MANAGING THE RISKS FROM MEDICAL PRODUCT USE

CREATING A RISK MANAGEMENT FRAMEWORK

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

U.S. Department of Health and Human Services
Food and Drug Administration
May 1999

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

MANAGING THE RISKS FROM MEDICAL PRODUCT USE

Table of Contents

Executive Summary *1*

Findings 2

Conclusions, Recommendations, and Options 12

Introduction *16*

Legislative and Management Initiatives Have Helped Speed Review Time 16

Concerns Have Been Raised About the Effects of PDUFA 17

The Commissioner Asked the Task Force to Look Into Public Concerns About the Risk Management System 18

Part 1: Background — What Are the Risks and What Is FDA's Role in Managing Risk? *20*

Goals Are to Maximize Benefit, Minimize Risk 21

What *ARE* the Risks Involved With Using Medical Products? 23

What Is FDA's Role in Minimizing Risk? 29

Conclusions 31

Part 2: Is the FDA Maintaining the Quality of Its Premarketing Reviews? *33*

Has the Rate of Serious Adverse Events Increased? 33

How Well Is the Agency's Quality Control System Working? 37

What Factors in the Development Process Could Affect Risk Identification? 43

Conclusions and Recommendations 49

Part 3: How Does FDA Conduct Postmarketing Surveillance and Risk Assessment? *51*

Overall Postmarketing Risk Assessment Is Complex 52

FDA Uses a Number of Approaches to Assess Risk 54

Initiatives Underway to Expand Postmarketing Risk Assessment 63

Other Efforts Being Considered to Expand FDA's Risk Assessment 65

Conclusions, Recommendations, and Options 69

Part 4: Managing the Risks From Medical Product Use *71*

Current Risk Management for Medical Products 71

Federal Risk Management Framework 73

Is the Current Risk Management System Working? 76

DOCKET ALARM

Find authenticated court documents without watermarks at docketalarm.com.

The Time Is Right for a New Systems Framework **77**
FDA's Overall Risk Management Activities **79**
Conclusions, Recommendations, and Options **90**
Members of the Task Force ***98***
Bibliography ***100***
Acronym List ***103***
Appendices ***1***
Table of Contents ***1***
Appendix A ***A-1***
Appendix B ***B-1***
Appendix C ***C-1***
Appendix D ***D-1***
Appendix E ***E-1***
Appendix F ***F-1***
Appendix G ***G-1***
Appendix H ***H-1***
Appendix I ***I-1***

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

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.

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

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.

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.