You’re the new head of FDA? Um, congratulations

ERIC F. GREENBERG ATTORNEY-AT-LAW

Taking over the leadership of FDA is a little like jumping into a rushing river. You’re starting from scratch on virtually any issue, and instead you join dozens of important developments already in progress. What’s worse, most of them are controversial. Actually, it’s like jumping into a rushing river while crowds of people along both banks throw stones at you.

And FDA’s new commissioner, Dr. Robert Califf, started out somewhat controversial himself. He was nominated by President Obama in September, then after a long delay was confirmed by the Senate in late February. He had been FDA’s deputy commissioner for medical products and tobacco. The delay was due to the objections to his nomination from several senators, who complained, for example, about what they saw as his too-tight relationship with the drug industry (Califf used to run a clinical research center at Duke University, which, no surprise, got money from pharmaceutical companies), among other concerns. In a Senate hearing, Califf said his record makes clear by his actions that he wasn’t swayed to loosen standards.

Califf comes to the head of FDA with some experience in medical research and academia as well as in FDA itself. The question of what’s the best background for an FDA leader is deceptively complex. On the one hand, it’s clearly logical to have someone who knows a lot about the regulated industries the agency oversees, but it might be that many of those could see the world from the industry perspective, perhaps unduly. You could give the job to someone with an academic career, but they might lack management skills or knowledge of the agency.

Of course, if you find someone with career experience at FDA, or in other government public health bodies, there’s a risk that such a person with government-only experience might reflect all the worst tendencies we fear from bureaucracies, rather than a practical perspective.

And remember it’s one of FDA’s organizational curses that it regulates such a variety of product types: if you pick someone with experience in the drug or device field, they may bring little knowledge of cosmetics or foods. And FDA’s other curse is that it deals with so many controversial issues of direct public health interest that no matter what it does, someone will be complaining.

Thus, the new commissioner steps into the complex, ongoing implementation of food safety regulations growing out of the Food Safety Modernization Act, complete with a controversy over whether foreign suppliers of food packaging will need to verify their compliance with the law; into a continuing squabble over the best way for FDA to regulate substances considered Generally Recognized As Safe; into ongoing rules changes about food labeling; into an active program of drug and dietary supplement oversight, particularly imported ones; into the continuing battle to stay one step ahead of drug counterfeiters worldwide, and to continue to develop methods to help thwart abuse of prescription opioids and other drugs; into FDA’s still-developing, relatively new powers over tobacco products, which are themselves evolving; and into the endless challenge of staying up-to-speed with emerging technologies that present unique regulatory challenges, such as products that combine drugs and devices, and products that incorporate intentionally engineered nanoscale materials. Among other issues.

Califf said, “I look forward to further building the FDA’s excellent workforce, while relentlessly focusing on the completion of priority projects and continuing to develop the science base that we need to give consumers and patients even more confidence that their food is safe and their medical products are safe and effective.” His challenge is increased a bit on the food side, as the widely respected deputy commissioner for foods and veterinary medicine, Michael Taylor, announced his departure from the agency soon after Califf was confirmed.

Well then, should we expect a vibrant, active FDA to charge ahead on all fronts under the banner of its new commissioner? Only maybe, because it’s a presidential election year, and the conventional wisdom has it that little will be done until after the election, when either a new regime takes over or a new administration decides to move ahead with initiatives and philosophies that had previously been started.

Califf will have to choose how best to address each issue the agency faces. As with any regulatory agency, FDA must choose from among its arsenal of regulatory tools, including rulemaking, guidance documents, enforcement actions, or even mere publicity in order to implement its policies or instructions from Congress or the President.

There is at least one sign that FDA has been slowing its oversight recently. FDA’s total number of facility inspections, its primary tool for industry oversight and for initiating enforcement actions, went down to 13,468 in fiscal 2015, from 15,879 in fiscal 2014. There were reductions in both domestic and foreign inspections. Domestic inspections have been going down steadily since a high of 17,697 in fiscal 2011. It’s not clear what this reflects, though budget considerations are a common cause of such changes.

Speaking of budgets, when it requested its fiscal 2017 budget of $5.1 billion (an 8% increase), FDA said that would include increased money for food safety, medical products, the agency’s own infrastructure, and the administration’s new National Cancer Moonshot, announced by President Obama in his last State of the Union address.

That reminds me: Add annual budget worries to the new commissioner’s list of concerns. PW

Eric Greenberg can be reached at greenberg@efg-law.com, or visit his firm’s Web site at www.ericgreenbergpc.com.