

Subject: Provenge Safety Concern

BCC list: 500 members of the medical, scientific, regulatory, and legal communities

Dear Colleague,

The document attached/at the following link <http://scr.bi/9HeQex> was written by a group of scientists and physicians whose concern for their safety has forced them into hiding. In it they postulate a design flaw in the Provenge PhIII trials with potentially profound implications. Those who previously voiced legitimate scientific concerns regarding this drug had their lives threatened, were forced to employ body-guards and have been traumatized into silence. Every dissenting voice is squashed. This fear extended to the FDA reviewers, who stated if it doesn't get approved this time, there will be bloodshed. It is our constitutional right to express our opinions. If money and power can scare dissenters into silence, it is a sad day indeed for our nation and for humankind.

I call upon you to read this argument and make your own independent, critical assessment of its merits. If you see the merit of the concerns it voices, I call upon you to express those views to the FDA and CMS (Leslye Fitterman, PHD; Leslye.fitterman3@cms.hhs.gov) who have been trusted with the power of protecting the American public.

In my personal opinion (and that of select esteemed colleagues) that a legitimate concern has been raised, which is that the immune cells that are explicitly removed from placebo patients in the Provenge trials could have significantly compromised these patients and their ability to fight their cancer. This possibility must be explored as an alternative explanation for these trial results, because if it is right, it implies that Provenge treatment is harmful to patients because of all the immune cells that are lost during this treatment, and not prolonging life at all!

If any of you reach the same independent assessment of this piece as I do, it is our moral obligation to have a voice heard and demand this matter is investigated. We must stand up against those that wish to use the power of the sword to threaten legitimate scientific discourse and concern for patient safety. We cannot allow the big money invested in this drug to feed on the fear and desperation of cancer patients and their families to co-opt their voice to silence those very people that are trying to protect them.

Sincerely,

A concerned physician, scientist and citizen

p.s. Scientific progress since 1999, when the FDA agreed to the design of these trials, has significantly increased our understanding of immune aging. Now that we know that the aged immune system cannot replace lost cells in the way that the youthful immune system can, we should identify the possible mistakes of our earlier ignorance. We infected thousands of people with HIV and Hepatitis C through blood infusions before we discovered that these are blood-borne pathogens. We gave thalidomide to thousands of pregnant women before we understood that this was causing birth defects. We used epo to drive hemoglobin levels to unhealthy levels until we learned that this is harmful. We make mistakes, and scientific progress reveals those mistakes. The sooner we rectify earlier mistakes, the sooner we curtail the unintentional harm we are causing.