BIOTECHNOLOGY POLICY

MORE CHANGES IN U.S. REGULATORY BODIES

WASHINGTON, D.C.—Determining who's overseeing what in the landscape of U.S. biotechnology policy-makers is like sifting through alphabet soup: The characters seem to be constantly recombining.

Officials in the President's Office of Science and Technology Policy (OSTP) recently replaced the five-year-old Biotechnology Science Coordinating Committee (BSCC) with the Biotechnology Research Subcommittee (BRS). The change reflects a decision to move OSTP away from the controversial regulatory matters that preoccupied the defunct BSCC. Meanwhile, another federal entity with overlapping interests, the National Biotechnology Policy Board (NBPB), is coming to life. Mandated by Congress several years ago, the NBPB will provide advice to the Secretary of Health and Human Services. The board, with members from government, industry, and academic institutions, scheduled its first meeting for the end of October.

A year ago, critics were flailing the BSCC for its closed-door way of doing business and its so-called meddling in regulatory agency activities. Indeed, some critics called for its abolition (*Bio/Technology* **8**:13, Jan. '90). Despite the criticisms, the BSCC stayed in operation long enough to draft principles for regulating the deliberate release of "organisms with modified hereditary traits" (*B/T* **8**:706, Aug. '90). Soon after those principles were published in the Federal Register, however, the committee was disbanded. Shortly thereafter, following a more general reorganization within OSTP, a successor subcommittee was designated. Although at first the BRS was named the Biotechnology Science Subcommittee, it was quickly renamed because the BSS acronym loomed as embarrassing.

"OSTP asked us to emphasize science and technology research opportunities...rather than to be a forum to arbitrate regulatory issues," says BRS chairman David Galas, who is associate director for health and environmental research in the U.S. Department of Energy. However, the subcommittee will still play "some role" in evaluating the scientific basis for biotechnology regulations, he adds. In the main, BRS will try to anticipate research trends and to coordinate federal efforts to realize those trends.

For instance, Galas foresees federally sponsored biotechnology research shifting somewhat away from biomedical research and towards more agricultural, chemical, energy, and environmental efforts. Hence, the subcommittee includes members drawn from a broad range of federal agencies, and they will consider diverse matters including the human and other genome projects, structural biology, and database management. Most policy-making and budget decisions will be made at other levels, but the details of the process are still "fuzzy," Galas says.

There is considerable overlap in membership and interests among the three top federal bodies with a prominent role in biotechnology—the BRS, the NBPB, which plays an advisory role for HHS policy making, and the Biotechnology Working Group within the Vice President's Competitiveness Council. Currently, the latter's roster is described as "free flowing," and its activities are not very visible to public scrutiny. However, of the three, the working group seems vested with the greatest political clout for policy making, particularly as it is populated in part with high level Administration officials.—**Jeffrey L. Fox**

CORPORATE STRATEGY

SCHERING ACQUIRES A TASTE FOR BIOTECHNOLOGY

LONDON—Schering AG (Berlin, Germany) is staking a claim to a share of the U.S. biotechnology market. Its recent acquisition of the therapeutic arm of Triton Biosciences (Alameda, CA) follows the purchase earlier this year of Codon (So. San Francisco, CA). And indications are that the company will consider further U.S. acquisitions, with some observers expecting companies active in neurology/CNS to be likely targets.

Schering's product development strategy appears to focus on use of biopharmaceuticals as one part of combination therapies, rather than as stand-alone entities. Hence the company is looking to firms with products to offer. According to Ralf Harenberg of investor relations at Schering, the company had been looking at several biotech firms since late-1989, but most of the smaller independent concerns were "empty nutshells—they developed a lot of products but had licensed them all out." Consequently, they didn't have a product pipeline that could interest Schering. Harenberg points out that one of the things that made Codon attractive was its development of some cardiovascular products which complement Schering's chemical entities in this area. Triton, a subsidiary of Shell Oil (London), was able to retain the rights to its developments. Triton's pipeline, while hardly of Saudia Arabian proportions, does contain some products which mesh with Schering's activities in oncology: fludarabine phosphate, which is awaiting marketing approval for the treatment of chronic lymphocytic leukemia and TAB 250, an oncogene antibody therapeutic. In addition, Triton co-developed Betaseron (beta interferon) with Cetus (Emeryville, CA) for treating renal cell carcinoma.

Andrew Tivenham of the Europe desk of stockbrokers James Capel points out, however, that other Triton products, including a therapeutic for acquired immunodeficiency syndrome now in phase I trials, "are peripheral to the mainstream of Schering's interests—and Schering may want to look for partners there." Tivenham believes Schering will build up its strength in specialist areas like cancer and cardiovascular drugs and ignore areas like AIDS and herpes. "Obviously, Schering is not there with Roche, Merck, and Glaxo, but it will keep pushing up with this sort of small acquisition."

Data compiled by German consultants Raucon (Dielheim) show pharmaceuticals to be Schering's fastest growing sector, with sales just over Dm3 billion in 1989 (up 14.9 percent over the prior year). But biopharmaceutical activities were only a small proportion of the over Dm460 million spent on pharmaceutical R&D in 1989. Schering does have a cross-indication biotechnology research group in its Berlin research headquarters, but federal grants have funded much of its work. The Codon and Triton acquisitions thus represent a significant expansion in this area.

Both Codon and Triton have experience in taking biopharmaceutical products through the development and regulatory process in the U.S.—something Schering sought, notes Harenberg. "With knowledge of the approval procedures—especially in the U.S.—you have a better chance to get the approval relatively fast. That, of course, is one of the reasons we acquired Triton." —**John Hodgson**