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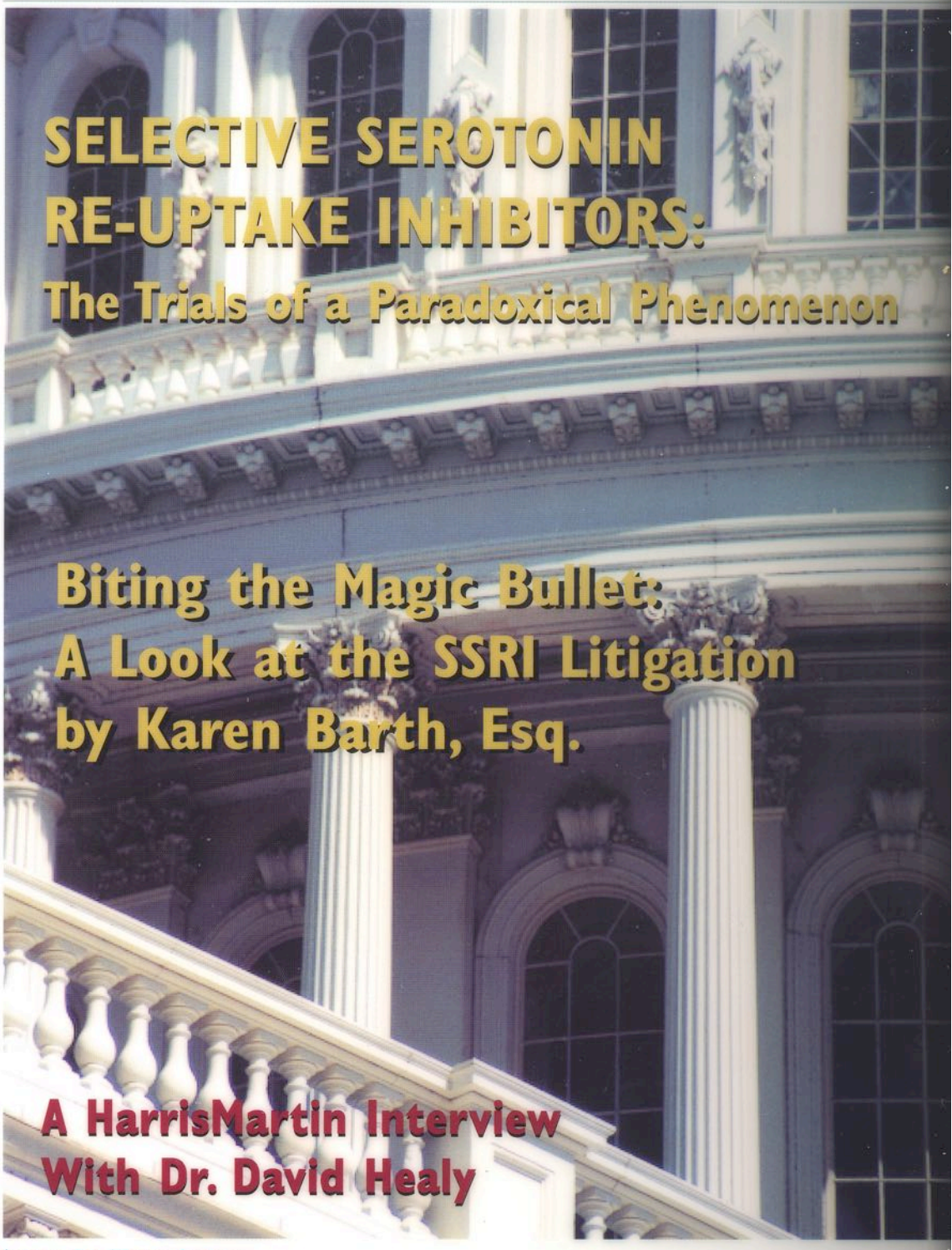

SELECTIVE SEROTONIN RE-UPTAKE INHIBITORS:
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Biting the Magic Bullet: A Look at the SSRI Litigation by Karen Barth, Esq.

A HarrisMartin Interview With Dr. David Healy

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Prempro

Nationwide Class Action Lawsuit Has Been Filed Against the Manufacturers Of Prempro

CHICAGO—A nationwide class action lawsuit filed against the manufacturers of Prempro seeks to establish a medical monitoring class, personal damages class and a reimbursement class for all individuals who used or purchased the drug after November 1995. *Lewers, et al., v. Wyeth, Inc.* No. 02-C-4970 (N.D. Ill.).

The July 15 complaint filed in the U.S. District Court for the Northern District of Illinois came on the heels of a July 9 report from the National Heart, Lung and Blood Institute (NHBLI) that announced it would halt a study investigating the effects of estrogen plus progestin therapy on heart disease and hip fractures. The data revealed that women participating in the estrogen-progesterin group were at an increased risk of invasive breast cancer, coronary heart disease and pulmonary embolism compared to women taking a placebo, the suit says.

The lawsuit claims that Prempro is a defective product because Wyeth failed to conduct sufficient pre-clinical testing, failed to provide adequate warnings with the drug, and misrepresented the safety and efficacy of the drug in their advertising.

Gayle Lewers, a resident of Lake Zurich, Ill., was prescribed, purchased and ingested Prempro on a daily basis from 1996 through April 1999. She claims her use of Prempro resulted in the development of five breast tumors. One of the tumors was malignant and was removed in a mastectomy procedure in April 1999, the lawsuit says.

New York City resident Elizabeth Katz took Prempro every day from April 1996 through the present. She is asymptomatic but seeks medical monitoring for potential illnesses that may be related to her ingestion of Prempro, according to the lawsuit.

Edith Livingston of Goldsboro, N.C., suffered from invasive breast cancer that required four cycles of chemotherapy and a radical mastectomy. She claims her ailments are related to her daily ingestion of Prempro from October 2001 through March 2002. Her husband, Walter Livingston, is also named as a plaintiff.

Prempro is composed of medroxyprogesterone acetate (MPA) and Premarin, a conjugated estrogen developed by Wyeth in 1942. Prempro is commonly prescribed to women to treat the symptoms of menopause. Estrogen has been prescribed to women to aid in the relief of similar conditions; however, studies revealed that its use could lead to an increased risk in endometrial cancer. The combination of estrogen and progestin, also referred to as hormone replacement treatment (HRT), offered patients the ability to relieve menopausal symptoms and reduce the risk of endometrial cancer, the lawsuit says.

The FDA approved the marketing of Prempro as separate tablets of Premarin (0.625 mg) and an MPA known as Cycrin (2.5 mg) in December 1994. The tablets were packaged together for concomitant use as part of a therapeutic regimen for post-menopausal women with an intact uterus for the treatment of symptoms associated with menopause, vulvar and vaginal atrophy as well as the prevention of osteoporosis. In December 1995 the FDA approved single-tablet doses of Prempro (Premarin 0.625 mg, MPA 2.5 mg). The FDA approved an enhanced single-tablet dose of Prempro (Premarin 0.625 mg, MPA 5 mg) for marketing in January 1998, the suit says. The lawsuit alleges that the plaintiffs could not have known of the potential dangers associated with Prempro prior to the July 9 statement from the NHBLI because Wyeth failed to conduct adequate pre-clinical testing.

"... Adequate testing would have shown that Prempro possessed serious potential side effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made," the suit says

The Women's Health Initiative (WHI), a 15-year study by the National Institute of Health (NIH) and the NHBLI, is designed to research strategies for the prevention of major causes of death and disability in women, such as breast and colorectal cancer, heart disease and osteoporosis. The WHI Clinical Trial and Observation Study was established to investigate inadequacies in women's health care research and provide information to women and physicians regarding the effects of HRT and calcium/Vitamin D supplements on the prevention heart disease, cancer and osteoporosis. The WHI Clinical Trial and Observation Study began in 1993 and involves more than 161,000 women ages 50 to 79 participating in clinical trials conducted at 40 centers throughout the country, the lawsuit says.

The study that was recently halted by the NHLBI was comprised of 16,608 women ages 50 to 79 who had not undergone a hysterectomy. The study consisted of a group of women given Prempro (Premarin 0.625 mg/MPA 2.5 mg) and another group given a placebo. The women were interviewed every six months to gather information on any symptoms or concerns. Participants in the study were also subjected to annual in-clinic examinations, annual mammograms and clinical breast examinations, the complaint states.

Formal monitoring by an independent data and safety monitoring board (DSMB) began in 1997 and was conducted every six months. In 1999, following five analyses of the data, the DSMB noted a small rise in the number of reported adverse cardiovascular events, the suit says.

The DSMB provided information to participants regarding a statistical increase in the number of heart attacks, stroke and pulmonary embolism in 2000 and 2001; however, the study continued since the number of events still hadn't surpassed the statistical safety boundary, the lawsuit states.

The decision to end the study was the result of the data found during the DSMB's May 31 meeting. The information revealed another increase in the reported number of cardiovascular events and an amount of invasive breast cancer reports that had gone beyond the safety boundary. The data for women in the estrogen-plus-progestin group included: a 41 percent increase in strokes; 29 percent increase in heart attacks; 100 percent increase in blood clots; 22 percent increase in cardiovascular disease; 26 percent increase in breast cancer, the complaint says.

According to the lawsuit, there are approximately 50 million post-menopausal women in the United States and an estimated six million women currently taking estrogen plus progestin. As a result of these figures, the HRT market is a multi-million dollar business, the lawsuit says. The claim states Wyeth spent more than $40 million in consumer advertising for their line of HRT products and the sales of Prempro reached approximately $949 million during the year ending May 2002.

The complaint also states that Wyeth's marketing tactics and insufficient warning labels are in violation of the Federal Food, Drug and Cosmetic Act and the Pennsylvania Unfair Trade Practices and Consumer Protection Law.

Kenneth B. Moll, Hal J. Kleinman, Carrie Graziani and Michael S. O'Meara of Kenneth B. Moll and Associates in Chicago represent the plaintiffs.

Document is Included
See Page 33
Complaint Ref#DRU-0208-07