

United States Senate

SPECIAL COMMITTEE ON AGING

WASHINGTON, DC 20510-6400

(202) 224-5364

November 14, 2007

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
5600 Fisher Lane, Room 1555
Rockville, MD 20857

Dear Dr. von Eschenbach,

I am writing to you in reference to my earlier correspondence with you, dated November 8, 2007, in which I made information and document requests regarding the Food and Drug Administration's (FDA) dealings with Genentech, Inc. As an addendum to that initial inquiry, I additionally request that the following information and documents be provided to my Committee staff:

- 1.) The FDA Establishment Inspection Report (EIR) regarding Genentech's San Francisco facility, including, but not limited to the "483", as well as, any and all exhibits related to this EIR. Please also supply any and all letters, correspondence, or documentation to or from the company relating to this inspection and the issues raised by it.
- 2.) Through review of public documents and interviews with FDA staff, my staff has determined the FDA has not indicated to Genentech, in any way, shape or form, that it must limit its supply of Avastin to compound pharmacists. However, officials from Genentech continue to state that the FDA is opposed to Genentech supplying Avastin to compounding pharmacists (please see, "Genentech President Defends Company's Decision to Embargo Avastin Sales to Compounding Pharmacies"; http://www.aao.org/advocacy/genentech_recap.cfm). Please clarify, in writing, the FDA's official position on Genentech's ability to provide Avastin to compounding pharmacies.
- 3.) As a result of the aforementioned inspection in question one, we understand that four lots of Avastin were destroyed. There seems to be some uncertainty concerning whether or not the four lots of Avastin cited by FDA inspectors were usable for cancer-related purposes, despite the manufacturing concerns cited, or whether they instead were contaminated sufficiently to require the destruction of all lots. Please clarify this point by relating specifically whether or not these lots of Avastin could have been used by the company for

non-ocular purposes; and what written or verbal instructions or communications were made by any FDA officials to the company on that point. The company claims to have suffered a substantial financial write-off due to what it understood to be FDA's instructions or concerns about the Avastin lots in question.

I look forward to receiving your response along with the documents and information requested no later than November 28, 2007. Should you have any questions regarding this request, please contact Jack Mitchell or Cecil Swamidoss of my staff on 202-224-5364.

Sincerely,

A handwritten signature in black ink that reads "Herb Kohl". The signature is written in a cursive, slightly slanted style.

Herb Kohl
Chairman