

## Report on Research Compliance Volume 18, Number 12. November 25, 2021 In This Month's E-News: December 2021

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By Theresa Defino

◆ **A month after rumors circulated that President Biden planned to tap former Food and Drug Administration (FDA) Commissioner Robert Califf to serve again, the nomination has become official.** On Nov. 12, Biden announced his intention to nominate Califf, who had served under President Obama from February 2016 to January 2017. Calling him “one of the most experienced clinical trialists in the country,” Biden said Califf “has the experience and expertise to lead the Food and Drug Administration during a critical time in our nation’s fight to put an end to the coronavirus pandemic.” He added Califf would provide “a steady, independent hand to guide the FDA.” Three days later, the nomination was referred to the Senate, and then to its Health, Education, Labor and Pensions Committee, which will hold hearings; they have not yet been scheduled. Califf is currently professor of medicine and of cardiology at Duke University. The FDA position requires Senate confirmation.

The watchdog organization Public Citizen has expressed opposition to Califf’s nomination, as it did when President Obama put his name forward, saying he is actually not independent and has too many ties to pharmaceutical firms. “During just the few years before his previous stint as FDA commissioner, Califf reported receiving personal fees for consulting from at least 19 major pharmaceutical manufacturers, including Amgen, GlaxoSmithKline, Johnson & Johnson, Novartis and Pfizer,” Public Citizen said in a statement. “After exiting the FDA, Califf revived his lucrative ties with FDA-regulated pharmaceutical companies, receiving consulting fees totaling tens of thousands of dollars from AstraZeneca, Boehringer Ingelheim Pharmaceuticals, Eli Lilly, Merck Sharp & Dohme and Sanofi. And in February 2018, he was appointed to the board of directors of the biopharmaceutical company Cytokinetics.” (11/18/21)

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