EDITORIAL CORRESPONDENCE:
BIO/TECHNOLOGY, 65 Bleecker St., New York, NY 10012. Telephone: (212) 477-9600. Telex: 668497UW.
BIO/TECHNOLOGY, 4 Little Essex Street, London WC2R 3LF. Telephone: (01) 836 6633. Telex: 262024.

To supplement coverage of Japanese developments, BIO/TECHNOLOGY has an editorial liaison with the editorial staff of Japan Chemical Daily, Ltd. and Japan Chemical Week.

THE FIRST WORD

EVENING THE ODDS

You guys killed me," Gary Strobel told *Bio/Technology* editor Jennifer Van Brunt a few weeks ago, referring to last month's "First Word."

Dr. Strobel, of course, is the Montana State University plant pathologist who stirred up a storm of unwelcome publicity when news broke that he had field-tested a recombinant bacterium without official permission.

It still appears to us that, by any rational standard, Dr. Strobel's experiments were as innocuous as any field test involving the Dutch Elm Disease fungus can be. Treatment of the pathogen seems to fit U.S. Department of Agriculture protocols. And he got proper USDA permissions, he says. Such pathogens are field-tested all the time, and the record of safety is exemplary.

But it bears repeating: *Right now, deliberate release is a political issue, not a scientific issue.* Thanks to a lot of horsetrading among politicians, industry, and regulators, the current balance—albeit an uneasy balance—inclines towards continued progress in applied biotechnology, clinical and environmental.

But, as the ashes of Dr. Strobel's experimental elms are cooling, one wonders how much was traded away to attain that balance. The burden of regulation on industry, though substantial, is an accepted cost of the bargain, spavined and broken-winded as it may be.

But have academic researchers been sold down the river? In the language of countless breast-beating editorials, did the system fail Gary Strobel?

Dr. Strobel told Dr. Van Brunt that he had cleared his experiments through USDA—an agency the plant pathologist was used to dealing with. But it was only through a chance conversation with a colleague that he learned that the EPA had to give its approval, too.

It was late in the game, so Dr. Strobel submitted an application and, three days later, began his experiment without any word from EPA.

No one can blame Dr. Strobel for being bewildered by the regulations. We have lost count of how many hundreds of *Federal Register* pages the various rules now fill. A researcher should spend his time researching, not parsing federal regulations. Most biotechnology companies have, or will have, people to manage their regulatory affairs; it is a necessary cost of doing business. How many institutions have similar resources? Do the various institutional review boards have the breadth of knowledge required by the rapidly evolving regulatory matrix? Does Montana State University have a regulatory affairs liaison to whom Strobel could have turned? Do his societies maintain panels that could have helped? Did the EPA or the USDA make any effort to reach this researcher—or thousands like him—with information in a convenient and useful form?

Ignorance of the law may indeed be no excuse. But there is no excuse either for laws that are overlapping, contradictory, obscure, and practically impossible for the small independent researcher to find, much less comply with.

So we may denounce Dr. Strobel's misjudgment, but we must also denounce the state of affairs that made that misjudgment possible—that made some such public error inevitable.

The regulatory apparatus has gone to great lengths to see that all of the regulatory loopholes are closed, that there is a continuity of jurisdiction from the smallest research plot to the largest industrial application. Theoretical provisions have been made for expediting applications for academic research. What we need now, in the aftermath of Steven Lindow's five-year wait and Gary Strobel's abortive protest, is assurance that the system will now begin to work in a timely, efficient manner.

—Douglas McCormick