PCRM PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE
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Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Ln, Room 1061
Rockville, MD 20852

I am writing to express our concern that FDA has yet to take action on our organization's petition to strengthen warnings to clinicians and potential patients about the risks of estrogen products used in growth-suppression therapy in children. Our petition was sent to you nearly a year ago, and action is long overdue.

In reviewing FDA's recent newly released warnings for estrogen-containing products, we note that the section on pediatric usage is wholly inadequate to address the risks. We therefore reiterate our requests as follows:

1. We request that the FDA mandate the following addition to the product labeling for all estrogen-containing products intended for oral use:

Estrogens are not approved for suppression of growth in adolescents, and, because no studies have monitored adverse effects in treated cases for more than ten years post-treatment, the safety of such use has not been established.

2. We also request that a notice be sent by certified mail to all pediatric endocrinologists practicing in the United States to notify them of this change.

3. We further request that the FDA mandate the following advisory in the labeling intended for patients:

Although estrogens are sometimes prescribed for tall adolescent girls in an attempt to limit their growth, the safety of this practice has not been established, particularly since estrogens may have significant side effects when used at high doses for long periods of time.

As you know, one-third of surveyed U.S. pediatric endocrinologists currently offer estrogen treatment for tall stature, despite the absence of studies establishing its benefits or elucidating its long-term risks. Modification of product information for practitioners and patients is justified, and we request your urgent action.

02P-0067 LET 2

Sincerely,

Neal D. Barnard, M.D.