Self-Serving Trade Secrets: A Response

I welcome the opportunity to comment on your proposed editorial[1] for the *Journal of Pharmaceutical Sciences.*

The quotes from PMA testimony are accurate, but I do not agree with your interpretation of them in implying that "data critical to the informed use of a new drug" is being withheld by the current system or that health care practitioners are denied ready and convenient access to "information which may either save lives or prevent needless deaths." As you know, the review process for New Drug Applications leading to required labeling for a new drug product, which is followed by the FDA, takes the following points into consideration. The package insert must contain full disclosure and list all pertinent indications and contraindications for the proper use of the product. Also, FDA now releases a summary of the clinical data establishing safety and efficacy for approved new drugs. For drugs not subject to NDA procedures, and for all antibiotic drugs, all of this data is available.

The "purely economic profit considerations" which you refer to should not be dismissed so cavalierly, since they represent a most important incentive for continued research support. If indeed you agree, as you seem to indicate in your editorial, that the control of drug testing and related research should remain with the private industry, rather than with government, you should also be concerned with how the research-based pharmaceutical industry will maintain the initiative and wherewithal to continue its innovative work.

We would agree that the patent system has worked successfully to foster innovation and we do not want it to be discontinued or altered to discriminate against pharmaceutical protection. Patent protection, however, in and by itself is not always sufficient, either because such protection is not available or it is of limited scope. Also, on the average, the effective life of a patented new drug discovery is diminished (currently about nine years) because of the time delays associated with obtaining new drug approval from the FDA.

The incentive to conduct research and development of new therapeutic entities should be provided by a plurality of systems, including the patent laws, trademark laws, trade secret concepts, and, with respect to new drugs, government protection of raw clinical data supporting product safety and efficacy. This plurality of systems is available to other industries and we see no reason to prejudice new drug research incentive by eliminating any one mechanism.

Finally, we think it is somewhat inflammatory to imply that needless deaths may be occurring under the present system and that data critical to the informed use of a new drug is being denied practitioners. The FDA approval process is basically sound, although refinements certainly could be made. FDA approved labeling is detailed and precise and apparently health professionals have not been clamoring for additional information. The data in question would primarily be of value to a drug manufacturer to support a second NDA and thereby avoid adding to the scientific knowledge.

Ed, I appreciate the opportunity to comment on your proposed editorial, and would ask that, if possible, this letter be printed along with it.

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Received July 19, 1976.

[1] E. G. Feldmann, *J. Pharm. Sci.*, 65 (7), i(1976).

Editor's note: An advance copy of Dr. Feldmann's editorial for the July 1976 issue was sent to Mr. C. Joseph Stetler, President of the Pharmaceutical Manufacturers Association, with an invitation to comment. Unfortunately, the Journal publication schedule did not permit this response from Mr. Stetler to be published in that same issue in which the editorial appeared.