

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

December 12, 2008

Via facsimile transmission: 609-924-6648

Mitchell A. Leon
President
DesignWrite Inc.
175 Wall Street
Princeton, NJ 08540

Dear Mr. Leon:

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs. As a senior member of the United States Senate and as Ranking Member of the Committee, I have a special responsibility to the more than 80 million Americans who receive health care coverage under those programs to ensure that taxpayer and beneficiary dollars are appropriately spent on safe and effective drugs.

Over the last year, the Committee has been examining a practice used by drug companies referred to as “medical ghostwriting.” I have been informed that this practice involves marketing or medical education companies that draft outlines and/or manuscripts of review articles, editorials, and/or research papers. This information is then presented to prominent doctors and scientists, particularly those affiliated with academic institutions, to review, edit and sign on as authors, whether or not they are intimately familiar with the underlying data and relevant documentation. In addition, it is not always apparent in the publication that individuals and companies other than the listed authors were deeply involved in the study and/or drafting of the final manuscript.

Articles published in medical journals are widely read by practitioners, and relied upon as being unbiased and scientific in nature. Concerns have been raised, however, that some medical literature may be subtle advertisements rather than publications of independent research.

I am aware that your company is a medical communications and education company that might shed some light on the policies and procedures in this area. Furthermore, it is my understanding that Wyeth hired DesignWrite Inc. to assist with several manuscripts on their hormone therapy products. Accordingly, I request that you provide the Committee with information regarding the policies, procedures and practices used by DesignWrite. In addition, I would appreciate a response to the following requests. In complying with this request, please respond by repeating the enumerated request, followed by the accompanying response; attach and identify all relevant documents or data by title and the number(s) to which they are responsive.

1. Please provide the Committee with a list of all manuscripts and/or reports prepared by DesignWrite on behalf of Wyeth for the period of January 1, 1995 through the date of this letter. For each study and/or report, please provide the following information:
 - a. Title of study and/or report and/or review article;
 - b. Brief description;
 - c. Period of time for which the work was done;
 - d. Author(s) who signed his/her name on to the study or report;
 - e. Payments¹ made to the author(s);
 - f. Extent of involvement/participation of the author(s) in the drafting of the outline and/or final manuscript;
 - g. Journal where study and/or report was published;
 - h. Total payments from Wyeth for completed work;
 - i. Name of any third party(ies) hired by DesignWrite to assist with the study and/or report outline and/or manuscript and the payments made to the third party(ies); and
 - j. Copy of the contract(s) executed between DesignWrite and Wyeth.
2. Please provide all internal and external correspondence, notes, drafts of outlines or articles, agreements with writers, and all communications and meeting minutes regarding each of the studies and articles identified above.
3. Please identify any litigation in which DesignWrite provided information regarding an article, editorial, and/or research study. For each lawsuit please provide the following information:
 - a. Names of the parties, including representative counsel;
 - b. Docket number; and
 - c. The court in which the litigation was brought.
4. For the articles: (1) "Progestins and Breast Cancer" published in the *American Journal of Obstetrics and Gynecology*; (2) "Sex Hormone-Binding Globulin and Breast Cancer Risk" published in *Primary Care Update for OB/GYNs*; and (3) "Hormone replacement Therapy and Breast Cancer: A Qualitative Review," published in *Obstetrics and Gynecology*, please provide the following information:
 - a. Please describe in detail the extent of the involvement/participation of the listed authors in the development and/or drafting of the final manuscript.

¹ Payments include fees, honoraria, and any other transfers of value.

b. Please identify all individuals at DesignWrite and any other third party(ies) hired by DesignWrite that contributed either directly or indirectly to the development and/or the initial and/or final drafts of the manuscript. In particular, please provide the title and role of the following individuals, including a copy of their respective resumes/curricula vitae:

- i. Karen Mittleman;
- ii. Kathy Ohleth;
- iii. Caron Pruiett;
- iv. Bernie Janas; and
- v. Ann Contijoch.

In cooperating with the Committee's review, please note that 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.

Thank you in advance for your assistance and cooperation. Please provide a point of contact for this matter by no later than January 11, 2009. All documents responsive to this request should be sent electronically, on a disc, in searchable PDF format to Brian_Downey@finance-rep.senate.gov. If you have any questions, please do not hesitate to contact Angela Choy or Paul Thacker at (202) 224-4515.

Sincerely,



Charles E. Grassley
Ranking Member
Committee on Finance

Attachment

GENERAL INSTRUCTIONS

1. The term “DesignWrite 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 “DesignWrite 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.
6. The term “payment” means fees, honoraria, and any other transfers of value.