insulin to the BGA next year and the agency's position, enshrined in German pharmaceutical law, remains that the compound is completely novel. A full three-year trial to establish quality, safety, and efficacy will, therefore, be required. This is "unfortunate" according to Hoechst's Brauer: "They are still not thinking in terms of the biological equivalence of human insulin made in *E. coli* to the semisynthetic [version] that we get through transformation of bovine to human insulin."

If one effect of the Gene Law is to focus objectors' attentions on medicinal approval, the other is to devolve responsibility for process approval onto individual German states (the Lander), which now number 16. The Law stipulates that the Lander authorities must submit applications and supporting data to the Central Biological Safety Committee (ZKBS) in Berlin, who advise on the appropriate safety classification of the proposed project. That classification prescribes the subsequent administration of the project, notably whether a public hearing is necessary. The ZKBS advice is not binding, so that in theory at least, a second Lander-based committee could reclassify projects.

Guenter Dettweiler of the ZKBS confirmed that the Lander could reclassify if they wished, but while a proposal for a second oversight authority was part of the discussion leading up to the gene Law, he hadn't heard of any further plans since. He doubted whether the Lander could come up with a body that had the same range of expertise as the ZKBS. Diter Brauer felt a Lander safety commission "would have no legal function."

Nevertheless, there is clear political pressure in some of the German states to decentralize this critical decision-making stage. Katrine Gruber believes that each state should have an expert advisory body and has pressed the parliament in North Rhine Westphalia (which includes Aachen and Koln) to come up with a clear position on this. The Green party also has influence in a number of Lander including Berlin, Lower Saxony, and Hamburg. And at least a dozen scientists from various Lander including Bavaria, Baden-Wuerttemberg, and Lower Saxony have been asked to join local expert commissions. While industry and the Federal authorities may be skeptical about the ability and utility of state-based committees, the Lander governments themselves are clearly determined to have as much say as possible in applying the Gene Law. —John Hodgson

OPINION

BANDSHIFT

Proclaiming a trend does not break new ground as much as it gives a name to the ground already occupied. So we wonder what to make of the rumblings about "a new reality"—a new pragmatism settling in among U.S. biotechnology companies.

Some say the dream of growing brand-new pharmaceutical companies based on biology ceased with Genentech's acquisition last winter. The fast flow of venture money has trailed off. For years we have heard cries that the pharmaceutical giants eventually will gobble up everything, and that biotech's separate identity is bound to be lost. And now, with the stratification of companies into the haves and have-nots (with the haves striving to walk and talk just like traditional pharmaceutical companies), some want to rethink the priorities and directions for new research.

A shift in attitudes may indeed be underway. In this issue we note the demise of the U.S. Biotechnology Science Coordinating Committee and the institution of a successor committee by the Bush Administration. This latest executive shuffle may hint at a shift in emphasis at the Office of Science and Technology Policy (albeit at the federal government's glacial pace)—away from government emphasis on biomedical endeavors and towards concerns about policies affecting the agricultural, energy, and environmental applications for biotechnology.

It makes sense that biopharmaceutical companies matured faster than other biotech firms. There has always been the background of traditional drug discovery and development and the looming presence of the cash-rich pharmaceutical giants. A regulatory mechanism for assessing risk and benefit is well established; already in place was a long history of product filings and a tradition of balancing risk versus clinical benefit in treating serious, often fatal diseases. Pharmaceutical companies knew these ins and outs: Biotech brought in little that was new and changed little of what was. The fledgling biopharmaceutical companies had only to imitate what the pharmaceutical industry already was doing. And for a decade biotech's identity was cast against that backdrop.

Now we are moving beyond health care products into much broader consumer areas. The biotechnologies are holding out the twin promise of more economical products and (presumptively) less environmentally risky products (both to replace hazardous chemicals and to remediate the damage from residual chemical pollutants). These applications capture the public mind in a different way than pharmaceuticals: The products are vitally important, but nonetheless "discretionary." Accompanying this change must be a fresh look at how the applications for the biotechnologies are seen in these new marketplaces. The regulators here have less experience to bring to bear on product assessment. And we cannot bring into this new arena the same expectations for public acceptance that accompanied pharmaceutical development.

One astute and oft-cited Wall Street analyst is fond of saying that, while health care is revolutionary, agriculture is evolutionary. New agricultural products should offer only incremental improvements, building on a traditional base in order to be championed by industry and accepted by consumers. (By extension, the same would hold true for other products to be introduced into the environment.) Put another way, biotech may have to shift gears and become more reactionary and less revolutionary. We must remember that our image of what the biotechnologies offer has been heavily influenced by the health care sector and a crusader's belief in radical innovation. That rapid rate of change may not be welcome elsewhere.

—Mark Ratner