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OPPOSITION TO H.R. 3502

HON. ALBERT GORE, JR.

OF TENNESSEE

IN THE HOUSE OF REPRESENTATIVES

Wednesday, July 13, 1983

● Mr. GORE. Mr. Speaker, I rise in opposition to H.R. 3502, legislation to extend the patent term for certain pharmaceutical products by up to 7 years. This bill represents an unwarranted boost to the profits of an extremely successful industry at the expense of the public, particularly the poor and the elderly, and I urge my colleagues to oppose it.

Proponents of the legislation argue that pharmaceutical innovation is in a state of decline due to premarket regulatory review requirements. But the facts refute this contention. The pharmaceutical industry is among the most profitable of all major American manufacturing industries. While most sectors of the economy reeled during the recession of 1981-92, pharmaceutical profits increased dramatically. In 1981, profits increased 20 percent. In 1982, profits increased an additional 25 percent. If, as is asserted, there is a regulatory review "problem," it is not reflected in the industry's profits.

Nor is there any evidence of a decline in pharmaceutical innovation. Twenty-seven new drugs were approved for marketing in 1981; 28 were approved in 1982. The number of new drugs approved by the Food and Drug Administration (FDA) for marketing in 1981 and 1982 has been higher than in any year since 1962, when the efficacy testing requirements were added to the Federal Food, Drug and Cosmetic Act in landmark changes.

Industry expenditures for research and development have increased substantially over time, even after adjustment for inflation, according to a 1981 report prepared by the Office of Technology Assessment. This trend is expected to continue. The coming decades have been characterized by industry observers as a "golden era" for new drug development, based in part on the potential for dramatic advances in the application of genetic engineering.

Even if, in the face of the overwhelming evidence of the current prosperity of the pharmaceutical industry, it is believed that a stimulus to innovation is desirable, that stimulus already exists. The Economic Recovery Tax Act of 1981 provided a new 25 percent R&D tax credit for firms that increase R&D expenditures. In fact, the pharmaceutical industry is taking advantage of this new provision, according to the National Science Foundation (NSF). According to NSF, pharmaceutical R&D is growing at a 20-percent annual rate, spurred by the tax credit, reduced FDA approval time, and recent research breakthroughs and new marketing opportunities.

The R&D tax credit has an obvious advantage over patent term extension. It insures that additional revenue will be channeled into research and development. In contrast, drug companies have repeatedly refused to commit themselves to reinvesting even one dime of the additional profits that they will reap if patent term extension legislation is enacted. While the companies talk in general terms about the possibility of greater R&D expenditures, they will make no commitments. Their silence on this point is notable.

Moreover, even if the pharmaceutical companies reinvest the percentage of extra sales that they have historically reinvested, approximately 8.5

cents of every sales dollar, it is a poor investment for the public to spend $1 to get 8.5 cents of research. The existing R&D tax credit avoids this problem as well.

The final argument advanced by proponents of the legislation is the so-called equity claim. The argument that it is unfair for products subject to premarket regulatory review to lose market exclusivity that nonregulated products retain is based upon a fundamental misapprehension of the nature and purpose of the patent system. The patent system is not intended to and does not operate to grant an inventor any period of market exclusivity. Rather, the inventor is granted the right to exlude others from marketing the product for the statutory 17-year period.

This is an important distinction to bear in mind. It is based upon the recognition that no inventor enjoys 17 years of market exclusivity. Marketing considerations and other factors involved in refining an invention into a commercially viable form significantly limit the period of market exclusivity for all inventors, irrespective of whether the product is subject to premarket regulatory review.

In fact, it would be inequitable to give inventors of regulated products a period of patent-term extension for the regulatory review period when the product would not be marketed anyway because it is not in a commercially viable form. Inventors of nonregulated products do not have this regulatory umbrella that under the legislation would allow time to be recovered even when the product would not otherwise be marketed.

The drug companies have implicitly acknowledged another aspect of this fatal flaw in the premise of the legislation. The companies concede that most of the safety and efficacy testing that they conduct would be done even if there were no regulatory requirements, in order to protect themselves from product liability claims. Yet still they seek special treatment.

There is an additional reason why the time is not ripe for consideration of this legislation. The Congress does not yet have the factual information necessary to evaluate accurately the effect of the regulatory process on patent protection, or the effect of the companies' own internal decisionmaking process on patent protection. We have requested this information and hope it will be provided in the near future.

I ask that my colleagues carefully review the arguments on both sides of this bill. It is not a simple issue, but I believe the public interest is best served by rejection of this legislation. It will simply guarantee substantially higher profits for an industry that is already extraordinarily profitable. In a period in which health care costs are skyrocketing out of control, the public can ill afford such an additional burden.●