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Cooper, Carvin & Rosenthal

Lawyers

A Professional Limited Liability Company

Charles J. Cooper
(202) 220-9660
ccooper@coopercarvin.com

Suite 200
1500 K Street, N.W.
Washington, D.C. 20005

(202) 220-9600
Fax (202) 220-9601

February 2, 1998

BY FACSIMILE AND U.S. MAIL

Catherine Colette
Director, Women's Rights Department
American Federation of State,
County and Municipal Employees
1625 L Street, NW
Washington, DC 20036

Leslie R. Wolfe
President
Center for Women's Policy Study
1211 Connecticut Avenue, NW, #312
Washington, DC 20036

Linda F. Golodner
President
National Consumers League
1701 K Street, NW, #1200
Washington, DC 20006

Marcia Greenberger
Co-President
National Women's Law Center
11 Dupont Circle, NW, #800
Washington, DC 20036

Wayne Shields
President & CEO
Association of Reproductive
Health Professionals
2401 Pennsylvania Avenue, NW, #350
Washington, DC 20037

Susan Wysocki
President
National Ass'n of Nurse Practitioners
in Reproductive Health
503 Capital Court, NE, # 300
Washington, DC 20002

Judith L. Lichtman
President
National Partnership for
Women & Families
1875 Connecticut Avenue, NW, #710
Washington, DC 20009

Ladies and Gentleman:

I am counsel to Duramed Pharmaceuticals, Inc. ("Duramed"), and I am writing to demand that you withdraw the false statements concerning Duramed's product, Cenestin, set forth in the letter submitted last week to Dr. Janet Woodcock of the Food and Drug Administration ("FDA") above your signatures. The letter states that "the safety of [Duramed's estrogens product] is unproven and unknown," and that FDA

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approval "may subject millions of women to risks which the Food, Drug and Cosmetic Act was intended to protect against." These statements are false and highly prejudicial to the reputation of both Duramed and its product. Moreover, the statements appear to have been made with knowledge of their falsity and to have been intentionally calculated to visit substantial damage on Duramed and its product.

Duramed has submitted extensive evidence demonstrating the safety and effectiveness of Cenestin that more than satisfies not only the relevant provisions of the Food, Drug & Cosmetic Act and the regulations that the FDA has established for proving the safety of all new drugs, but also the specific criteria that FDA scientists established for the approval of *this particular drug*. In addition, Duramed has submitted the product chemistry, manufacturing controls, and pharmacokinetic bioavailability data typically provided by NDA sponsors.

The letter to Dr. Woodcock suggests it would somehow be improper for the FDA to rely upon safety data produced in studies done on other estrogen replacement drugs. The letter acknowledges that "FDA, in reviewing NDAs, sometimes relies on data derived from studies of a drug with the same active ingredient," but claims that "this is not that situation." The letter is simply wrong on this point. The FDA commonly relies upon studies done on other estrogen class drugs in approving new drugs, even where the new drug does not contain precisely the same combination of active estrogens. For example, within the last few months, the FDA approved Activelle, estradiol patch, and Levlite in reliance upon safety studies done on a broad range of estrogen class drugs. Thus, to the extent Duramed relied upon studies demonstrating the safety of other estrogen class drugs, such reliance is fully in keeping with both the Act and longstanding FDA practice.

Dr. Woodcock's 1997 memorandum concluding that the FDA could not approve any synthetic generic version of Premarin at that time is not to the contrary. The conclusion set forth in the memorandum was based entirely on Wyeth-Ayerst's failure to adequately characterize Premarin. Specifically, Dr. Woodcock was concerned that another ingredient occurring naturally in the urine of pregnant mares (and hence in Premarin) *might be* an active ingredient of Premarin, and that possibility precluded approval of generic synthetic versions of the drug. The active ingredients of Cenestin are present in like amounts in Premarin. In addition, nothing in Dr. Woodcock's memorandum called into question the practice of considering studies done on estrogen class drugs in evaluating the safety of a new estrogen replacement drug.

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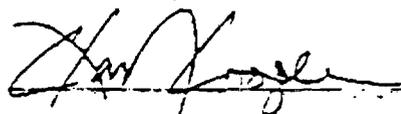
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Although the letter submitted under your signatures did not appear to challenge the effectiveness of Cenestin, I would be remiss if I did not point out that the clinical data Duramed has submitted to the FDA demonstrates beyond all question the effectiveness of Cenestin in treating vasomotor symptoms in menopausal women.

We are aware that the letter submitted to Dr. Woodcock was prepared by Wyeth-Ayerst's lobbyists, Foreman, Heidepriem & Mager, Inc. We are also aware that the letter was distributed by the Foreman firm to a significant number of different organizations, most of which do not appear to have the expertise to independently evaluate the technical and regulatory issues so definitively addressed by the Foreman letter. A number of organizations dedicated to serving women's interests did not sign this letter. Those organizations that refused to serve as Wyeth-Ayerst's pawns in its continuing campaign to preserve its monopoly over estrogen replacement drugs have fulfilled their mission of advancing women's health. It is our hope that your signatures on the letter to Dr. Woodcock merely reflect your uncritical acceptance of Wyeth-Ayerst's false claim that Duramed has not proven the safety of Cenestin. Now that the record is clear, we believe that you will want to - and in fact you have a duty to - withdraw the erroneous statements that have been made to the FDA in your names.

Finally, we must be clear on one point. Duramed will not tolerate the public dissemination of statements falsely impugning the safety of its products. Such statements are actionable, and Duramed will not hesitate to take whatever actions are necessary to defend its rights.

Sincerely,



Charles J. Cooper

cc: Jane E. Henney, M.D.
Janet Woodcock, M.D.