The Senator Grassley Report on Ghost Authorship and Policies at Journals and Medical Schools

Overview by Paul Thacker
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(Former Investigator, Senate Finance Committee, Sen. Chuck Grassley)
A growing legal scandal engulfed the Capitol when allegations surfaced that attorneys for Goldman Sachs ghostwrote a legal opinion for Justice Clarence Thomas in a matter heard last fall by the Supreme Court involving shareholders suing the company’s top executives for fraudulently hiding financial losses in early 2008.

Drafts of documents and emails obtained by *The New York Times* show that Goldman attorneys apparently wrote entire passages and tinkered with sentences in the opinion summary, to slant language in favor of Goldman executives and against shareholders.

Contacted at his home last night, Justice Thomas refused comment as did other members of the Supreme Court.
Justice Thomas Ghostwriting Talking Points

- These accusations are blatantly false and inaccurate.
- I conceptualized this opinion, wrote the original outline and worked on all of the content.
- I had to edit and rewrite the draft several times to produce the final opinion. The final product reflects this process.
- The work and conclusions of the opinion are mine.
- I stand by the opinion.
Are Physicians and Judges Similar?

- Held in high social regard and have a unique knowledge set not interpretable by the general public.
- Need extensive years of professional education.
- Expected to make decisions based on a set of objective facts and precedent.
- Require continual education to stay abreast of changes (research/law).
- Should avoid bias.
- Make decisions that can dramatically effect the lives of many people.
• Senate Finance Committee has jurisdiction over tax, trade, social security, and medicare and medicaid

• Healthcare is now a larger portion of the federal budget than defense

• The pharmaceutical industry’s largest customer is the U.S. federal government, which pays for about 1/3 of drugs sold in the United States

• Pharmaceuticals account for about 15% of healthcare expenditures, in both government programs and the private sector

“It doesn't take a pig farmer from Iowa to smell the stench of conflict…”
Who Do You Think You Are?!

• The power to oversee or investigate is implied rather than enumerated in the Constitution

• The Supreme Court has affirmed the power of Congress to investigate
  
  – *McGrain v. Daugherty*, 273 U.S. 135, 177, and 181-182 (1927): Congressional investigation of the Department of Justice during the Teapot Dome scandal. The majority wrote, “We are of [the] opinion that the power of inquiry—with the process to enforce it—is an essential and appropriate auxiliary to the legislative function.”

• Statutory Authority can be found in several whistleblower protection laws going back to the 1912

  – *Anti-Gag Legislation and Whistleblower Protection Laws for Federal Employees*. The 1912 act countered executive orders, issued by Presidents Theodore Roosevelt and William Howard Taft, which prohibited civil service employees from communicating directly with Congress. “the right of any persons employed in the civil service . . . to petition Congress, or any Member thereof, or to furnish information to either House of Congress, or to any committee or member thereof, shall not be denied or interfered with.” 37 Stat. 555 (1912), codified at 5 U.S.C. § 7211 (2006).
• American Journal of Medicine
• Annals of Internal Medicine
• Annual Review of Medicine
• Archives of Internal Medicine
• Nature Medicine
• PLoS Medicine
• The Journal of the American Medical Association (JAMA)
• The New England Journal of Medicine (NEJM)
1. What is the journal’s position regarding the practice of ghostwriting?

2. Does the journal have any written policies regarding ghostwritten articles? If so, please provide a copy of those policies.

3. Is an author who submits an article for publication required to disclose to the journal the direct or indirect involvement of any drug or device company or other third party in the development and/or writing of the article?

4. What are the journal’s policies or practices regarding public disclosure of the involvement of any drug or device company or other third party in the development and/or writing of a journal article, in particular when the listed authors are not affiliated with the company or third party?

5. Since 2004, has the journal taken action against any author for failing to disclose the involvement of a third party in the development and/or drafting of a manuscript? If so, please provide details.
• Columbia University College of Physicians and Surgeons
• Duke University School of Medicine
• Harvard University School of Medicine
• Johns Hopkins University School of Medicine
• Stanford University School of Medicine
• University of California, San Francisco School of Medicine
• University of Pennsylvania School of Medicine
• University of Washington School of Medicine
• Washington University in St. Louis School of Medicine
• Yale University School of Medicine

November 18, 2009
1) What is the university’s position on medical ghostwriting and/or the use of third party marketing and/or medical education companies in drafting medical review articles and research papers for faculty?

2) Does the university have any written policies regarding ghostwritten articles? If so, please provide a copy of those policies. Also, please identify the type(s) of information faculty members are required to document and/or report to the university regarding their publication activities. In the event that your institution has made changes to its internal policies and procedures since 2004, I would also greatly appreciate understanding those changes.

3) If the university currently does not have written policies on ghostwritten articles, is the university in the process of developing a policy? If not, why not?

4) Since 2004, has the university received and/or investigated any allegations that a faculty member failed to disclose the involvement of a third party that may be paid by a device or drug company in the development and/or drafting of a manuscript? If so, how many allegations did the university receive and what was the outcome of each investigation? Were any actions taken against the faculty member? If so, please provide details.

5) Please explain the university’s position on plagiarism and its policy on students submitting papers purchased from paper mills or plagiarized in other ways.

6) Since 2004, has the university received and/or investigated any allegations that a student failed to disclose the involvement of a third party in the development and/or drafting of a paper? If so, how many allegations did the university receive and what was the outcome of each investigation? Were any actions taken against the student? If so, please provide details.
Ghostwriting in Medical Literature

Minority Staff Report

111th Congress

United States Senate Committee on Finance
Sen. Charles E. Grassley, Ranking Member

June 24, 2010
Despite acknowledgment of medical writers for “editorial assistance,” the role of pharmaceutical companies in medical publications remains veiled or undisclosed

- The company is rarely acknowledged for underwriting the manuscript
- The company’s editorial involvement is rarely disclosed, often denied
- The term “editorial assistance” has no meaning
Some medical schools explicitly prohibit ghostwriting in their policies

- Six medical schools explicitly prohibit ghostwriting—Columbia, Johns Hopkins Medicine, Stanford Medicine, UCSF, UW Medicine, and Washington University.
- UW Medicine and Yale prohibit gift authorship.
- Three of the medical schools’ policies—Harvard, Duke, and Yale—prohibit guest, honorary or courtesy authorship but not ghostwriting explicitly.
- Yale prohibits faculty from adding as co-authors “highly respected individuals merely as an attempt to increase the likelihood of publication.”
- Penn Medicine does not use the term “ghostwriting” in its authorship policies, but stated that it has policies against plagiarism and it considers ghostwriting to be the equivalent of plagiarism.
Detection of ghostwriting by medical schools is limited

- All reported that they do not allow or condone ghostwriting calling it “unacceptable,” a “violation of university policy,” “inconsistent with principles of sound research and scholarship,” and “contrary to the values and principles of academic medicine.”

- Payments are made to ghostwriting company so nothing appears in faculty financial disclosures.

- UW Medicine investigated a faculty member in 2005 who failed to disclose involvement of a third party that was paid by a drug company. They concluded that the faculty member had made significant intellectual contribution to the work and had a role in writing and reviewing the manuscript. This did not violate university policy led to Ghost Authorship Policy in 2007.

- UCSF reported that a faculty member submitted a paper in which a ghostwriter had plagiarized another author’s work. The professor retracted his name from the article. UCSF recommended that the university develop resources to educate everyone about the serious matter, but did not impose sanctions because the faculty member did not know that the article had been plagiarized.
Strengthening journal authorship policies appears to have limited effect on ghostwriting and disclosure of industry financing of medical articles

- *Annals of Internal Medicine*, the *Archives of Internal Medicine*, and *JAMA* also require disclosure of individuals who contribute to a publication, such as medical writers, industry employees, and/or other contributing non-authors.

- *JAMA* requires authors to sign statements certifying substantial contribution. Others are named in the acknowledgment section.

- *NEJM* uses the ICMJE author disclosure form which asks if the author or the author’s institution was paid for preparing the manuscript, and if so, by whom and what was the nature of the compensation. However, it does not ask if someone else was paid to assist with the manuscript.


- *Nature Medicine* stated that it has an authorship policy that defines an author which should prevent some authors’ willingness to appear on papers in which they did not contribute. The journal added, however, that because they are not strictly a medical journal “ghostwriting is not a problem significant enough to warrant an official position against it.”

- *Annual Review of Medicine* stated that no ghostwriting is permitted and authors and topics are chosen by a committee. *NEJM* also stated that most editorials and review articles are solicited by an *NEJM* editor.

- The *American Journal of Medicine* stated that it rejects any manuscript that appears to be written by someone other than the authors.
• Editor-in-chief of a medical specialty journal contacted the Committee and said that his journal handles articles that it suspects were ghostwritten by questioning or editing the articles.

• At least one third of the papers submitted to his journal were written by science writers hired by an agency and paid for by a pharmaceutical company.

• In some cases, it was clear that the academic expert had limited input in the writing of the article.

• He was also concerned that medical literature “has become inundated with repetitive promotional articles.”
National Institutes of Health does not have explicit policies on disclosure of industry financing of ghostwritten articles

NIH does not use the term “ghostwriting” in its policies. They noted that a case involving NIH-funded researchers may be appropriate for consideration as a case of plagiarism handled by the Office of Research Integrity.
Why Do We Care?
Dustin Yankus diagnosed with bipolar disorder in 2001

His doctor prescribed the antiepileptic Neurontin
• In May 2002, the 16 year-old boy committed suicide.

• Dustin’s parents were left wondering why their child was prescribed Neurontin when there was no solid evidence it was effective for bipolar disorder.
WARNER-LAMBERT TO PAY $430 MILLION TO RESOLVE CRIMINAL & CIVIL HEALTH CARE LIABILITY RELATING TO OFF-LABEL PROMOTION

WASHINGTON, D.C. - American pharmaceutical manufacturer Warner-Lambert has agreed to plead guilty and pay more than $430 million to resolve criminal charges and civil liabilities in connection with its Parke-Davis division’s illegal and fraudulent promotion of unapproved uses for one of its drug products, Associate Attorney General Robert D. McCallum, Jr. and Massachusetts U.S. Attorney Michael J. Sullivan announced today. The drug Neurontin was approved by the Food and Drug Administration in December 1993 solely for adjunctive or supplemental anti-seizure use by epilepsy patients.

Under the provisions of the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to FDA. Once approved, the company may only promote the drug for those uses. However, the company may promote the drug for any other diseases or conditions where there is substantial evidence that the drug can be effective, if the drug has not been specifically approved for such use.

"This illegal promotion of unapproved uses of Neurontin for the treatment of bipolar mental disorder, various pain disorders, Amyotrophic Lateral Sclerosis (ALS, a degenerative nerve disease commonly referred to as Lou Gehrig's Disease), attention deficit disorder, migraine, drug and alcohol withdrawal resulted in the disqualification of patients at risk," stated U.S. Attorney Michael Sullivan. "This scheme deprived federally-funded Medicaid programs across the country of the informed, impartial judgment of medical professionals -- judgment on which the program relies to allocate scarce financial resources to provide necessary and appropriate care to the poor. The pharmaceutical industry will not be allowed to profit from such conduct nor subject the poor, the elderly and other persons insured by state and federal health care programs to experimental drug uses which have not been determined to be safe and effective."

"The plea agreement and settlement announced today marks the end of an exemplary effort to use all of the appropriate anti-fraud weapons available to us in a concerted manner to send clear and unequivocal messages to the pharmaceutical industry," said Assistant Attorney General Peter D. Keisler. "To insure a just result, we in the Civil Division will vigilantly join our tools for fighting fraud on consumers with those available to remedy fraud on the federal health care programs."

WARNER-LAMBERT TO PAY $430 MILLION TO RESOLVE CRIMINAL & CIVIL HEALTH CARE LIABILITY RELATING TO OFF-LABEL PROMOTION

In 2004, the manufacturer of Neurontin agreed to plead guilty to two felonies and paid $430 million in penalties for promoting Neurontin for unapproved uses including...you guessed it...bipolar disorder.
To promote sales, Pfizer crafted ghostwritten material and orchestrated an “echo chamber” of positive findings for Neurontin to treat bipolar disorder.

In this case, from 1998 to 2007 Pfizer organized the publication of 15 case series and six case reports that claimed Neurontin was effective for the treatment of bipolar disorder. In addition, nine letters to the editor mimicked these publications. To legitimize the off-label use of Neurontin, Pfizer manufactured the publication of review articles citing the case reports. These concluded that Neurontin was safe and effective for the treatment of bipolar depression.

Sales of Neurontin

1995
$97.5 million

2003
$2.3 billion
(90% of scrips for off label purposes)
Dr. Catherine Clarey, a senior medical director at Pfizer, says more than 10 million prescriptions for Neurontin have been written in the United States since 1996.

She says there is "absolutely no evidence" that Neurontin can cause suicidal behavior.
Like other antiepileptic drugs, NEURONTIN may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.
Dustin Yankus
1986 - 2002