

# Project On Government Oversight

Exposing Corruption Exploring Solutions [www.POGO.org](http://www.POGO.org)

December 8, 2010

Mr. Stuart C. Clark  
Carr Ferrell  
120 Constitution Drive  
Menlo Park, CA 94025

Lawrence J. Myers  
Smith Moore LLP  
Atlantic Center Plaza  
1180 West Peachtree Street, NW  
Suite 2300  
Atlanta, GA 30309-3482

Dear Mr. Clark and Mr. Myers:

In response to your letters (Attachment A) and after a comprehensive internal review, the Project On Government Oversight ("POGO") will make minor changes to the online version of its November 29, 2010, letter to National Institutes of Health ("NIH"), which expressed concerns about the integrity of federally funded research.

Your letters describe alleged "false statements" by POGO as related to the physician handbook titled *Recognition and Treatment of Psychiatric Disorders: A Psychopharmacology Handbook for Primary Care*, which listed as authors Alan F. Schatzberg, MD, of Stanford Medical Center and Charles B. Nemeroff, MD, formerly with Emory University School of Medicine and now at University of Miami School of Medicine.

First, when the handbook was published, Dr. Nemeroff and Dr. Schatzberg thanked Scientific Therapeutics Information, Inc. ("STI") for "editorial assistance" and GSK for "providing an unrestricted educational grant." In your letter, you describe the initial materials provided by STI as "boilerplate." That statement, as you can see from the discussion below, appears to be far from the truth. Therefore, we will only make minor changes to POGO's letter to NIH, which is posted on POGO's website. (Attachment B)

According to the 2007 deposition taken in cases involving Paxil against SmithKline Beecham Corporation, now operating as GlaxoSmithKline ("GSK"), Ms. Sally Laden calls herself a "freelance writer" specializing in "science and medical

1100 G Street, NW  
Suite 900  
Washington, DC  
20005-3806  
Phone: 202-347-1122  
Fax: 202-347-1116

[www.POGO.org](http://www.POGO.org)  
[pogo@pogo.org](mailto:pogo@pogo.org)

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writing.” Her testimony further stated that she takes data, condenses it into a manuscript, and works “with the authors to make sure they are happy with the data as presented.” She further agreed that her role was to help in the preparation of the initial draft, edit the subsequent draft, and address reviewers’ comments.

In a letter dated February 4, 1997, and addressed to Dr. Nemeroff, Ms. Laden provided an updated status of the handbook. Ms. Laden’s letter stated that “We have begun development of the text,” and she established a timeline for which Dr. Nemeroff and Dr. Schatzberg would receive draft copies of that text. That letter introduced Ms. Coniglio as the “primary technical writer and project manager” and Ms. Laden as the “technical **editor**.” (Emphasis added) POGO understands that the letter was also circulated to GlaxoSmithKline employees.

After a review of the February 25, 1997, “**PRELIMINARY DRAFT**” (emphasis and capitalization in original) and of the 1999 published version of the handbook, POGO feels strongly that its statements regarding STI’s involvement in the drafting of the handbook are accurate and supported by the evidence. Complete sentences and paragraphs that were in the 1997 “preliminary draft” created by STI appear in the handbook. For example, the draft “developed by” Ms. Coniglio and Ms. Laden reads:

Alzheimer’s Disease (AD) is the most common primary, progressive degenerative dementia in the elderly and the fourth leading cause of death in the United States (Keefover, 1996; Raskind, 1993). At an annual cost of more than \$67 billion in the US alone, AD has important public health implications, especially in concert with the unparalleled growth of the aged population (Keefover, 1996).

This nearly mirrors the text that appears in the published book, which reads:

Dementia of the Alzheimer’s type, or Alzheimer’s disease (AD), is the most common primary, progressive, degenerative dementia in the elderly and the fourth leading cause of death in the US. At an annual cost of more than \$90 billion in the US alone, AD has important public health implications, especially in concert with the unparalleled growth of the aged population. [Footnotes omitted]

Additional language and tables on Alzheimer’s Disease follow nearly word for word the 1997 “preliminary draft,” as do passages involving Tacrine, Cholinergic Agonists, and Selegiline, and the glossary. As POGO stated in its NIH letter, that first edition was “Developed by” Diane M. Coniglio, PharmD and Sally K. Laden, MS of STI.

According to a statement from the American Psychiatric Association the book “was written by the two authors....They did receive editorial assistance, but they were the authors.” In a statement to the *Miami Herald*, Dr. Nemeroff was quoted saying, “Such editorial assistants can provide help with such tasks as tracking down references and the like, but certainly do not have the clinical expertise or experience to put such a volume together.” These statements are undermined by Ms. Laden’s February 4, 1997, letter to Dr. Nemeroff that outlines technical and editorial assistance that was to be provided by STI as well as the detailed content of STI’s “preliminary draft” which was published in the book. Per written guidance about “Byline

Authors” from the International Committee of Medical Journal Editors (“ICMJE”), Ms. Coniglio and/or Ms. Laden should have been listed as “authors” if their support included conception and design, gathering data, drafting or revising intellectual content, and approving the version to be published.

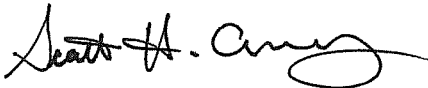
Second, according to your letters, the allegation “that GSK was given all three drafts, and was sent page proofs for final approval” is false. We would like to point out that this process is laid out in the timeline provided to Dr. Nemeroff by Ms. Laden of STI. We would also like to point out that this timeline and STI’s “preliminary draft” were provided by GSK during litigation in another case and therefore were in GSK’s possession. We also note that with regards to GSK’s involvement in the handbook, Dr. Nemeroff’s told the *Miami Herald*:

I would guess that [GSK] would have had to review the content to comply with [Food and Drug Administration] regulations on a pharmaceutical company distributing a publication, but this is hardly my area of expertise.

The evidence available at this time indicates that GSK apparently was involved in the handbook drafting process. Because POGO is currently unable to document the nature and extent of GSK’s actual involvement, POGO will alter the NIH letter as indicated in Attachment B.

Finally, your allegations concerning Mr. Thacker’s previous employment with the Senate are extremely vague and not related to POGO or our work. Please contact the Senate directly if you have concerns about the actions of a Senator or his staff.

Sincerely,

A handwritten signature in black ink, appearing to read "Scott H. Amey", with a stylized flourish at the end.

Scott H. Amey  
General Counsel

Enclosures: 2

cc: Francis S. Collins, MD, Ph.D., Director  
National Institutes of Health

## **Attachment A**

carr/ferrell<sup>LLP</sup>  
ATTORNEYS AT LAW

WRITER'S DIRECT DIAL & EMAIL  
(650) 812-3415  
clark@carrferrell.com

December 1, 2010

By Facsimile and U.S. Mail

Ms. Danielle Brian  
Executive Director  
Program on Government Oversight  
1100 G Street, NW, Suite 900  
Washington, DC 20005-3806  
Fax: (202) 347-1116

Mr. Paul Thacker  
Program on Government Oversight  
1100 G Street, NW, Suite 900  
Washington, DC 20005-3806  
Fax: (202) 347-1116

POGO Letter to NIH Dated November 29, 2010

Dear Ms. Brian and Mr. Thacker:

I represent Dr. Alan Schatzberg, who has instructed me to write to you concerning various false statements in your joint letter to the NIH dated November 29, 2010 (the "POGO Letter"). That letter is currently prominently displayed on POGO's website, and has therefore been widely published, including in California, and has caused serious harm to Dr. Schatzberg, also including in California.

The POGO Letter falsely states, as a purported fact, that "STI also ghostwrote a physician textbook, *Recognition and Treatment of Psychiatric Disorders: A Psychopharmacology Handbook for Primary Care*, for Drs. Alan Schatzberg of Stanford Medical Center and Charles Nemeroff, formerly with Emory School of Medicine and now at University of Miami School of Medicine."

The POGO Letter also falsely states, as a purported fact, "that STI wrote the first draft" of the book *Recognition and Treatment of Psychiatric Disorders: A Psychopharmacology Handbook for Primary Care* (the "Book").

The POGO Letter further falsely states, as a purported fact, "that GSK was given all three drafts, and was sent page proofs for final approval."

The purported support for your above-described false statements about alleged ghostwriting includes a February 4, 1997 letter from STI which sets out proposed

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Mr. Paul Thacker  
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timelines and milestones, but does not recite the actual terms upon which Dr. Schatzberg was retained to write the Book. Nor does the letter accurately describe the timelines of the interactions and specific roles of STI, APPI and the authors, which were not finalized until early 1999, on terms quite different from those set out in the STI letter. Further, the letter does not state (or "note") that GSK "was given" any drafts or "was sent" any page proofs for final approval.

Also offered as purported support for your above-described false statements about alleged ghostwriting is a February 25, 1997 "preliminary draft" which contains largely boilerplate material, and also contains the notation "under development" for all substantive portions of that "preliminary draft." This "preliminary draft" therefore provides no factual support for your statements that the entire Book was ghostwritten – as a comparison of the content of the draft and the content of the Book makes readily apparent.

This is not the first time that Mr. Thacker has been involved in making false statements concerning Dr. Schatzberg. In the course of Mr. Thacker's former employment by Senator Grassley he made a series of false accusations of impropriety against Dr. Schatzberg on behalf of Senator Grassley. Dr. Schatzberg was convincingly exonerated of all of Mr. Thacker's and Senator Grassley's accusations of impropriety, as he will be with respect to the latest series of false accusations by POGO and Mr. Thacker.

In light of the foregoing, I am instructed by Dr. Schatzberg to demand, as I hereby do, that POGO and Mr. Thacker should deliver the following retractions to the NIH, and should also publish those retractions on the POGO website with equal prominence to the POGO Letter:

1. That no documents to which POGO or Mr. Thacker have access state or otherwise support the accusation that STI ghostwrote the Book;
2. That no documents to which POGO or Mr. Thacker have access state or otherwise support the accusation that anyone at all ghostwrote the Book either; and,
3. That there is no factual support for POGO's and Mr. Thacker's statement that GSK was shown drafts and page proofs of the Book for approval of the editorial content.

I am also instructed to demand that POGO and Mr. Thacker should publish an unreserved apology to Dr. Schatzberg for any and all injury sustained by him and to his

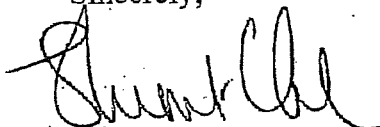
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reputation as a result of the false statements in the POGO Letter. Such apology should be published in the same manner as is indicated above with respect to the retractions.

Since time is of the essence, please confirm to me in writing by no later than noon Pacific Standard Time on Friday, December 3, 2010 that the requested retractions and apology either have been published, or will be published immediately.

Please note that while publishing the demanded retractions and apology will not avoid liability for defamation, it may mitigate the damages that Dr. Schatzberg is entitled to recover.

Sincerely,

A handwritten signature in black ink, appearing to read "Stuart C. Clark", with a stylized, cursive script.

Stuart C. Clark



# SMITH MOORE LEATHERWOOD

December 2, 2010

**VIA FACSIMILE and U.S. MAIL**

**Facsimile: (202) 347-1116**

Ms. Danielle Brian

Executive Director

Program on Government Oversight

1100 G Street, NW, Suite 900

Washington, DC 20005-3806

**Facsimile: (202) 347-1116**

Mr. Paul Thacker

Program on Government Oversight

1100 G Street, NW, Suite 900

Washington, DC 20005-3806

RE: Program on Government Oversight (POGO) Letter to National Institutes of Health (NIH) dated November 29, 2010

Dear Ms. Brian and Mr. Thacker:

This firm represents Charles B. Nemeroff, M.D., Ph.D.

I am writing to you concerning various false and defamatory statements in your joint letter to the NIH dated November 29, 2010. That letter is currently prominently displayed on POGO's website and has therefore been widely published, including in Georgia and Florida, and has caused serious harm to Dr. Nemeroff, also including in Georgia and Florida.

The letter falsely states, as a purported fact, that "STI also ghostwrote a physician textbook, *Recognition and Treatment of Psychiatric Disorders: A Psychopharmacology Handbook for Primary Care*, for Drs. Alan Schatzberg of Stanford Medical Center and Charles Nemeroff, formerly with Emory School of Medicine and now at University of Miami School of Medicine."

The letter also falsely states, as a purported fact, "that STI wrote the first draft" of the book *Recognition and Treatment of Psychiatric Disorders: A Psychopharmacology Handbook for Primary Care*.

The letter further falsely states, as a purported fact, "that GSK was given all three drafts, and was sent page proofs for final approval."

The purported support for these false statements about alleged "ghostwriting" includes a February 4, 1997 letter from Scientific Therapeutics Information, Inc.'s (STI) which sets out proposed timelines and milestones, but does not recite the actual terms upon which Dr.

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Direct 404.962.1040 | Fax 404.962.1250 | larry.myers@smithmoorelaw.com

Smith Moore Leatherwood • Attorneys at Law

Atlantic Center Plaza 1180 West Peachtree Street Suite 2300 Atlanta, GA 30309 • 404.962.1000 • www.smithmoorelaw.com



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Nemeroff and his co-author were retained to write the book. Nor does the letter accurately describe the timelines of the interactions and specific roles of STI, APPI and the authors, which were not finalized until early 1999, on terms quite different from those set out in the STI letter. Further, the letter does not state (or "note") that GSK "was given" any drafts or "was sent" any page proofs for final approval.

Also offered as purported support for your false statements about alleged ghostwriting is a February 25, 1997 "preliminary draft" which contains largely boilerplate material, and also contains the notation "under development" for all substantive portions of that "preliminary draft." This "preliminary draft" therefore provides no factual support for your statements that the entire book was ghostwritten - as a comparison of the content of the draft and the content of the book makes readily apparent.

This is not the first time that Mr. Thacker has been involved in making false statements concerning Dr. Nemeroff and his co-author. In the course of Mr. Thacker's former employment by the Senate Committee on Finance and Senator Grassley he made a series of false accusations of research bias and impropriety against Dr. Nemeroff. Several internal reviews by Emory University, including by its Institutional Review Board (IRB) and a special committee, the results of which have been made public (including reports to NIH), concluded that these allegations were without merit.

Dr. Nemeroff demands that POGO and Mr. Thacker deliver the following retractions to the NIH, and publish those retractions on the POGO website with equal prominence to the POGO letter:

1. That no documents to which POGO or Mr. Thacker have access state or otherwise support the accusation that STI ghostwrote the book;
2. That no documents to which POGO or Mr. Thacker have access state or otherwise support the accusation that anyone at all ghostwrote the book either; and,
3. That there is no factual support for POGO's and Mr. Thacker's statement that GSK was shown drafts and page proofs of the book for approval of the editorial content.

Dr. Nemeroff also demands that POGO and Mr. Thacker publish an unconditional apology to Dr. Nemeroff for any and all injury and damages sustained by him and to his personal and professional reputation as a result of the false and defamatory statements in the POGO letter to NIH. The apology should be published in the same manner as is indicated above with respect to the retractions.

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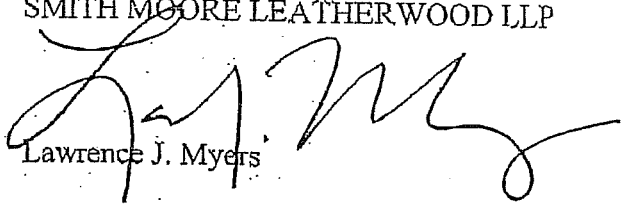
Please confirm to me, in writing, by no later than 5:00 P.M. Eastern Standard Time on Friday, December 3, 2010 that the requested retractions and apology either have been published, or will be published immediately.

Though publishing the demanded retractions and apology will not exonerate you from liability for defamation, it may mitigate the damages that Dr. Nemeroff is entitled to recover by law.

I look forward to hearing from you.

Very truly yours,

SMITH MOORE LEATHERWOOD LLP

  
Lawrence J. Myers

/klv

## **Attachment B**

**Drs. Alan Schatzberg and Charles Nemeroff**

*NIH funding since FY 2006: \$23.3 million*

*NIH funding FY 2010: \$2,374,242*

STI also **authored entire portions of** a physician **handbook**, *Recognition and Treatment of Psychiatric Disorders*, for Drs. Alan Schatzberg of Stanford Medical Center and Charles Nemeroff, formerly with Emory University School of Medicine and now at University of Miami School of Medicine.

A draft of the handbook states that it was sponsored by GSK and written by Diane M. Coniglio and Sally K. Laden of STI. (Attachment D) In a letter addressed to Dr. Nemeroff, Ms. Laden provided an updated status of the handbook. Her timeline states that she wrote the first draft, which was then sent to Drs. Nemeroff and Schatzberg, the publisher, and GlaxoSmithKline. The timeline also notes that GSK was given all three drafts, and was sent page proofs for final approval. (Attachment E)

However, in the handbook's published preface, Dr. Nemeroff and Schatzberg only thank STI for "editorial assistance" and GSK for "providing an unrestricted educational grant." (Attachment F)

The fact that STI wrote the first draft undermines Drs. Nemeroff and Schatzberg's assertion that STI provided mere "editorial assistance." Also, GSK's **apparent** involvement in **drafting the handbook, including** sign-off of page proofs **as laid out in STI's timeline**, undermines the assertion that the company's grant was "unrestricted." **Based on the evidence available to POGO at this time, the nature and extent of GSK's actual involvement is undetermined.**

According to the NIH Reporter database of grants, Dr. Schatzberg is the primary investigator on four NIH grants. The funding for these grants in 2010 is \$2,374,242. Over the last five years, the NIH has given both researchers \$23.3 million in grants.[6]