

BREAST CANCER ACTION

March 5, 2007

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD20852

RE: Docket No. 2006N—0062

Comments submitted by Breast Cancer Action regarding proposed rule on expanded access to investigational drugs.

FDA's proposed rule for expanded access is a welcome clarification for seriously ill patients seeking experimental treatment for advanced breast cancer. Breast Cancer Action strongly supports the proposed rule as they codify existing practice and advance the goals of the rule as explained in Part III.

Our comments will address two major concerns with regard to expanded access: providing appropriate access to experimental treatments, and protecting the integrity of randomized clinical trials (RCTs) of investigational new drugs.

We strongly encourage access to Phase III experimental drugs for seriously ill patients who are ineligible for randomized clinical trials but who could possibly benefit from such treatment. FDA's proposal would not change current criteria for access, which we support. It also promises greater efficiency by aggregating various types of individual requests so that FDA can make decisions in a more timely way than on a case-by-case basis. Detailed, standardized reporting of events and results from expanded access by investigators and sponsors would allow FDA to capture data that might otherwise not become evident in RCTs, which frequently select for "healthier" patients.

As described, Section 312.310 proposes that sponsors be "strongly encouraged" to submit expanded access protocols with their IND application. This eases FDA's consideration of expanded access applications for individuals and intermediate sized groups and streamlines the FDA review process.

We are concerned that expanded access not undermine randomized clinical trials of new drugs. As written, the proposed rule continues to protect randomized trials by requiring that those eligible for expanded access must meet two criteria, one of which is that the patient has no alternative therapy available. If the patient were eligible for an RCT, s/he would have an alternative treatment available and not be eligible for expanded access. In addition, the stipulation that providers submit reports of drug effectiveness and safety problems among their patients who are given experimental treatment outside of clinical trials will provide useful additional data on those who are, in general, sicker than those eligible to be research subjects.

The requirement that the person seeking expanded access be suffering from a "serious or life-threatening condition" should not be problematic in the setting of metastatic breast cancer, since

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having metastatic disease is both serious and life threatening. It should be clear that those with *in situ* breast cancers would, under this criterion, never qualify for expanded drug access.

Section 312.320 proposes to rein in so-called "open-label safety studies" that purport to improve safety characterization of new drugs later in their development, but that are actually disseminating drugs widely without adequate data collection or oversight. We support the proposed rule, which would limit expanded access in these circumstances to treatment INDs or protocols, which require a more formal review process.

Thank you for undertaking this project and resisting political pressure to give open access to untested drugs while at the same time making expanded access available to those most in need.

Respectfully submitted,



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Jane Zones
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As a matter of policy, in order to avoid the fact or appearance of a conflict of interest, Breast Cancer Action does not accept funding from any pharmaceutical companies.