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TUNING THE ADVISORY MECHANISM

The Recombinant DNA Advisory Committee (RAC) of the National Institutes of Health is the new biology's monument to its own foresight and probity. The mechanism has served long and well, but it was never intended to cover the teeming diversity of commercial biotechnology. Thus it was inevitable that the U.S. Cabinet Council Working Group on Biotechnology would recommend some new advisory apparatus to relieve the RAC of its burgeoning—if *ad hoc*—commercial responsibilities.

The council's plan basically is this: Five agencies will share the responsibility for regulating emerging biotechnologies. The NIH and the National Science Foundation will make the rules for grant-supported research. And the U.S. Department to Agriculture, the Environmental Protection Agency, and the Food and Drug Administration will regulate biotechnologies according to their ultimate uses. Thus FDA would regulate drugs. USDA would regulate biotechnologies producing food. The EPA would regulate pesticides and chemicals. The cabinet council proposes that each of these agencies maintain an advisory body of its own. These "agency-based" advisory boards would each send two representatives to a parent Biotechnology Science Board (BSB) drawing its other members from from science, government, law, philosophy, and the public at large.

The agency-based advisory boards would bear the brunt of the work, reviewing and presumably ruling on most proposals. Summaries of each application (shorn of all proprietary information) would be forwarded to the BSB, letting the parent board elect to take a closer look. The parent board would also be the forum for public comment on biotechnology, and would establish guidelines for research and commercialization.

Indeed, there are compelling reasons for such a division of labor. The cabinet council recommends—properly—that these five agencies regulate biotechnology under existing laws. Only a small, focused, and responsive body will be able to review applications as quickly as those laws require. And we do need a centralized board to codify scientific standards.

But where will the all those scientists come from? Some who have served on the NIHRAC doubt that we will be able to staff six advisory bodies.

Suppose the regulators can sort the purposes and products of genetic manipulation into bins marked USDA, EPA, FDA, NIH, and NSF (and it seems likely they can). Will the varied techniques of biotechnology divide so neatly? Or will the five agencies and six advisory councils find they need the same information from the same advisors? Will the USDA's fundamental questions about the environmental impact of recombinant *Rhizobium* be so different from EPA's questions about *Pseudomonas* that they require inquiry by two entirely different bodies? Must a handful of researchers be pulled away from their inquiries to rush from agency RAC to agency RAC to serve on duplicate subcommittees pressing to render their decisions in time to meet the law? What will happen to the trove of practical knowledge accumulated by the NIHRAC in its years as *the* clearinghouse for genetic experimentation? Will this knowledge—much more valuable in aggregate that it could be fragmented—be dispersed to the four winds, the five agencies, and the six advisory boards? Can the parent Biotechnology Science Board enforce standardization and scientific discipline if the agency advisory groups are not part of the parent body?

It would be wiser to establish a single Biotechnologies (note the plural) Science Board. Subcommittees or working groups should deal directly with the regulating agencies. Other working groups—on fermentation, downstream technology, ethics, gene therapy, deliberate release, or any technology about which there might be questions of feasibility or the public welfare—should equip themselves to advise the agency working groups and to formulate general standards for their specialties. This proposal is close in spirit to the cabinet council's own, but the differences are more than semantic. They are a matter of unity over duplication, of basic principles over bureaucracy, of efficiency over excess.

—Douglas McCormick