
MANAGING THE RISKS FROM MEDICAL PRODUCT USE

CREATING A RISK MANAGEMENT FRAMEWORK

*REPORT TO THE FDA COMMISSIONER
FROM THE TASK FORCE ON RISK MANAGEMENT*

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EXECUTIVE SUMMARY

As one of her first initiatives after being sworn in as FDA Commissioner, Dr. Jane Henney established a Task Force to evaluate the system for managing the risks of FDA-approved medical products, focusing particularly on FDA's part in the system. This report is the result of that review.

Briefly, the Task Force assessed risk management practices within the overall healthcare delivery system, focusing on the roles and responsibilities of each participant. The Task Force applied a risk management model used in other Federal sectors. We also examined the various risks from medical products and their sources. The Task Force then evaluated FDA's role in the current system. First, we reviewed the Agency's *premarketing* risk assessment and approval processes to determine if serious adverse events are occurring at a higher rate now than they have in the past. Next, the Task Force evaluated FDA's *postmarketing* surveillance and risk assessment programs to see if they are doing the job they were intended to do. Finally, the Task Force analyzed all of FDA's risk management activities to evaluate the Agency's role in the overall system for managing medical product risks. Our findings are summarized here.

FINDINGS

The time is right for a new framework

The key finding of our review is that the time is right to apply a systems framework to medical product risk management. The FDA plays only a part in the complex system of risk management. Numerous other groups participate in decision making related to the use of medical products. A systems framework for risk management should enable a better integration of the efforts of all the involved parties. Such a framework also should facilitate a better understanding of both the risks involved in using medical products and the sources of those risks. A better understanding of risks and a more integrated risk management system will enable more effective risk interventions.

The current risk management system has evolved over time

At the turn of this century, healthcare in this country was generally provided by a family practitioner who treated patients from cradle to grave. As illustrated in the following figure, medical products today are developed and used within a complex system involving a number of key participants: (1) manufacturers who develop and test products and submit applications for their approval to the FDA; (2) the FDA, which has an extensive premarketing review and approval process and uses a series of postmarketing surveillance programs to gather data on and assess risks; (3) other participants in the healthcare delivery system, including healthcare practitioners; and (4) patients, who rely on the ability of this complex system to provide them with needed interventions while protecting them from injury.

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