THE LAST WORD

by Nachama Wilker and Seth Shulman

WHO IS PROTECTING THE PUBLIC'S HEALTH?

Thirty years ago, a revolution occurred in agriculture that included some of the same companies involved in biotechnology today. With the advent of synthetic chemical pesticides, some of the most toxic chemicals known to humanity were brought to market with little debate or concern for potential environmental consequences. As is so often the case in the infancy of a new technology, the unbounded expectations for these chemicals distracted regulators from their ecological hazards. Now, a generation after this revolution, despite some benefits, we are faced with serious public health problems and a yearly production of some 60 million tons of hazardous chemical wastes.

While the promise of biotechnology can be presented as almost limitless, this potential is inevitably accompanied by some of the same types of risks associated with chemical technologies. The risks associated with biotechnology, however, have a set of significant characteristics that distinguish them. Chemical substances do not reproduce themselves. Biological organisms, on the other hand, have the potential to reproduce, to proliferate in our environment, and even to mutate further and recombine with other organisms already present in the ecosystem. From our past experience with the inadvertent introduction of organisms such as the gypsy moth and the citrus canker, we have learned how difficult it is to eradicate organisms once they have established themselves.

Incidents in the past few months have highlighted major weaknesses in the laws and regulatory structure that govern the biotechnological revolution. The Environmental Protection Agency (EPA) suspended the first permit it had ever issued for the release of a genetically altered organism into the environment. This action came in response to unauthorized open-air tests conducted by a California-based biotechnology company. In another case, it was revealed that a pseudorabies vaccine for livestock, containing a living genetically altered virus, had not only been field tested in four states, but was available on the commercial market. The vaccine was originally approved for field trials by the U.S. Department of Agriculture (USDA) prior to the agency's knowledge that the vaccine contained genetically altered material.

The use of any live virus raises serious health concerns and should have been given closer consideration as a part of the USDA's process. It is well documented that animals serve as major reservoirs for the transfer of disease to humans. Swine flu and Rocky Mountain Spotted Fever are potent examples. For any live-virus vaccine there is a substantial chance that it will leave a residue of low-level infection in the inoculated animal. This phenomenon raises the possibility that the new virus can recombine with other low-grade viral infections carried by the animal and thereby generate a new strain with altered, and perhaps deleterious, properties. These are scientific and medical reasons to take seriously the protocol violations by the USDA in its handling of the world's first genetically altered product to be field tested and brought to market.

In this more recent case, it appears that even after the USDA received the information that the vaccine contained genetically altered material, they continued to usher the vaccine through open-air testing to licensing for sale on the market—all without even the most rudimentary attention to regulatory guidelines or democratic public procedure. The actions of the USDA were all undertaken

- Without consulting its own scientific review board or outside scientific advisors or other federal agencies, such as the EPA, who are involved in regulating environmental release of genetically engineered products;
- Without notifying state officials in the four states where the field tests were conducted of the genetically altered nature of the organisms; and finally,
- Without acknowledging the existence of this program to inspectors from the General Accounting Office (GAO) who last fall completed an investigation of USDA's procedures for handling the products of biotechnology.

Both the EPA and USDA cases highlight the current inadequate and ad hoc state of regulation. Neither of these cases would even have come to light were it not for public vigilance and scrutiny. And in both cases the critical development of guidelines for risk assessment, physical and biological containment, mitigation, and monitoring of environmental and public health risk have been circumvented. The protection of proprietary information by private companies is being placed above the public's right to know as a $3-billion biotechnology industry searches for products and profits.

There is no question that biotechnology may offer us the potential to be less dependent on chemical pesticides. But so far the world's only two field tests of genetically altered microbes have both involved flagrant violations of regulatory guidelines and public trust.

The recent publication of an updated regulatory framework for biotechnology by the Office for Science and Technology Policy, while clarifying some points, still leaves large gaps. Important questions raised by these two incidents—such as what constitutes an environmental release—still need to be answered. Only through establishing clear policy statements and protocols can we begin to ensure that violations of this nature will not occur again.

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