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Freeing the Biotech Revolution

by Henry I. Miller and Gregory Conko

This is the second of two excerpts from The Frankenfood Myth: How Protest and Politics Threaten the Biotech Revolution, *by Henry I. Miller and Gregory Conko (Praeger 2004).*

Soon after the techniques of recombinant DNA modification were first demonstrated in 1973, the scientific community engaged in a long-term effort to gauge the relative safety and risk of this new biotechnology. Within a short period of time, a broad scientific consensus began to gel around the conclusion that the new molecular biotechnology—also known variously as gene splicing, genetic engineering, or genetic modification—is merely an extension, or refinement, of less-precise technologies that we have long used for similar purposes.

Except for wild berries and wild mushrooms, all grains, fruits, and vegetables grown in North America, Europe, and elsewhere come from plants that have been genetically improved by one technique or another. We discussed some of these techniques in the last issue of *Monthly Planet*.

Scientific discoveries and increasingly sophisticated laboratory techniques have brought us a long way from basic hybridization. Conventional plant breeding has long been far more sophisticated than the basic selection and hybridization of plants of a single species. Early in the 20th century, for example, plant breeders discovered how to breach the so-called "species barrier," much revered by biotechnology's opponents, to produce entirely new plant species that never existed before and that could not occur in nature. Compared with these more crude forms of genetic modification, the new biotechnology is far more precise and predictable, and poses neither new nor unique risks.

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Nevertheless, despite the recommendations of countless scientific organizations that recombinant DNA-engineered varieties be evaluated in the same way as the products of conventional plant breeding, regulators in the United States and many other countries, over the past two decades, have created a series of rules that treat biotechnology as though it were inherently risky and in need of intensive oversight and control.

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Regulations specific to gene splicing have hugely inflated the costs of research and development and made it difficult to apply the technology to many classes of agricultural products—especially ones with low profit potential such as non-commodity crops and varieties grown by subsistence farmers. This is unfortunate, because the introduced traits—including the ability to grow with lower amounts of water and agricultural chemicals—often increase productivity and are beneficial to the environment. The world would have been far better off if, instead of implementing regulation specific to the new biotechnology, governments had approached the products of gene splicing in the same way they regulate similar products—pharmaceuticals, pesticides, new plant varieties, and so on—made with older, less precise and predictable techniques.

But regulators, always eager to expand their power and budgets, have responded to calls by activist groups whose members fear technological progress and are suspicious of for-profit agricultural companies. The activists understand that overregulation advances their agenda by inflating R&D costs and discouraging innovation. And, sadly, instead of demanding scientifically sound, risk-based regulation, some biotechnology firms have lobbied for this same kind of discriminatory, excessive government regulation in order to gain short-term advantages.

Biotechnology's early promise of more nutritious and better tasting foods has not come to full fruition because it is simply too expensive to obtain regulatory approval for gene-spliced varieties of any but the most profitable crops.

These firms hope that superfluous regulation will act as a type of government stamp of approval for their products. The time and expense engendered by overregulation also act as market entry barriers to start-up competitors. Tragically, those companies seem not to understand the ripple effect from overly restrictive regulations based on the false premise that there is something uniquely worrisome and risky about the use of gene-splicing techniques.

Biotechnology's early promise of more nutritious and better tasting foods has not come to full fruition because it is simply too expensive to obtain regulatory approval for gene-spliced varieties of any but the most profitable crops. Regulatory requirements alone can add over $1 million in costs for developers of biotech varieties in the United States alone—and several million more to secure regulatory approval in major export markets.

New varieties of the big commodity crops—such as corn, cotton, soybeans, and wheat—are often worth tens of millions of dollars in seed sales annually for several years. But seed sales of a new fruit or vegetable variety can be as low as a few hundred thousand dollars during their entire marketable lives. Naturally, adding a million dollars in regulatory costs to these "small market" crops can make them commercially non-viable.

Academic research labs and the many small start-up firms created during the 1980s have developed scores of biotech crop varieties, but, as a result of costly overregulation, precious few of them have ever been brought to market. More and more small-scale researchers, who once saw gene splicing as the future of food, are leaving biotechnology behind.

According to the director of Harvest Plus, an alliance of charitable organizations devoted to producing and disseminating staple crops rich in micronutrients such as iron, zinc, and vitamin A, the group has decided that, although it will "investigate...the potential for biotechnology to raise the level of nutrients in target crops above what can be accomplished with conventional breeding...there is no plan for Harvest Plus to disseminate [gene-spliced] crops, because of the high and difficult-to-predict costs of meeting regulatory requirements in countries where laws are already in place, and because many countries as yet do not have regulatory structures."

To remove the unnecessarily stringent controls on the new biotechnology will require reform both within the United States and abroad. Some of the remedies needed here are also applicable to other areas of research: Regulatory policy must, like doctors, first do no harm. Sound science and common sense should be the basis for decisions. Both the degree and the cost of oversight must be commensurate with the potential risk. And policy makers should design regulations to work with market forces, which will come into play in any case.

Federal agencies also need to reform the way they approach the new biotechnology specifically, by replacing scientifically unjustified process-oriented regulatory triggers with risk-based paradigms. Just because an activity involves the process of gene splicing does not mean that it should be subjected to case-by-case review. Of course, forces outside government must push in a more constructive direction before we can expect government to change the public policy that is hamstringing the new biotechnology.

First, individual scientists should participate more in the public dialogue on policy issues. Scientists are especially well qualified to expose unscientific arguments and should do so in every possible way, including writing scientific and popular articles, agreeing to be interviewed by journalists, and serving on advisory panels at government agencies. Scientists with mainstream views have a particular obligation to debunk the claims of their rogue colleagues, whose declarations that the sky is falling receive far too much attention.

Perhaps surprisingly, most scientists have not demanded that science policy be rational. Instead, they have insisted

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Jim Benson, CEO of Poway, California-based SpaceDev, signs one of the company's three hybrid rocket motors that would blast SpaceShipOne to win the $10 million Ansari X Prize.

What is to be done? The conventional wisdom is that massive government oversight is essential to assuring the safety and effectiveness of medical therapies. But Gates and Allen did not get to where they are by accepting conventional wisdom, and for that reason they should rethink just where to put their money and effort.

Devoting just a fraction of those resources to researching medical regulation, rather than medical science, could be incredibly fruitful. Advances in medicine may require difficult scientific breakthroughs. Advances in medical regulatory policy might only require the reframing of basic questions, such as the role of FDA.

FDA's veto power over new therapies has a gruesome side effect: Every approval of a new life-saving drug or device means that people died waiting for that approval to be issued.

Is FDA really the only institution capable of evaluating new therapies? Are doctors and patients truly incapable of deciding whether to use experimental therapies?

Rethinking these issues, especially in the context of the very information technologies that Gates and Allen helped create, might well change the world.

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only on transparency, or predictability—even if it only delivers the predictability of research delays and unnecessary expense. Others have bought into the myth that a little excess regulation will assuage public anxiety and neutralize activists' alarmist messages. Defenders of excessive regulation have made those claims for decades, but the public and activists remain unappeased, and technology continues to be shackled.

The second strategy involves groups of scientists: professional associations, faculties, academies, and journal editorial boards. These organizations should do much more to point out the flaws in current and proposed policies. For example, scientific societies could include symposia on public policy in their conferences and offer to serve as advisors to government bodies and the news media.

Third, reporters and their editors can do a great deal to explain science-related policy issues. But in the interest of "balance," the news media often give equal weight to all the views on an issue, even if some of them have been discredited. All viewpoints are not created equal, however. Journalists need to distinguish between honest disagreement among experts, on the one hand, and unsubstantiated extremism or propaganda, on the other.

Fourth, biotechnology companies should eschew seeking short-term advantage and actively oppose unscientific, discriminatory regulations that set dangerous precedents. Companies that passively accept government oversight triggered simply by the use of gene splicing techniques, regardless of the risk of the product, ultimately will find themselves the victims of the law of unintended consequences as excessive regulation stifles them.

Fifth, venture capitalists, consumer groups, patient groups, philanthropists, and others who help bring scientific discoveries to the marketplace, or who benefit from them, need to increase their informational activities and advocacy of reform. Their actions could include educational campaigns and support of organizations that advocate rational, science-based public policy.

Finally, the government should no longer assume sole responsibility for regulation. Nongovernmental agencies already accredit hospitals, allocate organs for transplantation, and certify the quality of consumer products ranging from seeds to medical devices. Moreover, in order to avoid civil legal liability for damages real or alleged, it is in the best interests of the practitioners of agricultural biotechnology to adhere to sound practices.

Flawed, overly risk-averse federal regulation of the new biotechnology has slowed the rate of innovation in that crucial area of research. We need to find other, more scientific and efficient ways, to guarantee the public's safety while encouraging new discoveries.

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