Talk is swirling around Washington as to who may replace Dr Andrew C. von Eschenbach at the helm of the US Food and Drug Administration (FDA). One well-known blogger has even begun a voting contest where readers can choose from several candidates for FDA Commissioner and cast a vote. There is little question that the policy environment is pregnant with change, but in most cases, it is quite possibly less important who is appointed rather than what the changes may entail.

This was obviously true with the presidential election. Given that both the McCain and Obama positions favored the import of prescription drugs, the ability of the government to negotiate prices under Medicare Part D, and the increasing uptake of generic drugs before the campaign, it is virtually certain that the outcome of the presidential contest mattered less to the pharmaceutical and biotechnology industries than the contests in Congress. Not only did the November 4 election decide that Democrats were to achieve solid majorities in both chambers, it has also paved the way for new congressional committee assignments and chairs.

This is the one area where “who” may matter, although only in a matter of degree. Consider the case of the chairmanship for the Committee on Energy and Commerce. A clash of the titans emerged between 2 powerful and prominent members of Congress—Congressman John D. Dingell, the current chair, and Congressman Henry Waxman, who emerged the winner. This committee is key to the oversight of various aspects of the FDA and the regulation of pharmaceutical industry. The activity of this committee for October 2008 includes the following investigations, announcements, statements, and reports:

- Dingell, Stupak to Investigate Melamine Contamination in Chinese Milk Products (10/2)
- Dingell, Stupak Question FDA’s No-Bid Contract with a PR Firm (10/2)
- Dingell, Stupak Question Whether FDA Knowingly Allowed Dangerous Drugs to be Sold to U.S. Consumers (10/8)
- Dingell, Stupak Continue DTC Ad Investigation (10/14)
- Dingell, Stupak Continue Investigation into FDA’s Questionable Handling of Bisphenol A (10/14)
- Dingell, Stupak Request Interview with von Eschenbach on Bisphenol A (10/15)
- GAO Report Finds FDA’s Foreign Drug Inspection Program Needs Significant Improvement (10/22)

Ironically, Congressman Dingell made the case that he is the preferable chair, because he is friendlier to industry with this 1-month track record. Now that Congressman Waxman has prevailed over Congressman Dingell for the chairmanship, one can expect a great deal more intensity in terms of the breadth and depth regarding scrutiny of the FDA and the pharmaceutical industry than was shown in October 2008.

However, for the balance of the change, “who” is not as important as “what” in terms of what must be accomplished. There is also a great deal of unfinished business with respect to the FDA itself. Once a gold standard agency, the FDA has suffered tremendously during the past 8 years and will have a great deal to do to reclaim its position as a flagship agency overseeing one fourth of the nation’s economy.

The following qualities are the ones that President-Elect Obama may seek for the individual who will take over the FDA. That person must:

- Have a solid grasp of the pharmaceutical industry, without being directly associated with it. There are members in the Senate, particularly Senator Kennedy, who may insist that the individual have no ties to the pharmaceutical industry itself. Still, the designee must have a good understanding of clinical research and public health.
- Be able to balance the policymakers hunger for safety, while assuring that the pipeline produces to provide access. Although the public appetite is extremely risk averse, our slant to caution may bring a slowdown in new drug approvals. Longer approval time in the end means potentially higher drug prices, as patented drugs will have less time on the market to recoup research and development costs.
- Have the credibility and gravitas to tell policymakers on the Hill to stop using the agency as a political means, to gently remind members of Congress that it is a new administration, that there is a 1-party rule, and that most of them are in that very same party.
- Possess solid visionary and have noteworthy communication skills. The agency is in trouble not only from a functional point of view, but it has also done very little to proactively address the descent of its image and to communicate and assure the public and policymakers that it has a vision. In fact, the agency does not seem to acknowledge much of a problem, much less to have a
plan for solving it. The new commissioner will need to understand this, act on it, and seize leadership.

In addition to these qualities, the first order of priority should be to completely implement the Food and Drug Administration Amendment Act (FDAAA). Right now the pipeline is getting clogged with Complete Response Letters and shifting the Prescription Drug User Fee Act dates, as the FDA tries to understand and implement the FDAAA. The FDA has been charged with implementing a fairly broad scope of reforms, but the longer it takes to identify and follow a roadmap for doing so, the more in the dark drug sponsors are going to be, which again contributes to a sluggish pipeline.

And as the policy and the communications environments undergo breathtaking changes, it is important that the agency enunciate some points of view about the uses of digital and social media by pharmaceutical companies in marketing. The potential uses for social and digital media are extraordinary, from public service announcements to patient education videos, to risk management tools; however, because regulatory cultures of most pharmaceuticals are generally conservative, most are waiting for the FDA to say something with regard to the use of such media.

The FDA appears nowhere near doing this, even though other industries have begun to embrace and strategically anticipate and respond to the migration into digital media. It is time for the FDA to be a leader, not continue to be a follower, and give companies some guidance. And that guidance should be the medium, not the message.

All this and more needs to be accomplished by an Obama-appointed FDA Commissioner, and in no short order, for the sake of the agency, public health, and the economy.

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