



For Immediate Release
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**National Physicians Alliance Voices Concern
over FDA recommendation to ease limits on Avandia**

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The National Physicians Alliance expresses its concern about the recent FDA advisory committee recommendation to ease limits on Avandia. We agree with the decision to keep some restrictions in place given that numerous other available options for patients with diabetes and also given the importance of adequately informing clinicians and patients of potential harms.

Our concern lies with the committee's reliance on a single industry-funded study that failed to show an increased cardiovascular risk, despite such risk having been suggested by several earlier studies, as well as with the subsequent translation of the committee's decision in the media as a statement that there is no increased cardiovascular risk from use of this drug.

As physicians committed to avoiding conflicts of interest in medical practice, we are concerned about transparency and the issue of the potential for conflict of interest or the appearance of such conflict which has the potential to impair the trust prescribers and patients need to have in the FDA process. By convening a committee so different in composition of its members from the one that previously reached an opposite conclusion about Avandia's safety, the FDA put the committee's recommendations into some degree of question.

Physicians and other medical providers need accurate, unbiased, reliable information about the safety and efficacy of the drugs we prescribe. Our first obligation to our patients is to do no harm. FDA is our partner in this work, by following its own regulations on approving drugs based on adequate, well-controlled trials and by providing a trusted imprimatur that when we prescribe, we can rely on the medications we give our patients to be safe and effective. Although new additions to our armamentarium are welcome, this need for a solid understanding of their risks and benefits must come first.

We ask that the FDA consider the issue of conflict of interest closely in the makeup of its committees and that whenever possible, those committees be made up of experts without any financial conflicts to avoid both real and perceived influence upon the results of their deliberations. The decisions made by such committees have the potential to affect thousands if not millions of lives. Even the appearance of conflict in such work risks undermining its value.ⁱ

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Uniting physicians across medical specialties, the National Physicians Alliance creates research and education programs that promote health and foster active engagement of health care providers with their communities to achieve high quality, affordable health care for all. The NPA offers a professional home to physicians who share a commitment to professional integrity and health justice. www.npalliance.org

ⁱCain DM, Detsky AS. Everyone's a Little Bit Biased (Even Physicians). JAMA. 2008; 299(24):2893-2895.

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