

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

April 29, 2008

Via Facsimile: (601) 853-1567

Mr. Max E. Draughn
Chief Executive Officer
Hawthorn Pharmaceuticals, Inc.
P. O. Box 2248
Madison, MS 39130

Dear Mr. Draughn:

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs, and accordingly, a responsibility to the more than 80 million Americans who receive health care coverage under these programs. As Ranking Member of the Committee, I have a duty to protect the health of Medicare and Medicaid beneficiaries and safeguard taxpayer dollars authorized by Congress for these programs.

In October 2006, I began examining concerns that some prescription drugs being sold on the market are not approved by the Food and Administration (FDA). Earlier this year, I also asked the Centers for Medicare and Medicaid Services (CMS) how much Medicaid has paid for some of these drugs and questioned whether or not the Medicaid and/or Medicare programs are being inappropriately billed for unapproved prescription medications.

I am writing to you because it has been alleged that Medicaid and/or Medicare may be improperly covering prescription drugs manufactured by your company Hawthorn Pharmaceuticals, Inc.'s (Hawthorn), in particular the Dytan (diphenhydramine tannate) product family of respiratory medicines, and that these drugs have not been reviewed by the FDA. I would appreciate Hawthorn's response to the following questions regarding its products, in accordance with the attached general instructions and definitions. In responding to this letter, please repeat the enumerated question, followed by Hawthorn's response.

1. Has the Dytan product family received any FDA review? If so, when did the review take place and what was the FDA's determination? Please provide the relevant documentation supporting your response.
2. Have the Dytan products or any other Hawthorn products been assigned a code under FDA's Drug Efficacy Study Implementation (DESI) program? If so, please identify each product and its assigned DESI code.

3. Has Hawthorn filed a New Drug Application with the FDA for any of its other prescription drug products? If not, why not? If so, what is the status of those applications?
4. According to the CMS web site, Hawthorn participates in CMS's Medicaid Drug Rebate Program. Please list all Hawthorn products that are covered under the Medicaid Drug Rebate Agreement between Hawthorn and CMS.
5. Please provide annual sales figures for each of the Dytan products for the period of January 1, 2002 through December 31, 2007. If your company negotiated separate contracts with Pharmacy Benefit Managers (PBM) for Medicare Part D, please provide annual sales figures for each Dytan product as received from these PBMs for the period of January 1, 2002 through December 31, 2007. If not, please provide an estimate of sales attributable to the Medicare Part D program.

In addition, for the last three years, the Committee has investigated various aspects of the pharmaceutical industry, including consulting arrangements and industry funding for Continuing Medical Education (CME). These investigations have revealed that pharmaceutical companies spend a great deal of money funding medical education and product promotion, often with little or no transparency. We have also learned that a former sales representative for your company stated that Hawthorn heavily promotes its products to doctors so that they will prescribe the products to Medicaid patients.

To better understand the payments and benefits that Hawthorn provides to doctors who prescribe its products, please identify the 10 doctors who received the highest total amount in payments or other transfers of value from your company each year during the period of calendar year 2002 through calendar year 2007. For purposes of this letter, the phrase, "payments or other transfers of value" means any compensation, gift, honorarium, speaking fee, consulting fee, food, entertainment, gift, travel, discount, cash rebate, service, or other transfer of value.

For each doctor, please provide the following information for each payment:

- a. Date of payment.
- b. Payment description (CME, honorarium, research support, etc.).
- c. Amount of payment/

In cooperating with the Committee's review, no documents, records, data, or other information related to these matters, either directly or indirectly, shall be destroyed, modified, removed, or otherwise made inaccessible to the Committee.

I look forward hearing from you no later than May 13, 2008. If you have any questions, please do not hesitate to contact Angela Choy or Brian Downey of my Committee staff at (202) 224-4515. All formal correspondence should be sent electronically in PDF format to Brian_Downey@finance-rep.senate.gov or via facsimile to (202) 228-2131.

Sincerely,



Charles E. Grassley
Ranking Member

Attachment

GENERAL INSTRUCTIONS

1. The term “Hawthorn Pharmaceuticals, Inc.” means its corporation, or one or more of its divisions, subsidiaries or affiliates, or related entities, including any other companies or corporations with which “Hawthorn Pharmaceuticals, 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. In the event that a document is withheld on the basis of privilege, provide the following information concerning any such document: (a) the privilege asserted; (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.
7. Each document produced shall be produced in a form that renders the document susceptible of copying.
8. 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.
9. 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.
10. 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.
11. All documents shall be Bates stamped sequentially and produced sequentially.

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.