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A Cautionary Tale

Commissioner of Food and Drugs Margaret A. Hamburg, M.D., who was confirmed May 18, 2009, by a unanimous Senate voice vote, recently outlined her commitment "to prevent harm to the American people" through swift, aggressive, and effective enforcement of FDA laws and regulations.

In a statement to a group of industry representatives, attorneys, consumers, and others attending a speech sponsored by the Food and Drug Law Institute in Washington, D.C., she said: "The FDA must be vigilant, the FDA must be strategic, the FDA must be quick, and the FDA must be visible. We must get the word out that the FDA is on the job."

In her address, Dr. Hamburg outlined six initial steps designed to hone the effectiveness and timeliness of the FDA's regulatory and enforcement system. (Please turn to page 8 of this issue to review the action plan.)

In keeping with the spirit of Dr. Hamburg's vision for improving safety and preventing harm to the American people, in the first seven months of 2009, the FDA approved more than 30 Risk Evaluation and Mitigation Strategies (REMS) for both new drug and biologic license applications. There were 24 approvals in 2008, when the REMS legislation took effect. REMS is the hot topic around the conference table and our experts say it took the industry until the end of 2008 to realize that the regulation was going to create a profound sea change in how drugs are developed, approved, and marketed in the United States.

A REMS is a strategy to manage a known or potential serious risk associated with a drug or biological product. A REMS can include a medication guide, patient package insert, a communication plan, elements to assure safe use, and an implementation system, and it must include a timetable for assessment of the REMS. Our forum experts discuss the various nuances in developing a REMS, but the overriding consensus is that the strategy will require input from all functional areas and a dedicated cross-functional team that is empowered to make decisions. To learn about more best practices related to developing a successful REMS, please turn to page 8.

While safety may continue to take center stage, social media are running a close second on the marquee. Twitter, the most recent entry to the arena, may not have the same audience yet as Facebook and MySpace, but it's gaining ground. In February 2009, Nielsen ranked Twitter as the fastest-growing site in the member communities category, and in May 2009 it ranked as the fastest-growing Web brand, increasing 1,448% year over year, from 1.2 million unique visitors in May 2008 to 18.2 million in 2009.

The increased use has piqued a mild interest among the pharma industry regarding whether having a Twitter account is advisable from a marketing point of view. Please turn to page 16 to read what our experts have to say about building a business case for Tweeting. Please Tweet Robin Robinson at @robinrae22 with your comments. We will report back next month with an update.

Safety continues to be top priority