

Marti Nelson Cancer Foundation

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June 18, 2002

Via fax and email

The Honorable W.J. Tauzin, Chairman
House Committee on Energy and Commerce
The Honorable James C. Greenwood, Chairman
Subcommittee on Oversight and Investigations
United States House of Representatives
Washington, DC 20515

Dear Representative Tauzin and Representative Greenwood,

We are writing with reference to your hearing on June 13, 2002:

"An Inquiry into the ImClone Cancer-Drug Story"

As you know from our prior letters (dated January 29, 2002 and February 11, 2002), we had grave concerns regarding the regulations and laws governing proprietary information. From the information disclosed in the hearing, it seems clear that **confidentiality measures intended to protect trade secrets were used also to hide unfavorable information from patients who need it more than anyone else.** If the FDA's Refusal To File letter had not been leaked to the CancerLetter, the patients – and also the general public – would still be in the dark.

We hope that your hearing will results in changes that give first consideration to the public's right to know. The concerned public, in the case of a cancer drug, includes not only investors but also cancer patients who have much more than money at stake. It is our position that letters such as the very important letter that FDA sent ImClone on December 28 should not be part of the proprietary protections normally afforded to companies. The FDA in our view needs wider discretion in deciding what information should be immediately placed in the public domain. **The FDA must protect the public health and welfare, and the story of Erbitux is a good example of how the FDA is hamstrung by laws that prevent them from acting in the public interest.**

There are a number of other areas where protection of the commercial proprietary interests of a pharmaceutical company are in direct conflict with the public interest or more specifically the patient's interest. For example, there are times – mostly related to issues of safety -- when the FDA places a clinical trial on "hold," thereby stopping the trial. Although these FDA "hold" actions are rare in the case of life threatening diseases, they have been increasing in recent years. **When a trial is placed on "hold," no information is available to**

patients about why the FDA took this action because that information is considered “confidential and proprietary.” The practical result is that the patient has to stop treatment and is given no specific reason about why this action was taken nor are they informed about when the trial will resume if ever. Once again the interests of the pharmaceutical industry are placed ahead of the interests of the public.

We urge you to consider crafting legislation which provides the FDA with the ability to protect the **public** welfare in exceptional situations such as this. We will be in contact with your offices to discuss this further.

Thank you very much for your attention to this critical issue,

Bob Erwin
Kathy Hanley
Nancy Roach
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www.CancerActionNow.org