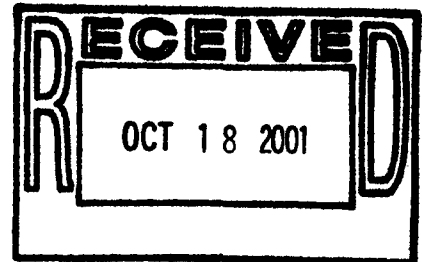

From: Barbara
Sent: Thursday, October 18, 2001 07:56 AM
To: jameson@niehs.nih.gov
Subject: NAMS Drug Company Sponsors

October 18, 2001

To: Dr. C.W. Jameson
National Toxicology Program
Report on Carcinogens
P.O. Box 12233
79 Alexander Drive
Bldg.4401, Room 3127, MD-EC-14
Research Triangle Park, NC 27709



Dear Dr. Jameson,

I hope it is not too late to ask that this note be added to the comments supporting the National Toxicology Program's decision to include steroidal estrogens in the Tenth Edition of the Report on Carcinogens. I write in response to an Oct 8, 2001 Reuters Health News article entitled "Listing of Estrogen as 'Known Carcinogen' Hotly Debated." The article, which appears on Medscape, states that at the 12th annual meeting of the North American Menopause Society (NAMS), Dr. Clay B. Frederick, a member of the National Toxicology Program presented the case for considering estrogen as a carcinogen, while Dr. James V. Fiorica of the H. Lee Moffitt Cancer Center in Tampa spoke for the opposition. The Reuters article begins with the statement, "Members of the North American Menopause Society are protesting the move to add estrogen to the list of human carcinogens compiled by the National Institute of Environmental Health Sciences." It concludes with the statement, "Dr. Wolf Utian, executive director of NAMS, said his group is considering submitting a formal response to the RoC."

NAMS is a well-respected organization, and Dr. Fiorica of the H. Lee Moffitt Cancer Center in Tampa is a well-respected physician. However, both appear to have financial ties with hormone manufacturers, and I ask that this potential conflict-of-interest be

presented alongside any commentary the NAMS may submit. According to its own website, NAMS, a nonprofit organization, has eighteen current corporate "Partners in Menopause." Here is the list:

"NAMS Partners in Menopause

NAMS wishes to acknowledge the following 18 companies for their participation in the Partners in Menopause Education program for 2001. These companies are loyal supporters that actively participate in evaluating ways in which the mission of the Society can be better achieved.

**Allergan
Berlex Laboratories
Eli Lilly and Company
GlaxoSmithKline Consumer Healthcare
LDS Consumer Products
Merck & Co.
Monarch Pharmaceuticals, Inc. Women's Health
Novogen Inc.
Novogyne Pharmaceuticals
Organon, Inc.
Ortho-McNeil Pharmaceutical, Inc.
Pfizer
Pharmacia Corporation
Procter & Gamble Pharmaceuticals
Protein Technologies International
SmithKline Beecham Consumer Healthcare
Solvay Pharmaceuticals, Inc.
Warner-Chilcott
Wyeth-Ayerst Pharmaceuticals**

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At the same New Orleans meeting where NAMS disputed the carcinogenicity of estrogen, it presented three research grants of \$20,000 each conjointly with pharmaceutical companies, one with Solvay and two with Wyeth-Ayerst.

In addition six awards of merit were awarded conjointly with Pfizer, Organon, Protein Technologies, Eli Lilly (2) and Ortho-McNeil. In addition, the NAMS/Wyeth-Ayerst Nurse Practitioner Reporter Program recognized 10 outstanding nurse practitioners. As for Dr. Fiorica, he contributed to a recently-expired (August 31) Continuing Medical Education (CME) Medscape Women's Health Treatment Update called "Straight Talk on HRT: Benefits and Limitations." This continuing education tool for medical professionals is "Supported by an unrestricted educational grant from Wyeth-Ayerst Laboratories."

On a second matter, I wish to note that any continuing debate on the role of estrogen in cancer usually centers on the breast. There can be no debate whatsoever as to the role of estrogens in promoting cancer of the endometrium. This was assumed to be the case since 1947, and confirmed to the full satisfaction of FDA in 1975. Back in the December, 1947 issue of The American Journal of Obstetrics and Gynecology, Dr. Saul Gusberg (later to be president of the American Cancer Society) published a report of 29 patients whose endometria were profoundly disturbed by estrogen therapy prescribed in menopause, - 20 with hyperplasia, nine with cancer. In December, 1975, following the publication of five high-quality studies from independent investigator-groups (see Zeil and Finkle, Kaiser-Permanente, Los Angeles; Donald Smith et al, University of Washington, Seattle; Thomas Mack et al, University of Southern California; Donald Austin, California Tumor Registry; Stadel and Weiss, National Institutes of Health,) the FDA concluded that- "The probability that endometrial cancer will occur in a postmenopausal woman with an intact uterus who does not take estrogen is 1 in 1,000 a year. The risk among estrogen users is 4 to 8 in 1,000 a year, or higher, depending on length of use." In 1991 the author of this letter, among several other women's health advocates, petitioned Dr. Bernadine Healy to redesign the NIH Women's Health Initiative study so that it would not expose women with intact uteri to unopposed estrogens. Dr. Healy responded she'd been advised that such cancers could be averted with careful monitoring. Unfortunately, she was wrong. As SCIENCE MAGAZINE reported in Vol 269, August 11, 1995, -three years after Dr. Healy dismissed our concerns, - the study arm that we objected to was

"quietly dropped." (See "Women's Health Research Blossoms" by Charles Mann, p.766-770.)

I have been covering hormone products as a major part of my science-writer beat since 1960. I have written three books and hundreds of articles on hormones and related topics. I interviewed most of the key scientists who developed estrogens or estrogen applications all the way back to Sir Charles Dodds, and Dr. John Rock. Based on all of the evidence and research I have been following the past 40 years, I believe the decision to include Estrogens as a known carcinogen is not only called for but long over due.

Sincerely,

**Barbara Seaman
(Journalist and Author)**