

March 14, 2007

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Division of Dockets Management [HFA-305]
Food and Drug Administration
5630 Fishers Lane – Room 1061
Rockville, Maryland 20852

RE: [Docket No. 2006N-0061] – RIN 0910-AF13
Charging for Investigational Drugs

AND

[Docket No. 2006N-0062] – RIN 0910-AF14
Expanded Access to Investigational Drugs for Treatment Use

To Whom It May Concern:

The undersigned organizations represent cancer patient advocates, providers and researchers. We support the two proposed regulations referenced above because we believe they will facilitate access to potentially life-extending drugs for patients without other treatment options.

The proposal on "Charging for Investigational Drugs" provides important clarification in several distinct areas. First, it provides long overdue specificity as to the circumstances in which a sponsor may charge for costs of an investigational treatment. Charging for investigational therapies may be necessary to ensure access in rare circumstances, but those circumstances should be carefully defined and limited to avoid exploitation by unscrupulous companies. We also support the refinement of the rules to provide greater flexibility in investigator-initiated clinical research, which is particularly important in identifying new uses for marketed cancer drugs.

The second proposed rule, providing additional detail for expanded access to unapproved therapies for patients without other treatment options, is also commendable. The proposal delineates how patients, providers and pharmaceutical sponsors may work together to obtain access to investigational treatments prior to marketing approval. This information has not been readily available, resulting in confusion on the part of sponsors as to how they might develop such programs for the benefit of patients. The proposed rule provides a sort of roadmap as to how patients, providers and sponsors may participate in a process to create expanded access to investigational drugs. While the guidance in the proposed rule is helpful, we are aware that many physicians find the process of applying for individual access to be unduly burdensome. We have also learned that individual patients and their families who have exhausted all treatment options and who are ineligible for clinical trials will endeavor to use the current mechanisms available through the Food and Drug Administration (FDA) and seek compassionate use of

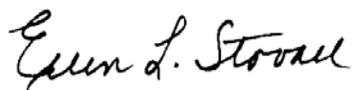
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unapproved therapies. They report that they find the process lacking in consistency with no clear reason given by either the sponsor or the FDA why access may or may not be possible. We urge the agency to take any appropriate additional measures to reduce this burden on physicians and these barriers to patients and their families and to facilitate access for individual patients.

In general, we believe the proposal strikes the right balance to achieve enhanced access without jeopardizing the safety and efficacy of new drugs or accrual to clinical trials for new cancer therapies. Our groups support both these proposed regulations and encourage their adoption by FDA. We appreciate the responsiveness of FDA to the concerns of cancer patient advocates, as reflected in these proposals, and look forward to working with the agency to implement successfully these provisions for expanded access to investigational therapy and responsible charging for such investigational products.

Sincerely,



Ellen Stovall
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