BLASTX (*2*) to compare these sequences (translated in six frames) with the protein sequences of the SWISS-PROT database release 24 on a silicon graphics cluster. The results were processed by taking the five best "hits" of each BLASTX output and filtering them to remove those with Poisson probability [$P(n)$] greater than $10^{-5}$. A sequence showing the lowest $P(n)$ with a eukaryotic protein was considered to be "eukaryotic-like," while a sequence with a top-matching prokaryotic protein was designated "prokaryotic-like." The complete results of this search are available by electronic mail.

2. S. F. Altschul, W. Gish, W. Miller, E. W. Myers, D. J. Lipman, *J. Mol. Biol.* **215**, 403 (1990).

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## Biotechnology in Japan

June Kinoshita, in her article "Is Japan a boon or a burden to U.S. industry's leadership?" (News, 29 Jan., p. 596), recounts a survey of Japanese pharmaceutical biotechnology that provides in some respects an update of a survey performed by the U.S. Food and Drug Administration (FDA) in 1988 (*1*).

Kinoshita cites a number of significant obstacles that prevent Japan from being a major competitor, but she does not mention that the regulatory climate in Japan has been, at best, equivocal toward new biotechnology. Japan has adopted a technique-based regulatory approach—with special requirements for products derived from recombinant DNA, and several areas have been significantly impeded. For example, despite a medical and scientific infrastructure that could support clinical trials of human gene therapy, no Japanese group is close to moving into the clinic, and no Japanese company has been created with gene therapy as its goal. By contrast, gene therapy trials are already under way in the United States, Italy, France, the Netherlands, and China, with almost 100 patients having been treated and the numbers rising exponentially (*2*).

Japan's attitude toward the new biotechnology is similarly reflected in agricultural biotechnology. Only a single field trial of a recombinant DNA–manipulated plant has been carried out in Japan (and none of microorganisms), and Japanese research and development in this area is behind what one would expect. The Japanese government has provided little encouragement in the form of clear, predictable, risk-based regulation to those contemplating field trials. Moreover, the Japanese Ministry of Health and Welfare has imposed a strict regulatory regime specific to foods and food additives manufactured with recombinant DNA techniques (*3*).

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**References and Notes**

1. H. I. Miller, *Bio/Technology* **7**, 736 (1989).
2. W. F. Anderson, presentation at BioEast Conference, Washington, DC, 27 January 1993.
3. *Guidelines for Foods and Food Additives Produced by Recombinant DNA Techniques* (Ministry of Health and Welfare, Government of Japan, Tokyo, 1992).

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## Gene Therapy Approval Process

I would like to comment on several statements in the article "Harkin seeks compassionate use of unproven treatments" (News & Comment, 11 Dec., p. 1728) by Larry Thompson regarding a request by the San Diego Regional Cancer Center (SDRCC) that the National Institutes of Health (NIH) adopt a policy to expedite the review and approval of gene therapy protocols in cases involving terminally ill patients.

The central issue, all but lost in the article, is that NIH did not at the time have in place a policy to review and act on requests by terminally ill patients seeking the benefits of new gene therapy methods (*1*). The request was not a means of avoiding peer review but an attempt to streamline an existing process that in some cases literally exceeded the life expectancy of the patients seeking help.