Another long leaderless period in store for FDA

Mark McClellan's departure from the FDA commissioner post will lead to another long hiatus without a permanent leader.

Simon Frantz

After 16 months as US FDA commissioner, Mark McClellan is leaving to become administrator of the Centers for Medicare & Medicaid Services, the US federal agency that oversees the country's health care programmes.

Lester Crawford, the deputy commissioner who temporarily headed the FDA before McClellan was appointed commissioner in November 2002, will resume his role as interim commissioner.

This raises the spectre of another long period without a leader for the FDA, a growing trend made all the more visible by the fact that McClellan's term was shorter than the time taken to appoint him (see figure). Most people predict that the earliest that a full commissioner would be instated is mid-to-late 2005. It is unlikely that a candidate will be nominated until after the US elections in November — if one was nominated before then there is no guarantee that they would remain in position if the administration changes.

Long periods without a permanent commissioner undoubtedly have an effect on the agency. An acting commissioner has the same responsibilities as the full commissioner, but the acting commisioner's ability to initiate programmes is less, so they are not able to exert as much control within the agency. "The FDA is fortunate to have a strong and able staff to carry on the fundamental work of the agency — drug reviews, inspections and so on. But the leader provides the direction and overall momentum for the Agency's initiatives," says Jane Henney, former FDA commissioner and now senior vice president and provost for health affairs for the University of Cincinnati, Ohio, USA.

The FDA has instigated a strategic plan that should maintain its focus, but there could be times in which a full commissioner is needed, says Kenneth Kaitin, director of the Tufts Center for the Study of Drug Development. "If a high-profile drug is removed from the market for safety reasons, it's always advantageous to have a commissioner who can reassure the public that the FDA remains committed to ensuring drug safety. Also, should there be a bioterrorism attack in this country, the agency will be called on to respond rapidly, and the absence of a sitting commissioner would put the FDA at a significant disadvantage."

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The main reason for long periods between permanent commissioners is changes made to the selection process in 1990. Before then, no Senate confirmation was required. But now the FDA's nomination passes from the President to Senate for approval. In recent years, Senator Ted Kennedy (D-Massachusetts) has applied a 'litmus test' to nominees. "Senator Kennedy will not accept a nominee who has any past ties to industry, which rules out most of the qualified candidates who would be willing to accept the job," says Henry Miller, research fellow at the Hoover Institution, Stanford University, and former FDA official.

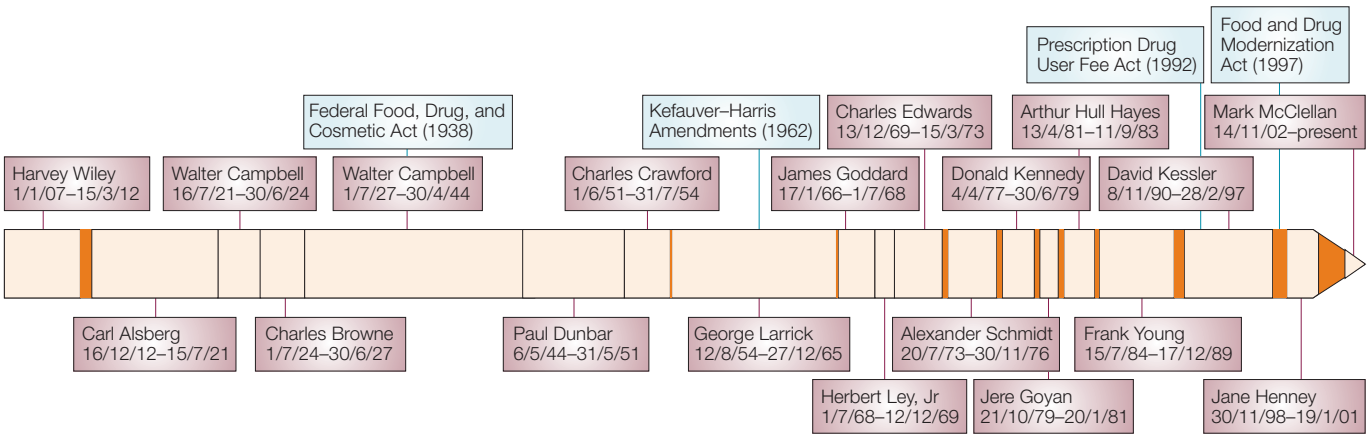
But industry too creates hurdles, says John Cohrssen, former counsel to the House, Energy and Commerce Committee. "Many powerful industries are regulated by the FDA, as the agency covers food, drugs, devices and so on, compared with the UK's Medicines and Controls Agency which just covers drugs. If a nomination isn't attractive to a particular industry then they'll raise a ruckus." At the same time, any suggestion of industry involvement causes concern within consumer groups, who want to protect consumer advocacy.

To cap it off, if a nominee is from a non-governmental background, they won't have active clearance, and will have to undergo FBI searches for a couple of months before they start to check that there are no skeletons in their cupboard.

Election year will further compound any delay in finding the right person for the post. "The Republicans and Democrats are more likely to be thinking about getting their candidates re-elected, not who should be the FDA commissioner," says Carl Feldbaum, president of Biotechnology Industry Organization.

Feldbaum suggests that the biotechnology and pharmaceutical industry should start preparing for all eventualities. "What we can do now is to draw up a shortlist of candidates for either case: whether the Republicans get re-elected or the Democrats get elected."

Cohrssen says this is a good idea, and that all the FDA-regulated industries and consumer groups should be suggesting criteria for who and what makes a good commissioner. "Not a lot of commissioners have had extensive management experience, but this is important when managing such a diverse agency. You might be able to manage your area, but if you don't manage all the different parts of FDA, you lose control. If this happens, it will be hard for the agency to innovate, which is necessary for the rapid development and approval of new medicines and other important products."



Recently, leaderless periods between FDA commissioners (dark orange bands) have become more frequent. DATA FROM FDA.