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Conflict-of-interest restrictions needed to ensure strong FDA review, analysis suggests

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A 2012 law that loosened conflict-of-interest restrictions for FDA advisory panels could weaken the agency's review system and could allow more drugs with safety problems to gain market approval, says a new analysis published June 7 in *Science* by researchers at the George Washington University School of Public Health and Health Services (SPHHS).

The 2012 legislation removed measures put in place by an earlier law passed in 2007, according to the report by Susan F. Wood, PhD, an associate professor of health policy at SPHHS and Jillian K. Mador, a medical student at the GW School of Medicine & Health Sciences (SMHS). The 2007 FDA Amendments Act put caps on the number of experts with conflict of interest who could serve on FDA advisory panels in order to ensure an impartial review of new drugs, the authors said.

They say there is good reason to worry about the revisions in the law that now allow FDA panels to have more members who report a conflict—such as consulting fees from drug companies. The removal of the requirement for "caps" on advisory committee members with financial conflicts was seen as a top priority of the pharmaceutical industry during the 2012 passage of the FDA Safety and Innovation Act.

"Panels top-heavy with experts who have financial ties to industry might be more likely to dismiss or ignore scientific evidence of risks or other problems," said Wood, who is a former FDA official and the lead author on the paper. "This analysis also suggests that loosening the restrictions

could lead to an appearance of conflict—and to potentially biased recommendations for approval or disapproval of a FDA regulated product."

The authors point to historical examples of cases in which loaded panels voted for drugs that were later found to have serious safety problems.

The 2012 law was passed after the drug industry complained that the conflict of interest restrictions slowed down the FDA approval process and made it hard to fill panel positions with qualified experts. But Wood and Mador looked at the evidence and concluded that there are plenty of scientists with expertise to fill these positions—without the ties to the industry.

The analysis goes on to say that the restrictions did not affect FDA's productivity in the past and there is little reason to think that reinstituting the caps would slow down the process of bringing safe new drugs to market today. The analysis also demonstrates that the caps have never been reached, so FDA had apparently been successful in identifying experts without financial conflicts.

The analysis concludes that the evidence does not support the decision to remove the caps on conflict of interest and points out that Congress will soon begin discussing reauthorization of the 2012 law which is revised every five years. The authors urge the scientific and medical community to weigh in early on those discussions in order to point out concerns—and to ensure that the FDA Advisory Committee and review process remains strong and effective.

Wood and Mador's new analysis, "Uncapping Conflict of Interest," appears in the June 7 issue of *Science*.

More information: "Uncapping Conflict of Interest?," by S.F. Wood

et al. *Science*, 2013.