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THE FIRST WORD
ROBERTS RULES OF DISORDER

A friend asked recently, "Do you really want to do another editorial on BST [bovine somatotropin]?"

The answer, frankly, is no. Lawyers say, "Hard cases make bad law." What has happened here is a bit different: Hard choices have made bad politics. Clearly, evolving biotechnologies have raised the specter of economic change on the farm. Fair enough: as we have pointed out here before, technological change (beginning with railroads and refrigeration) made the modern family farm possible in the first place. In every country, food-producing capacity is a volatile issue: despite the modern emphasis on high technology and service economies, deep in the body politic's brontosaurian after-brain dwells the recollection that food is the basis of all power and all stability.

As the first in line, the pioneer posed to receive the unexpected arrow, bovine growth factor is a natural target. It is a stalking horse. Or perhaps we should think of it as a marker protein making its way through an anything-but-transparent slab of bureaucracy at a rate that makes SDS-PAGE gel electrophoresis look fleet and fluid as a mountain cataract.

Still, February was an exceptionally cold month for BST on both sides of the Atlantic. During the first week, the European Economic Community's (EEC) council of agricultural ministers formally extended its moratorium on approving the commercial use of BST. Though apparently politically motivated, the order had at least the merit of official standing. As much could not be said for the "gentlemen's agreement" (the EEC's term) by which the Council bridged the gap between the end-of-year expiration of an earlier moratorium and its February meeting.

Monsanto, one of the quartet of companies waiting to market BST, absorbed a second blow during February's second week. The U.S. Food and Drug Administration ordered the company to stop what the agency insisted was public promotion of the milk-stimulating drug. Just at press time, our hometown newspaper (*The New York Times*) reported that the director of the FDA's Center for Veterinary Medicine cited several score of "clearly promotional" statements by the company. FDA officials denied that this procedural action had anything to do with procedural complaints raised by Jeremy Rifkin and the Foundation for Economic Trends close on the heels of a U.S. National Institutes of Health panel's finding that BST presented no human-health risk.

Whatever the public-health window-dressing, opposition to BST still seems based more on fear of economic change and fundamental (not to say fundamentalist) aversion to biotechnology. And it still seems to us that the place for such opposition, if any, is in the world's legislatures—not in regulatory forums established for scientific review.

And that is the tragedy. In trying to play realpolitik, those who should lead have lost their way. Another friend has observed that the European Commission's Committee for Veterinary Medicinal Products (CVMP), for example, has thrown a series of procedural barriers in BST's path: committee members have come to approval hearings ill-prepared, have called for further data whose relevance is at best questionable, have cancelled and postponed meetings on both Monsanto and Eli Lilly formulations of the drug.

"While regulatory systems dealing with high technology inevitably move in mysterious ways," he says, "the mystery at CVMP and the CPMP (Committee for Proprietary Medicinal Products) is becoming so deep that even the participants cannot fathom it." The process, he points out, should be essentially a scientific endeavor, dedicated to upholding standards of safety, quality and efficacy. But the players in the regulatory drama—industry and the reviewers alike—have been seduced by the intrigues of the political process and rendered impotent.

CVMP probably will approve BST in March. The drug must then make its way through individual national authorities, and also clear the hurdle of the moratorium. "The process is inappropriate," our friend complains, "and closed, so that you can't even guess at the true meaning of these [regulatory] actions."

Regulators cannot approve products even when they want to. And so industry cannot produce products even though they eminently deserve approval.

—Douglas McCormick