

# REMS: A Standardized Approach to Risk Management

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## Abstracts

Risk Evaluation and Mitigation Strategies. Until recently, the Federal Drug Administration's REMS program impacted drugs that would not have been otherwise approved due to their risks.

The hurdles, costs and additional barriers in getting a drug to market were faced by few. Yet increasingly, risk mitigation is becoming a key feature in the American pharmaceutical landscape.

Where the FDA once focused on individual high-risk products, it has now turned its attention to drug-class REMS, such as those affecting long-acting opioids. And criticism is mounting. Increasingly, stakeholders want more input into the development of the REMS process, and greater transparency in REMS decisions.

And while increased REMS requirements will undoubtedly affect drug companies, pharmacists, health plans, physicians and their patients, there are benefits, from improved promotional opportunities and value propositions to drug life extension.

In *REMS: A Standardized Approach to Risk Management*, FirstWord examines how the industry faces increasing regulatory hurdles through the implementation—and expansion—of federal risk management initiatives. The sharply-written report addresses the drawbacks and benefits to drug-class REMS, as well as insights into how such programs have affected drug roll-out and marketing. Based on the most current information, interviews and news, the report offers the pharmaceutical industry a much-needed roadmap to how REMS will affect business.

**The report offers insights into:**

The benefits and drawbacks to REMS

The implications to the industry of drug-class REMS

## **KEY FEATURES**

Complete background on the historical and regulatory development of REMS

Breakdown of the challenges and negative impacts associated with REMS

Examination of the case for and against class-wide REMS

Chart outlining best practices and recommendations from recent stakeholder meetings

## **CASE STUDIES EXAMINED IN THE REPORT**

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Cephalon's COVERS program

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Celgene's STEPS program

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