Lester Crawford

Veterinarian Lester Crawford has been nominated to be Commissioner of the US Food and Drug Administration. Can he provide the agency with the leadership it so desperately needs?

President George W. Bush gave Lester Crawford a special valentine this year, telling him on February 14 that he was being nominated to be commissioner of the Food and Drug Administration (FDA). A long-term, if only quietly ardent, suitor to the post, Crawford has served four separate stints at the agency, including twice as acting commissioner.

Little wonder, then, that he was relaxed enough around the time of the White House announcement in mid-February to display some of the glad-handing and wisecracking for which he is so well known. A departure from his more flamboyant predecessors (Mark McClellan, Jane Henney and David Kessler), Crawford, now in his mid-sixties, has been a team player for the Bush Administration, someone comfortable playing on defense and not needing to dazzle. But is a defensive player the best candidate to balance political pressures for greater safety with the agency's need to streamline drug approvals, increase efficiencies and tackle entrenched bureaucracy?

Close observers describe Crawford as personable, funny, friendly, beguiling, easy-going and, above all, colorful. He is someone given to telling oddball stories and sometimes throwing personal high jinks into the middle of otherwise serious discussions—uncommon behavior from someone serving in a high post in an embattled federal agency. However, those who work with him are quick to add, his charm, although genuine and distinctly Southern in flavor, hides a smart and incisive intellect; those ever-so-charming tales that he spins are apt to be used artfully to his advantage.

"Crawford will often deviate from the written text when he's giving a speech," says Michael Doyle of the University of Georgia in Athens. "He may be in the middle of a serious presentation when all of [a] sudden he'll make fun of the situation.… It's just comical, and he does it all the time." But, Doyle adds, Crawford can be "really serious, particularly about safety," has a strong grasp of many issues, and is adept at leveraging the expertise of others. Others who know him say he is "deliberate and a consensus builder," "incredibly bright" and routinely "underestimated."

Crawford's professional training is in veterinary medicine and pharmacology. Before his recent FDA postings, he served about a decade ago as administrator of the Food Safety and Inspection Service at the US Department of Agriculture and did stints consulting for the World Health Organization and as a negotiator when the World Trade Organization was taking shape.

News of his nomination as FDA commissioner was "enthusiastically" welcomed by Jim Greenwood, the new president of the Biotechnology Industry Organization (BIO). BIO, which has repeatedly insisted that FDA needs more than an acting commissioner, notes that Crawford's nomination "sends the right signal to patients and consumers—that there will be vision and leadership in the agency."

Of course, not everyone is convinced of Crawford's leadership credentials. One industry observer commented that the "expectation is that he will be a caretaker at best and at worst asleep at the wheel." Henry Miller, a fellow at the Hoover Institute, is even more damning: "The FDA is being saddled with a weak leader, one who has shown himself to be a reed in the political winds; the consummate 'go along to get along' guy." Some consumer advocates are also outright critical. Michael Jacobson, who directs the Washington-based Center for Science in the Public Interest (CSPI), warns that Crawford's "past… in industry raises questions about his appropriateness to lead the beleaguered [FDA]," which Jacobson refers to as an "agency in crisis, especially on the drug side."

Whether FDA is truly in crisis is debatable, but Crawford will be working in a politically sensitized atmosphere where drug safety is high on the agenda not only of liberals but also of staunch conservatives, such as Republican Senator Charles Grassley from Iowa and Republican Senator Michael Enzi from Wyoming. The day after Crawford was nominated he announced plans to form a new drug safety oversight board, whose reviews will include biotech therapeutics, and to open new channels for disseminating information about product safety for the sake of "greater transparency." In describing these new approaches, Crawford promised "to maintain an environment in which any individual can freely express a scientific point of view," comforting words for whistle-blowing FDA scientists, such as David Graham (who was critical of the agency's handling of the risks of COX-2 inhibitors) and Andrew Mosholder (who raised concerns about the safety of antidepressants).

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In the meantime, Crawford faces a substantial set of regulatory challenges. In recent months, FDA has dealt very visibly with influenza vaccine shortages because of plant safety problems (*Nat. Biotechnol.* **22**, 1329, 2004), a contentious debate over the safety of several COX-2 inhibitor drugs (*Nat. Biotechnol.* **23**, 1, 2005), continuing concerns over mad-cow disease and now the specter of bioterror attacks against the US population and its food supply (*Nat. Biotechnol.* **22**, 1503, 2004). The last of these promises perhaps the greatest financial windfall; Crawford is hopeful that, as well as drug user fees, the agency can benefit from increased funding of the FDA's counterterrorism program.

The dominance of product safety and biodefense-related issues in the near term will most likely be detrimental to progress on several important biotech regulatory matters. In tackling the biogenerics issue, one industry observer expects Crawford to be slow and methodical: "Don't expect a quick conclusion or draconian decisions." It is also unclear whether FDA will make much progress in the near term on the entry of animal biotech products into the food supply. Here, CSPI's Greg Jaffe is cautiously optimistic, however; Crawford's "door has been open for us to voice our concerns."

Industry will be hoping that Crawford's door will also be open to their concerns. One of those will be whether business as usual at the FDA is in the best interests of biotech.

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