Senate nears final vote on Obama's pick to lead FDA

Clinical-trials expert Robert Califf expected to win approval after months of political delay.

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Robert Califf has drawn criticism for his ties to industry.

Update: On 24 February, the US Senate confirmed Califf as the next FDA commissioner.

After a five-month delay, the US Senate is finally poised to vote on the nominee to head the US Food and Drug Administration (FDA): cardiologist and clinical-trials expert Robert Califf.

On 22 February, lawmakers voted to limit debate on Califf's nomination. That procedural tactic sets the stage for a final vote this week that would determine whether he will lead the FDA.

President Barack Obama nominated Califf last September, but a handful of lawmakers has delayed consideration of the nomination over concerns about the FDA's approval last November of genetically engineered salmon for use as food and the agency's policies on opioid painkillers.

Another lawmaker, Senator Bernie Sanders — a Democrat from Vermont who is running for president — has objected to Califf himself. Sanders finds fault with Califf's many connections to the pharmaceutical industry, which he forged over years of heading a major clinical-trials centre at Duke University in Durham, North Carolina, before joining the FDA last January.

In an article this month in the *New England Journal of Medicine,* Califf listed more than a dozen pharmaceutical companies in his conflict-of-interest disclosure[1]. No previous FDA commissioner has been so closely tied to the pharmaceutical industry, says Michael Carome, director of the health-research group at Public Citizen, a consumer activist group in Washington DC. "It would be dangerously naive to think he has not developed deeply ingrained attitudes that tilt in favour of the medical-device and drug industries," says Carome.

But Califf's supporters say that he has maintained his independence. "I've never experienced a situation where I thought he was not reporting the results of the studies in a fair, open and honest way," says cardiologist Steven Nissen at the Cleveland Clinic in Ohio, who has been critical of the influence that the pharmaceutical industry wields over the FDA.

Smooth sailing?

After today's procedural vote, the Senate is expected to confirm Califf in a matter of days.

Daniel Carpenter, a social scientist at Harvard University in Cambridge, Massachusetts, says that Califf's nomination will probably not be the last to spark debate over potential industry influence in government.

"The fact that [Califf] was officially at Duke but had all of these ties with industry shows how intertwined the biomedical complex has become with universities," Carpenter says. "Future appointments from universities to the FDA and other agencies are increasingly going to be appointments from people who have these conflicts of interest."

In 2013 and 2014, Califf received roughly US$52,000 from industry partners, primarily for travel and consulting, according to the government's Open Payments database. About 55% of all full professors at US medical centres have received money from industry, often as payment for consulting, notes Eric Campbell, a sociologist at Harvard Medical School in Cambridge.

"Close relationships in academia and industry are essential to moving science forward," Campbell says. "But the question is: is that same level of closeness necessary and appropriate regarding a government regulatory agency and the industry it is trying to regulate?" The key, he says, will be how the FDA manages Califf's potential conflicts.

Nissen points to one incident that gives him confidence in Califf's independence. In 2008, Nissen told an FDA advisory committee that the agency should require diabetes drugs to be tested for their effects on cardiovascular health, in addition to their ability to lower blood sugar. It was a controversial opinion, and some experts — particularly in industry — said that it would discourage the development of new diabetes drugs by making the required clinical trials prohibitively expensive.

Nissen thought that he had little chance of convincing the FDA panel of his argument. But after Nissen's talk, Califf gave his own presentation in which he voiced support for Nissen's proposal. Later that summer, the FDA announced that it would require the extra trials for full approval of the drugs. "I could never have gotten that initiative done if there weren't some people like Califf who would stand up and say, 'I agree'," says Nissen. "I'm sure he took some heat from industry."

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Updates

Updated: Added information on final Senate vote to approve Califf.

References

1. Califf, R. M., Woodcock, J. & Ostroff, S. *New Engl. J. Med.* http://dx.doi.org/10.1056/NEJMsr1601307 (2016).