BIOTECHNOLOGY FLIRTS WITH THE REGULATORS

by Fred Lee Smith, Jr.

Biotechnology, like other unfamiliar high tech industries, offers great hopes but arouses even greater fears. Politicians, the record proves, are far more likely to respond to fears than hopes. Although Representative Manuel Lujan (R–NM) claimed that: "We don't want to regulate [biotechnology] out of business," (*Bio/Technology* 5:671, July '87), he and his fellow politicians appear to be doing exactly that.

That threat must seem distant to industry Pollyannas. After all, they correctly point out, biotechnology is doing well at the moment. Research gains are common, state governments are eagerly establishing special programs, Congress seems willing to expand the intellectual property laws on demand, and most scientific concerns have been resolved. Everything is coming up (bio-engineered) roses.

Why then the doom and gloom? Simply because America's recent political history suggests that novel technologies face threats not readily eliminated by logic or economics. Today's political support has been paid for by accepting regulatory controls and public review requirements which will become increasingly threatening over time.

Industry leaders seem to place great confidence in the Environmental Protection Agency (EPA). Under current policies, EPA has now assumed a critical "gate-keeping" role that allows it to decide which products will live and which will die. How EPA will ultimately exercise these powers is unclear; however, its record in such areas as pesticides suggests concern. To EPA, like most political risk regulation agencies, safety is found in the *status quo*; man-created products promote risks. The agency seems unconcerned that improved technology can reduce the risks created by nature itself.

The issue, of course, is not *whether* biotech should be regulated at all, but rather *who* should regulate and *how*. Industry short-changes its own capabilities in this area. Consider how a firm responds to risks: The engineer/scientist proponent of a new product may well urge quick approval. Modern firms, however, knowing that a product may fail, have created an internal "devil's advocate's" corps of accountants and lawyers that effectively scrutinize new product introductions. Market-mediated regulation weighs both the risks of technological stagnation and innovation.

A political regulator faces the same difficult problem of how to approve "good" products and stop 'bad' ones. Political regulators have every reason to consider carefully the risks of hasty approval of a dangerous product. But unlike their private-sector counterparts, they lose no profits and have little reason to fear criticism for delaying or rejecting a novel product. As former Food and Drug Commissioner Alexander Schmidt once noted, the incentives facing the agency and its employees clearly favor delay. The risks of innovation are heavily weighed, while the risks of technological stagnation rarely touch the scales. This anti-technology bias endangers the biotechnology industry.

Why have biotech leaders failed to raise—perhaps, even to understand—the basic question of whether the public interest is best advanced by private or political regulation? Some probably accept the conventional wisdom that political control is inherently superior to private restraint. Others see regulation simply as a way to restrict competition and increase profits, or as the *quid pro quo* for political subsidies. Still other firms have ceded the policy-making function to their Washington representatives. That is a mistake. Washington reps have great tactical value, but they thrive on influencing regulation at the margin, not on mounting a strategic challenge to the concept of regulation itself.

What is to be done? Specific steps industry should take include:

- Lobby to restore faith in the moral legitimacy of change. Most Americans believe that rational risk-taking can benefit mankind, but industry must defend this belief more vigorously. Once, thousands saw Luther Burbank on the Bell Telephone Hour; now millions see Jeremy Rifkin on CBS News. If the anti-technology advocates are to be countered, industry must work to dramatize and humanize the benefits and the morality of science.
- Publicize the victims of political regulation. Those penalized by the slowdown of technology—AIDS victims denied access to new treatments, for example—deserve far more attention in the press. Their plight illustrates well the risks of political regulation and provides a way to reeducate the American public on the anti-technology bias of some political regulators. Biotech leaders should also spring to the defense of the next Gary Stroebel that comes along, publicizing aggressively the position of the "little guy against the bureaucracy."
- Champion a Post-Approval Regulatory Audit to document the anti-technology bias of current policies. All biotech products finally approved by regulators should be tracked by a federal agency, perhaps the Office of Management and Budget or the Office of Technology Assessment. The agency would collect data on the greater effectiveness of the new product and apply this marginal improvement retrospectively to the population held at risk during the approval period. Those data would create an official record of the costs of technology delay.
- Finally, industry must ensure that public participation is truly *public*. Well-financed, well-organized special interest groups must not be allowed to dominate the policy debate. In principle, the public interest movement would include an array of organizations, some favoring and some fearing technology. In fact, anti-technology groups dominate, shifting power away from innovating firms.

From this perspective, the current health of the biotechnology industry is illusory. Biotech is all too much like a young tree now green and healthy, but surrounded by numerous and rapidly growing strangler figs. Its youthful vigor is all too likely to languish as the threats, now potential, materialize.

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