

THE TATIA ODEN FRENCH MEMORIAL FOUNDATION

A NON-PROFIT ORGANIZATION DEDICATED TO SAVING THE LIVES
OF THOSE GIVING LIFE TO OTHERS

MAILING ADDRESS:
87 HAMILTON PLACE
OAKLAND, CA 94612

EXECUTIVE BOARD MEMBERS

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KIYO D. ODEN, J.D., M.P.H.
MARDSDEN WAGNER, M.D., M.S.

(510) 268-0446

FAX: (510) 268-1983

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June 14, 2005

Dockets Management
FDA
5630 Fishers Lane, RM 106
Rockville, MD

RE: Docket Number 2005D - 0169

The Tatia Oden French Memorial Foundation is formally submitting the following comments regarding the Draft Guidance Document for Consumer Medication Information (CMI).

We agree with the Center for Drug Evaluation and Research that the consumer should be well informed regarding all drugs that they are given. We feel it is the responsibility of the FDA to be the "watch dog" arm of the government to perform this function. Therefore, although the patient information insert is a step in the right direction, when a drug is used "off label" the patient information sheet is not always distributed to the patient, seen, read, or even acknowledged by the physician. The result of which is the absence of useful information which a consumer needs in order to make a fully **informed** decision.

We agree with the July 2002 FDA Advisory Committee recommendation that states the "FDA should take a more active role in advising and encouraging the private sector to meet the next target goal set for year 2006."

In regards to the Action Plan Criteria for Defining Useful Information, The Tatia Oden French Memorial Foundation would **add** criterion # 9, which states:

"This information is widely known, readily available to the public, and widely distributed."

Criterion 2:

UNAPPROVED indications should also be included in the CMI regardless of whether the information is customized for individual patients. The contraindications need to be **very clear no matter how seldom the side effect(s) occur**.

Circumstances in which the medication should not be used **MUST** be made known to the consumer, not just noted on the PI.

Criterion 4:

We strongly agree with the statement ".....provide enough detailed risk information for the consumer to understand the significance of the hazard described." This information is **not** provided at the present, specifically when the off label use of drugs occurs. The Foundation strongly feels that the physician must provide this information. The essence of the Hippocratic oath mandates it.

The Tatia Oden French Memorial Foundation feels very strongly regarding the non-FDA approved uses of all drugs. While recognizing the possibility of discovering new "cures" for various medical conditions we feel it is imperative that controls involving guidelines for usage, reporting mechanisms of side effects and catastrophic events and most important of all full

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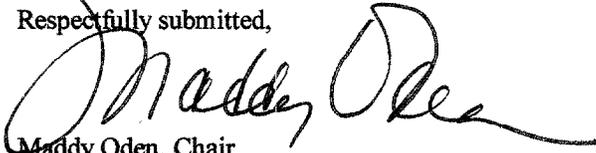
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disclosure of all known side effects be stringently overseen by either the FDA or an outside agency so that consumers in all focus groups will be fully informed and protected.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Maddy Oden". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Maddy Oden, Chair

The Tatia Oden French Memorial Foundation