

Butler, Jennie C

From: Bechtel, Christine
Sent: Tuesday, April 30, 2002 10:06 AM
To: Butler, Jennie C
Subject: FW: Request to present at FDA Hearing on Risk Commun/Mgt on May 22, 2002



FDA RISK MGT
MEETING SYNOPSIS... Jennie - one of the email requests to speak. Chris

-----Original Message-----

From: Joseph Cranston [mailto:Joseph_Cranston@ama-assn.org]
Sent: Friday, April 26, 2002 3:53 PM
To: bechtelc@cder.fda.gov
Cc: Clair Callan; Margaret Garikes; Sandy Marks
Subject: Request to present at FDA Hearing on Risk Commun/Mgt on May 22, 2002

Pursuant to a telephone conversation with Cindi Fitzpatrick, I was asked to inform you via email that the American Medical Association requests permission to present its views at the FDA's Part 15 Hearing entitled, "Risk Management of Prescription Drugs" (Docket No. 02N-0115), to be held at The National Transportation Safety Board Boardroom and Conference Center in Washington, DC, on May 22, 2002.

The information I was asked to provide is as follows:

Docket No. 02N-0115

Presenter Name, Title, Address, Phone, and Email

Joseph W. Cranston, PhD
Director, Science, Research & Technology
American Medical Association
515 North State Street
Chicago, IL 60610
Phone: 312-464-4554
E-mail: Joseph_Cranston@ama-assn.org

Affiliation

Dr. Cranston is an employee of the American Medical Association (AMA) and will be speaking on behalf of the AMA.

Request for Time

The AMA would appreciate being allotted 10 minutes to make its presentation.

Synopsis of Presentation

Attached as Microsoft Word document.

02N-0115

APE 10

**FDA Public Meeting
“Risk Management of Prescription Drugs”**

Synopsis of American Medical Association’s Comments

1. The AMA will acknowledge that evidence suggests some of the drug withdrawals in recent years were the result of inappropriate use because the communication of important new risk information to physicians, primarily via “Dear Doctor” letters, was not reaching some physicians.
2. The AMA will express its eagerness to work with the FDA, the pharmaceutical industry, and other stakeholders, to identify more effective means of communicating risk information to physicians.
3. The AMA will suggest some possible options for more effective and timely risk communication to physicians. These will include:
 - a) Revising the content and/or method(s) of transmission of “Dear Doctor” letters;
 - b) Using pharmaceutical company sales representatives to detail risk, as well as benefit, information about their companies’ products;
 - c) Simplifying professional labeling, as already proposed by the FDA, and making up-to-date versions readily available via electronic communications vehicles (e.g., the Internet); and
 - d) Having the FDA, the pharmaceutical industry, and physician organizations undertake a major physician education initiative on risk communication.
4. The AMA will provide some general comments about the potential value of new information technologies in helping to communicate important new risk information more effectively. Ideally, physicians need decision support at the time a prescribing decision is made. Brief mention will be made about the possibilities of computerized physician order entry (CPOE) and prospective drug use review at the point of prescribing as a means to this end.
5. Finally, the AMA will raise concerns about potential FDA risk management approaches, such as limiting prescribing of a drug to a subset of physicians, mandatory physician registration to prescribe a drug, or requirements for laboratory test results before dispensing is allowed. AMA is concerned that the FDA is attempting to regulate medical practice and does not believe such restrictive approaches are an appropriate means of managing risk.