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February 11, 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:

Following our letter of January 29, we would like to expand on and clarify some important points for your consideration as you proceed with your investigation of the drug development issues that have been brought to the public's attention as a result of the ImClone case. These points can be summarized in two categories, both of which are important to consider from the perspective of patients and consumers.

Policy issues:

1. Refusal to File (RTF) letters: driven by data or timeline?
2. Blanket confidentiality: necessary to protect trade secrets?

We believe it is very important to keep in mind that ImClone's potential product, Erbitux (C225) has generated legitimate excitement among scientists, oncologists and cancer patients based on objectively obtained treatment results which have been previously reported in the scientific and medical literature. There is evidence that C225 is an active agent and we believe that this important fact should not be lost in the furor over how ImClone and the FDA have handled the research and review process. Although ImClone is at the center of the current controversy, the issues that need to be addressed are larger than any single company or product.

Issue 1: Refusal to File (RTF) Letters

The Food and Drug Administration Modernization Act (FDAMA) timeline imposed on FDA's review process requires, in the case of a fast-track application, that an application, such as ImClone's C225, be acted upon (approve or disapproved) within 6 months. It's our understanding that a 6-month "clock" starts the day that the application is filed. It is our further understanding that an RTF letter is rare but when it is issued, it should be due to a failure on the part of the sponsor to provide the FDA with the data and documentation that is required before a drug's safety and effectiveness can be determined.

The FDA may have good reason to use the RTF letter. However, this raises the question of whether the RTF letter was the most expeditious way to handle this application. In other words, why wasn't it possible for the FDA and ImClone to work out the data and

documentation issues during the 6 month "clock," rather than stopping the 6 month "clock" only to restart it perhaps in 2 or 3 months, or maybe even longer.

Clearly, the intent of FDAMA is to get safe and effective therapies to patients in the most timely way possible. We wonder if an examination of RTFs, NDAs and BLAs issued since implementation of the FDAMA show a pattern of increasing or decreasing total approval time. We wonder if the ImClone RTF letter was issued so that the FDA could maintain its timeline, or if it was issued because the data provided by ImClone was insufficient. We can't evaluate this issue ourselves because of our second issue – confidentiality of FDA records due to the proprietary concerns of drug sponsors.

Issue 2: Blanket confidentiality

The new drug approval process is almost totally confidential due to proprietary concerns. We agree that there is a legitimate need for confidentiality of some information at some points in the process. At the same time, the lack of transparency in the entire process can be very harmful to everyone involved, especially when during the process, an active drug is just stopped from coming to market for reasons that the public is not allowed to know. This is an even more serious when that public is patients dying of cancer. The ImClone experience illustrates how lack of transparency and a high-profile drug (C225) have combined to create a situation where no one knows what the facts are.

ImClone and the FDA have been discussing C225 for years. The RTF letter as excerpted in the CancerLetter tells the FDA side of the story and raises serious concerns about ImClone's data as submitted. At the same time, we think it is important to remember that the article reflects only one side of the story. If ImClone were compelled to reveal their correspondence and meetings minutes, what would those documents show on ImClone's behalf? What would an independent third party with full access to all FDA – ImClone correspondence and records say? We – the public – have no way of evaluating the FDA's concerns because we have no access to the meetings, the agreements or the conclusions reached along the way.

This lack of transparency seems to have created a lack of trust in C225, ImClone and the entire drug development process as evidenced by press reports. For example, in this case, patients and investors were led to believe that C225 would be approved this spring. Many of this group are not educated in the nuances of the drug development process – all they see is that a promised therapy is not going to be available for reasons that aren't publicly available. Does this breed trust? Although the press has portrayed ImClone as the villain in this saga, is that really fair? Is ImClone a small company that made mistakes in the course of a very complex and expensive product development process or did they deliberately deviate from a clearly defined path based on financial motivations, as some in the press have implied? Unfortunately, in the face of stockholder lawsuits and a press frenzy, it is very difficult for patients and their caregivers to get at the simple truth. At least part of that truth seems to be that a promising new therapy for a fatal disease is caught up in a process that is anything but transparent.

This is particularly unfortunate because preliminary data indicates that C225 works for EGFR-positive patients for some period of time – and C225 is intended for patients who have exhausted approved treatment options. These people don't have time to wait for the dust to settle from this investigation and the various lawsuits that have been filed against ImClone by investors. Life and death decisions are being made by our fellow citizens while one promising option languishes unavailable to help those who need it most.

We urge the Committee to consider these issues and to evaluate the potential need to change existing regulations to better serve the public.

Thank you.

Bob Erwin, Director
Marti Nelson Cancer Research Foundation