

OWL OF SOUTHEAST FLORIDA

Marilyn Z. Robinson, OWL President
804 Solar Isle Drive
Fort Lauderdale, Florida 33301
954-767-8914 FAX 954-767-9530
MZR100@aol.com

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Commissioner of Food and Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner:

First, we want to commend you for your continued leadership on issues relevant to women's health and, in particular, for the FDA's approval of a generic version of the anticancer drug Taxol. We are writing to urge you to take every step possible to ensure that the lower-cost generic remains available.

Many women with breast and ovarian cancer would be deprived of this life-sustaining drug if the artificially high prices previously charged for the brand name were re-instated. That devastating loss could result if the FDA does not pursue reconsideration of a recent decision by the DC Circuit Court of Appeals.

A three-judge panel of the appellate court reversed the trial court's prior order that cleared the way for approval of generic paclitaxel by de-listing from the FDA's Orange Book a patent filed by American BioScience Inc. The panel's decision apparently was based on questions of the adequacy of the record; the judges did not consider the validity of ABI's patent.

The injustice of desperately ill patients being deprived of affordable treatment would be compounded by the fact that the drug was originally developed with millions of dollars of tax-funded research by the National Cancer Institute.

We feel strongly that the FDA should seek reconsideration of the appellate panel's order. This issue is critical to the health of women, and we will do everything in our power to support the FDA in keeping generic paclitaxel on the market.

Sincerely,

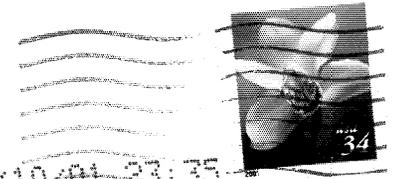


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OWL of Southeast Florida
804 Solar Isle Drive
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