Erbitux Oversight Alliance
607 Elmira Road PNB 331
Vacaville, CA 95687
707 421 5886

January 29, 2002

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,

In your letter dated January 18, 2002 to Dr. Bernard Schwetz, Acting Commissioner of the Food and Drug Administration, you make the following comment:

> "For the sake of protecting patients and investors from deception, we are interested in learning whether FDA laws need to be clarified to permit the FDA on its own accord, and in appropriate circumstances, to share non-public information with other federal agencies."

As patient advocates, we are also interested in the topic of confidentially in the drug development process.

Clinical trials – research using patients as test subjects – are a crucial piece of the drug development process. A patient entering a clinical trial is given an "Informed Consent" document that explains the pros and cons of the agent being tested. A patient cannot truly grant informed consent if the "informed" part is only partial.

While we understand and support the incentives that are necessary to attract private, commercial investment capital to the development of important new medical therapies, **we have grave concerns that confidentiality measures intended to protect trade secrets may be used also to hide unfavorable information from patients who need it more than anyone else.** For example, because of wide-spread publicity about ImClone's anti-cancer agent C225 [Erbitux], thousands of cancer patients were encouraged and anxiously awaited its approval as repeatedly promised by ImClone press releases and statements. Their optimism was proved unwarranted on December 28, 2001 when ImClone's new drug application for C225 was not even accepted for review by the FDA because the application deficiencies were so great. A patient reading ImClone's press release about the FDA's action would have thought that the FDA's refusal to file action was just a minor bump in the drug approval road. In fact, according to subsequent Wall Street reports, this FDA action will likely result in at least a year or more delay in C225's approval. **Why should a patient have to rely on Wall Street to learn about urgent medical information when their government has the accurate unadulterated information?**

We hope that your investigation into this matter will 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. **It is the FDA after all that protects the public interest and the story of ImClone's C225 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 this issue in your investigation. If we can be of help in any way, please don't hesitate to contact us.

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

Bob Erwin, Director
Marti Nelson Cancer Research Foundation
Robert.Erwin@CancerActionNow.org