BUSINESS & REGULATORY NEWS

Kessler's departure from FDA gets mixed response

When David Kessler said he was leaving his post as Commissioner of the US Food and Drug Administration (FDA, Rockville, MD), most observers in- and outside the agency were caught off guard. And although representatives from certain industry sectors—notably those who produce tobacco products, but also some within the biotechnology food, drug, and traditional drug industries—may be celebrating, others cannot be so sure that Kessler's successor will prove more friendly or fairminded. Many observers expect the next commissioner to be nominated from outside the agency and for his/her Senate confirmation hearings to be exceptionally rigorous and politically charged.

David Kessler, who announced last year he is to resign after six years at the helm of the FDA.

Kessler arrived at FDA when morale was at a low point following a scandal involving allegations of bribe-taking among officials who reviewed generic drugs. Since then, he has instituted wide-ranging administrative reforms, reorganized the agency's upper management structure, and personally maintained a high profile on a disparate assortment of hot-button issues, such as accelerated AIDS drug approvals, regulation of tobacco products as drug-delivery devices, and several food labeling, additive, and safety issues.

In the aftermath of Kessler's surprise resignation announcement, many within the agency seem to genuinely regret his impending departure. "He's a taskmaster and sets real deadlines, but he is tireless, works incredible hours himself, and makes things happen," says one insider, "We think he's fabulous." Insiders also point with some pride to independent reports, including a 1996 audit by the US Government Accounting Office (Washington, DC), indicating that FDA approves new pharmaceutical products about as fast, if not faster, than do comparable agencies in other countries, such as the United Kingdom's Medicines Control Agency (London).

Kessler is being praised in some industry circles. "He is an extraordinary and intelligent public servant with public health foremost in his mind," says Carl Feldbaum, president of the Biotechnology Industry Organization (BIO, Washington, DC). "He deserves credit for setting a new tone at FDA."

But elsewhere, Kessler's departure is noted with outright jubilation or noteworthy brevity. For instance, no one at the Pharmaceutical Research and Manufacturers of America (PhRMA, Washington, DC) is yet willing to review his record or assess his impact. Instead, the organization grudgingly welcomed the Prescription Drug User Fee Act (PDUFA), which became law during his tenure, and released a tersely worded statement indicating that Kessler did "much to raise the profile" of the agency, and that PhRMA looked forward to working in a "collaborative relationship" with his successor.

At times during Kessler's years at FDA, he seemed to be working as much as anyone to establish just such a relationship, some agency watchers point out. One example revolves around the new HIV protease inhibitors, several of which were approved by FDA during 1996 in record time—sometimes with agency officials almost pushing the companies into the marketplace with products before they could produce enough of them to meet anticipated demand (*Nature Biotechnology* **14**:426, April 1996).

By passing PDUFA, Congress helped provide some of the impetus for these speedier FDA product reviews. The legislation allows FDA to specify a substantial "user" fee for companies that is based on pharmaceutical products and manufacturing facilities. In turn, these fees bring FDA additional resources—about $90 million per year, much of which goes toward personnel costs—while mandating faster review of candidate pharmaceutical products. The law, which expires next September, is likely to come up for reconsideration and probable renewal relatively soon after the 105th Congress convenes later this month.

BIO, PhRMA, and FDA officials have already been discussing how to amend the reauthorization bill, with an eye toward reducing overall drug development-to-market time. From BIO's standpoint, some modest steps to ease the impact on small companies when the agency responds to interim, sometimes less-than-stellar, clinical findings would be particularly welcome in an amended version of this bill, according to Feldbaum. "Biotechnology companies are in a fish bowl, and a letter from FDA can cause their valuation to drop and bring them to a halt in a way that wouldn't phase a major pharmaceutical company," he points out.

Another more controversial bill, introduced in 1995 by now-retired Senator Nancy Kassebaum (R-KS), may well be reintroduced in modified form, Feldbaum notes. Her bill, "The FDA Performance and Accountability Act," sought to make the agency more industry-friendly and to solidify certain administrative reforms that Kessler helped to put in place. Feldbaum suggests that members of Congress will use the to-be-named commissioner's confirmation hearings as an important forum for reshaping and driving home some of the key messages to be embodied in such anticipated reform or "modernization" legislation.

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In the food area, some critics of Kessler's practices and policies say he paid too much attention to activists and consumer groups, delaying the marketing of genetically engineered tomatoes and other products, such as bovine somatotropin for dairy cows, aimed at boosting food production. But others say that he helped bring the debate over such issues away from politics and back into a more scientific realm. "The debate was over whether engineered tomatoes are 'ethical,'" Feldbaum recalls, "It was high strung and awkward. Now the discussion has shifted, FDA reviews the foods, they go on the market, and they sink or swim as products depending on whether they're tasty, rather than ethical."

"Kessler inherited an agency that was averse to change and with a culture that was not sensitive to the biological drug products being developed by biotechnology companies," Feldbaum continues. "But I think he "budged" the agency in the right direction, and it's still moving in that direction."

Jeffrey L. Fox