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/THE FIRST WORD

Out with the Old, In with the New: Time for a New Drug Development Agency?

The U.S. Food and Drug Adminstration (FDA), a federally mandated agency, stands between companies and their profits, the Congress and the White House, congressional members and their constituents, consumers and their products. It is difficult to imagine a less enviable position. Or a less tenable one. During the 1980s, when pharmaceutical companies and biotech companies had money to burn, the FDA tendency to swing between gun slinging and when-in-doubt-do-nothing stasis could be, however unhappily, accommodated. But now when it takes, on average, 2.5-3 years to get a new drug through, and biotech companies are facing burn rates of $500,000 a month, there is no room for tolerance.

During current FDA commissioner David Kessler's tenure, some aspects of the regulatory process have improved. The agency's second annual performance report on the implementation of the Prescription Drug User Fee Act of 1992 indicates that the FDA may finish dealing with a large backlog of overdue submissions ahead of schedule, and that the approval time for new drug applications received in 1993 was more than six months faster than before the act was put in place.

Things could be even better still, but it will take more than adding some desks and rearranging the furniture. It may require tearing down the house and rebuilding.

This issue features a provocative proposal from Stanley Crooke, chairman and chief executive officer of Isis Pharmaceuticals, outlining such a radical reform. He argues that it is time to end the debate about who is responsible for the "drug lag" and to stop "tinkering" with an outmoded, overloaded regulatory system.

In "Comprehensive Reform of the New Drug Regulatory Process" (p.25), Crooke presents an eight-point plan to speed the development of new drugs, the centerpiece of which is the creation of a new agency that would concentrate solely on drug and biologics regulation.

Included in his proposal is a plan to reinforce corporate behavior that is consistently in compliance with good drug development practices by creating a corporate rating system that rewards compliance with faster drug application reviews and approvals. Much of his proposal rests upon changing the nature of the relationship between submitting companies and the FDA from an adversarial to a cooperative one. In it, regulatory issues are addressed by the FDA and drug development companies working together from the earliest stages of the process. Such cooperation could substantially reduce the amount of time needed to review and approve a new drug application. Crooke also maps out some alternative labeling practices, as well as methods for getting formularies into the decision-making process and for monitoring drugs after they have been released to the market.

The author himself notes that many people will take issue with these ideas, and some obvious objections quickly come to mind: How accurately can you predict a company's future drug development performance from its previous track record? What is the political load? Can regulatory integrity be maintained in this industry friendly scenario? No industry-based regulatory scheme could be entirely autopoietic; to quote American writer H.L. Mencken, " Conscience is an inner voice that reminds us that someone might be looking."

This proposal, and others like it, deserve serious discussion now. It is a cause that the Biotechnology Industry Organization could, from its post in Washington, take under its organizational wing and nurture. The creation of a new, more agile drug development and regulatory system that balances the need to bring safe, efficacious drugs to market rapidly with the need to control risk and guard the public welfare would be something we would all welcome in 1995.

-SUSAN HASSLER