

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

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

VOLUME II

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8:00 a.m.

Hilton Gaithersburg
620 Perry Parkway
Gaithersburg, Maryland

Cyto-aggregation may lead to thrombosis, predisposing ACS.

COX-2 inhibitors prevent the synthesis of Prostaglandin (PGE2) that is responsible for triggering the pain, but they have no inhibitory effect on arachidonic acid (AA) a byproduct of phospholipase A2, which is also prothrombotic.

Our new iHAD test is intended to evaluate the response of individual blood cells to IRAs in assessing the baseline CVD risk based on the severity of cytotoxicity.

We urge all individuals taking the COX-2 inhibitors or considering taking the drug to take the iHAD test.

DR. WOOD: Thanks.

No. 6, Jim Tozzi.

MR. TOZZI: Thank you, Mr. Chairman, Distinguished members of the Committee. Having been a resident of New Orleans, I cannot speak that

fast, and I have burned up 10 minutes or 10 seconds

I am Jim Tozzi. I am the member of the Board of Advisors of the Center for Regulatory Effectiveness. The Center receives no funding from the pharmaceutical industry although a number of years ago we did receive grants from the industry.

The Center is a regulatory watchdog. To this end, we have a particular interest in the FDA compliance with the requirements of the recently passed Data Quality Act. When the agency makes determinations regarding the benefits and risks associated with the use of non-steroidal anti-inflammatory drugs--sorry, I am an economist--anti-inflammatory drugs. They may be anti-inflammatory, too.

The Data Quality Act required OMB and FDA to issue guidelines which would maximize the quality, the objectivity, the integrity, and the information FDA disseminates to the public.

So, you may be asking why am I here. Well, the guidelines require certain analytical results to be reproducible and

unbiased--reproducible and unbiased. The Data Quality Act places no requirements on the distinguished members of this committee, however, the FDA cannot rely upon the information it receives from the advisory committee unless the advisory committee information meets the requirements of the Data Quality Act.

Furthermore, any third party, such as CRA, can petition under this act for FDA not to use the results if they do not comply with the Data Quality Act, and I thank FDA for allowing--.

DR. WOOD: No. 7. Dianna Zuckerman.

MS. ZUCKERMAN: The National Research Center for Women and Families is an independent nonprofit organization with no conflicts of interest on this issue.

We focus on research, but we know that when Americans take medication, they don't expect to have to read the studies that have been conducted on the product, and their physicians don't expect to have to read them either, and the patients don't expect to have to carefully