



National Black Women's Health Project, Inc.

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October 28, 2005

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Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

RE: Docket Number 2005P-0411

Dear Ms. Butler:

As you may know, the Black Women's Health Imperative (Imperative) is a leading African American health education, research, advocacy and leadership development institution. We are the only national organization devoted solely to the health of the nation's 19 million Black women and girls. I am writing to bring to your attention problems resulting from the misleading and unregulated advertising done by a number of companies promoting so-called bio-identical hormone replacement therapies.

The results of the Women's Health Initiative clearly showed that hormone therapy carries distinct benefits and risks. Fearful of traditional hormone therapy, many women have sought out "natural" alternatives, incorrectly assuming that natural products are safe, efficacious, and approved by the FDA. These beliefs have been reinforced by slick marketing efforts, which have successfully convinced many women that bio-identical hormone replacement therapy (BHRT) products can relieve menopausal symptoms without any side effects or risks. However, as FDA well knows, all products have side effects, and any representation to the contrary is simply false and misleading.

The Black Women's Health Imperative is particularly disturbed by the misleading website advertising and promotion of BHRT products, especially in light of the Internet's wide reach. Recognizing the importance and power of the Internet in today's world, as well as the growing rate of Internet use by African American women, the Black Women's Health Imperative set out two years ago to build an online resource that contained trustworthy and authoritative information that focused on African American health. Today, our website, www.blackwomenshealth.org, is the proud recipient of several awards, and attracts 65,000 unique visitors and one million hits per month.

Combined Federal Campaign #0468

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Jennie Butler, Administrator
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We have taken great pains to ensure that the health information posted on the Imperative's website is truthful and accurate. The same cannot be said for some compounding pharmacies' information. To protect the health and safety of women, the FDA needs to step in and take enforcement action against these false and misleading advertising claims. Furthermore, the FDA must enforce the laws governing the production, distribution, and marketing of these products. It is hard to understand why the FDA hasn't taken any action to date.

The Black Women's Health Imperative is also concerned about the economic cost to many women who choose to use BHRT. While these products are sometimes covered by insurance, in most cases they are not. Many women are paying out of pocket for products that they have been led to believe are superior to FDA-approved forms of hormone therapy, but which are not superior and may in fact be more dangerous.

The BWHI strongly believes that the FDA must take immediate action and end its silence on this issue. We are eager to learn more about the steps you plan to take to address the problems detailed in this letter.

Sincerely,

Lorraine Cole, Ph.D.
President and CEO