

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

0630 '03 NOV 26 19:48

Dear Madam or Sir at the FDA,

November 23, 2003

We attempted to send our docket recommendations last Saturday by email. However, we noticed that the text format in our document somehow moved in the process of emailing it to your office. Therefore, I am sending you a paper copy that is easier to read. Thank you kindly for your time, and attention.

Sincerely, Kristin A. Altar RN, BSN

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2003N-0344

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Posted to FDA Docket # 03n-0344

November 22, 2003

As health care professionals, we believe that the direct-to-consumer prescription drug advertising (DTCA) currently offered in our mainstream media can be balanced with objective and sound health-promoting information that includes the consumers as partners in their own health decision-making process.

After much research into the issues surrounding DTCA, we submit to you a workable alternative that will address present concerns:

DTCA Interpretive Guides

1. In the form of pamphlets, messages on TV and radio, and in websites 2. Created to target various consumer educational levels, learning styles, culture and language differences
3. Content:
 - a. explanation that the purpose of advertisements is to bring about pharmaceutical company profits
 - b. explanation that there are both beneficial and substandard advertisements
 - c. definition of terms commonly used in ads, such as "adverse reaction, contraindication, GI, GU, CNS, generic, pregnancy categories", etc.
4. Tips on how the consumer can effectively approach their health care providers with the DTCA learned information.
5. Life style and behavioral changes that can improve conditions treated by the advertised drugs.
6. Instructions that the consumer seek further treatment information from their health care providers.

We see an equitable resource for funding these DTCA Interpretive Guides:

Tax Incentives for Pharmaceutical Companies.

Contributions could be made to an educational fund with revenues received from tax credits given to pharmaceutical companies, based on a certain percentage of their advertising costs. The result will be that companies who spend more on advertising will contribute proportionally to this fund. This design will not penalize the pharmaceutical industry, whose profitability, we do understand, leads to new life saving treatments.

The educational fund could be utilized by agencies currently collaborating in the dissemination of public health information, such as the CDC, NIH, or the FDA's Office of Training and Communication

We look forward to hearing your response to our posting.

Thank you.

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and Janelle Stank BSN

University of Maryland, School of Nursing Graduate Students
Participating in NURS606 ~Systems in Health Care Delivery" — Fall 2003