. The panel also reviewed published studies but was unable to see the unpublished data because by law the FDA cannot release it until making a final decision. And the drug's manufacturers (Monsanto Agricultural Co., American Cyanamid, Elanco—an Eli Lilly subsidiary—and Upjohn) have refused to release the raw data, arguing that it includes propietary information and that there is so much of it that the committee couldn't possibly analyze it all.

The panel conceded that its conclusions may have been compromised by the absence of the unpublished data held by the manufacturers. Yet they saw enough, the panelists said, to conclude that rBST does increase milk production and that milk and meat from treated cows is safe for human consumption. Furthermore, "based on the data reviewed by the committee," the hormone "does not appear to affect appreciably the general health of dairy cows."

The effect on the treated cows has, in fact, been a contentious subject. Epstein, who has obtained leaked portions of the unpublished studies, claims they show that cows dosed with the hormone have an increased incidence of reproductive problems and mastitis (inflammation of the udder), a common and costly bovine disorder. And that could have an effect on the health of people who consume their milk if treated cows get more antibiotics and fertility drugs than untreated cows.

NIH's panel admitted that they didn't have enough information to settle the question of whether rBST does in fact cause mastitis. But the FDA is now attempting to resolve that question—and they're dealing with the full array of data: studies of some 20,000 cows who have received the hormone, including a pile of documents from Monsanto 67 feet tall.

The critics also expressed concern over published studies indicating that milk from cows who got rBST had elevated levels of a second growth hormone called insulin-like growth factor-I (IGF-I). The panel recommended further study of the effects of IGF-I on human health, but added that it felt there is little to worry about, since the levels in milk are less than those generally found in adults' saliva.

Although this doesn't convince Epstein, Rifkin *et al*, it has made a believer—almost—of the panel's lone dairy farmer: "I've never used it," says James Clark, Jr. of Ellicott City, Maryland. "But I'd consider it." ■ **ANN GIBBONS**