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

NIH panel: bovine hormone gets the nod

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