June 15, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, MD 20852

Re: Draft Guidance on the Open Public Hearing; FDA Advisory Committee Meetings

To whom it may concern:

We welcome the opportunity to comment on the Food and Drug Administration's (FDA) Draft Guidance on the Open Public Hearing at FDA Advisory Committee Meetings.[1] The Open Public Hearing (OPH) is an essential component of Advisory Committee (AC) meetings. With the FDA increasingly funded by the pharmaceutical and device industries it is supposed to regulate (through the Prescription Drug User Fee Act), the OPH serves as a vital venue at which perspectives truly independent from those of industry may be publicly aired. However, this important role is endangered by industry's practice of stacking the public hearing with sympathetic speakers who appear to be independent and who are not subject to rigorous conflict of interest disclosure requirements.

The OPH has increasingly become a venue for industry-funded speakers to influence the meetings by effectively extending industry presentations beyond the industry's allotted presentation time. Whether as individual patients or under the guise of patient groups, these testimonies often seek to provide heroic stories of a product's effectiveness and to generate an apparently urgent need for approval (or opposition to a ban on the drug). But while it is common practice for sponsors to fly out and accommodate patients who have positive things to say about their product at the OPH, there is rarely anyone to fly out the patients with negative experiences. Such anecdotes thus distort the official public record and are not good science.

A crucial task of the FDA's policy on the OPH must be to aid AC members in distinguishing genuine, independent public comment from thinly veiled extensions of the sponsor's presentation. The way to do this is to ensure that the process is as transparent as possible.

In an analysis of transcripts from Center for Drug Evaluation and Research (CDER) AC meetings from January 2001 to June 2003, we found that only 63% of OPH speakers included a conflict of interest disclosure statement. Of those who included a disclosure statement, 44% did have a conflict of interest. There were 30 instances in which a public speaker was flown by sponsors to a meeting, including one meeting in which four people were flown in. Ninety percent of public conflicts were with the sponsor of the drug under discussion. Because conflict of interest disclosure at the OPH is not required by the FDA,

there is considerably less detail in the disclosures of public speakers than there is for AC members and voting consultants, all of whom are required to file conflict of interest data.

We also found that groups appearing to represent patients are often conflicted. In at least 23 instances (68% of patient groups with organizational conflicts), patient groups had received funding from a company potentially affected by the day's deliberations. This finding amplifies the growing concern that pharmaceutical industry sponsorship is becoming more prominent in non-profit, patient advocacy groups that were once viewed as grassroots organizations independent of industry influence.[2,3]

Prompting by the committee chair appeared to improve disclosure. In meetings where a need-for-disclosure announcement was made by the chair, generally at the beginning of the open public hearing, 72% of speakers disclosed a conflict compared to 58% during meetings at which no such announcement was made. AC Chairs need to make such prompting a ubiquitous feature of the OPH.

The FDA's Draft Guidance on the Open Public Hearing falls short of measures that would ensure a more transparent OPH. The draft guidance does not require disclosure of financial conflict of interest at the OPH, as has recently been required for AC members and voting consultants.[4] Instead, the guidance merely "encourages" disclosure and stresses that choosing not to disclose will not preclude participation. Further, the guidance states that "neither the Chair nor any committee member should further question the person regarding any potential financial relationships."

It is difficult to understand why an AC member, through questioning, should be prohibited from determining or clarifying a conflict in OPH participants. Such a prohibition will only serve to protect the most conflicted speakers from transparency, as the well-intentioned will be more likely to disclose. If anything, the FDA should be encouraging this sort of dialogue. In its current form, the OPH has become somewhat of a safe haven for industry-funded representatives to make misleading presentations without being held accountable.

For example, at a November 18, 2003 meeting of the Anesthetic and Life Support Drugs Advisory Committee, a drug's generic manufacturer declined to participate in the meeting's formal proceedings, only to show up at the OPH. AC voting consultant Dr. Dan M. Roden expressed his frustration with the industry representative for his tactic of hiding behind the lack of accountability at the OPH:

> I find it truly offensive that you can come up here and lecture us and then have the luxury of sitting down without having to defend your position. You were invited to be a participant in this panel meeting and elected not to. It seems to me that by taking advantage of this public forum, you have the opportunity to stand up and say whatever outrageous thing you want and then sit down without us having the opportunity to review your presentation and your data beforehand.[5]

Another troubling presence at AC meetings is speakers who take advantage of the OPH to advertise a product or service with only vague, if any, relevance to the meeting's topic. These self-serving promotions only waste the AC's time and crowd the OPH so that legitimate public testimony is sometimes limited to time slots as brief as a couple of minutes. This is not enough time for much more than an introduction.

The FDA should strengthen the OPH guidance to ensure a greater degree of relevance and transparency. Specifically, we call on the FDA to:

1. Require disclosure of any financial conflict of interest for all OPH speakers, to be disclosed verbally by the speaker at the beginning of their presentations with detail similar to that disclosed by AC members and voting consultants at the beginning of meetings. If the OPH speaker fails to include a disclosure statement, they should be prompted to do so.
2. Permit AC members and voting consultants to question OPH speakers about the nature of their conflict.
3. Screen presentation descriptions submitted by potential OPH speakers and exclude those that are clearly off-topic or are blatantly advertising.
4. Allot a minimum of five minutes for each OPH presentation.

These measures will not prevent public sessions from being stacked with speakers funded by and sympathetic to industry. However, by helping to illuminate some of the ties between the OPH participants and industry, we believe these steps will aid AC members and voting consultants in interpreting comments and identifying the degree to which financial interests have shaped the public session.

Thank you for your consideration.

Sincerely,

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[1] Federal Register: February 15, 2005 (Volume 70, Number 30). Accessed 6/09/05 at: http://www.fda.gov/oc/advisory/GuidancePolicyRegs/Guidance_OPH_FRNotice_021505.htm

[2] Lenzer J. Lay campaigners for prostate screening are funded by industry. *British Medical Journal*. 2003;326:680.

[3] O'Harrow R. Grass roots seeded by drugmaker; Schering-Plough uses 'coalitions' to sell costly treatment. *The Washington Post*, September 12, 2000.

[4] Food and Drug Administration. Draft guidance on disclosure of conflicts of interest for special government employees participating in FDA product specific advisory committees. January 2002. Available at http://www.fda.gov/oc/guidance/advisorycommittee.html.

[5] Food and Drug Administration. Transcript of the Anesthetic and Life Support Drugs Advisory Committee Meeting, Tuesday November 18, 2003. Accessed 6/09/05 at http://www.fda.gov/ohrms/dockets/ac/03/transcripts/4000T1.pdf.