



# OUR BODIES OURSELVES

## Executive Director

Judy Norsigian

## Board of Directors

Elizabeth Daake

Sally Deane, Chair

Vilunya Diskin

Nancy Forsyth

Teresa Harrison

Ileana Jiménez-García

Mary Jo Marion

Liza Molina

Patricia Roche

Bonnie Shepard

Fiona Smith, Clerk

Laura Anne Stuart

Amanda Buck Varella

Cecelia Wu, Treasurer

## Advisory Board

Marjorie Agosin

Hortensia Amaro

Byllye Avery

Joan Bavaria

Linda Ellerbee

Teresa Heinz

Cathy Inglese

Wanda Jones

Florence Ladd

Susan M. Love

Meizhu Lui

Ngina Lythcott

Cynthia Pearson

Vivian Pinn

Ellen Poss

Isaac Schiff

34 PLYMPTON STREET  
BOSTON, MA 02118  
TEL: (617) 451-3666  
FAX: (617) 451-3664  
www.ourbodiesourselves.org

*These were emailed  
on May 4, but  
may not have  
transmitted  
properly. We  
are sending  
a hard copy  
as well!*

May 4, 2004

Division of Dockets Management (HFA 305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: Docket #2004D-0042**  
**Draft Guidelines for Industry and FDA**  
**Brief Summary: Disclosing Risk Information in Consumer-Directed Print**  
**Advertisements**

Although the FDA's proposed guidelines assume that the advertising of prescription drugs directly to consumers is an acceptable practice that will likely do more benefit than harm, we do not believe that this is true. Especially given the large numbers of misleading and deceptive ads that now clog the airways (and the inability of the FDA to curtail such misleading advertising), it would be most difficult to conclude that DTC ads could have a net benefit for consumers.

We wish to repeat earlier statements and concerns regarding the harm likely to result from the dissemination of misleading information and suggest that DTC ads cannot possibly serve a public health function without far greater controls placed over what pharmaceutical companies can and cannot do. We would do well to follow the lead of most other countries, where DTC advertising is simply not allowed.

That said, if DTC ads are allowed to go forward, advertising **MUST** be more honest and clear about the risks as well as the benefits of drugs being advertised. Also, there must be stricter guidelines about the time lapse between two drug ads for the same product (at least two hours). This would help minimize distortions that could be created by showing two different yet complementary ads for the same drug that could easily circumvent the intent of the guidance.

We also recommend the following:

- That the brief summary be in lay language and in easily legible font size;
- That the brief summary include efficacy information;

- That the brief summary highlight the most common and the most serious adverse reactions, contraindications, warnings and precautions;
- That the adverse reaction and efficacy information be given in absolute risk figures and that penalties be imposed for mixing absolute and relative risk figures;
- That a statement be included indicating how long the drug has been monitored in clinical trials and noting that some side-effects show up only after long-term use;
- That a statement be included indicating the number of people who have taken the drug in clinical trials;
- That a statement be included to remind consumers that FDA approval does not guarantee the drug is safe and efficacious for all users;
- That a statement be included to remind consumers that the information is not comprehensive and directing readers to a source of FDA-approved labeling information;

Sincerely,

A handwritten signature in cursive script that reads "Judy Norsigian".

Judy Norsigian

Executive Director, Our Bodies Ourselves