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.

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

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).

Henry I. Miller Director, Office of Biotechnology, Food and Drug Administration, Rockville, MD 20857

References and Notes

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

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.

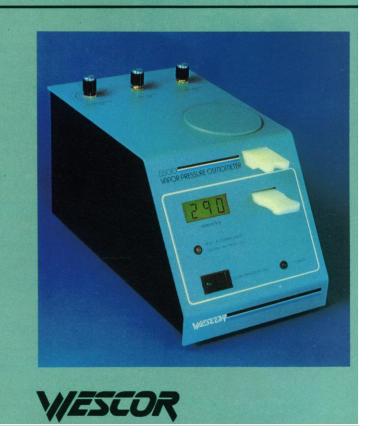
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The SDRCC request before the Recombinant DNA Advisory Committee (RAC) on 4 November dealt solely with this issue. A completely different SDRCC gene therapy protocol reviewed by the RAC 1 year earlier was not under review at the recent RAC meeting, nor is it the basis of the gene therapy protocol under consideration for the patient who is discussed in the article.

Ivor Royston

President and Scientific Director, San Diego Regional Cancer Center, San Diego, CA 92121

Notes

1. On 14 January, the RAC voted 9 to 3, with 1 abstention, to adopt an interim policy allowing internal NIH review and approval of genetic treatments for dying patients when the RAC cannot meet quickly enough to evaluated them (L. Thompson, News & Comment, 22 Jan., p. 452).

The Cost of Regulation

I was pleased to see that Philip H. Abelson's editorial "Regulatory costs" (8 Jan., p. 159) made use in the first paragraph of my data on regulatory cost (1). I agree with the points Abelson makes and hope that his message-that the cost of regulation has mushroomed-receives broad acceptance.

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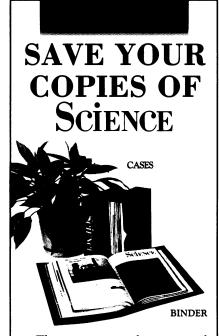
References

1. T. D. Hopkins, Ed., Regulatory Policy in Canada and the U.S.-Proceedings of a Conference (Rochester Institute of Technology, Rochester, NY, 1992), pp. 3-6; Office of Management and Budget, Budget Baselines, Historical Data, and Alternatives for the Future-January 1993 (Gov-ernment Printing Office, Washington, DC, 1993), p. 111.

From the Vatican

In Constance Holden's article "Scientists' campaign to save Earth (News & Comment, 27 Nov., p. 1433), Henry Kendall, chairman of the Union of Concerned Scientists (UCS), is said to have claimed that the Pontifical Academy of Sciences has adhered to the USC's campaign to save the Earth. As president of the Pontifical Academy of Sciences, I would like to say that this statement is not true. Any Pontifical academician who may have signed the UCS "Warning to humanity" has done so only in his own name.

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New challenges and opportunities in the application and characterization of ultrapure water: Y. Egozy, discussion leader

M. K. Balazs, "Ultrapure water for the semiconductor industry: Analytical problems and solutions.

G. A. O'Neill, "New criteria for water purity in biosciences and technology."

G. Foutch, "Ultrapure water for nuclear power plants by mixed bed ion-exchange: Model predic-tions and industrial results."

Recent advances in production of ultrapure water: H. Hamann, discussion leader.

G. C. Ganzl, "The use of electrodeionization for the production of ultrapure water."

F. M. Cutler, "Advances in the applications of mixed bed ion-exchange in the ultrapurification of

Novel configurations of adsorbents and ion-exchangers for enhancement of efficiency: R. Al-bright, discussion leader

D. D. Frey, "Effect of sorbent morphology on the performance of separation processes."

W. Fries, "The superior performance of ion exchange resins with short diffusion paths: SDP resins."

V. A. Davankov, "Sorption properties of hyper-crosslinked polystyrene sorbents."

W. Müller, "Chromatographic sorbents based on reactive polymers grafted onto inert supports: The 'tentacle' concept."

Polymers as catalysts: P. A. Yarnell, discussion leader.

W. Ford, "Catalysis by ion exchange latexes."

G. Challa, "Hydroformylation with polymer-bound rhodium-triorganylphospate catalysts. Interaction of proteins with surfaces: R. Wood,

discussion lead

J. Stahlberg, "Theoretical models for protein adsorption."

F. Arnold, "Molecular recognition by metal ion complexes and patterned metal-complexing polymers.

F. Regnier, "Fimbriated stationary phases for liq-uid chromatography of proteins."

Progress in chiral separations: F. Heifferich, discussion leader

D. Armstrong, "Recent advances in chiral sorbent development for LC, GC, SFC and CE."

G. Vigh, "Chiral separation of drugs by displacement chromatography.'

Reactive polymers: Preparation, properties, and applications: S. Alexandratos, discussion leader

R. M. Izatt, "Ion-selectivities using macrocyclobound silica gels.

G. Schumuckler, "Mixed liquid ion exchangers as extractants for metal salts

F. Cantwell, "Changes in the electrical double layer potential due to diffusion of cations into the hydrated layer at the silica surface."

C. J. King, "Recovery of carboxylic acids with functionalized sorbents and extractants."

Chromatography of proteins: N. H. L. Wang, discussion leader

S. Cramer, "Novel displacement systems for protein purification."

K. Unger, "Novel adsorbents with thin polymer coatings for bioseparations.'

W. S. Hancock, "Protein interaction with hydro-phobic surfaces in reversed phase chromatography.'

A. Marton, "Calorimetry in the characterization of stationary phases for biopolymer HPLC.

Short presentations: J. D. Sherman, discussion leade

Poster presentations: F. X. McGarvey and H. C. Hamann, cochairs