

## Letters

### Supercollider Funding

M. Mitchell Waldrop did a fine job of reporting issues related to the Supercollider (SSC) (Research News, 25 July, p. 420). However, he did not note the important comments on the SSC that were made in the Department of Energy (DOE) Energy Research Advisory Board (ERAB) study "Guidelines for DOE long-term civilian research and development," which was issued in December 1985 and which I chaired. ERAB looked at all DOE civilian R&D and made the following summary statements regarding the SSC:

- Increased funding of the SSC must not preempt other DOE civilian R&D priorities, as there are important, less expensive projects to fund in the near term.

- The SSC site selection contest under way may be premature.

- Because of its size, the SSC will require a national commitment, which must be based on (i) adequate research and engineering studies to support capital costs and project schedules; and (ii) international participation to defray a part of the costs. Initiation of the SSC is a basic science issue, not an energy issue.

ERAB member opinions on the SSC varied dramatically. Some felt that money for construction should be found, no matter what. At the other extreme, some members felt that the high energy physics "emperor has no clothes" and even \$550 million per year for such abstract research is a national waste.

To believe that the SSC can be funded in these days of severe federal budget deficits without having an impact on other research is totally unrealistic. Available funds for research are and will continue to contract. Nevertheless, it may be in the national interest to sacrifice other research in order to move ahead with this exciting new venture.

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### Biotechnology Regulation

By analogy to molecular biology's "one gene—one enzyme" hypothesis, Daniel E. Koshland, Jr., proposed recently (Editorial, 2 May, p. 561) a "one-license—one hearing" policy toward federal agencies' evaluation of new biotechnological products. Koshland

correctly decried some of the regulatory and litigation-related delays and described the frustrations of industrialists and academics, but his solution is oversimplistic.

It is obvious that biotechnology is neither well circumscribed nor homogeneous, but encompasses many disciplines from molecular biology and entomology to crystallography and bioprocessing engineering. New biotechnology ranges from fish farming enhanced by recombinant DNA-derived hormones and food plants with improved protein quality to microbes programmed to produce interferon or to degrade toxic wastes. Thus, governmental oversight for ensuring that products do not compromise public health or safety cuts across the jurisdiction of many regulatory agencies. These agencies, in turn, have various statutory mandates, different agency missions, and disparate degrees of scientific expertise.

Recognizing these complexities, the Administration in 1984 formed an interagency working group under the former White House Council on Natural Resources and the Environment (now the Domestic Policy Council). The working group has sought to achieve a balance between regulation adequate to ensure health and environmental safety and flexibility sufficient to avoid impeding the implementation of the new technologies. It concluded that existing laws—perhaps with some clarification—were adequate for oversight of the new products, but that some mechanism for coordinating scientific information and regulatory philosophy would be useful. Consequently, in November 1985 the Biotechnology Science Coordinating Committee (BSCC) was formed. Its function is *not* to perform redundant reviews of individual product applications or to second-guess agency decisions but rather to ensure that there is coordination among the various agencies overseeing biotechnology product regulation and that comparable principles and rigor are employed in agency evaluations.

The agencies recently published major statements of policy on oversight of biotechnology (1), in which the BSCC attempted in two important ways to avoid the regulatory redundancy and delays of concern to Koshland. First, for the situations where more than one agency could share jurisdiction, a *lead* agency was identified; second, the principle was established that where there is shared jurisdiction, one agency can defer to the scientific review of another. While "one license—one hearing" could be the goal to which we aspire, there are examples where it cannot suffice; for example, the nature and extent of the review (by the Environmental Protection Agency) of an enzyme intended as a drain cleaner would of necessity be quite

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different from the review [by the Food and Drug Administration (FDA)] if the same enzyme were intended for use as a thrombolytic agent administered intravenously to patients.

We are convinced that protection of human health and the environment, stimulation of industries using new biotechnology, and assurance of safety of products are mutually compatible. The FDA's record of having approved more than 150 products (including in recent weeks the first interferons and a monoclonal antibody that treats acute renal transplant rejection) that use recombinant DNA or hybridoma techniques in their manufacture is evidence of this conviction.

However, government cannot perform regulatory oversight of scientific and commercial endeavors in a vacuum. We require the advice and criticism of academics and of the public. And while we welcome such commentary as Koshland's in *Science*, there are alternatives to effecting better regulation. The most direct is to analyze and comment on the scientific assumptions in statements of policy, and we urge individual scientists and professional organizations to make the required investment in time and energy to do so. The FDA's last statement of

policy on biotechnology elicited a dismal response: a mere 34 official comments. Can that really be all the interest there is in the scientific and regulatory approaches of a major regulatory agency—with responsibility for products accounting for 25 cents of every consumer dollar—to important new technologies?

In addition, public education via lectures and articles directed at nonspecialists, while less direct, is a worthy investment.

Perhaps there was appropriate but unintended irony in Koshland's metaphor of "one gene—one enzyme," which is not an invariant principle. It is now known that certain messenger RNA precursors can be spliced in alternative ways, such that a single primary messenger RNA transcript may ultimately yield two or more very different polypeptides. Likewise, "one license—one hearing" can be a useful, although not universally applicable, model.

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#### REFERENCES

1. *Fed. Regist.* 51, 23301 (26 June 1986).

*Response:* The Biotechnology Science Coordinating Committee appears to be an excellent approximation of the simplicity and responsibility that were advocated in my editorial. I do not think the lack of letters indicates lack of interest but perhaps a past experience of scientists having suggestions fall on deaf ears. Miller and Young deserve great credit for their good solution to a difficult problem and for a receptiveness that will encourage responses.

I hope that Washington bureaucracy does not get as complex as gene expression. If it does, we may have to extend the adage "Ontogeny recapitulates phylogeny" to "Sociology recapitulates enzymology."

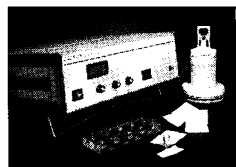
—DANIEL E. KOSHLAND, JR.

*Erratum:* In the article "Mathematicians recognize major discoveries" by Gina Kolata (Research News, 15 Aug., p. 722), Fields Medal winner Michael Freedman was incorrectly described as being a member of the University of Southern California faculty. Freedman is Charles Lee Powell Professor of Mathematics at the University of California, San Diego. In addition, several names in the article were spelled incorrectly. Field's should have been Fields, Nevalinna and Navanlinna should have been Nevanlinna, Kirky should have been Kirby, Atiyah should have been Atiyah, and Strasen should have been Strassen.

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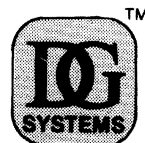
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