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A NEW KIND OF "DRUG LAG"

Much has been said and written about the purported "drug lag" in the United States. Although we are certain that most of our readers are quite familiar with this issue, for the sake of those who are not, a brief description would be in order.

Basically, the present drug laws in this country require a demonstration of both safety and effectiveness before the marketing of a new drug is permitted. Moreover, the implementing regulations spell out in more precise terms and in greater detail the types of testing and test data that must be compiled in support of the claims made in the application submitted for approval. For example, controlled, double-blind clinical studies generally are considered essential in the effort to document the effectiveness claimed for a new drug.

The documentation required, both in a qualitative and a quantitative sense, coupled with the administrative procedures utilized generally results in new drugs appearing on the U.S. market at a later date than in most countries abroad. Depending upon the interests and politics of the person commenting, this situation is depicted as ranging from a very serious problem in which desperate patients are denied lifesaving therapy for years on end, to a blessing in which the public is guarded and shielded from inadequately tested, dangerous agents that are promiscuously marketed in other countries.

The drugs involved are new chemical entities which are patentable and, therefore, the firm submitting the New Drug Application would retain exclusive property rights—except, of course, for possible licensing and royalty agreements—to that agent for the life of the patent. Hence, there is a strong profit motive which greatly encourages the interested company to actively pursue its efforts toward obtaining government approval for marketing the new drug discovery.

Indeed, various allegations have been made that certain firms and certain drug industry representatives have pursued this objective too vigorously to the point of bringing improper pressures to bear upon the government agency's medical scientists in a zealous effort to win such approval for their new drugs.

The purpose of this editorial, however, is not to enter this familiar "drug lag" controversy. Rather, it is to call attention to the neglected compounds that have great potential as useful drugs, but which are shunned by drug companies simply because they are unpatentable. For all its benefits and advantages, the free enterprise and patent system discourages private industry from investigating the potential therapeutic value of such unpatentable compounds.

Consequently, a "research lag" exists because research and development relating to these compounds—which happen to be in this category of known compounds or naturally occurring substances—simply are not conducted. A rather dramatic illustration is the drug lithium carbonate. The value of lithium in treating manic-depression was suggested many years ago; indeed, reports of its effectiveness appeared in the late 1940's. However, as recent as 1965, no commercial firm was sufficiently interested in pursuing these leads because lithium and its common salts are naturally occurring substances which are not patentable.

Eventually, we understand that the American College of Neuropsychopharmacology, in a move that would have been without precedent, seriously considered submitting a New Drug Application in its own name in order to win government approval for the agent as a drug. What abruptly changed this situation and prompted industry interest in the mid-1960's was a recognition that the clinical usefulness of lithium is dependent upon its formulation as a slow-release dosage form and that such timed-release products are patentable.

We are not suggesting that the drug industry was negligent or derelict in failing to devote research dollars to study lithium or any other such unprofitable entity. But we are suggesting that a void exists in our present system, which results in potentially useful drugs being neglected.

Various possible remedies are available to fill this research gap, including private foundations, academic institutions, and various public facilities such as hospitals operated by the Public Health Service or Veterans Administration. However, it would appear that the most logical central facility to assume this role is the National Institutes of Health and, specifically, the National Institute of General Medical Sciences. Moreover, it strikes us that federal research dollars—which often are spent in such questionable pursuits as to merit U.S. Senator William Proxmire's celebrated "Golden Fleece Award"—would be well utilized if expended for this purpose.

—EGF