innovative, breakthrough drugs. According to Ernst and Young, the U.S. biotech industry in 1994 spent \$68,000 per employee on R&D. The large pharmaceutical companies spent \$39,000 per employee. R&D currently accounts for 91% of biotech industry expenditures. The large pharmaceutical companies spend about 16% on R&D.

It is true that biotech companies have had difficulty over the past 18 months raising capital to fund R&D and product development. This has led to more, and more unusual, deals being struck with large pharmaceutical companies and other sources of funding. It isn't true, however, that these deals presage the disappearance of the independent biotech company. Quite the contrary.

Both big pharmaceutical and emerging biotech companies recognize that a small entrepreneurial environment is more conducive to innovation. Because of this, we will continue to have emerging and even startup biotech companies, and we will certainly continue to need them.

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"Don't Need, Don't Look"

To the editor:

Criticizing the overinterpretation of the results of field trials of "transgenic" (or, more accurately, recombinant DNA-derived transgenic) plants, Margaret Mellon and Jane Rissler conclude that field trials do not routinely gather extensive data on safety and therefore that "care should be taken in citing the field test record as strong evidence for the safety of genetically engineered crops" (*BioTechnology* 13:96, January). In the narrowest sense, they are correct but ignore that the quite appropriate and usual purpose of such field trials is to gauge the performance of the plant being tested.

The key to understanding and predicting the risk of transgenic plants (among others) is to exploit the consensus view of biologists that, in the words of the U.S. National Research Council 1989 report (*Field Testing Genetically Modified Organisms: Framework for Decisions*), "...no conceptual distinction exists between genetic modification of plants and microorganisms by classical methods or by molecular techniques that modify DNA and transfer genes," and also the vast body of knowledge about organisms modified with traditional techniques. This approach leads directly to the conclusions that risk is a function of the characteristics of the organism and the environment into which it is to be introduced, and that the range of an organism's potential characteristics and environments is vast. Thus, the most rational approach to risk analysis when risk is not readily demonstrable (a situation sometimes referred to as "very low risk") is to use established scientific principles and to identify significant gaps in understanding that can be addressed by the conduct of

properly designed experiments. This approach would rely heavily on previous knowledge about the behavior of genetic variants of organisms that have been manipulated by conventional methods or that are present in nature, under various conditions of testing and use. This might be thought of as a "vertical" approach to the understanding of risk. Thus, a tomato breeder or a government regulator of polio vaccines assessing the potential risks of a new rDNA-derived tomato or vaccine, respectively, is likely to rely more heavily on background information on tomatoes and poliovirus manipulated via traditional techniques than on information about rDNA-manipulated pigs or bacteria.

An individual breeder of corn, soybean, wheat, or potato may introduce into the field 50,000 new genotypes per year, and there have been no unmanageable problems from these introductions made through the use of established practices. Moreover, aside from routine observation of the plants' traits, it would be unusual for a breeder to design trials specifically to assess environmental safety.

The assessment of safety and risk should be approached in a way that is logical. It is one thing to design a risk assessment experiment that will answer a question that may be important to plant breeders, to regulators, and even to the public. It is quite another to expend substantial resources to confirm a foregone conclusion, or, at best, to obtain very limited information. Rather than a case of what Mellon and Rissler called, "don't look, don't find," what we have is, "don't need, don't look."

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Margaret Mellon and Jane Rissler reply:

Miller argues for the safety of transgenics by asserting that "an individual breeder of corn, soybean, wheat, or potato may introduce... 50,000 new genotypes per year" without creating unmanageable problems. This argument considerably overstates the variety inherent in modern crop breeding. The new genotypes referred to are the individual products of sexual crosses, most of which are genetically very similar because of the use of highly inbred cultivars. Miller may have been thinking of new crop varieties, but, if so, individual breeders introduce only one or two, not tens of thousands, of new varieties in a single year. Even considering *all* the new varieties introduced by *all* breeders, the argument for generic safety fails because the products of traditional breeding are different from transgenics in a number of ways. For example, traditional breeding generally involves the shuffling of different versions of genes of similar function within a restricted gene pool, while transgenics are usually engineered to express new genes with completely new functions taken from unrelated sources.