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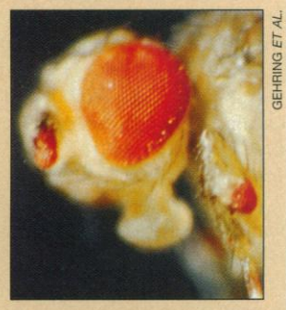
LETTERS

Open eyes

An investigator in New Zealand describes events that led up to a clinical trial for testing the safety of gene therapy for patients with Canavan disease. Two authors discuss research about the *eyeless* gene in *Drosophila* fruit flies (ectopic eye on antenna, right) and its significance to evolutionary theory. Concern is raised over the availability of nonhuman primates for use in AIDS research in the United States. The value and difficulty of maintaining a shipshape oceanographic fleet is noted. And the future of linear accelerator–based free electron lasers is pondered.



GEHRING *ET AL.*

Gene Therapy in New Zealand

I would like to respond to the News & Comment article "New Zealand's leap into gene therapy" by Eliot Marshall (15 Mar., p. 1489).

I was not a visiting professor at Yale University, as Marshall states, but a full-time associate professor of surgery and medicine and director of a gene therapy laboratory for 8 years. I accepted a position to return to New Zealand in April 1995, at about the same time I agreed to take on the Canavan project.

Canavan disease did not figure in the movie *Lorenzo's Oil*, which was a story about adrenoleukodystrophy. Although both are genetic diseases that affect the brain's white matter, they differ in terms of their inheritance (autosomal versus X-linked), the gene involved (aspartoacylase in Canavan disease), and in the rate of progression, with Canavan disease untreatable and fatal within the first decade of life.

In my press release, I stated, "The best we can hope for is that the procedure is safe; anything over and above that will be a bonus." I specifically avoided stating that this study would save the children's lives or alter the disease process.

It is not correct that I did not notify regulatory agencies either in New Zealand or the United States. The first individual I suggested that Roger Karlin (the father of one of the children with Canavan disease) speak to in March 1995 was Nelson Wivel, director of the U.S. Recombinant DNA Advisory Committee (RAC), to discuss regulatory issues. Yale was well aware of my research from an early stage, as the families together with the Yale Development Office had a major public campaign to generate research support; I submitted the protocol to the Yale Human Investigation Committee (HIC) in November 1995, as soon as we had amassed sufficient preclinical gene expression and safety data. Moreover, at the time of my accepting the position in New Zealand, I had asked New Zealand authorities to establish a gene therapy advisory committee in time to review a protocol that I had hoped to submit by December 1995.

The Yale HIC chairman, Robert Levine, was made aware of the Canavan project in June, not October, 1995; the project had only gotten under way in April 1995. I had always intended to submit the project to the Yale HIC and moreover had openly discussed the project with several members of the RAC, including the director. In my discussions with Wivel, he endorsed my decision to bypass the RAC, as long as an analogous committee would review the proposal in New Zealand.

It is true that I did try to expedite the review process. I believed that, although the study was ultimately presented as a Phase I safety study, any possible therapeutic effect would only be possible if the procedure was not delayed. The children were becoming increasingly and rapidly moribund, and delay would also mask the primary outcome measures of toxicity and evidence of gene transfer.

I am happy to state that both children appear well, and we plan to assess indirect measures of gene transfer within the next few weeks.

Matthew During
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Eye Evolution

The beautiful work on the *eyeless* gene by Walter Gehring and his colleagues (Reports, 5 Aug. 1994, p. 785; 24 Mar. 1995, p.