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SELF-SERVING TRADE SECRETS

If one of the "pollsters" who conduct opinion surveys were to ask a representative sample of Americans as to whether industry "trade secrets" should be adequately protected by law from forced disclosure—as, for example, under the Freedom of Information Act—one could safely predict that the response would be overwhelmingly in favor of such protection. The concept of trade secrets is a fundamental tenet of the capitalistic system, and one to which we ourselves subscribe.

Divergence of views arises when individuals are asked whether particular kinds of information are properly classified as trade secrets. Specifically, it is in this respect that we find that we must disagree—and disagree strongly—with a position articulated by spokesmen for the Pharmaceutical Manufacturers Association.

This spring, three of their top staff officials testified before the HEW Review Panel on New Drug Regulation; and they addressed the subjects of retaining control of drug testing under industry, rather than government auspices, and of adopting an additional phase in the clinical testing of new drugs in terms that made a rather credible and persuasive case for the industry position.

On the other hand, on the subject of trade secrets, we feel that the PMA presented a position that is self-serving to the detriment of the common good and the public welfare. Their prepared statement read in part:

> *"Much of the company information in question is data relating to safety and efficacy of new drugs. This information represents the results of many years of animal and clinical testing at enormous cost to the sponsoring company. The data would be of particular value to companies wishing to market competing products, in that expenditure of large amounts of research and testing time and money could be avoided . . . .*
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> *"We urge your committee to evaluate critically the current FDA thinking that data supporting new drugs should not be protected from public disclosure. FDA has recently testified that the incentive to conduct new drug research is best protected by the U.S. patent laws and that limited FDA protection of safety and efficacy data is contrary to the public interest.*
>
> *"We strongly disagree with this premise. Although patent protection is essential for drug research, animal and clinical data generated by the new drug originator should not be handed out by the FDA to competitors so as to obviate the need to conduct any clinical research with follow-on versions of the new drugs."*

For our part, we strongly disagree with this approach for two reasons. First, we believe that patient welfare demands that health care practitioners using a drug should have ready and convenient access to all clinical data relating to that drug's safety and efficacy. And second, we believe that purely economic profit considerations are not sufficient to justify requiring duplicative clinical testing with the inherent risks to the subjects or patients involved.

We do agree that competitors ought not get "a free ride" by unjustly and unfairly benefiting from the work of others. However, there are other means to achieve this objective without resorting to secrecy of data that are critical to the informed use of a new drug.

Specifically, we object to PMA's cavalier dismissal of the patent system as the most appropriate vehicle for this purpose. We would remind the PMA that the patent system was, in fact, established to provide just this kind of industry protection. If the PMA feels that the system is not working satisfactorily for some reason, then the proper remedy is to modify the patent system, and not to hide and lock up information which may either save lives or prevent needless deaths.

Edward G. Feldmann