March 12, 1982
5130 Minocqua Crescent
Madison, Wisconsin 53705

Mr. Robert Spiegel
Editor
Wisconsin State Journal
1901 Fish Hatchery Road
Madison, Wisconsin 53713

Dear Mr. Spiegel:

I have read the article on Sunday, March 7, concerning the position taken by Representative Kastenmeier on the extension of patent life for drugs that are held up because of regulatory considerations. I believe you were quite unfair in the treatment of the enlightened position taken by Representative Kastenmeier. The simplistic idea that this will end up costing our patient population more money is regretably a superficial point of view. The production and marketing of drugs and medicinals is a highly competitive business. We are not only in competition with our own companies within the United States but also in competition with foreign drug houses who have less of a problem with regulatory agencies than we have. As it is, there are many drugs that are now not developed by our companies simply because adequate patent protection is not available or that the number of patients who will use the drug are too small to justify investment of capital. The investment of capital for development of a new drug is often of the order of $10-50 million. Clinical studies required for proof of efficacy and safety are enormously expensive. A drug company that seeks to develop such a compound takes on the expense and obligation of the development. Because of extensive requirements by the FDA, often ten or more years elapse before approval is obtained. Since patent life is now 17 years, the company that has expended the funds and time of development find that patent life has essentially expired. This then permits other companies to market the same drug for much less because they have not incurred the development cost. In the absence of adequate protection, therefore, a drug company is not willing to invest $10-50 million unless they are certain that they will end up recooping their investment and making some profit for the stockholders who have invested their money in the company. Although on the surface it may appear that a drug will cost slightly more money if it is marketed by a company who has patent protection, this is much better than not having the drug available at all. After all, the aim of our research efforts in biomedical science is to develop new treatments for disease. If because adequate patent protection is not available the treatments are not developed for use, all investment in basic research is lost. The loser in this event is the taxpayer and patient.

Representative Kastenmeier has been very careful in examining all sides of the question. This is how a legislator should go about his business. Representative Kastenmeier is holding hearings on the matter and is, fortunately for us who have elected him, interested in a fair and balanced viewpoint, taking into account all considerations. Of great concern to him I am sure is that our population have available to us the benefits of scientific investigation. These can only be made available if the investment in developing these basic science findings to the market are returned to the companies who have the foresight to develop them in the first place.

I believe patent life extension to take into account delays incurred because of regulatory agencies are an imaginative way to encourage the development of drugs from our basic science findings. I applaud Representative Kastenmeier in his open point of view, and I am disappointed in the opposing statements relayed in the State Journal article.

Sincerely yours,

H. F. DeLuca
Professor and Chairman
Department of Biochemistry
University of Wisconsin-Madison

HFD:pm