An Updated Review of the "Drug Lag"

At the time this editorial is being written—and which, due to the lead-time necessitated by the *Journal's* production schedule, is long before our subscribers will have an opportunity to read it—the public press and broadcast media are filled with widely contradictory assessments as to whether the United States or the Soviet Union currently enjoys overall military superiority.

In many respects, this debate reminds us of a similar one in the health care field which has raged on with comparable intensity and, seemingly, for as lengthy a period of time. We refer to the so-called "drug lag"—a highly controversial subject which we have addressed in editorials on several previous occasions and most particularly in the April 1978 issue of this journal.

All sorts of data, statistics, and "evidence" are paraded out by those on each side of the question in an attempt to prove their claim that either (*a*) in this country, drugs are approved much more slowly than in other developed nations, with the result that the American public is deprived of significant public health benefits, or (*b*) there really is little, if any, difference in the speed of U.S. drug approvals when compared across the board with other major nations.

Furthermore, it cannot be claimed that the issue has suffered from lack of attention or study. Indeed, at least four separate analyses have either just been completed or are about to be so.

These include: (*a*) a study by the FDA's Office of Planning and Evaluation, which was released in mid-March 1982; (*b*) another study conducted at George Washington University under a contract from FDA's New Drug Evaluation Division, which also was released in mid-March 1982; (*c*) an analysis being conducted by the FDA Commissioner's Task Force on New Drug Review, which is soon to submit its report through Health and Human Services Secretary Richard S. Schweiker; and (*d*) the findings and recommendations of the Federal Drug Approval Process Commission, a body sponsored by the U.S. Congress and serving under the chairmanship of F. Gilbert McMahon of Tulane University. At the time of our writing, this latter body was circulating a "final draft" version of its recommendations, and the formal report itself was due to be released almost any day.

Hopefully, each of these studies in its own way will contribute to an understanding of the process and to improvements in its operation.

But even while these studies were still under way, we noted a number of new drug approvals that were announced with accompanying FDA statements that the approval was processed in some sort of expedited manner. Two of the most recent "fast-track" drug approvals included the antiviral herpes agent, acyclovir, which cleared FDA in less than 9 months, and the calcium channel blocker, verapamil, which completed all its FDA processing in just over a year from first filing.

These examples—and several similar ones—demonstrate that, given the right set of circumstances, FDA drug approval can be quite swift.

Finally, we were especially impressed with an FDA year-end report released in early January of this year, in which it was claimed that over twice as many new drug entities were approved during 1981 (27 in all) as compared with 1980 (12 in all). Furthermore, the FDA's statistics showed that the average period from submission of application to final approval for marketing of new chemical entities has dropped from 37.5 months in 1979 to 31.2 months in 1981. With respect to the "fast-track" drugs, the decline was even more dramatic: from 17 months in 1976–78 to just 10 months in the 1979–81 period.

Even the General Accounting Office—not known for handing out very many good "report cards"—issued a conclusion to an investigation it completed in late 1981, which stated that the FDA, since 1978, has "approved more drugs in less time than before, despite an increased workload."

All of this suggests to us that if truly there ever was a drug lag, it no longer exists—or is at least of manageable proportions and susceptible to administrative remedies within the regulatory agency. Consequently, new legislation or major changes in the pertinent existing regulations would now appear to be of doubtful value.

Indeed, legislative or regulatory tinkering could actually prove to be more disruptive than beneficial, insofar as expediting the judicious approval of new drugs. With those thoughts in mind, we personally would recommend that, for the immediate future anyway, Congress "cool it" with respect to amending the present drug approval provisions of the Federal Food, Drug, and Cosmetic Act.

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