

# Congress of the United States

Washington, DC 20515

May 23, 2011

Keith Katkin  
President and CEO  
Avanir Pharmaceuticals  
101 Enterprise, Suite 300  
Aliso Viejo, CA 92656

Dear Mr. Katkin:

As Members of Congress with leadership positions on Committees of jurisdiction over health care issues, we take very seriously our responsibility to protect the interests of our nation's health consumers and taxpayers, and the public and private health care systems that they pay and rely on for affordable drugs.

As such, we continue to be concerned about high drug prices generally, and specifically with reports that your company is charging high prices for Nuedexta, a medication used to treat involuntary emotional outbursts known as pseudobulbar affect. Neudexta is a combination of quinidine and dextromethorphan, generic drugs that have been available for decades and cost a fraction of Neudexta. In October 2010, Avanir obtained FDA approval for this combination and received a three year term of exclusive marketing. Although we recognize that we all benefit when FDA approves a new, safe and effective formulation, it is not clear that the significantly higher prices charged for this drug are justified given that it is merely a combination of long-used and inexpensive generic medications.

Doctors and patients were understandably upset at the news that this drug, once available for about \$20, was now going to be \$600. In order to address these concerns, we request that Avanir Pharmaceuticals submit written documentation in response to the following questions and requests for information. The Attachment of this letter will specify in full detail what materials are to be included in response to this request.

1. What was the total cost of the clinical trials that led to the approval of Nuedexta? Please detail all expenditures. Has the company committed to post-market studies, and if so, what is the cost of those studies?
2. Please provide copies of all correspondence with FDA related to Nuedexta, including emails and formal letters.
3. How was the initial list price of Nuedexta established? Please provide all internal documentation relating to the determination of the price, including but not limited to emails, correspondence with shareholders, and internal memos.

4. How much has Avanir Pharmaceuticals spent on marketing Nuedexta since its approval? How much does Avanir Pharmaceuticals plan to spend on marketing this drug in the next year? What percentage of the marketing budget will be directed to Nuedexta over the next year?
5. Some analysts project revenue from Nuedexta to be approximately \$4,365/patient after stocking fees and discounts are subtracted from Nuedexta's stated annual wholesale cost of \$5,868. Is this accurate? What is the total cost, and estimated unit costs, to manufacture Nuedexta, and the components of such costs? What are the expected revenues and profits from sales of Nuedexta? What are the anticipated revenues and profits from sales of Nuedexta to Medicare, Medicaid, and other federal or state health care programs?
6. Is Nuedexta available outside the United States? If so, what is the list price and profit margin in all other countries?
7. How many people have taken advantage of "co-pay cards" made available by Avanir to reduce the out-of-pocket cost of Nuedexta?
8. How much is Avanir Pharmaceuticals projecting in Nuedexta sales and profits for fiscal year 2011?

Please furnish this documentation by electronic mail, fax, or hand delivery, no later than close of business on June 10, 2011. Any questions concerning this request may be directed to Jack Mitchell or Sarah Molinoff of the Senate Special Committee on Aging staff at (202) 224-5364. Thank you.

Sincerely,



Senator Herb Kohl



Congressman Henry Waxman



Congressman Frank Pallone



Congresswoman Diana DeGette

## ATTACHMENT

### GENERAL INSTRUCTIONS

1. The terms "Avanir Pharmaceuticals" and "your institute" mean its corporation, or one or more of its divisions, subsidiaries or affiliates, or related entities, including any other companies or corporations with which "Avanir Pharmaceuticals" 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.