

Association of Conflicts of Interest of Public Speakers at Meetings of the Dermatologic and Ophthalmic Drug Advisory Committee and the Ophthalmic Devices Panel of the US Food and Drug Administration



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INTRODUCTION

As part of its mission, the FDA evaluates specific drugs and medical devices for safety and efficacy through meetings of special advisory committees such as the Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) and the Ophthalmic Devices Panel (ODP). Included in these meetings is an Open Public Hearing (OPH) portion, during which patients, physicians, drug representatives, advocacy groups, and other parties are allowed to present opinions on the drug or device. It has recently been called into question whether conflicts of interest may sway a speaker's argument toward approval of a drug or device.

OBJECTIVES

Our study investigated the financial conflicts of interest of open public hearing speakers at meetings of the Dermatologic and Ophthalmic Drug Advisory Committee and the Ophthalmic Devices Panel to determine whether a relationship exists between receipt of payments by public speakers and the nature of their recommendations regarding approval for the therapy.

METHODS

We identified DODAC and ODP meetings on the FDA website from February 2009 to December 2019 and reviewed the published transcripts of these meetings.

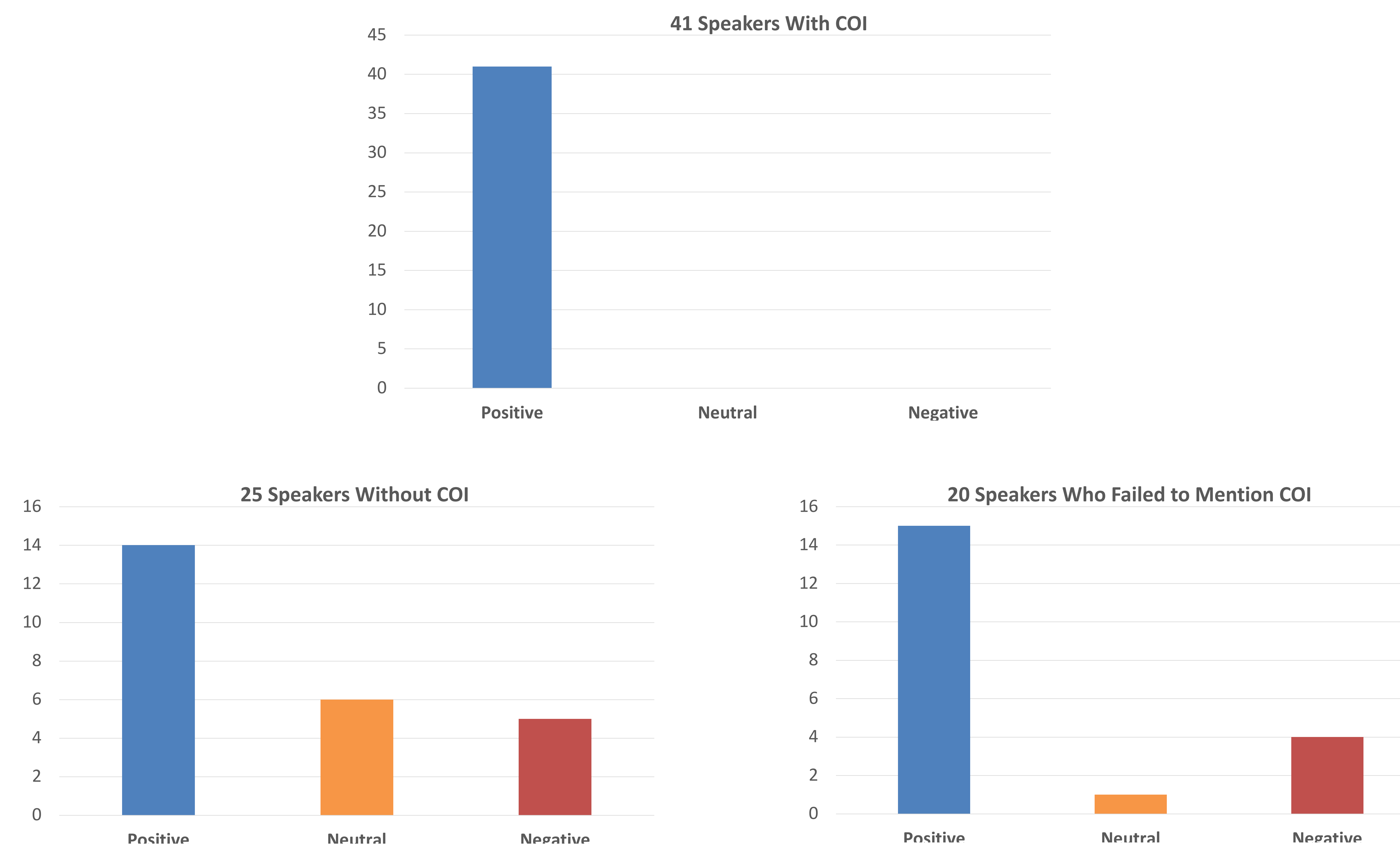
- Data Points of Speakers:
 - Affected by disease
 - Treated with drug or device
 - Reported COI
 - Nature of Testimony:
 - Positive
 - Negative
 - Neutral

RESULTS

Table 1: Characteristics of Dermatologic and Ophthalmic Drug Advisory Committee (DODAC) and Ophthalmic Devices Panel (ODP) hearings

Advisory Committee	Drug/Device name	Pharmaceutical company	# of speakers	# of speakers with COIs
ODP	Implantable Miniature Telescope (IMT)	VisionCare Technologies Inc.	7	4
DODAC	Elyea (Aflibercept ophthalmic solution)	Regeneron Pharmaceuticals, Inc.	2	1
DODAC	Lucentis (Ranibizumab injection)	Genentech Inc.	13	3
DODAC	Jetrea (Ocricplasmin intravitreal injection)	ThromboGenics, Inc.	5	2
ODP	Argus II Retinal Prosthesis System	Second Sight Medical Products, Inc.	9	2
ODP	Trulign Toric Accommodating Posterior Chamber Intraocular Lens	Bausch + Lomb	2	1
ODP	Visian Toric Implantable Collamer Lens	STAAR Surgical Company	7	5
ODP	Kamra Inlay	AcuFocus, Inc.	4	4
DODAC	Secukinumab	Novartis	3	3
ODP	AcrySof IQ ReSTOR Multifocal Toric Posterior Chamber Intraocular Lens	Alcon Inc.	8	5
DODAC and ODP	Riboflavin ophthalmic solutions with UV-A irradiation	Avedro Inc.	14	1
DODAC	Deoxycholic acid injection	Kythera Biopharmaceuticals	11	9
DODAC	Brodalumab injection	Valeant Pharmaceuticals Luxembourg S.a.r.l.	1	1

Nature of Speaker Testimonies Based on COI



CONCLUSION

We investigated DODAC and ODP meetings to evaluate the association between financial conflicts of interest and the likelihood that speakers would provide a positive testimony regarding a drug/device. Our results showed that speakers with a COI were significantly more likely to speak positively regarding the drug/device. Nearly one-half of the 86 Open Public Hearing speakers in our study had COIs involving the drug/device sponsor, with payments for travel and lodging being the most common. All of these speakers provided positive testimonies. The potential of COIs to heavily influence drug/device approval should be seriously considered by the DODAC and ODP. We recommend that the FDA require full disclosure of COI information from public speakers. Such a requirement would allow the committee to fully understand the context of the public speakers' comments, allowing them to determine the comments' validity.

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