

Characteristics of Open Public Hearing Speakers of the Tobacco Products Scientific Advisory Committee meetings

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Dear Editors,

The FDA has regulated the manufacturing, distribution and marketing of all cigarette, roll-your-own, and smokeless tobacco products since 2009; in 2016 it expanded that regulation to all tobacco products¹. The Tobacco Products Scientific Advisory Committee (TPSAC) is an advisory panel that makes recommendations for approval regarding various tobacco products. The meetings of this panel include presentations from representatives of the tobacco industry and an Open Public Hearing section. The Open Public hearing section of this meeting allows for advocacy groups and the general public to make statements regarding the topic or product being discussed by the committee. These speakers include physicians, cancer survivors and their families, and representatives from patient advocacy groups and other organizations. Also included are speakers from various backgrounds whose presence at the meeting is funded by the tobacco companies or other outside groups. At the start of each Open Public Hearing section, participants are encouraged to disclose any financial conflicts of interest (FCOI) at the beginning of their testimony. However, they are also told that not disclosing any FCOI will not preclude them from speaking. Here we describe the association between Open Public Hearing speakers and financial conflicts of interest with the tobacco industry.

The methods have been previously described in relation to oncology and analgesic drugs^{2,3}. We obtained transcripts of TPSAC meetings between March 2010 and April 2015 (n=26). We excluded any meetings that did not have speakers during the Open Public Hearing section (n=8). We used a pilot tested Google Form to extract the following information: 1) speakers' names, 2) the organization they represented, if any, 3) the product being discussed, 4) does speaker currently use the product, and 5) whether the speakers reported any FCOI and, if so, the company names providing the payments. We then classified the person's statement as either positive, negative or neutral. SJ and CC performed all data extraction independently and resolved any discrepancies by mutual agreement. A third author (MV) was available to adjudicate any discrepancies, but was not ultimately needed.

Our study included 108 speakers over 20 meetings of the TPSAC (Table 1). Of the included speakers, 48 (44%, 48/108) reported a conflict of interest. Out of those 48, 33 (68%, 33/48) received funding directly from tobacco companies. Positive statements or statements against the ban of a tobacco product were made by 58 (53%, 58/108) of the speakers, 22 (20%, 22/108) made neutral comments, and 28 (26%, 28/108) made negative statements or spoke in favor of banning a tobacco product.

Of the included speakers that disclosed any FCOI, the majority had received funding from a tobacco company. The level of industry involvement described by this study is consistent with the findings of previous studies^{2,3}. The Open Public Hearing sections are designed to allow for the unique perspectives of the general

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public on these drugs and devices, and the manufacturers of these products are given time elsewhere in the meeting agenda to give their input. In order to preserve the integrity of the Open Public Hearing forum within the TPSAC meetings, we advocate for the least amount of industry involvement possible. We also urge the TPSAC to require the actual disclosure of any FCOI, instead of merely encouraging it.

Table 1. Characteristics of included TPSAC meetings

<i>Date</i>	<i>Topic</i>	<i>Number of speakers</i>	<i>Number disclosing FCOI</i>
30 August 2010	Tobacco products	6	5
16 July 2010	Menthol	8	3
15 July 2010	Excluded	0	-
30 March 2010	Excluded	0	-
31 March 2010	Menthol	11	6
7 October 2010	Menthol	2	2
18 November 2010	Menthol	7	2
10 February 2011	Menthol	7	6
10 January 2011	Menthol	10	6
11 January 2011	Excluded	0	-
21 July 2011	Excluded	0	-
22 July 2011	Dissolvable tobacco products	5	2
17 March 2011	Menthol	4	2
18 March 2011	Excluded	0	-
2 March 2011	Menthol	4	3
18 January 2012	Dissolvable tobacco products	0	-
19 January 2012	Dissolvable tobacco products	14	3
20 January 2012	Dissolvable tobacco products	0	-
1 March 2012	Dissolvable tobacco products	4	2
30 April 2013	Modified risk tobacco product applications	7	1
16 April 2013	Modified risk tobacco product applications	5	3
16 April 2014	Dependence and addiction	2	0
17 April 2014	Tobacco products	2	1
18 April 2014	Modified risk tobacco product applications	5	1
9 April 2015	Modified risk tobacco product applications	5	0
10 April 2015	Excluded	0	-

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CONFLICTS OF INTEREST

Authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none was reported.

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PROVENANCE AND PEER REVIEW

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