

Calabio

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May 31, 2000

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

**RE: Notice of request for participation by consumer and interested persons in  
public hearing June 28, June 29, 2000  
[Docket No. 00N-1256];  
FDA Regulation of OTC Drug Products Hearing**

To Whom it May Concern:

**Pursuant to filing requested in the Federal Register/Vol. 65, No. 82/April 27, 2000  
the following person and representative of group wishes to participate in the above-  
referenced part 15 hearing:**

Name: Bruce Philip Barnett, M.D.  
Address: Suite 345, 16830 Ventura Blvd., Encino, California  
Telephone: 818 789 0623 (office); 818 344 8035 (home)  
affiliation: representative of decedent Elnois Calabio and her surviving spouse and children,  
sponsor: HEEGER & BARNETT, LLP, for the Calabio family

Brief summary of presentation:

On October 7, 1999, at the age of 48, registered nurse, wife and mother, Elnois Calabio, succumbed to the end stages of irreversible dermatomyositis and interstitial pulmonary fibrosis directly caused by her use of a prescribed cholesterol-lowering medication, simvastatin (Zocor). Mrs. Calabio had no substantial risk factors for heart disease. Her blood pressure was controlled. Her cholesterol was slightly high, but not considered dangerous. Tragically, in her last days she knew that the cholesterol lowering drug her doctor had recommended to extend her life was in fact the cause of her fatal illness. She told her husband to do what he could to let no other person die as she would from the use of Zocor.

Tragically, Mrs. Calabio was one of many Americans who died last year from the side effects of prescribed medications. Clearly, cholesterol lowering drugs are no less potent than any

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of the many prescribed medications that can kill if improperly used, or even when used according to the manufacturers' directions. Newer cholesterol lowering drugs, like the statins, have a complex mechanism of action with widespread side-effects that have not yet been fully disclosed to consumers.

Yet drug companies brazenly promote the statins. Their advertisements appeal to our emotions and capitalize on fears of premature death. Technical disclaimers do little to familiarize consumers with the potential risk of taking a medication that drastically alters one's biochemistry. The advertisement text may say ask your doctor, but the actual media message is another: *why endure diet and arduous daily exercise when a pill can do so much more?* The drug companies know well that few doctors, if any, can withhold from eager patients a medication made magic by media.

No amount of advertising magic, however, changes the scientific fact that the statins can kill some individuals in a matter of months. On the other hand, the longevity benefits can only be measured after using the drugs for years. It remains to be seen whether or not society, in the long term, benefits from use of statins so widespread as their manufacturers would hope. For the time being, OTC marketing of statins is a very bad idea. We still need to pay more attention to time-tested alternatives such as diet and exercise.

Personal Disclosure:

I am a physician and an attorney specializing in medical-legal law. My cv and resume are enclosed. I represent Mr. Calabio and his sons in their claim that Merck has not fully disclosed the reported deaths and pulmonary complications that medical research has attributed to Zocor.

Time requested for the presentation: 10 minutes for Bruce Barnett and 10 minutes for Calabio family (including time for questions).

I appreciate your consideration and hope to have an opportunity to give meaningful oral testimony.

Sincerely yours,



Bruce Philip Barnett, M.D.

enc.

**Bruce Barnett. M.D., J.D., M.B.A., Suite 345, 16830 Ventura Blvd. Encino, CA 91436**

**SELECTED PUBLICATIONS AND PRESENTATIONS**

- Barnett, B. "California Legislature Determines Fate of Medical Board " **LACMA PHYSICIAN**, January, 1998.
- Barnett, B. "Bill Protects Physicians Against Double Jeopardy" **LACMA PHYSICIAN**, October, 1997.
- Barnett, B., "No-Cause Termination Bar is No Cure" **LACMA PHYSICIAN**, July, 1997.
- Barnett, B., "Legal Issues in the Management of Pharmacy Benefits - An Overview of Challenges" 43:4 **Medical Trial Technique Quarterly** 53 (1997).
- Barnett, B., "The Americans With Disability Act and Recovering Substance Abusers - Medical/Legal Considerations in Preventing Discrimination," 43 **Medical Trial Technique Quarterly** 45 (1996).
- Barnett, B., Morris, L, "The New California Administrative Procedure Act: A Step Towards Due Process," **PAN OBSERVER** Fall 1996.
- Barnett, B., "Collecting Payments from HMO's for Non-contracted Physician Services," **ABA Health Insurance Law Committee Newsletter**, Fall 1995.
- Barnett, B., and Waxman, M. "HMO Reimbursement and the Noncontracted Physician," **Medical Interface**, Sept., 1992.
- Barnett, B. "RBRVS to the Rescue - HMO Payments and Medical Group Survival in a Maturing Health Care Industry," **Group Practice Journal**, July/August 1992.
- Barnett, B. "Medical Groups Managing Medicaid - The Next Horizon," **Group Practice Journal**, September/October 1991.
- Barnett, B. "Will Managed Care Rescue Medicaid?" **Medical Interface**, Sept. 1991.
- Barnett, B., and Dini, J. "Managing the Million Dollar Contract," **Group Practice Journal**, November/December 1990.
- Barnett, B. "When Death is Imminent," **Group Practice Journal**, September/October 1990.
- Barnett, B. "Doctor as Terrorist, Patient as Hostage," **Group Practice Journal**, November/December 1989.
- Barnett, B. "How to Take the Risk out of Medicare HMO Management," **Group Practice Journal**, Sept./Oct. 1989.

Recent Lectures to Professional Societies:

- "Medical-Law 2000," Lecture series to UCLA Medical Residents, May and June, 2000
- "New Legal Developments for California Psychiatrists" Lecture at annual UCLA Psychiatry Research Day, June 26, 1999.
- "Law for Doctors" Lecture Series to UCLA Residents, May, 1999
- "Physicians at Risk" Lecture before the Shasta County Medical Society, April, 1998.
- "Legal Obstacles in Contracting for Managed Care Business," American Association of Clinical Chemistry, Atlanta, Georgia. 7/97.
- "Physicians Under Siege," Medical Center of North Hollywood. 1/97.
- "Current Status of the Medical Profession," California Certified Public Accountants Education Foundation - San Francisco and Los Angeles. 10/96.
- "Legal Obstacles in the Management of Pharmacy Benefits," American Society of Pharmacy Law, Nashville, Tenn. 3/96.