

APCO recently hosted a two-hour forum at the Willard Hotel in Washington with current and former U.S. Food and Drug Administration (FDA) officials to discuss the transition and what health care stakeholders can expect at FDA in 2009. Following is a summary of highlights from the forum, "Transitioning to a New FDA."

Keynote: Janet Woodcock, Director, Center for Drug Evaluation and Research (CDER)

FDA will face three key challenges in 2009:

1. *Food Safety:* The U.S. food safety system needs to be brought in line with those of other "grown-up" countries. The U.S. needs to work with regulatory agencies in other countries to assure a reliable international inspection system.
2. *Resource and Staffing Deficit:* Congress continues to add new responsibilities to FDA but most are unfunded mandates that cannot be implemented with current resources. Nevertheless, Congress holds the FDA accountable.
3. *New Administration and New Commissioner:* The transition to a new Administration will take time as new staff is brought up to speed and the organizational structure is implemented. This can delay or hinder the seamless continuity of new and existing programs.

At CDER, the impact of the new reality of a "global village"—particularly on safety, quality, and the supply chain—will determine CDER's course over the next year. CDER is focused on the following safety-related issues:

- ✦ *Electronics:* FDA is implementing an electronic inventory system, but still lacks the authorities and resources for policing at the borders and refusing entry to products that are unapproved or fail to meet U.S. safety and quality standards.
- ✦ *Science:* The science underlying FDA's current Good Manufacturing Practice (GMP) regulations is 50 years old. FDA will work to harmonize safety/GMP standards with modern science.
- ✦ *Tracking System:* FDA is bolstering safety oversight with a tracking system that applies the pre-market safety processes to drugs post-approval.

Initiatives to expect in 2009 include:

- ✦ *Product Use:* Expect FDA to work with insurers, professional societies, and other health care stakeholders to help improve the use of drugs. Electronic health records will likely play a role.
- ✦ *Pharmacovigilance:* Expect the purchase of a new pharmacovigilance system; the current system was built as a prototype in the 1990s and was never intended to last for as long as it has.

- ✦ *Sentinel System:* Expect a new system for more active safety surveillance of drugs.
- ✦ *Pharmacogenomics:* Expect FDA to continue relabeling products to help improve patient safety profiles based on genetic testing.
- ✦ *Consumer Information:* Expect FDA to examine the materials (including those not produced by drug companies) that are handed out by pharmacists and others. A recent survey showed the current process for distributing such materials isn't working. Numerous Citizens' Petitions have asked FDA to do something about the readability of patient package inserts.

Panel Discussion

APCO's Wayne Pines, a former FDA Associate Commissioner, moderated a panel discussion with James Benson (former Acting Commissioner and former Director of the Center for Devices and Radiological Health), William Hubbard (former Senior Associate Commissioner for Policy), and Nancy Ostrove (current Director of Risk Communication and former Deputy Director of the Division of Drug Marketing, Advertising, and Communications). Also contributing was Julie Zawisza, Director of Communications for CDER.

On the Transition:

- ✦ Both Benson and Hubbard indicated we should expect anxiety and uncertainty from the staff in the Commissioner's Office while waiting for the appointment of the new Commissioner and while the new Commissioner settles in.

On Risk Communication:

- ✦ Ostrove said we won't see any major changes in the structure of who does risk communication or how it's done, but do expect an appreciation for the need to do it and for it to be science based. Her office is currently working on a strategic plan for risk communication and expects to present the plan to the Risk Communications Advisory Committee in the near future.

On Desirable Characteristics in the New FDA Commissioner:

- ✦ Hubbard asserted the agency needs an "outstanding manager" given the number and breadth of issues facing it; an academician likely won't have the management skills to handle them.
- ✦ Benson said the Commissioner doesn't need to be as strong a manager if his or her deputy is a good manager. Instead, he said it is important for the Commissioner to be a strong communicator.

On Whistleblowers:

- ✦ Ostrove and Zawisza both noted Woodcock's commitment to CDER's Equal Voice program, which provides an opportunity for all staff members to express their views before product or other decisions are made.
- ✦ Zawisza noted that the agency is working to embed in the culture of CDER systematic processes to ensure communication happens across groups and between staff and

managers (particularly around controversial decisions) and to ensure that a diversity of opinions are heard during official advisory committee meetings.

On Funding for Food Safety:

- ✦ Hubbard agreed with Woodcock on the need to shift toward a more worldwide program of inspections and regulation of food that includes working with other regulatory systems. FDA doesn't have the resources to do it all itself.
- ✦ Benson noted that the agency has worked with other regulatory systems on developing international standards for more than 30 years but made little headway. He urged consideration of legislation so that food manufacturers and perhaps others are charged a user fee for inspections.

On Prescription Drug Importation:

- ✦ Hubbard noted that while the push for prescription drug importation "has died off somewhat," he is concerned it will come back soon, given the balance of political power. He believes personal importation will continue and that the FDA will not be allowed or even able to block access to the prescription drugs available on the Internet.

Surviving the challenging public policy environment requires more than understanding the current environment; it demands being able to see beyond the next bend in the road. APCO's deep bench of experienced health policy professionals provides predictive counsel to clients, identifying future health care trends and developing policy agendas that better position them for the future. Our health policy team takes an integrated approach to meeting clients' policy, business and communication objectives, reflecting the new reality in which public policy routinely intersects with business practices and decisions. By leveraging resources from offices around the globe and drawing on the best thinking from across the disciplines—including policy communication, government relations, advocacy, corporate positioning and issue management—APCO's Health and Regulatory Policy Practice helps clients positively shape their operating environment.

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