

# Announcements of Voting Results

## 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.

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## Highlights

- **QUESTION 1A:** The Question 1A announced vote (Celebrex CV toxicity) was: Yes 32, No 0.
- **QUESTION 1B:** The Question 1B announced vote (Support for marketing Celebrex) was: Yes 31, No 1.
- **QUESTION 2A:** The Question 2A announced vote (Bextra CV toxicity) was: Yes 32, No 0.
- **QUESTION 2B:** The Question 2B announced vote (Support for marketing Bextra): The initial vote was “not properly recorded” for 1 member. When this was done the vote was reported as: Yes 14, Abstain 5, No 12. A discussion of the inadvisability of abstaining then took place. Following this, the vote was retaken and was reported as: Yes 17, Abstain 2, No 13.
- **QUESTION 3A:** The Question 3A vote (Vioxx CV toxicity) was: Yes 32, No 0.
- **QUESTION 3B:** The Question 3B announced vote (Support for marketing Vioxx) was: Yes 17, No 15.
- **QUESTION 6:** The Question 6 announced vote (Modified labeling for approved NSAIDs) was: Yes 28, No 0. <Not all voting members present>.

## Verbatim Announcements of Voting Results

### *Voting Results for Questions 1A and 1B*

DR. WOOD: Let's return to where we were before lunch. We were about to begin the discussion--oh; before we do

that, I should announce the vote. Like in Iraq, it takes a long time for the votes to be counted. The results of Question 1.a.

were 32 to 0, in case any of you missed that, and, for Question 1.b., 31 to 1.

### ***Voting Results for Question 2A***

DR. WOOD: With our new computerized system, it is 32 to 0.

### ***Abstention Discussion: Dr. Nissen & Dr. Woods***

DR WOOD: YES, Dr. Nissen

DR. NISSEN: I am disappointed in the abstentions. We all sat here and listened to the evidence.

DR. WOOD: Steve, I don't think we should badger people into voting

DR. NISSEN: I actually do want to ask people, as we move forward, to think about making a commitment one way or the other because what you have is a minority of us making a decision. I think it is appropriate that people weigh in. So, one man's opinion.

### ***Question 2B: Valdecoxib: Clarification of Dr. Elashoff's vote***

DR. WOOD: Dr. Elashoff's vote was not properly recorded because it was unclear what she said, apparently. Would she like to vote?

DR. ELASHOFF: I was told I had to say something other than "unclear," so I said no.

DR. WOOD: So you said no. That being the case, roll of the drum, the vote is 14 yes, 5 abstain and 12 no.

### ***Voting Results for Question 3A***

DR. WOOD: Okay. The vote is 32 yes.

### ***Voting Results for Questions 2B and 3B***

DR. WOOD: Okay. I am now in a position to read you the votes for Question 2.b. and 3.b., at least for now. The vote for 2.b., which was the vote on

valdecoxib, for those of you who have forgotten already, was 17 yes, 2 abstain and 13 no. The vote on 3.b., which was the rofecoxib vote, was 15 no, 17 yes.

### ***Voting on Question 6***

DR. WOOD: Okay. Before we move on to that, I have got the vote on Question 6; 28 yes, no abstentions, no no's.