FDA Nominee Received Industry Fees

Government says Robert Califf donated consulting payments to nonprofit groups

Robert Califf, nominated to lead the U.S. Food and Drug Administration.
Photo: Jared Lazarus/Duke University/Associated Press

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By Joseph Walker Sept. 18, 2015

President Barack Obama’s nominee to lead the U.S. Food and Drug Administration received more than $200,000 in consulting fees from pharmaceutical companies between 2009 and early 2015, according to corporate data. The fees were donated to nonprofit groups, a government spokesman said.

Robert Califf, previously a cardiologist and clinical trial researcher at Duke University, joined the FDA in February as the agency’s deputy commissioner for medical products and tobacco. On Tuesday, the White House said it planned to nominate Dr. Califf as commissioner of the whole agency.

From 2009 through early 2015, Dr. Califf received consulting fees of roughly $205,000 from companies including Johnson & Johnson, Merck & Co., GlaxoSmithKline PLC and one medical-device maker, records show. The payments are documented by the federal Open Payments database, and PharmaShine, a database of pharmaceutical disclosures operated by Obsidian Healthcare Disclosure Services LLC. Drug makers spent an additional $21,000 on travel, meals and other expenses for Dr. Califf, data show.

Dr. Califf didn’t respond to requests for comment. Kevin Griffis, a spokesman for the Department of Health and Human Services, said Dr. Califf had ceased all work with drug makers once he was hired by the FDA and that he has gone through a rigorous screening process for potential conflicts of interest. Mr. Griffis said Dr. Califf had donated all the consulting fees he has received since the mid-2000s to nonprofit groups.

“Dr. Robert Califf’s professional career has been dedicated to advancing biomedical research, including the rigorous evaluation of the safety, efficacy and appropriate use of both new medical
products and those already on the market,” said Mr. Griffis, assistant secretary for public affairs at HHS.

Because disclosures of drug makers’ payments to doctors only began in recent years, it is difficult to make comparisons of payments to former FDA commissioners.

The most recent consulting payment to Dr. Califf—about $5,100—came from AstraZeneca PLC in January of this year, about a month before Dr. Califf joined the FDA, according to the company. The payment related to Dr. Califf’s participation at an AstraZeneca employee education session about cardiovascular disease held in December 2014, a company spokeswoman said.

Dr. Califf has in the past publicly disclosed his consulting work with drug makers, though not the precise dollar amounts. Drug companies have long paid doctors for services, including for consulting on research projects or speaking to other doctors about a disease or medication. Such working relationships between drug makers and doctors can be helpful in bringing new medicines to patients, companies and many doctors say. But industry payments have drawn greater scrutiny in recent years amid concern they could taint doctors’ prescribing decisions.

That concern led to a 2010 law establishing Open Payments, a federal database that reports company payments to doctors starting from mid-2013. Prior to that, some drug makers posted physician payments on their websites, and that data is aggregated by PharmaShine.

The amount Dr. Califf received from pharmaceutical companies in 2014—about $32,000, mostly for consulting—places him among the upper half of doctors in terms of payments, according to Open Payments data. Of more than 600,000 doctors in the Open Payments database, half received $161 or less in 2014, and only about 3% received $10,000 or more, according to a Wall Street Journal analysis.

Historically, FDA commissioners haven't performed consulting work for drug makers regulated by the agency before their tenures as commissioners, said David A. Kessler, who served as commissioner from 1990 to 1997.

Margaret Hamburg, who resigned as commissioner in March, served on the board of directors of medical and dental-supplies company Henry Schein Inc. from 2003 to 2009, and resigned from the board before becoming commissioner in 2009. Dr. Hamburg said in an email that she had divested all financial interests in the company, including the forfeiture of any stock options.

Lester Crawford, who served as commissioner for two months before abruptly resigning in 2005, later pleaded guilty to not reporting his ownership of stock in companies regulated by the FDA while he was employed by the agency.

Reached by telephone Friday, Dr. Crawford said he wasn’t aware of the stock ownership at that time and failed to report it out of carelessness.
Prior to joining the FDA, Dr. Califf helped found and build the Duke Clinical Research Institute, which helps run clinical studies for pharmaceutical companies. For instance, Dr. Califf led a clinical trial of J&J blood thinner Xarelto, and in 2011 he presented the study results to an FDA advisory committee that evaluated whether to recommend approval of the drug. Dr. Califf’s presentation at the FDA was among the work for which J&J paid him $48,560 in consulting payments in 2011, a company spokesman said.

Dr. Califf said at the beginning of his presentation that he received consulting fees from J&J, adding that all of his “consulting fees are donated to not-for-profits, but still constitute a potential conflict that should be acknowledged.”

Public Citizen, a nonpartisan group focused on public health, this week called on the Senate to reject Dr. Califf’s nomination, saying it would accelerate a trend of FDA decision-making that is more aligned with industry than patients.

Others, however, say Dr. Califf has proved his ability to act with independence. Among his supporters is Sanjay Kaul, a cardiologist at Cedars-Sinai Medical Center in Los Angeles who served as an FDA adviser at the 2011 Xarelto advisory committee meeting where Dr. Califf spoke.

“Even though I have not always agreed with him on many issues, I respect him for his intellect and integrity,” Dr. Kaul said in an email. “There is no doubt in my mind that he will leverage his inside knowledge of how the industry works to promote innovation without compromising public safety.”
Will Industry Ties Hamper Nominee for FDA Commissioner?

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Dr. Cardiff in his office at the Duke Clinical Research Institute,
Photo courtesy of Jeremy M. Lange/New York Times

Even many people with conservative or anti-government leanings acknowledge that the U.S. Food and Drug Administration (FDA) is among the most vital agencies for ensuring public health and safety. The FDA regulates roughly a quarter of every dollar that is spent in the U.S., with approval decisions that could have life-or-death consequences for thousands of citizens as well as for the companies who need FDA approval in order to survive. This is why the Obama administration’s Tuesday nomination of Dr. Robert M. Califf to serve as the next FDA commissioner may not lead to confirmation as a mere formality in the Senate. The nomination follows Dr. Margaret A. Hamburg’s resignation in March from the position she held since 2009. As a groundbreaking clinical researcher, Dr. Califf help to found the $200 million Duke University Clinical Research Institute, turning it into one of the leading research facilities in the country. The institute, however, has received 63 percent of its funding through private industry. This fact, along with other notable ties between Califf and the pharmaceutical industry, has led some advocates to question whether or not these connections will ultimately influence Califf’s regulatory judgment.

Dr. Califf, a cardiologist, has been serving as the FDA’s deputy commissioner for medical products and tobacco since he joined the agency in February, divesting interest in his pre-FDA activity. Although he has donated his proceeds from private industry to nonprofit groups since the mid-2000s, Dr. Califf has taken some form of financial support from over 20 companies according to a disclaimer added to the end of a European Heart Journal article he penned last year. His financial disclosure form for 2014 alone lists consulting fees provided to him from seven companies, and his salary at Duke was funded in part by drugmakers Merck, Novartis and Eli Lilly. According to the Wall Street Journal, Dr. Cardiff has received over $200,000 from corporations between 2009 and 2015. Perhaps most notably and potentially concerning is the clinical trial that he led in 2011 for Johnson & Johnson’s blood-thinner Xarelto, in which the report of the study was used for an FDA recommendation panel’s evaluation of the drug, leading to its approval. Johnson & Johnson paid Califf $48,560 for consulting fees in 2011. Despite
widespread commercial success, Xarelto has been the subject of widespread multidistrict litigation due to severe bleeding side-effects.

Cardiff’s supporters note that his activity with industry is beneficial and should exemplify his experience and understanding of the process. Harvard political science professor and FDA expert Daniel Carpenter, says “In a sense, he’s the ultimate industry insider.” Dr. Caleb Alexander, co-director of Johns Hopkins University Center for Drug Safety and Effectiveness responded warmly to the nomination in an interview, saying “He has a very good understanding of industry and academia, and think that will serve him well.” His supporters also note anti-industry stands he has taken while at Duke, including his advocacy that study results be published independently and without companies reviewing or approving the manuscript reports, against the desires of the drugmakers. Stanford professor and chair of the medical department Dr. Robert Harrington, who worked with Califf at Duke recalled, “This is a long-held, steadfast position that has cost his groups research in the past.” Another former colleague at Duke, Dr. Adrian Hernandez also credited Califf for his impartiality, saying “He was really passionate about ensuring we were independent. I’ve seen plenty of times when a company wanted to do something in a certain way and his answer was no.”

Even in light of the support, the industry ties weigh heavily on advocacy group Public Citizen’s Dr. Michael Carome, who said “He has amassed an extensive record of close collaboration with industry, through consulting fees, speaking fees and research grants supporting his salary.” This will color his views when it comes to making regulatory decisions.” It should be noted that former FDA chief Hamburg served on the board of medical supplier Henry Schein from 2003 until her appointment in 2009. Hamburg divested her interest in the company, including future stock options, prior to assuming the position. Also in 2005, Lester Crawford resigned abruptly from the position two months after his confirmation after it was discovered that he owned stock options from companies under FDA regulation. Although Crawford pleaded guilty to the offense, he continues to claim that it was an act of carelessness, and not a result of intentional wrongdoing. While there has been interplay in the past between industry and FDA administrators, Califf’s ties are likely unprecedented, although financial disclosures between pharmaceutical companies and doctors only began in recent years, making comparisons to past commissioners difficult. Even though the administration nominated Califf, a registered Democrat whose conservative leanings also make him popular among Republicans, to be a compromise candidate to prevent a lengthy fight over his confirmation, it remains to be seen his ties become a source for alarm among some lawmakers.