

United States Senate

SPECIAL COMMITTEE ON AGING

WASHINGTON, DC 20510-6400

(202) 224-5364

November 7, 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,

As Chairman of the Special Committee on Aging (Committee), I take very seriously the Committee's responsibility to protect and advocate on behalf of our nation's seniors. Part of this responsibility is ensuring that seniors are receiving appropriate and cost-effective prescription drugs.

Therefore, I read with great interest an October 12, 2007 *Wall Street Journal* article entitled "Genentech to Limit Avastin Availability, Use of Cancer Treatment For Eye Ailment Hurts Sales of Targeted Drug." The article detailed Genentech Inc.'s plan to stop making its cancer drug Avastin available to certain pharmacies. Most troubling about this proposed plan is the fact that it may be due in part to an effort to boost sales of a chemically similar, yet far more expensive drug- Lucentis. The article specifically states:

"Medicare, which offers health coverage for the elderly and disabled and is a big purchaser of the two drugs, has said curbing Avastin could cost taxpayers \$1 billion to \$3 billion a year. Using a cheaper drug not only would preserve Medicare funds, but would trim beneficiaries' exposure to high co-payments, program administrators say."

Any instance that could cost taxpayers potentially one to three billion dollars is of great concern to me. Therefore, I have authorized the Committee staff to make inquiries concerning the circumstances surrounding Genentech's announced partial withdrawal of Avastin from the marketplace. As part of this ongoing investigation, I request that the following information and documents be provided to my Committee staff:

- 1.) All documentation, notes or minutes of meetings between Genentech officials or company lobbyists and the Food and Drug Administration (FDA), including but not limited to materials to and from the Office of the Commissioner.
- 2.) All documents and all related information pertaining to any ocular-related applications of Avastin by Genentech.

- 3.) All correspondence, e-mail messages, or other documents addressed to or from Wiley Chambers, M.D., Deputy Director, Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, CDER, involving Genentech that relate to Avastin and/or Lucentis.
- 4.) The FDA Establishment Inspection Report (EIR) regarding the New England Compounding Center in Framingham, MA., including, but not limited to the "483", as well as, any and all exhibits related to this EIR.
- 5.) A copy of any written response Genentech may have made to the FDA in response to the agency's public statement on Avastin dated October 16, 2007.
- 6.) Copies of any correspondence in follow-up to the FDA warning letter written to the New England Compounding Center dated December 4, 2006. A written description of any actions taken in follow-up to the above mentioned warning letter to the New England Compounding Center.

I look forward to receiving your response along with the documents and information requested no later than November 14, 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

ATTACHMENT

1. The terms “document” and “documentation” are to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, e-mails, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.
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