

The Honorable Richard Durbin
U.S. Senate
Washington, DC 20515

June 8, 2005

Dear Senator Durbin,

The undersigned organizations offer our strong support for your effort to prohibit scientists with direct conflicts of interest from serving on Food and Drug Administration advisory committees. Your proposed amendment to the FY2006 FDA appropriations bill will go a long way toward restoring public trust in the integrity of the FDA advisory committee process, which has been undermined in recent months.

Under current practice, the FDA routinely waives conflicts of interest for some of its advisory panel members. For instance, on February's panel evaluating the safety of Cox-2 inhibitors like Merck's Vioxx, 10 of 32 scientists had financial ties to firms whose products were under review. Had their votes been excluded, two of the three drugs under review would have been voted down by the panel. Two months later, an FDA advisory committee reviewing an application to approve the controversial silicon gel breast implant included a scientist who had made a promotional video for its manufacturer. As the New York Times editorialized (March 4, 2005), "Unless the FDA makes a more aggressive effort to find unbiased experts or medical researchers start severing their ties with the industry, a whiff of bias may taint the verdicts of many advisory panels."

The FDA claims that finding qualified advisers without conflicts of interest is "very difficult" and that using less qualified scientists would harm public health. But as the esteemed medical journal The Lancet recently editorialized (May 14, 2005), "It is hard to believe that in a country with 125 medical schools – not to mention the pool of international experts – the FDA cannot find experts who do not have financial ties with companies whose products are under review." Indeed, the Office of Medical Applications of Research at the National Institutes of Health, which also conducts medical reviews, adheres to a strict "no conflicts of interest allowed" policy when establishing its panels.

By allowing scientists with direct conflicts of interest to serve on its advisory panels, the FDA undermines the objectivity of its outside advice and damages its credibility with the public. While correcting these abuses represents just one aspect of the overall reform agenda needed to restore the FDA's ability to effectively carry out its mission of protecting the public from unsafe or ineffective drugs, biologics, medical devices and food, your proposed amendment prohibiting the use of waivers on FDA advisory panels is a necessary and timely first step.

Sincerely,
Annie Appleseed Project
Center for Medical Consumers
Center for Science in the Public
Interest
Consumers Union

National Consumers League
National Research Center for
Women and Families
National Women's Health
Network
U.S. PIRG