THE LAST WORD

by Harvey S. Price

REGULATORY REFLECTIONS

A recent *Wall Street Journal* article ("Attempts to Regulate Gene Splicing Harmony Between U.S., Industry," Jan. 9, 1985) noted a remarkably cooperative spirit between the regulators and the regulated in the first stages of commercial biotechnology's development. Establishing such harmony, and maintaining it as difficult regulatory details are resolved, has been a major goal of the Industrial Biotechnology Association since its creation in 1981. If this encouraging situation holds reasonably well, it may serve as a model for the enhanced government/industry cooperation that could vitalize this country in the coming years.

Those familiar with the issues generally agree that, biotechnology's anticipated benefits notwithstanding, it is unrealistic to expect that commercial development will be free in the near term to proceed on the basis of non-regulation or self-regulation. It would be futile and naive to press for such an outcome for a combination of reasons: biotechnology's novelty and fast pace of research, coupled with apprehension about the nature of the technology itself plus an overall mistrust of industry among some in both government and the general public. Nor can public education rapidly overcome these reservations. While there is certainly much misinformation that needs to be corrected, the current level of empirical data and actual experience leaves ample room for differing regulatory judgements and opinions among reasonable people.

In acknowledgment of this reality, the biotechnology industries should view regulation within exsisting legislative authorities not as a necessary evil, but as a satisfactory vehicle for enabling products to reach the marketplace expeditiously. Then, once the public has become familiar with products and appreciates their benefits, we can more effectively demystify the technolgy, candidly discuss its capabilities and limitations, and bring the question of risks versus benefits into a perspective less susceptible to scientifically unsound, emotionally inflamatory rhetoric.

This strategy of finding an acceptable middle ground on regulation is a variation of one that proved successful in the early days of rDNA research. This year marks the 10th anniversary of the Asilomar Conference, a gathering of scientists stimulated by the uncertainties and possible dangers involved in early biotechnology research. Following the meeting, some critics predicted impending catastrophe if experimentation were not halted. Severe governmental restrictions were close to enactment. Nonetheless, a solution was reached that the National Institutes of Health (NIH) developed "Guidelines for Research Involving Recombinant DNA Molecules," and some of the less troublesome experiments were allowed to proceed.

Less than ten years later, with the benefit of both experience and additional scientific data, the dire predictions which frightened many and nearly aborted subsequent commercial development have been shown to be unfounded. As scientists have expanded their knowledge and perfected the techniques of rDNA technology, the governmental requirements have been relaxed. This moderate approach—establishing precautionary measures for going forward, then modifying them in the light of new scientific and experiential evidence—has served both industry and the public well.

But, if we are to proceed cautiously rather than argue endlessly, the mood of the times demands more regulatory formality than NIH guidance alone, certainly for the post-research stages of commercial development. So the mission agencies like the Environmental Protection Agency (EPA) are the logical candidates to undertake a responsible and moderate regulatory role.

Certainly opinions differ as to the applicability of existing regulatory authorities to biotechnology. Nevertheless, formal involvement of EPA and other federal watchdogs, as well as NIH, will be more conducive to the introduction of products than would the most likely alternative: passage of major new regulatory legislation, and its attendant litigation over interpretation. The industrial biotechnology community, with perhaps a shade more candor than many have come to expect from the commercial sector, thus encourages, and is working to create at the outset, a non-adversarial regulatory approach with which reasonable people should be comfortable.

But at the same time regulatory requirements, however imposed, can become tremendously burdensome. In fact, the potential damage, particularly to new firms, of obstructive regulation can hardly be overstated. Thus, the imposition of any regulatory framework does pose risks for a still young, innovative field, as many governmental leaders acknowledge. They also understand that U.S. leadership in commercial biotechnology is a valuable national asset, and one that it would be foolish to stifle or drive offshore. We feel confident, then that regulators and legislators will be receptive to our view that unnecessary costs, delays, and duplications should be eliminated or at least minimized, and that while regulatory oversight must continue to be comprehensive and rigorous, it should also ensure that biotechnology is permitted to move forward and develop its potential.

Of particular importance to industry is the need, regardless of how the regulatory framework is ultimately structured, for flexible requirements that can be modified and relaxed as circumstances warrant. We feel that continued assessment of new experience and scientific evidence will be essential to satisfy regulators and the public alike that the catastrophes envisioned by a few are thoroughly unrealistic. This flexibility should be incorporated at the outset to ensure that reasonable safeguards do not in time become burdensome restraints.

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