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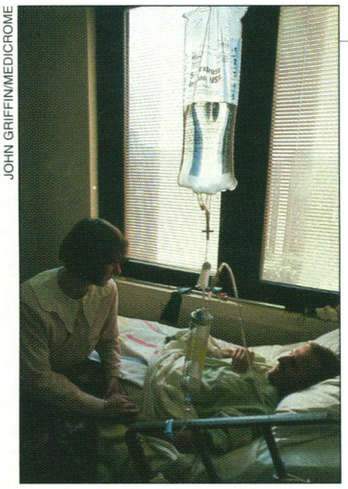

JOHN GRIFFIN/MEDICROME

**Looking for signs.** FDA will monitor ill effects of drugs on AIDS patients and other minority groups.

## FDA Mandates Diversity Data on Drugs

In May the Food and Drug Administration (FDA) made it clear to pharmaceutical firms that clinical data on prospective drugs, which has tended to focus on adverse effects in men, would have to include effects on the other half of the population—women (*Science*, 7 May, p. 743). Now FDA wants to go further: Starting next year, FDA-funded databases on adverse drug effects must include data on specific minority populations.

FDA has kept some 1 million case studies of adverse drug effects reported since 1969 in case an approved drug is belatedly found to harm patients. But because FDA epidemiologists don't want to rely solely on their own statistics, the agency has spent about $1 million a year since the late 1960s for access to several databases kept by U.S. hospitals and universities.

This year, however, FDA has placed some specific demands on grantees. "We want access to definable populations" such as pregnant women or nursing-home residents, says FDA epidemiologist Sandra Kweder. Other essential elements: data on ethnic groups and on AIDS patients, who often take drugs, or drug combinations, rushed through the FDA approval process. Patient advocacy groups have praised FDA's move.

## FDA Examines Industry–Researcher Ties

Can a researcher's financial stake in a drug company subvert his ability to conduct a fair clinical trial of that firm's drug? This week the Food and Drug Administration (FDA) took its first public step toward developing new rules on financial conflicts of interest by asking the agency's science board to discuss the topic at a meeting in Bethesda, Maryland.

Concerns about scientists' financial ties have blossomed with the growth of the biotechnology industry. Some institutions have taken a tough stand on industry affiliations—last October, for example, Stanford immunologist Irving Weissman resigned his position as a Howard Hughes Medical Institute investigator after Hughes objected to his involvement with SyStemix Inc., a company he cofounded (*Science*, 12 February, p. 884). The question for FDA, says Carol Scheman, FDA's deputy commissioner for external affairs, is whether "an investigator's financial interests can change the clinical process."

FDA

Carol Scheman

First under the magnifying glass are biotech companies, which, unlike big pharmaceutical firms, often are strapped for cash and choose to compensate clinical researchers with stock or other equity. This leads to a situation in which, says Scheman, if trial results "are positive, you're a millionaire; if negative, you lose your house."

The science board was expected to provide "general advice"; a rule may come later as part of a "certification" program to ensure the integrity of clinical data submitted to the agency. Although FDA officials believe equity holdings can influence trial results, they don't think such bias is always rooted in avarice. "It may be a desire for fame, or simply to please the drug company," says one administrator.

## Biodiversity Treaty May Face Senate Fight

Signing the Convention on Biological Diversity on 4 June was just the first step toward a functional "biodiversity treaty" for President Bill Clinton. Now the treaty must be ratified by the Senate, which next week is expected to receive treaty documents from the State Department. But the treaty's passage is by no means guaranteed: Some observers predict that a provision to compensate developing nations for the commercial use of their genetic materials could jeopardize its ratification or delay it until next year.

The biodiversity treaty calls for developed and developing countries to conserve the world's ecosystems. In June 1992, former President George Bush refused to sign the treaty at a United Nations conference in Rio de Janeiro, citing industry fears that portions of the treaty could result in compulsory licensing. For example, a biotech firm that developed a product from a native species might be required to grant the right to market the product to the country where the species originated (*Science*, 19 June 1992, p. 1624).

Clinton tried to assuage industry by drafting a statement clarifying the U.S.'s interpretation of the treaty's technology transfer language. Nevertheless, some congressional staffers say the language doesn't go far enough for conservative senators. The main bone of contention: a sketchy treaty provision that calls for developed countries to endow a multibillion-dollar fund to reimburse developing countries for genetic materials used for commercial purposes.

With a two-thirds majority needed, a little opposition can go a long way toward squelching the treaty. Most observers refuse to speculate on the treaty's chances until after they see the documents that go to the Senate. Still, says World Resource Institute biodiversity expert Walter Reed, "this issue could be a sleeper."

## Budget Cuts Loom for SSC

Congressional budget cutters are no longer alone in wanting to reduce the cost of the Superconducting Super Collider (SSC)—its own funding agency now plans to do the same.

Weary of congressional reports that have predicted large cost overruns on the SSC, the Department of Energy (DOE) earlier this year ordered up its own audit by a panel composed mostly of agency scientists. Its conclusion, released last week: huge cost overruns. Unless DOE makes "prompt and significant" changes to SSC operations, the panel stated, the project will cost some $1.7 billion more than DOE's $8.25 billion projection. That pushes DOE's estimated SSC cost (including $2 billion for delaying its completion until 2003) to roughly $12 billion—a figure that jives with the latest congressional estimates.

Instead of brushing off its own cost estimate as it had done with Congress' audits, DOE now appears ready to make some tough decisions. But rather than kill the project, as many in Congress desire, DOE plans by the end of the year to identify "items in the current project design that could be eliminated or altered" without losing much science. DOE's High-Energy Physics Advisory Panel will rank the proposed deletions by scientific impact, and DOE will cut from the bottom. Definitely going under the knife: building and management costs.

An SSC official says he's optimistic DOE can trim fat, but he warns this exercise won't lower costs to the often-quoted $8.25 billion. An updated DOE estimate of a slimmed-down SSC is due out later this year.