



*Center for Medical Consumers*

*U.S. PIRG*

*National Physicians Alliance*

December 3, 2007

The Honorable Andrew C. von Eschenbach, M.D.  
Commissioner  
Food and Drug Administration  
Parklawn Building - Room 14-71  
5600 Fishers Lane  
Rockville, MD. 20857

Dear Commissioner von Eschenbach:

The October 2007 report to the Food and Drug Administration (FDA) by Eastern Research Group, Inc. (ERG), *Measuring Conflicts of Interest and Expertise on FDA Advisory Committees (Conflicts)*,<sup>1</sup> shows that there are substantial conflicts of interest for many members of FDA's advisory committees. But it also shows that the FDA could easily locate experts with equivalent or greater expertise who apparently do not have a financial conflict of interest. The opposite conclusions highlighted in the FDA press release<sup>2</sup> and the report<sup>3</sup>, "this exercise suggests that any group of equivalently qualified alternative participants in FDA advisory committees will have substantial conflicts of interest and is likely to require numerous waivers" is simply not borne out by the data contained in the study.

On behalf of the undersigned organizations, we write to urge you, at the least, to finalize the proposed conflicts of interest guidance that the FDA published in March 2007. We believe the FDA can find advisers without conflicts of interest and with all the requisite expertise to fill all the necessary positions on its advisory committees. We also believe the FDA should seek greater balance when appointing committees by including more experts knowledgeable about safety, epidemiology, and post-marketing surveillance. While the proposed guidance didn't go that far, it is superior to the law recently enacted by Congress. The FDA proposed barring any member of an advisory committee from voting if he or she had any financial conflict of interest and from participating in the committee's discussion if the conflict exceeds \$50,000. This study shows that those barred could easily be replaced.

ERG examined 18 FDA advisory committees held between December 2005 and October 2006. Thirty-two (26 percent) of the 124 standing advisory committee members who attended at

least one of these meetings received a waiver of a financial conflict of interest.<sup>4</sup> The mean value of these conflicts was about \$26,000, the median value was about \$15,000, and the maximum value was about \$103,000.<sup>5</sup> Seventeen percent of the conflicts were above \$50,000.<sup>6</sup>

From this initial sample of 18 meetings, ERG then examined the four advisory committee meetings that had greatest number of waivers. In this smaller sample 17 individuals covering nine areas of expertise received waivers.<sup>7</sup> The ERG found that about two-thirds (11 out of 17) of these waivers could have been detected by a search of the disclosure statements accompanying the individuals' published articles. Just 3 of the 17 (18 percent) declared in published articles that they had no conflicts of interest.<sup>8</sup>

ERG used a metric for measuring experience – years of experience, number of publications, and how often their research is cited by other scholars – that we find troubling, since there are many ways of inflating one's publication credits and the metric undercounts other types of experiences. Yet using these same criteria, it took ERG just 88 person-hours to identify 70 potential committee members who had a level of expertise equivalent to or greater than that of the 17 members who actually received waivers.<sup>9</sup> Nearly half had declared conflicts of interest based on searches of public information. But ERG and FDA found that 30 of these potential members covering all the nine areas of expertise affirmatively declared that they had no conflicts of interest in published research.<sup>10</sup> Assuming a similar ratio of failures to disclose found in the ERG study, about 25 (83 percent) of these 30 potential members would probably have no conflict of interest if the FDA were to contact them and obtain additional financial information.

We agree with ERG that “[f]inding a committee with no financial ties to industry would require starting with a larger pool of candidates than FDA now uses...”<sup>11</sup> In Title VII of the Food and Drug Administration Amendments Act of 2007, PL. 110-85, Congress directed the FDA to develop such a larger pool.

We urge you to immediately both widen the pool of potential advisory committee members and improve and finalize the proposed FDA's waiver policy to help restore public confidence in the FDA.

Sincerely,

Center for Medical Consumers

Center for Science in the Public Interest

Consumers Union

National Physicians Alliance

U.S. PIRG

Union of Concerned Scientists

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cc: Randall Lutter, Associate Commissioner for Policy and Planning

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1. <http://www.fda.gov/oc/advisory/ERGCOIreport.pdf>
  2. <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01744.html>
  3. *Conflicts* at 11-7.
  4. *Conflicts* at 3-2.
  5. *Conflicts* at 4-2.
  6. *Conflicts* at 4-3.
  7. *Conflicts* at 7-1.
  8. *Conflicts* at 7-8. This ratio of one in six is slightly higher but in line with failures to disclose found by our report, *Unrevealed: Non-Disclosure of Conflicts of Interest In Four Leading Medical and Scientific Journals*, (July 2004), cited in *Conflicts* at 7-9.
  9. *Conflicts* at 7-4.
  10. *Conflicts* at 7-10.
  11. *Conflicts* at 7-10.