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Gene Technology and Democracy

I disagree with Rolf M. Zinkernagel about the issues involved in the current debate before next year's Swiss referendum on a constitutional prohibition of gene manipulation (Editorial, 14 Nov., p. 1207). Discussions of this topic are not confined to Switzerland; in fact, the rest of the German-speaking regions of Europe are intensely interested in the issue. Apprehension about gene manipulation is related not only to the particular mentality of the culture ("nature is good," and so forth), but also—arising from the pervasive awareness of the Nazi abuses of science and medicine—to a general perception of "pure biologic thinking" as tantamount to extreme right-wing ideology (*1*). The problem is not one of "not understanding molecular biology," as Zinkernagel seems to imply, but is a profound cultural issue that needs to be dealt with in that context.

Zinkernagel also does not acknowledge that in the debate in the Swiss Parliament, I, along with other members of the Labour Party, introduced a counterproposal that could have averted the referendum now threatening our biological research. This proposal would have eliminated major problems while retaining the prohibition on the patenting of genetically generated organisms. It was, however, defeated by the pharmaceutical industry and their political representatives.

There is distrust throughout Europe—not only in Switzerland—of giant companies whose solicitude for their shareholders appears to outweigh their concern for their thousands of workers. This is exemplified by the merger of Ciba and Sandoz into the mega-Novartis, notwithstanding the eminently sound financial states of both companies before the merger.

If it is felt that researchers are too heavily influenced by the economic interests of pharmaceutical giants, they tend to lose authority as opinion shapers in political and societal debates such as the one at issue. I am afraid that Zinkernagel (and many other researchers) incur that risk by their erroneous assessment of this situation.

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References

1. E. Schuster, *N. Engl. J. Med.* **337**, 1436 (1997).

The Swiss vote on the "gene protection initiative" is a blatant example of the failure of scientists to communicate the urgency of research in biotechnology and genetics to the public. The development of vaccines and fundamental knowledge is vital in medical research and must not be sacrificed to veto by technophobic and opportunistic politics. Bioethicists, biologists, and science educators in general must publicly challenge the conventional wisdom of "statists" who are jeopardizing the future and even human survival with pseudoscientific and reactionary misinformation about biotechnology. Society can ill afford to suppress the development of new treatments and approaches to research in molecular genetics. Suppression of new technology cannot guarantee prevention of abuse in biotechnology, because such work will proceed in secret even if it is banned.

Openness is the only choice for scientific advancement in biotechnology and for human survival.

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FDA "Reform"?

The Food and Drug Administration (FDA) reform bill (ScienceScope, 14 Nov., p. 1215) passed by the U.S. Congress includes requirements to speed the review of new vaccines and drugs and to reauthorize the Prescription Drug User Fee Act (PDUFA). But to say that the bill "leaves FDA's research structure untouched " is incorrect.

To enhance the review process and expand FDA's capacity to responsibly manage new types of biologics, some of the "user fees" (charges to companies that submit products for FDA review and approval) supported relevant research by scientists who perform much of the regulatory review. During the negotiations for the new PDUFA, an ancillary agreement (which was not included in the text of the act, but was made between FDA negotiators and the Pharmaceutical Manufacturers Association) was written that specifically prohibits the use of PDUFA funds to support such research.

Also, research at FDA must now compete with new initiatives in tobacco and food safety, as these will require funding from an FDA budget that has remained flat since fiscal year 1996. These and other factors will result in an estimated reduction of