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# United States Senate

SPECIAL COMMITTEE ON AGING

WASHINGTON, DC 20510-6400

(202) 224-5364

November 16, 2007

Susan Desmond-Hellman, M.D., M.P.H.  
President, Product Development  
Genentech, Inc.  
1 DNA Way  
South San Francisco, CA 94080-4990

Dear Dr. Desmond-Hellman:

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 my Committee staff to make inquiries concerning the circumstances surrounding Genentech's announced partial withdrawal of Avastin from the marketplace.

As you may be aware, in my capacity as Committee Chairman, I sent an October 18, 2007 letter to the Centers for Medicare and Medicaid Services (CMS) regarding the relative cost implications of your company's decision to make Avastin partially unavailable to the marketplace. While we're aware of your company's public explanations for it, this decision may serve to increase costs for critical ophthalmology medicines for seniors and the elderly, as well as eye care patients in general.

The Committee is continuing its review of this decision and its implications for public health policy. We appreciate the company's prior interview and offer to answer additional questions on this matter. After review and deliberation, we now request that Genentech provide the Committee with the following documentation and information:

(1) Any and all documentation, including e-mails and as specifically defined in the attached glossary, relating to any negotiations or discussions Genentech officials may have had with government or private sponsors of the forthcoming Comparison of Age-Related Macular Degeneration Treatment Trials Study (CATT Study) comparing Lucentis and Avastin. In a recent public presentation in New Orleans, you were asked about this subject, and indicated that you were unaware of any such informal or formal negotiations concerning Genentech's supplying of drugs for this trial, but you promised to look into it. Other sources have informed Committee staff that such talks or negotiations did take place.

(2) Any records, minutes, or notes of the Genentech Board meeting of July, 2007, during which the Avastin withdrawal or clinical trial issues relating to that subject may have been discussed or voted upon. Also, any internal company notes, records, minutes, or agenda items which included discussion of the Avastin withdrawal, or the relative costs of Lucentis and Avastin.

This request would include any and all correspondence or minutes of meetings with FDA concerning the inspectional issues relating to Avastin, which purportedly served as the basis for your company's decision to make Avastin partially unavailable. Please include all internal documentation relating to the October 11, 2007 Genentech letter to Retinal Community Members, which was signed by you.

(3) Any documents, records, minutes, or notes of meetings about the decision to partially withdraw Avastin between Genentech representatives and officials representing the Food and Drug Administration (FDA); the Centers for Medicare and Medicaid (CMS); the National Institutes of Health (NIH); the American Academy of Ophthalmologists (AAO); the American Society of Retinal Specialists (ASRS); the International Academy of Compounding Pharmacists (IACP); or the American Medical Association (AMA), which apparently has indicated disagreement with your decision.

(4) Any documentation relating to the company's decision to require purchasing contracts for some of its Avastin customers; and what the intended purpose of those contracts was, since reportedly they did not apply to all Avastin customers.

(5) Please provide any documentation surrounding the company's decision to issue a letter to an unknown number of patients, warning them against off-label use of Avastin and describing supposed adverse events associated with those uses of your product. This letter was described in writing by ASRS as being

“misleading and disingenuous.” Further, please identify any other similarly-worded letters that Genentech has disseminated regarding any other treatment or drug Genentech manufactures or has distributed in the past.

Please respond fully to this request by close of business on Friday, December 7, 2007. Feel free to contact Jack Mitchell (224-0741) or Cecil Swamidoss (224-3505) with any questions you may have concerning this request.

Sincerely,

A handwritten signature in black ink that reads "Herb Kohl". The signature is written in a cursive, flowing style with a large initial "H".

Herb Kohl  
Chairman

## ATTACHMENT

### GENERAL INSTRUCTIONS

1. The terms “Genentech, Inc.” and “your company” mean its corporation, or one or more of its divisions, subsidiaries or affiliates, or related entities, including any other companies or corporations with which “Genentech, Inc.” entered into a partnership, joint venture or any other business agreement or arrangement.
2. In complying with this document request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. In addition, produce documents that you have a legal right to obtain, documents that you have a right to copy or have access to, and documents that you have placed in the temporary possession, custody, or control of any third party.
3. No documents, records, data or information requested by the Committee shall be destroyed, modified, removed or otherwise made inaccessible to the Committee.
4. If the document request cannot be complied with in full, it shall be complied with to the extent possible, which shall include an explanation of why full compliance is not possible.
5. In complying with this document request, respond to each enumerated request by repeating the enumerated request and identifying the responsive document(s).
6. Each document produced shall be produced in a form that renders the document susceptible of copying.
7. It shall not be a basis for refusal to produce documents that any other person or entity also possesses non-identical or identical copies of the same document.
8. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (stating its date, author, subject and recipients) and explain the circumstances by which the document ceased to be in your possession, or control.
9. This request is continuing in nature. Any document, record, compilation of data or information, not produced because it has not been located or discovered by the return date, shall be produced immediately upon location or discovery subsequent thereto.

## GENERAL DEFINITIONS

1. The term “document” means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to the following: memoranda, reports, statistical or analytical reports, books, manuals, instructions, financial reports, working papers, records notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, interoffice and intra office communications, electronic mail (E-mail), contracts, cables, notations of any type of conversation, telephone call, meeting or other communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, discs, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disc, or videotape. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term “records” is 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 or magnetically or stored in any type of data bank, 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, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, 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.

3. The terms “relate,” “related,” “relating,” or “regarding” as to any given subject means anything that discusses, concerns, reflects, constitutes, contains, embodies, identifies, deals with, or is any manner whatsoever pertinent to that subject, including but not limited to documents concerning the preparation of other documents.

4. The terms “and” and “or” shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this document request any information which might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa to bring within the scope of this document request any information which might otherwise be construed to be outside its scope. The masculine includes the feminine and neuter genders to bring within the scope of this document request any information that might otherwise be construed to be outside its scope.

5. The term “communication” means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, written, electronic, by document or otherwise, and whether face to face, in a meeting, by telephone, mail, telexes, discussions, releases, personal delivery, or otherwise. Documents that typically reflect a “communication” include handwritten notes, telephone memoranda slips, daily appointment books and diaries, bills, checks, correspondence and memoranda, and includes all drafts of such documents.