European Union late in 2001. The treaty lays down a framework for researchers at companies and other institutions in developed countries to negotiate with officials in developing countries over obtaining native plant materials with potential commercial value.

The FAO treaty will set formal terms for "access to germ plasm and what those [who] want access [to it] must do to compensate the [source] countries," says Jeffrey Kushan, an attorney with Sidley Austin Brown & Wood (Washington, DC), who represents BIO on international intellectual property matters. However, many details about that compensation still need to be worked out in discussions over the coming year. "This will be a critical test of the new system—whether viable and realistic terms will be defined," he added.

Negotiating those details "will be complicated, and they will be difficult to implement," says Val Giddings, vice president for food and agriculture at BIO. But, he adds, it is "better to be part of this thing than to walk away." Biotechnology industry representatives helped to persuade Bush administration officials that, despite the vagueness of several provisions in the treaty and a forthcoming need to work through many complex details, "being engaged is the more likely strategy for producing the desired results," says Giddings.

Jeffrey L. Fox, Washington, DC

Study critiques corporate control of trials

With the biotechnology and pharmaceutical industries reporting a record number of drugs in phase 3 clinical trials, a survey of US medical schools is critical of industry control over these trials. Some academic researchers say that investigators must have greater say in how the studies are carried out and how the findings are released to ensure proper treatment of patients and maintain high standards for research goals.

Researchers at Duke University (Durham, NC) surveyed 108 US medical schools and concluded that they are not abiding by publication guidelines that were set forth in 2001 by the International Committee of Medical Journal Editors (*New Engl. J. Med.* **347**, 1335, 2002). This committee, consisting of the editors of 13 leading medical journals, was formed in 2001 to address concerns about a growing divergence between patient and commercial interest when it comes to clinical trials. The committee established guidelines recommending that authors disclose potential conflicts of interest and assure that investigators are fully responsible for the design of trials and control publication rights to clinical trial data—tasks that investigators are failing to accomplish, according to the new study.

Typically, when a firm is studying a therapeutic in human clinical trials, it enters into a contract with an academic institution to perform the studies, and it is these contracts that the report criticizes. The survey found that in only 10% of contracts did site researchers have a say in how data was collected and monitored, and in only 5% did they influence how the data was analyzed and interpreted. In addition, fewer than 1% of contracts guaranteed that results would be published and that an independent committee would control publication. Kevin A. Schulman, a professor at Duke's Center for Clinical Trial and Genetic Economics and lead author of the report, says medical schools say they feel powerless against the financial incentives offered by industry. "It's hard to raise the bar on research ethics unless the medical schools band together and make standard agreement," he said. "The overall issue is, 'do patients and physicians have all the information available.' We can't guarantee that's occurring."

The survey found that institutions rarely require the presence of an independent executive committee, a data and safety monitoring board, or a publications committee as a condition of their participation in multicenter clinical trials. "Such bodies can be important safeguards of integrity and safety in clinical trials," the report stated.

Roger Meyer, senior consultant at the American Association of Medical Schools (Washington, DC), said Schulman's study was flawed because it interviewed university officials rather than legal counsels at medical schools. "It's dangerous to wave a flag and say this is dangerous unless you have some data." The report's authors said they interviewed the most knowledgeable person at each institution.

But biotech executives say both industry and academia share a common financial and research interest in designing proper studies that will test a product. Ray Warrell, chairman and CEO of Genta (Berkeley Heights, NJ) and a former physician at Sloan-Kettering Medical Center (New York, NY), says, "The much more serious issue is the investment community and how aggressive they can be in acquisition of this knowledge." Warrell cites a *Wall Street Journal* article that claimed a man from an investment house was caught trying to obtain information about a Genta clinical trial by posing as a clinician. And, more recently, a research analyst was fined and suspended for trying to enroll in a clinical trial in order to obtain information about side effects of an insomnia drug (see p. 1183). "I think there's going to be continued tension on treatment of information that's supposed to be confidential," says Warrell.

Conflicts over the right to publish data have flared in recent years, and have resulted in lawsuits between some companies and institutions (*Nat. Biotechnol.* **18**, 1235, 2000). Art Caplan, a bioethicist at the University of Pennsylvania School of Medicine, says that patients could lose out as medical schools feel pressure to make alliances with industry. "Business culture says we publish good news, not bad news, that we keep things secret until we have the commercial aspects nailed down, and that we don't share information with others; and that if it's not immediately practical, we're not interested. None of this works to the patient's advantage."

Schulman agrees that this culture of not publishing negative data can be harmful to patients, because they expect to be told whether or not the medications they are taking help their condition. If the results aren't published for market reasons, the patients are given false expectations. Nonpublication of data can also mislead other patients who are making decisions on whether or not to purchase the medication under review.

Scrutiny of industry–academic collaborations is all the more necessary because the number of biotechnology products entering clinical development has reached record levels and is expected to continue to increase. A new survey by the Pharmaceutical Research and Manufacturers of America (Washington, DC) found that 371 biotechnology products are currently under review by the FDA, 108 of them in phase 3 clinical trials—more than ever before.

According to Caplan, the main problem is that medical schools haven't done enough to protect themselves from potential conflicts. He says it's up to them to enforce tougher ethical codes and to negotiate agreements with industry sponsors that guarantee publication rights whether or not the results are positive. "They are absolutely acting as patsies because they have not gotten their act together and said 'here are the minimum standards'," says Caplan.

Eric Niiler, San Diego, CA.