September 12, 2007

The Honorable Edward M. Kennedy  
Chairman  
Committee on Health, Education, Labor, and Pensions  
Room 644  
Dirksen Senate Office Building  
Washington, D.C. 20510

The Honorable Christopher J. Dodd  
Room 448  
Russell Senate Office Building  
Washington, D.C. 20510

Att: David Dorsey and Tamar Magarik

Dear Senator Kennedy and Senator Dodd:

We write to urge you to reconsider your position and to support in the Senate-House conference on the drug safety bill a provision in the House version of the bill (Title VII of H.R. 2900) that restricts conflicts of interest on advisory committees of the Food and Drug Administration (“FDA”). As you know, the Senate did not adopt this provision on May 9 when it defeated, by a vote of 47-47, the amendment offered by Senators Durbin (D-IL) and Bingaman (D-NM).

The House bill and the Durbin-Bingaman amendment permit only one waiver of a conflict of interest per advisory committee. Conflicted experts would, however, still be allowed to present evidence and answer questions, but they would not be allowed to vote or participate in the committee’s discussion.

According to its January 2007 report to Congress, the FDA granted waivers to 24 percent of the 928 members of its 47 advisory committees that met during the 14-month period November 10, 2005 through January 4, 2007.

Allowing conflicted members of an advisory committee to vote can have serious public health consequences. For example, in early 2005 a FDA advisory committee reviewed the safety of COX-2 inhibitors and concluded that all three of these drugs, including Vioxx, were safe enough to keep on the market. Ten of 32 scientists on that panel had financial ties to manufacturers of the drugs. Had their votes been eliminated, two of the three drugs in that class would have been voted down by the panel. (Vioxx was, of course, voluntarily withdrawn from the market by Merck in September 2004 because of safety concerns).

It is possible to find unconflicted experts. The FDA could choose its committee members from among the 123,000 faculty at the 125 medical schools in the United States and public
health experts at other federal agencies such as the National Institutes of Health (“NIH”), the Centers for Disease Control, and the Veterans Administration. The NIH’s Office of Medical Applications of Research and the Agency for Healthcare Research and Quality’s U.S. Preventive Services Task Force bar any conflicted scientists from serving on the panels that develop consensus statements on the implications of clinical trial evidence. The Center for Evidence-Based Policy at Oregon Health Sciences University bars any conflicted expert from its analysis of clinical trial evidence to determine what drugs, biologics, and devices provide the best medical outcomes; this evidence is then turned over to states for use in establishing what Medicaid will pay for, among other uses.

In March 2007 the FDA asked for public comment on a proposal to bar all conflicted experts from voting at an advisory committee meeting and to permit only those with conflicts below $50,000 to participate in the committee’s discussion. The New York Times editorialized on March 23 that this proposal was “encouraging” but “may still need to be strengthened.” The FDA has not yet made a final decision and, in event, could change its mind later.

In conclusion, it is important to restore the public’s confidence in the integrity of the FDA’s decisions by having Congress restrict the number of waivers the FDA grants.

Thank you for considering our views.

Sincerely,

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