Uncovering the financial ties of advocates for cancer drug approval

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Speakers who nominally represent cancer patients at advisory meetings on new drugs often have financial ties with the company seeking marketing approval. And those ties aren't always disclosed, according to an analysis appearing in *JAMA Internal Medicine*.

"The industry has hijacked that microphone - they're using it as their second presentation at advisory committee meetings," says senior author Vinay Prasad, M.D., M.P.H., a specialist in blood cancers for the OHSU Knight Cancer Institute, an assistant professor of medicine (hematology and medical oncology) in the OHSU School of Medicine, and senior scholar in the Center for Ethics in Health Care.

Prasad and co-author Matthew Abola, a medical student at Case Western Reserve University School of Medicine, scrutinized the speakers at all 49 meetings of the Food and Drug Administration's Oncologic Drugs Advisory Committee from 2009 to 2014. FDA advisory committees provide independent expertise and technical guidance on new drugs. Their recommendations are not binding but often predict FDA marketing approvals. At meetings, members often open the floor to public comment.

The researchers tallied how many public speakers at the advisory committee meetings were cancer patients and how many had taken the drug under consideration. They also counted how many speakers represented an organization, and how many had a financial association with the maker of the drug, personally or through an organization. They

classified each speaker's comments as favorable, neutral or negative toward FDA approval.

More than 90 percent of the speakers - 95 out of 103 - supported marketing approval. And 31 of the 103, or roughly 30 percent, reported financial ties to the maker of the drug, such as financial support for travel to the meeting or representing an organization that received funds from the drug company. Two speakers reported serving as principal investigators of pivotal trials.

In two instances, Prasad and Abola found financial ties that speakers failed to disclose. They discovered through online searches that in those two cases, the speakers represented organizations that had received money from the drug company prior to the meeting.

Close to half of the speakers were patients with the cancer in question, and 31 percent had used the drug in question (32 out of 103). As such, public speakers at meetings of the Oncologic Drugs Advisory Committee bring unique and valuable perspectives not represented by the sponsor, the FDA or expert panel members, Prasad and Abola say.

But they assert that the testimonies should be weighed carefully, considering the extent of drug company funding and influence in determining which patients appear at the hearings.

"Some of the stories are really compelling, but it's a mistake to assume that people who speak at these hearings represent the average patient or express what the average patient wants," Prasad says. "We're likely hearing more of the upsides. Patients who suffered real side effects, they are not the ones able to travel to these meetings."

Only six speakers presented negative opinions. They generally called for better data on the safety and efficacy of the drugs. None of the six

speakers reported financial ties.

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