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Is Obama's FDA nominee too close to industry?

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**Genevieve Pham-Kanter, PhD, guest blogger**

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Big Pharma has not been winning any popularity contests lately. According to this year's [Harris reputation poll](#), the pharmaceutical industry ranks somewhere near the airline and energy industries in terms of positive public perception. It is therefore no surprise that having financial relationships with drug companies creates a taint on doctors and medical researchers that can be difficult to overcome.

This is the issue hanging over Dr. Robert Califf, President Obama's nominee to be commissioner of the Food and Drug Administration. The Senate hearings for his confirmation begin today. Dr. Califf, an [accomplished and well-respected cardiologist, would replace the acting commissioner, Dr. Stephen Ostroff, who came to the FDA from Harrisburg](#). Dr. Califf has published more than [1200 peer-reviewed articles](#) and run several groundbreaking clinical trials. Along his journey of professional achievement, however, he has developed many well-documented [financial ties to the pharmaceutical industry](#), which are now raising [questions](#) as his nomination moves forward.

Conventional wisdom tells us that having no financial ties to industry is the ideal for public regulators, and that if one must have any industry connections, the fewer the better. But how bad are multiple financial ties? The answer is not so simple.

In [recent work published in the Milbank Quarterly](#) (summarized [here](#)), I looked at the voting patterns of

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physicians and researchers who served on committees that advise the FDA on new drug approvals. My findings may seem a bit surprising. On the one hand, individuals with financial ties to only one company were more likely to vote in favor of that company. But individuals with ties to many different firms voted no differently from those with no financial ties at all.

This finding runs counter to the conventional wisdom that, if having one financial tie is bad, having multiple ties must be worse -- but it actually makes intuitive sense. Individuals with multiple ties are less financially dependent on a single firm and therefore less likely to fall under the influence of any one company. In addition, it is possible that some researchers are simply very good at what they do and are sought out by many different firms for their expertise.

What does this tell us about Dr. Califf?

I examined Dr. Califf's voting record as a member of [FDA advisory committees](#) before he joined the agency as [Deputy Commissioner in February 2015](#). He was particularly active as a member of the agency's Cardiovascular and Renal Drugs Advisory Committee between 1997 and 2000. During this time, the committee held 16 voting meetings of which Dr. Califf attended and voted in 11, having already been excluded from the remaining meetings because of his financial ties. He disclosed direct financial conflicts for the drugs under consideration at two of the meetings and was granted waivers of conflict-of-interest rules, which permitted him to participate and vote. The drugs under review at both of those meetings were eventually approved, with Dr. Califf voting in favor of the sponsoring company in one case and against the sponsor in the other.

Although the purpose of most advisory committee meetings is to review applications for drug approval, members also vote on scientific questions related to the drugs under review. Dr. Califf cast votes on 39 of these questions, 24 times in favor of the drugs' sponsors. Most of these votes were in line with the decision of the majority, which favored the sponsor 85% of the time. Slightly more than one-third of the time, he voted in favor of the sponsor even though the majority voted the other way. Three of the drugs on which he voted--Posicor (mibefradil), Recludan (lepirudin), and Uprima (apomorphine)--were eventually withdrawn. A majority of members voted in favor of the sponsor in all three cases; Dr. Califf voted in favor of the sponsor in two of them.

This brief analysis suggests that despite his ties to several drug companies, Dr. Califf did not disproportionately favor or oppose the company sponsoring a new drug in his votes.

Of course, the concern remains that Dr. Califf's many industry ties could reflect an overall pro-industry bias, despite his apparently evenhanded voting record. Perhaps researchers, like him, who seek out many relationships with



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industry do so because they are predisposed to favor industry. Such a general bias could cause him as FDA commissioner to favor pharmacological approaches to treating diseases over other approaches like lifestyle changes or preventive care. It could also make him skeptical of regulation and partial to an agency environment that would be less burdensome for companies but possibly less safe for consumers. Dr. Califf's advisory committee voting history is silent on such issues. Hopefully, the Senate hearings will shed further light on them.

What this analysis of Dr. Califf's voting record does tell us is that conclusions about the effects of his financial ties to pharmaceutical companies must be weighed carefully. While they may suggest that he is predisposed to favor industry, they may also simply reflect his high level of expertise or a diversification strategy in financing his medical research. Industry relationships in medicine can be problematic, but they are not necessarily cause for unthinking panic. Beneath the surface of a history of industry ties lies a complex web of incentives and relationships that often tell a complex story. It is worth the effort to try to understand it.

Genevieve Pham-Kanter, PhD, is an assistant professor of health management and policy at Drexel's Dornsife School of Public Health.

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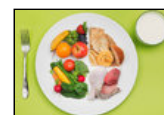
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