

Conflict of Interest Statement – Day 1

JOINT MEETING OF THE ARTHRITIS ADVISORY COMMITTEE AND THE DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE

February 16-18, 2005, Hilton Gaithersburg, 620 Perry Parkway, Gaithersburg, Maryland.

Dr. WOOD: Now we will have the "reading of the lesson" from Kimberly Topper.

MS. TOPPER: The following announcement addresses the issue of conflict of interest with respect to this meeting, and is made part of the record to preclude even the appearance of such. Based on the agenda, it has been determined that the topics of today's meeting are issues of broad applicability and there are no products being approved. Unlike issues before a committee in which a particular product is discussed, issues of broader applicability include many industrial sponsors and academic institutions.

All special government employees have been screened for their financial interests as they may apply to the general topics at hand. To determine if any conflict of interests existed, the agency has reviewed the agenda and all relevant financial interests reported by the meeting participants. The Food and Drug Administration has granted general matters waivers to the special government employees participating in the meeting who require a waiver under Title 18 United States Code, Section 208. A copy of the waiver statements may be obtained by submitting a written request to the agency's Freedom of Information Office, Room 12A-30 of the Parklawn Building.

Because general topics impact so many entities, it is not practical to recite all potential conflicts of interest as they apply to each member, consultant and guest speaker. FDA acknowledges that

there may be potential conflicts of interest but, because of the general nature of the discussions before the committee, these potential conflicts are mitigated.

Further, during today's session Dr. Bernard Levin will be presenting data on the prevention of colorectal sporadic adenomatous polyps trial, the PreSAP trial, a Pfizer-sponsored clinical trial. We would like to note for the record that Dr. Levin is attending this meeting as a consultant to Pfizer. With respect to FDA's invited industry representative, we would also like to disclose that Dr. Annette Stemhagen is participating in this meeting as a non-voting industry representative, acting on behalf of regulated industry. Dr. Stemhagen's role on this committee is to represent industry interests in general and not one particular company. Dr. Stemhagen is the Vice President of Strategic Development Services for Covance Periapproval Services, Inc.

In the event that the discussions involve any other products or firms not already on the agenda for which FDA participants have a financial interest, the participant's involvement and their exclusion will be noted for the record. With respect to all other participants, we ask in the interest of fairness that they address any current or previous financial involvement with any firm whose product they may wish to comment upon. Thank you.