

## FDA Decision Making

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Daniel Carpenter's review of Food and Drug Administration (FDA) decision making (Jan/Feb 04) provides insights into the FDA's challenges but gives less attention to what matters most to FDA front-line doctors and scientists: How can we take steps to maximize the public health benefits of new medical products while minimizing their known and potential risks?

The FDA has undergone a transition during the past decade to a more transparent and open decision-making process. There is broad understanding that the weighing of risks and benefits is driven by individual values. A key element in good drug regulation involves consulting those who will bear the risks: patients and prescribers. Even after drug approval, it is crucial to optimal drug use that both prescribers and patients be fully informed of the evidence about risks and benefits, so that individual trade-offs can be made.

To address these objectives, we are stressing efficient risk management—finding the least costly approach to achieving the most risk reduction for our population. Efficient risk management requires using the best scientific data, quality standards, and efficient systems and practices that provide clear and consistent decisions and communications for the public and regulated industry. The process for reviewing new drugs draws on the most complete and appropriate medical evidence, the expert judgment of FDA staff, and the advice of patients and doctors on our advisory committees. Approval comes down to decisions about how much risk and uncertainty Americans are willing to tolerate and, in turn, depends on the strength of the evidence on the benefits that a new drug or device will provide.

We are doing more to define risks and benefits of treatments at a lower cost. For example, we are taking new steps to develop better information about pharmacogenomics—the differences in the way people respond to drugs and the types and dosages of medications from which they are most likely to benefit and least likely to suffer an adverse event. Unfortunately, as medical technology has progressed, our systems for assuring the safety of medical treatments have too often remained in the past century. We are taking new steps to make these systems work better and to build new ways to assure better patient safety through modern information technology tools.

Recently we proposed a new rule, designed to get more extensive and timely information where we need it most, for new drugs, complications, and adverse events that are not well understood. It was designed with the goal of creating one global standard that regulatory agencies could use to get the best information possible on adverse events. We have also upgraded our systems for collecting and analyzing adverse-event information and are implementing new programs to monitor the safety of new drugs after they are approved. These and other steps mean that more safety monitoring and response activities are in place than at any time in the FDA's history.

**Peter Pitts**

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