Perspectives on President Obama, Part II

President Obama campaigned on the idea of change, addressing everything from foreign policy to healthcare. Change proposed by the federal government for healthcare often targets the way the FDA operates. Already making several signifcant decisions that will impact the medical device industry, Obama has shown he intends to make good on his promise of change. This was the topic industry leaders addressed for this month's Perspectives.

What changes do you see coming to the FDA and/or the industry as a result of President Obama's policies and do you expect the impact to be overall positive or negative?

Nader Fathi
CEO, SigmaQuest

President Obama's agenda is sure to have an impact for medical device manufacturers, as he seeks to instill greater consumer confidence and patient safety. The FDA and medical device manufacturers are to have policies and practices in place that prevent manufacturers from implementing products that result in patient illnesses and death.

The medical device industry has faced some major challenges in terms of quality. For example, Guidant, now part of Boston Scientific, recalled 109,000 potentially faulty defibrillators in 2005. Sorry to pick on Guidant, but issues like installing defective pacemakers in patients and not being able to recall the defective ones is not acceptable. In fact, which companies can assure the FDA that they can prevent like scenarios?

While the peanut butter scare is not related to the medical device industry, the issue isn't that far away. Peanut Corp. of America wasn't able to identify where peanut butter, containing salmonella was shipped so hundreds of thousands of products using the peanut butter were needlessly recalled. If defective food products and medical devices can be identified early on in the manufacturing process, extreme illnesses and deaths suffered by end consumers can be avoided.

In an interview on NBC's Today Show, President Obama said "I think that the FDA has not been able to catch some of these things as quickly as I expect them to." Due to Mr. Obama's push for quality, expect more momentum behind the FDA's Sentinel Initiative, the national integrated electronic system for monitoring medical product safety. Better yet, medical device manufactures should prove they can monitor their own products for safety.

Todd G. Gattoni
Member of Dykema Gossett PLLC

Given the election of President Obama and a Democratic-controlled Congress, one of the biggest questions facing the drug and medical device industry is whether there will be a major overhaul of the FDA, including significant changes in the Administration's policies and procedures. While it is unlikely the FDA will undergo an extreme makeover, it's safe to say we are poised to see the dawning of a new day at the Administration. Expect to see expanded powers and regulations, more robust application review and approval processes, increased focus on monitoring post-approval safety, increased staffing and funding, and permanent leadership. We may also see efforts to increase harmonization of global regulations, including the reporting of adverse events.

President Obama's approach to the banking, investment, and automotive industries likely provide clues as to changes he will pursue at the FDA. We are likely to see increased regulations and efforts to reduce the influence of drug and device companies at the FDA. The use and composition of advisory committees, which recommend drug approvals and are relied upon to assess complex medical and scientific issues, will likely see further change to reduce real and/or perceived conflicts of interest.

Ready or not, change is coming to the FDA.

Lori Kahler
Vice President of Quality Assurance and Regulatory Affairs, Ximedica

Scandals in the industry, including the recent salmonella outbreak, expose the inefficiencies in government organizations and highlight the need for change. President Obama's policies are likely to toughen legislation and increase inspections of all food, medical, and drug companies (both foreign and domestic.) Expect changes to the FDA's preemption policies, which would ensure drug and device approvals would neither preempt a manufacturer from warning the consumer of known risks nor limit the consumer's legal rights. Expect restrictions on marketing products for unapproved uses, as well as changes to how clinical trial outcomes are assessed to support product approval by requiring human studies to demonstrate actual health benefits.

These positive changes must be effectively directed at the inefficiencies across the government and private sectors. The burden must be shared, both fiscally and ethically, by the food, drug, and medical device industries along with federal and state organizations. The lack of FDA resources to prevent or limit the recent salmonella outbreak does not (and should not) limit the manufacturer's responsibilities (or the industry as a whole) to ascertain the burden of proof that their product meets all safety and efficacy requirements to ensure the safety of the public health.

Martyn Howgill
Executive Director of the Institute for Health Technology Studies (InHealth)

FDA has an impossible task, given the breadth of its scope and its limited resources.

Given the accelerating emergence of promising new diagnostic and therapeutic capabilities, the challenge isn't shrinking.

The stimulus legislation provides NIH with $10 billion for new research to be spent over the next two years—presumably because NIH is "shovel ready." The resulting knowledge is likely to stimulate yet more technology, straining FDA resources further.

Rarely mentioned is the opportunity cost for patients of a regulatory process that is under-funded and therefore, moves too slowly. Given the public and political expectation of perfect outcomes, we err on the side of caution. Many argue this is as it should be.

But technology over the past 30 years has helped produce dramatic improvements in life expectancy, reduced disabilities, and provided for less intensive care settings. In managing the advance of technology, we must strike the right balance between risks and rewards.

In the end, a healthier society is more productive. Stimulating productivity through health is central to the Obama prescription. If we can get the balance right, FDA has a vital and exciting role to play.

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