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Client Alert

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FDA Releases Strategy for Improving How the Agency Communicates Risk Information on the Products It Regulates

The U.S. Food and Drug Administration is frequently required to communicate risk information about drugs, medical devices, and biological products to healthcare professionals who prescribe and administer medical products, their patients, and consumers who buy nonprescription products. Indeed, communication about the appropriate use of FDA-regulated products is a key component in the effective management of medical product risks. It is important that these communications be clear and easily understood, yet meeting this standard is a challenging task. On September 30, 2009, FDA issued a Strategic Plan for Risk Communication, which outlines the agency's efforts to disseminate more meaningful public health information. The plan lays out a framework for the FDA to provide information about FDA-regulated products to health care professionals, patients and consumers in the form they need it and when they need it and also explains how the agency will oversees industry communications.

The plan defines three key areas in which strategic actions can help improve the FDA's communication about the risks and benefits of regulated products. Those three strategic goals are (1) strengthen the science that supports effective risk communication; (2) expand FDA's capacity to generate, disseminate, and oversee effective risk communication; and (3) optimize FDA polices on communicating product risks and benefits. The plan reflects the FDA's belief that risk communications must be adapted to the needs of different audiences and should be evaluated to ensure effectiveness. The plan also focuses on improving two-way communication through enhanced partnerships with government and non-government organizations, and focuses on policies that affect areas of high public health impact.

The overall strategy is intended to guide program development and research planning in an environment where rapidly evolving technologies enable patients to become increasingly involved in managing their health. The plan identifies over 70 specific actions for the FDA to take over the next five years, including 14 that the agency commits to accomplishing over the next twelve months. They include:

- Design a series of surveys to assess the public's understanding of, and satisfaction with, FDA communications about medical products
- Produce a research agenda for public dissemination to determine the

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most effective format and content for communicating risk information and provide technical assistance and other support to facilitate research
- Create and maintain a useful, easily accessible internal database of FDA and other relevant risk communication research
- Harmonize across FDA on appropriate criteria, titles, content, and format for public notifications of emerging risks of medical products
- Develop an expert model to characterize tobacco-use related consumer decision-making and better understand the likely impact of FDA oversight of tobacco products
- Develop templates for FDA press releases about regularly occurring events, such as product approvals, recalls, and public health advisories.
- Develop a "library" of multi-media communications on safe food practices for general education purposes and for use with crisis communications concerning food contamination episodes
- Post pictures of FDA- regulated products affected by Class I or high-priority Class II recalls as part of recall notices/information
- Establish an internal network to test messages informally with FDA employees
- Establish a significant new data collection mechanism to measure consumer reaction to food contamination recalls during the emergency so that messages can be adjusted as necessary for the greatest effectiveness
- Improve procedures and mechanisms that enable FDA to conduct timely testing of public risk/benefit communications
- Establish FDA guidelines specifying roles and responsibilities of different FDA experts in communications development
- Develop detailed action plans at the agency and center levels for implementing and achieving the proposed action steps, including timelines, responsibilities and resource needs
- Identify outcomes and develop measures for assessing progress toward goals and strategies

FDA's risk communication strategic plan is an ambitious one that will take time and substantial collaboration with stakeholders to implement. However, implementation of the goals announced in the plan will enhance the agency's mission of protecting and promoting public health.

A copy of the strategic plan for risk communication can be accessed here.