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October 30, 2013

Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
WO 2200
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg,

Last week, I wrote to you[1] about a current Food and Drug Administration (FDA) advisory committee chairwoman, Dr. Lynn Drake, concerning her participation in an upcoming conference advertised to help drug companies "walk away with strategies to successfully present before a committee and avoid potential roadblocks." Drake's specific session, titled "Pitfalls to Avoid as You Prepare for, and Present to, an Advisory Committee," was scheduled for February 7, 2014. According to the conference brochure, she would inform her audience about "mistakes she has seen first-hand that she wishes the sponsoring companies had avoided." I requested that you either ask her not to participate in this conference or remove her from her position as chairwoman of the Dermatologic and Ophthalmic Drugs Advisory Committee.

Apparently, neither the FDA nor Dr. Drake had seen the conference brochure prior to your receipt of my letter. Upon seeing the brochure, Dr. Drake said that she "gasped," adding, "Had I been privy to this document I would never have approved it." She stated that she will withdraw from the event.[2]

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[1] Public Citizen. Letter to FDA Commissioner Hamburg on FDA advisory committee chair participation in pharmaceutical industry conference (HRG Publication #2166). http://www.citizen.org/hrg2166. Accessed October 29, 2013.

[2] Reuters. FDA advisory panel chair pulls out of conference amid ethics flap. October 24, 2013. http://www.reuters.com/article/2013/10/25/us-fda-adcom-complaint-idUSBRE99O00320131025. Accessed October 29, 2013.

In response to my letter, the FDA, Dr. Drake and conference organizer CBI have made conflicting statements that cannot easily be reconciled, highlighting the serious, larger problem I alluded to in my letter:

> It is urgent that the FDA develop and articulate a written policy applicable to all advisory committee members to avoid repetition of this type of shameful episode, which could undermine public confidence in FDA advisory committees and in the agency itself.

The details and nature of these conflicts can be seen in the responses last week to the press to the following questions I presented in my letter:

(1) *Does the FDA think it is proper for current advisory committee members to participate in such conferences?*

Although the agency said Dr. Drake's participation was acceptable (see answer to (2) below), it now states that "its response was based on limited information."

(2) *Did Drake seek advice from the FDA before agreeing to serve on the faculty for this conference? If so, what was the FDA's advice?*

As reported by Reuters, Dr. Drake did seek the FDA's advice but, according to the FDA, her request to participate was based on limited information. She further stated that at the time of seeking the agency's advice she had not fully understood the nature of the meeting, which is being organized by CBI, a company that arranges conferences for the pharmaceutical industry and charges companies up to $2,199 to attend. "It was my understanding that this was an educational program," she said, adding that she was neither offered nor asked for payment beyond her expenses. "I believe there is value in educating the industry."

Also, she did not expect that her name and photograph would be used to promote the event for profit.[3] In sharp contrast to this, when asked about its policy on such programs, the sponsor of the conference stated that "CBI is always transparent with speakers as to our mission and works collaboratively with our faculty members as to their role in the program and the platform we create in delivering crucial content to the industry. CBI apologies for any perceived miscommunications." As Pharmalot Editor Ed Silverman added, "In other words, CBI is suggesting that Dr. Drake may have misunderstood what she was told or what to expect, but that the conference organizer was clear about what was to take place."[4]

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[3] *Ibid.*

[4] Pharmalot. Oops! FDA panel chair cancels speech to industry insiders. October 25, 2013. http://www.pharmalive.com/oops-fda-panel-chair-cancels-speech-to-industry-insiders?cid=nl.phrm01%0A. Accessed October 29, 2013.

(3) *Does the FDA have any explicit policy about current advisory committee members participating in closed-door, expensive conferences? If so, what is it? As a former member of FDA's Drug Safety and Risk Management Advisory Committee from 2008 to 2012, I do not remember reading or hearing about such a policy.*

If a policy exists that covers this kind of circumstance, it is grossly inadequate, as it allowed a green light for Dr. Drake's participation in this meeting — participation that would likely have occurred had I not brought the details to the FDA's attention. In a statement about the ethics training of advisory committee members, the FDA said it provides all advisory committee members annual ethics training, which outlines specific standards, including not using their public position for private gain.[5]

If the FDA gave the green light merely because Dr. Drake reported that she would not be using her position for private gain, but the further details of her participation were unknown (other than her participation in an "educational program"), then the FDA gave uninformed permission. It is essential that current FDA policy regarding the ethics of such programs be explicit so that this situation does not recur. The details of this episode could be turned into a teachable moment as part of the future education of advisory committee members.

Considering that the program for the upcoming meeting contained the following information, would the FDA have approved of Dr. Drake's participation had they been aware of these facts?

> Title: **"FDA Advisory Committee Prep: Real World Best Practices to Achieve Favorable Recommendations"**
>
> Title of Dr. Drake's session: **"Pitfalls to Avoid as You Prepare for, and Present to, an Advisory Committee."**
>
> Promised content of Dr. Drake's presentation: **"Hear directly from an FDA advisory committee chairperson about what mistakes she has seen first-hand that she wishes the sponsoring companies had avoided."**

Since the FDA admits it had "limited information" when it approved of Dr. Drake's participation, the agency would clearly not have approved her participation if the above facts had been known. Thus, uninformed permission seems to have occurred.

As a proud former member of an FDA advisory committee, it is impossible for me to overstate this: The FDA must rectify currently inadequate ethics training for advisory committee members,

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[5] Reuters. FDA advisory panel chair pulls out of conference amid ethics flap. October 24, 2013. http://www.reuters.com/article/2013/10/25/us-fda-adcom-complaint-idUSBRE99O00320131025. Accessed October 29, 2013.

and must immediately implement such policies. I hope to receive a response as quickly as possible to this request and would be more than willing to discuss the matter with FDA staff.

Sincerely,

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Public Citizen's Health Research Group