March 1, 2007

Frank Baldino Jr., Ph.D
Chairman and Chief Executive Officer
Cephalon, Inc.
41 Moores Road
Frazer, PA 19355

Dear Mr. Baldino:

Allegations have been raised about Cephalon's inappropriate marketing of narcotics.[1] As part of the Committee's ongoing oversight of the pharmaceutical industry's research and marketing practices, I am writing to request information about these allegations.

The Committee requests that Cephalon provide the following information relating to Actiq and Fentora, including, where appropriate, documents in your possession from prior owners of the rights to these drugs, including Anesta, Abbott Labs, or Cima Labs, Inc.:

1. A listing of all trials, studies, or reports initiated, supported or sponsored by the makers of Actiq and Fentora, including any conducted outside the United States. This list should include those trials, studies, or reports for any New Drug Application (NDA) or Investigational New Drug (IND) Application, including any supplemental applications. For each such trial, study, or report, provide the following information:

   a. The name of the authors and physicians that participated;

   b. The number of participants;

   c. The date it was initiated, completed, or terminated. If terminated, explain the reasons behind the termination.

   d. A summary of the methodology, findings, and conclusions;

   e. Whether the marketing department provided funding or other support for this study;

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[1] *Cephalon Used Improper Tactics to Sell Drug, Probe Finds,* Wall Street Journal (Nov. 21, 2006); *Off-Label Drug Use Flourishes Despite Curbs,* Wall Street Journal (Nov. 3, 2006).

f. Whether any compensation or benefit, monetary or otherwise (including support or assistance in creating manuscripts), was provided to any author, physician, or participant;

g. For those studies published or presented at major medical meetings, a copy of all publications and abstracts; and

h. If not published or presented, an explanation for why the study was not published or presented;

2. All documents relating to the development of the printed label that accompanied Actiq and Fentora. This should include all communications with the Food and Drug Administration (FDA) and those within your company;

3. All documents relating to internal audits of compliance with FDA's risk management program or risk MAPs;

4. All documents relating to allocations of product provided to Barr Labs in accordance with the Federal Trade Commission consent agreement;

5. All documents relating to compliance with Drug Enforcement Agency quotas on fentanyl, and potential shortages of fentanyl, including correspondence with FDA with regard to these quotas;

6. The following documents related to Actiq or Fentora for the time period from November 1997 to the present time for Actiq; and from September 2005 to the present time for Fentora:

a. All presentations, training sessions, or materials given to employees or agents who marketed or otherwise promoted Actiq or Fentora, including speakers and consultants;

b. All pamphlets, literature, and other information to be shown or given to physicians by sales representatives, and all related communications;

c. Any other communications provided to healthcare providers regarding the safety and efficacy of Actiq or Fentora, and all related communications;

d. All internal or external presentations or reports based on the marketing plan for these drugs, and all communications related to these presentations or reports;

e. All presentations or reports related to physician prescribing patterns, including data on specialty of prescriber and indications for use, and all communications related to these presentations or reports;

f. All internal or external presentations or reports relating to continuing medical education, and all communications related to these presentations or reports;

g. All internal or external presentations or reports relating to off-label use, and all communications related to these presentations or reports;

h. All documents relating to funding allocations for nonprofit medical professional or consumer/patient organizations; and

i. All marketing department correspondence with nonprofit medical professional or consumer/patient organizations.

The Committee on Oversight and Government Reform is the principal oversight committee in the House of Representatives and has broad oversight jurisdiction as set forth in House Rule X. An attachment to this letter provides additional information on how to respond to the Committee's request.

I request that you provide these documents by March 21, 2007. If you have any questions regarding this request, please contact Stephen Cha with the Committee staff at (202) 225-5056.

Sincerely,

Henry A. Waxman
Chairman

Enclosure

cc: Tom Davis
Ranking Minority Member

Responding to Oversight Committee Document Requests

In responding to the document request from the Committee on Oversight and Government Reform, please apply the instructions and definitions set forth below.

Instructions

1. In complying with the request, you should produce all responsive documents in your possession, custody, or control.

2. Documents responsive to the request should not be destroyed, modified, removed, transferred, or otherwise made inaccessible to the Committee.

3. In the event that any entity, organization, or individual denoted in the request has been, or is currently, known by any other name than that herein denoted, the request should be read also to include them under that alternative identification.

4. Each document produced should be produced in a form that renders the document capable of being copied.

5. When you produce documents, you should identify the paragraph or clause in the Committee's request to which the documents respond.

6. Documents produced in response to this request should be produced together with copies of file labels, dividers, or identifying markers with which they were associated when this request was issued. To the extent that documents were not stored with file labels, dividers, or identifying markers, they should be organized into separate folders by subject matter prior to production.

7. Each folder and box should be numbered, and a description of the contents of each folder and box, including the paragraph or clause of the request to which the documents are responsive, should be provided in an accompanying index.

8. It is not a proper basis to refuse to produce a document that any other person or entity also possesses a nonidentical or identical copy of the same document.

9. If any of the requested information is available in machine-readable or electronic form (such as on a computer server, hard drive, CD, DVD, memory stick, or computer backup tape), you should consult with Committee staff to determine the appropriate format in which to produce the information. Documents produced in electronic format should be organized, identified, and indexed electronically in a manner comparable to the organizational structure called for in (6) and (7) above. Documents produced in an electronic format should also be produced in a searchable format.

10. In the event that a responsive document is withheld on any basis, you should provide the following information concerning the document: (a) the reason the document is not being produced; (b) the type of document; (c) the general subject matter; (d) the date, author, and addressee; and (e) the relationship of the author and addressee to each other. Please note that the Committee generally recognizes only constitutional privileges.

11. If any document responsive to this request was, but no longer is, in your possession, custody, or control, you should identify the document (stating its date, author, subject and recipients) and explain the circumstances by which the document ceased to be in your possession, custody, or control.

12. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, you should produce all documents which would be responsive as if the date or other descriptive detail were correct.

13. This request is continuing in nature and applies to any newly discovered document. Any document not produced because it has not been located or discovered by the return date should be produced immediately upon location or discovery subsequent thereto.

14. All documents should be bates-stamped sequentially and produced sequentially.

15. Two sets of documents should be delivered, one set to the majority staff and one set to the minority staff. The majority set should be delivered to the majority staff in Room 2157 of the Rayburn House Office Building, and the minority set should be delivered to the minority staff in Room B350A in the Rayburn House Office Building.

16. Upon completion of the document production, you should submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control which reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee or identified in a privilege log provided to the Committee.

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, expense 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 (email), contracts, cables, notations of any type of conversation, telephone calls, meetings or other communications, 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). The term also means any graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, voice mails, microfiche, microfilm, videotape, recordings and motion pictures), electronic and mechanical records or representations of any kind (including, without limitation, tapes, cassettes, disks, computer server files, computer hard drive files, CDs, DVDs, memory sticks, 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, disk, videotape or otherwise. 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 "documents in your possession, custody, or control" means (a) documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, or representatives acting on your behalf; (b) documents that you have a legal right to obtain, that you have a right to copy, or to which you have access; and (c) documents that you have placed in the temporary possession, custody, or control of any third party.

3. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether face-to-face, in a meeting, by telephone, mail, telexes, discussions, releases, personal delivery, or otherwise.

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

5. The terms "person" or "persons" means natural persons, firms, partnerships, associations, corporations, subsidiaries, divisions, departments, joint ventures,

proprietorships, syndicates, or other legal, business or government entities, and all subsidiaries, affiliates, divisions, departments, branches, and other units thereof.

6. The terms "referring" or "relating," with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is in any manner whatsoever pertinent to that subject.