

Califf's FDA Nomination Widely Praised By Industry, Stakeholders

President Obama's nomination of Robert Califf to lead the FDA is drawing praise from those in industry and academia who see him as an outstanding choice and a strong leader deeply respected by the scientific community.

"When asked who was on my short list of potential commissioners, I said 'Robert Califf is the short list,'" Peter Pitts, president and founder of the Center for Medicine in the Public Interest and a former FDA associate commissioner, told *DID*.

FDA compliance consultant Steve Niedelman seconds the assessment, noting that Califf was also a contender six years ago when Margaret Hamburg was nominated.

The Biotechnology Industry Organization finds Obama's choice encouraging, saying the cardiologist and clinical trial expert has a firm understanding of the challenges and opportunities of 21st Century medicine. The Generic Pharmaceutical Association said Califf's deep expertise in research and health care quality will aid the FDA.

Group Questions Ties to Drugmakers

Not all supported Califf's nomination. Michael Carome, director of Public Citizen's Health Research Group, called for the senate to reject his nomination, citing Califf's long history of financial ties to drugmakers. Carome said his appointment would accelerate a decades-long trend where the agency makes decisions more aligned with industry than with public health and patients.

Carome questioned the need for clinical trial reform, saying there is too much drift toward making trials faster and easier.

Many disagreed with Public Citizen's assessment.

Margaret Anderson, executive director of FasterCures and past president of Alliance for a Stronger FDA, told *DID* that early in his tenure as deputy commissioner at the FDA, Califf spoke out about the science of patient input and related methodologies in clinical trials, a key focus of the 21st Century Cures Act.

A former academic colleague offered his support for Califf.

Robert Harrington, chairman of the Department of Medicine at Stanford University, worked with Califf at Duke University for more than a decade, and said the nominee understands both the appropriateness of industry-academic collaborations and the necessary boundaries. By necessity, Califf has collaborated with research funders, including private industry, to plan and implement clinical trials, he said.

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By Kellen Owings

Pitts says Califf's experience working with the FDA from the inside as deputy commissioner and his past dealings have earned the respect of senior staff within the agency. That respect will go a long way, as his success will be largely based on his ability to work with senior leadership.

Serving as deputy commissioner for the last half year has prepared Califf for upcoming issues, including the potential implementation of the FDA's responsibilities in the 21st Century Cures and a new PDUFA, Anderson said, calling him a calming presence to lead the FDA.