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Obama nominates FDA's No. 2 official to lead agency

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President Barack Obama has nominated the Food and Drug Administration's second-highest ranking official, Dr. Robert Califf, to lead the agency, which regulates consumer products ranging from medications to seafood to cigarettes.

The White House made the announcement late Tuesday in a statement naming officials nominated for various federal posts.

If confirmed by the Senate, Califf would take the reins at a critical juncture for the agency, which is under pressure from Congress to streamline regulations for medical products.

Califf, 63, joined the FDA as deputy commissioner in March after more than 30 years as a prominent cardiologist and medical researcher at Duke University. He is among the most cited medical authors in academia, with more than 1,200 journal articles.

His nomination to head the agency was widely expected after former commissioner Dr. Margaret Hamburg announced she would step down just days after appointing Califf to the role of deputy commissioner. He currently oversees the FDA's centers for drugs, devices and tobacco products.

Although he has spent most of his career in academia, Califf is deeply versed in FDA issues, especially the clinical testing of drugs and medical devices. He previously served on expert committees that advise the FDA

and was considered for the commissioner's job at least twice before—once under President George W. Bush and once earlier in the Obama administration.

"Dr. Califf has had a long and distinguished research career, and is internationally known for his expertise in clinical trials," said Dr. Aaron Kesselheim of Harvard Medical School. "He's thoughtful and personable, and I'm sure will be a strong advocate on behalf of the FDA during a very critical period."

The FDA's commissioner is subject to pressure from an array of outside interests, including corporations, politicians, consumer advocates and medical professionals. Most modern FDA commissioners have stayed on the job for less than three years.

Currently the FDA's chief scientist, Dr. Stephen Ostroff, is serving as acting head of the agency.

As head of the FDA, Califf would inherit a raft of projects and potential challenges, including unfinished tobacco regulations, food safety and labeling reforms and proposals from Republican lawmakers focused on streamlining drug reviews.

In July, the House of Representatives passed a sweeping bill that would require the FDA to reform drug reviews and consider more flexible clinical trial designs. The bill was praised by industry groups but criticized by safety advocates who warned it could erode safeguards against dangerous and ineffective products. The Senate is expected to take up its own version of the legislation this fall.

Califf's background as a drug researcher could make him receptive to some of the reforms coming out of Congress, though he has not testified on the legislation.

Complaints that the FDA is too slow in approving new products are a perennial theme for both the drug and medical device industries, though recent data undercut criticisms of the FDA as a plodding bureaucracy.

The FDA approved the highest number of new drugs last year in nearly two decades. Two-thirds of the drugs approved by the FDA last year went through streamlined processes, the highest proportion ever. Additionally, data show that the agency's typical time for approving drugs is significantly faster than Europe's or Japan's.

In 2006, Califf founded the Duke University Clinical Research Institute, a contract research group that has conducted studies for virtually all of the world's largest drugmakers. Another organization he founded, the Duke Translational Medicine Institute, has focused on new approaches to structuring clinical trials. A presentation he delivered last year advocated "disrupting clinical research," suggesting he might be open to rethinking how drugs are approved by the FDA.

But Califf's work for drugmakers could also complicate his path to confirmation, particularly among Senate lawmakers who say the FDA is already too cozy with the industry.

"Califf is in a sense the ultimate insider for the job, having been groomed for this position since the George W. Bush administration," said Harvard University professor of government, Daniel Carpenter. "Many will worry that, unlike many past commissioners—including his predecessor—he has little public health experience."

Hamburg served as health commissioner of New York City before her six years leading the FDA.

A disclosure form filed with Duke University last year shows Califf received research grants or consulting fees from a dozen drugmakers,

including Merck & Co., Roche and Eli Lilly & Co. Califf also held stock investments in two smaller drug companies—Portola Pharmaceuticals and N30 Pharmaceuticals—which he sold before joining the federal government.