

number of people in Gibbons' 11 May article. However, the article did not contain important data critical to an understanding of the impact that the oxymoron of "shared exclusivity" would have on the development of drugs to treat rare diseases.

A recent survey by Pharmaceutical Manufacturers Association revealed that 133 orphan drugs are in human clinical tests or at the Food and Drug Administration for review. These projects involve 85 companies, including many small firms that can now afford such costly and risky research because of the act's 7-year market exclusivity provision.

The National Commission on Orphan Diseases, authorized by Congress in 1985, recognized that the market exclusivity granted by the act was critical to orphan drug research and recommended lengthening the exclusivity period.

The importance of the act's exclusivity provision was reinforced by a recent survey by the Pharmaceutical Manufacturers Association (PMA) in which member companies were asked about their current and future investments in orphan drug research and development and about the possible impact of "shared exclusivity" on their ability to continue such investments. The response from the firms that accounted for 80% of PMA members' investment in orphan drug

research was that "shared exclusivity" would be sufficient reason not to pursue orphan research.

These same firms account for 91% of what PMA companies expect to spend in the future. In addition, more than one-third of the companies surveyed reported that uncertainty over the pending amendments *already* is a factor in decisions about drug research.

"Shared exclusivity" (or simultaneous development, as it is now being called) would dilute the most powerful incentive in the Orphan Drug Act and inhibit investments in rare disease research.

Gibbons' article did not mention that there are alternative approval routes for simultaneous developers. Companies may obtain designations for other indications for the same drug. The exclusivity obtained for the orphan use does not extend to other uses. Also, companies may obtain orphan designation for a similar, but structurally different, drug.

Between 10 and 20 million Americans suffer from 1 of the 5000 known rare diseases. These people are desperate for a medical breakthrough. Yet, H.R. 4638 and S. 2576 will gut the Orphan Drug Act—and their best hopes for that breakthrough.

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### Billion-Dollar Zeolite?

Joseph Alper's article "Archimedes, Plato make millions for big oil!" (Research News, 8 June, p. 1190) contains the surprising statement, "ZSM-5 converts methanol into the mixture of hydrocarbons known as gasoline—a reaction of billion-dollar significance." This is nonsense on two counts. First, there is no available large, cheap supply of methanol that could be converted into gasoline. And second, if there were, the federal government would likely rule that it must be used without conversion as a motor fuel, since it burns more cleanly than gasoline.

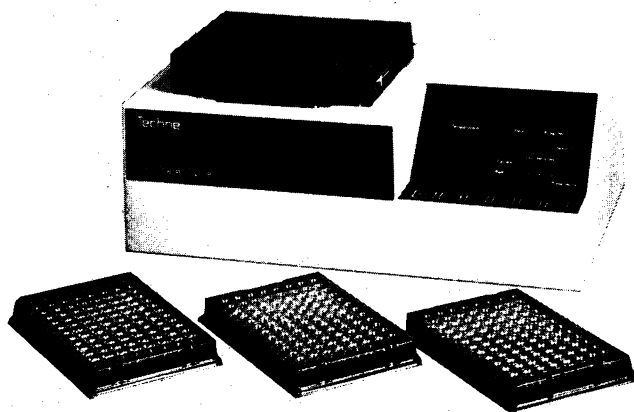
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*Erratum:* In figure 2B (p. 1236) of the report "Induction of CD4<sup>+</sup> human cytolytic T cells specific for HIV-infected cells by a gp160 subunit vaccine" by R. J. Orentas *et al.* (8 June, p. 1234), the labels for HIV-infected and mock-infected cells were reversed.

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