Nominee for FDA commissioner has close ties to drug industry

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President Obama nominated Robert Califf, a cardiologist and longtime researcher at Duke University, as the next commissioner of the US Food and Drug Administration (FDA) last week. Califf's nomination follows the resignation this spring of FDA commissioner Margaret A. Hamburg.

Califf has been serving since February as deputy commissioner of the Office of Medical Products and Tobacco at the FDA. As commissioner he would wield considerable power and influence over the regulation and approval of new prescription drugs by the agency. The Congress is halfway through an overhaul of the FDA approval process for drugs and medical devices, called the 21st Century Cures Act.

If confirmed by the Senate as FDA head, Califf would also have chief responsibility for the implementation of new food safety legislation passed by the US Congress in 2010, as well as regulation of tobacco-related products, such as e-cigarettes.

Pharmaceutical watchdog groups and other critics have noted Dr. Califf's long-held ties to the pharmaceutical industry, and warn that this relationship could influence his leadership in favor of the drug companies, a multibillion-dollar industry.

Califf is the founder of the Duke Clinical Research Institute (DCRI) in Durham, North Carolina, which he ran for more three decades. The $200 million center has managed clinical trials in more than 65 countries, involving more than 1.2 million patients. As is the case at many university research centers in the US, DCRI receives the majority of its funding—63 percent—from the private sector, while the remaining 37 percent comes from government grants.

Califf's corporate filings for January-September 2014 show that research grants or contracts from the following companies partially supported his university salary: Amylin Pharmaceuticals, Bristol-Myers Squibb, Eli Lilly & Company, Janssen Research & Development, Merck & Co. and Novartis.

In the same filing, Califf reported holding equity stakes in excess of $5,000 in both N30 Pharmaceuticals and Portola Pharmaceuticals.

Califf personally received more than $200,000 in consulting fees from pharmaceutical companies between 2009 and early 2015, according to the Open Payments database, and PharmaShine, a database operated by Obsidian Healthcare Disclosure Services LLC. Companies paying fees to Califf included Amgen, Bayer Healthcare, Johnson & Johnson, Merck & Co, GlaxoSmithKline, Novartis and Roche Pharmaceuticals.

According to Kevin Griffis, a spokesman for the Department of Health and Human Services (HHS), Califf has donated all the consulting fees he has received since the mid-2000s to nonprofit groups.

The most recent consulting payment to Califf, about $5,100, came from AstraZeneca in January of this year, just a month before he joined the FDA as deputy commissioner. According to a spokesman for the drug company, he was paid for his participation at a December 2014 AstraZeneca employee education session about cardiovascular disease.

In his work at DCRI, Califf led a clinical trial of Johnson & Johnson's blood thinner rivaroxaban, (marketed as Xarelto) and he presented the study results to an FDA advisory committee that evaluated whether to recommend approval of the drug. For this and other services, J & J paid Califf $48,560 in consulting payments in 2011, a company spokesman said. The FDA approved rivaroxaban for prophylaxis of deep vein thrombosis in July 2011, and for patients with non-valvular atrial fibrillation in November 2011.

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Public Citizen, a consumer advocacy group, has called on the Senate to reject Califf's nomination. In a statement, Dr. Michael Carome, director of Public Citizen's Health Research Group, said, "Strikingly, no FDA commissioner has had such close financial relationships with industries regulated by the agency prior to being appointed.

"Califf's appointment as FDA commissioner would accelerate a decades-long trend in which agency leadership too often makes decisions that are aligned more with the interests of industry, rather than those of public health and patients."

The FDA holds regulatory power over which drugs are approved for sale in the US. Remarkably, it has no control over what the pharmaceutical giants can charge for these drugs.

As the FDA states cynically on its web site: "We understand that drug prices have a direct impact on the ability of people to cope with their illnesses as well as meet other expenses. However, FDA has no legal authority to investigate or control the prices charges for marketed drugs. Manufacturers, distributors and retailers establish these prices."

Recent years have seen astronomical prices for new drugs or increases in the prices for vital medicines. The FDA and its commissioner are ultimately responsible for which drugs are approved and which drug companies can jump on the increasingly lucrative gravy train.

The following is only a partial list of recent drug price hikes:

• Repatha, a cholesterol-lowering drug from Amgen approved last month by the FDA, has an annual price tag of $14,000.

• Daraprim, a treatment for malaria and toxoplasmosis, was purchased by Turing Pharmaceuticals in August from Impax Laboratories for $55 million. The drug is now 5,455 percent more expensive than it was only two months ago, jumping from $13.50 to $750 a pill, bringing the annual cost of treatment into the hundreds of thousands of dollars.

• Praluent, a cholesterol-lowering drug from Regeneron and Sanofi recently approved by the FDA, is priced at $14,600 a year, 140 times more expensive than generic statins.

• Sovaldi, a hepatitis C drug released by Gilead Sciences in 2013, costs about $84,000 for a 12-week treatment, or $1,000 a pill.

• Harvoni, another hepatitis C drug from Gilead, was released in 2014 and is priced at nearly $100,000 for a course of treatment.

Not surprisingly, private insurance companies are balking at footing the bill for these drugs, leaving many patients without access to these medicines.

Earlier this year, a California woman sued insurer Anthem Blue Cross for refusing to cover the estimated $99,000 it would cost to treat her hepatitis C with the above-mentioned Harvoni. In a letter denying her coverage, Anthem claimed that the drug was "not medically necessary" because the woman did not have advanced liver damage.

The woman, Shima Andre, told the *Los Angeles Times*, "I can't believe that they demand that a person get sicker before they'll pay for a cure. If there's a cure for something and you have health insurance, they should cover it."

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