placed them squarely in conflict with the conclusions and recommendations expressed repeatedly in remarkably congruent terms by a large number of national and international scientific groups. All of these groups concurred with the U.S. National Academy of Sciences that "[a]ssessment of the risks of introducing rDNA-engineered organisms into the environment should be based on the nature of the organisms and the environment into which the organism is introduced, not on the method by which it was produced." The ABRAC approach was inconsistent as well with official U.S. government policy, as expressed in the so-called "scope policy" (*Federal Register* **57**:6753-6762, 1992), which reflected the consensus of the scientific community.

The guidelines were never approved by the Bush administration. It was only this sound policy decision that kept the OAB from jurisdiction over all field trials of rDNA-manipulated animals—and from massive increases in manpower and budget. Dr. Young's response to this setback was to send out thousands of copies of the guidelines bound and presented in a way that implied that they were en route to official sanction.

It is instructive that in his letter, Dr. Young does not refute the ABRAC/OAB's intention to regulate field trials "case-by-case, every-case" on the basis of scientific consensus or common sense, both of which certainly apply. He merely cites "neither time nor budget" for not adopting this scientifically indefensible policy. Moreover, his invoking the National Environmental Policy Act (NEPA) is disingenuous for two reasons. First, decisions to fund research are not considered, under NEPA, to be major agency actions that require an environmental assessment. Second, in the late 1980s, the Council on Environmental Quality (the White House agency that oversaw NEPA) urged the OAB repeatedly to conform fully with NEPA and to conduct an Environmental Impact Statement which would assess definitively the real risks associated with agricultural biotechnology research. This would have set the issue to rest; reassured the public; and clarified when, if, and to what extent the USDA needed to spend taxpayers' dollars to conduct extra reviews of particular field trials. The OAB refused.

As to the plaint that the ABRAC and the OAB do have well-circumscribed functions that are of "real value" and keep them fully occupied, a document entitled "Possible Future Issues for ABRAC" that was prepared by the OAB for a 1993 meeting in North Carolina tells a different story. The list in the document includes: "testing methods to validate the safety of whole foods and food components;" "food labeling for personal or religious dietary preferences;" "production of potent pharmaceuticals not known to occur naturally, in plants or animals;" "synthetic genes versus natural genes in engineered plants;" and "biotechnology as a trade issue."

Next, the budget issue. While perhaps the operating budget of $50,000 for the ABRAC may appear modest, it is only the tip of the iceberg. When one includes the government salaries and benefits for Dr. Young and his bureaucratically top-heavy staff at the OAB (the allusion in my article encompassed both the ABRAC and the OAB), the budget for FY94 is $625,015, according to White House figures. Moreover, direct government expenditure is only part of the total burden. The broader societal cost of regulation—particularly when it is poorly conceived and arguably unnecessary, as here—must be considered. Surely, at a time of "reinventing government," with the NIH and FDA directed to cut the number of their advisory committees by one-third, the ABRAC and the OAB are expendable.

Finally, I wonder whether Dr. Young's sharp personal attacks on me reflect an official position of the USDA, or simply another example of OAB's misuse of its government prerogatives—attempting to misinform public opinion and to intimidate a critic of government waste and abuse.

Henry I. Miller
Hoover Institute &
Institute for International Studies
Stanford University
Stanford, CA 94305

Frankly speaking

To the editor:

Felix Franks has written an important article describing the biophysics and material science principles that underlie the emerging marriage of the materials and life sciences (*Bio/Technology* **12**:253-256, March). He describes, in particular, the natural role that various sugars play in stabilizing biochemically active molecules.

We have independently verified Franks' conclusion and have successfully developed a nanocrystalline molecular transportation assembly that uses a glassy film of disaccharides to transport safely such molecules as viral antigens, hemoglobin, drugs and genetic material for the purpose of producing vaccines, synthetic blood, drug delivery vehicles, and gene therapy devices.

We salute Dr. Franks and his colleagues for helping spread the word on this rapidly emerging exciting new field of supramolecular chemistry.

Nir Kossovsky
Associate Professor of Pathology
Department of Pathology
UCLA School of Medicine
10833 Le Conte Avenue
Los Angeles, CA 90024-1732

Credit

In the article "Shopping for a Contract Research Organization" (*Bio/Technology* **12**: 526-528, May), Figure 1 comes from the lecture notes of "Pharmaceutical Contract Research in the 1990's: A Global Overview" given by Dr. R. Graham Hughes in Bad Hamburg, Germany, on December 2, 1993.