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## **Removal of Consumer Advocate From Dec. 8 Advisory Committee Meeting Is Bad Policy**

*Statement by Sidney Wolfe M.D., Director,  
Public Citizen's Health Research Group*

*Note: The Dec. 8 meeting concerns the dangers of birth control pills Yaz and Yasmin*

This morning, less than 48 hours from the beginning of Thursday's Food and Drug Administration (FDA) advisory committee meeting to discuss the risks of blood clots from the birth control pills Yaz and Yasmin, I was notified in a phone call from FDA's Office of Advisors and Consultants that I could not participate as a member of the Drug Safety and Risk Management Advisory Committee in that meeting because of what the agency calls my "intellectual conflict of interest." The instance of intellectual conflict of interest cited is our newsletter *Worst Pills, Best Pills News* (and [WorstPills.org](http://WorstPills.org)), in which we have categorized both drugs as "do not use," initially because they can cause dangerous elevations in blood potassium levels and, more recently, because they also significantly increase the risk of blood clots in the legs (venous thromboembolism or VTE) with the subsequent increased risk of blood clots in the lungs (pulmonary embolism). The caller stated that the decision had been agreed upon by Dr. Janet Woodcock, head of the Center for Drug Evaluation and Research (CDER) and sent to the commissioner's office.

I pointed out that it is likely, if not certain, that other members of the committee and of the Reproductive Health Drugs Advisory Committee, both attending the meeting on Thursday, have previously decided to stop prescribing the drugs or to keep prescribing them based on their knowledge of the increasing number of studies documenting this serious risk (some studies do not show the risk). In their personal medical practice, then, they acted on the basis of published information to advise women for or against the drugs. If intellectual conflict of interest means being informed and subsequently having opinions on a drug, many more members of advisory committees, even without a financial conflict of interest, would have to be excluded because they know too much. The resulting committees would be noticeably less well-informed than now is the case, and the FDA and the public would be the losers.

I have served on this committee for more than three and a half years and have devoted an enormous amount of time to preparing for and participating and voting in the meetings concerning

the approval or market withdrawal of many drugs. On four previous occasions – in meetings to consider Darvon, Avandia, Meridia and the Ortho Evra Patch (the subject of this Friday’s meeting) – I have voluntarily recused myself from participating on the grounds that – unlike the present situation – Public Citizen had petitions pending to ban these drugs pending before the agency.

To take advantage of my participation, I was told today, I would instead be given time during the public session of the meeting to present my views – an opportunity I was offered and accepted in the four cases cited above. Today, I declined, because I believe that my full participation, including the ability to ask questions and to vote on the issues, would have far greater influence on the matter being discussed than a limited public session presentation.

After discussing my views on this exclusion with Jayne Peterson of the Advisors and Consultants Office, who had made the original call to me this morning, she agreed to take the matter up again with other parts of CDER and get back to me by 11 a.m. today. She did; the new decision was that I could participate in the meeting, with the same limitation accorded to the drug industry representative: speaking but not voting. I declined, stating that this policy of intellectual conflict of interest was irrational and damaging to both the agency and the public.

For members of a scientific and technical advisory committee, possessing information and expert views on matters within the purview of the committee is not a conflict of interest. To the contrary, qualified experts are likely to have developed views on a variety of subjects based on their professional experience, including their own independent research and their review of data compiled by other researchers. The fact that experts have acquired information and reached conclusions in the course of their work should not be a disqualifying factor and, as a legal matter, does not render the advisory committee not “fairly balanced,” under the Federal Advisory Committee Act.

Disqualifying advisory committee members because they have views on scientific matters threatens the utility of advisory committees in several ways. First, it deprives agencies of advice from the very experts most qualified to give it – those who have actual knowledge and research experience concerning the subjects to be addressed by the committee. Second, it deters qualified scientists from accepting appointment to advisory committees out of concern that their very expertise may become a matter of distracting controversy. And finally, it encourages politicization of scientific matters as interested parties seek to exclude scientists whose views are inconvenient to them.

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