

ALLIANCE FOR HUMAN RESEARCH PROTECTION

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Dr. Andrew von Eschenbach, Commissioner
Food and Drug Administration

Re: Draft Guidance for Industry on Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices (Docket No. FDA-2008-D-0053)

Dear Dr. von Eschenbach:

The following comments update our June 7, 2007 letter of concern to which you have not yet responded. [See attached]

This follow-up letter was prompted by two reports published by the *Journal of the American Medical Association*,¹ analyzing evidence recently uncovered during Vioxx litigation. They reveal how Merck manipulated the data, minimizing the impact of Vioxx-related deaths in ghostwritten journal reports.

Numerous other cases currently under litigation have uncovered a mountain of evidence demonstrating the insidious impact of ghostwritten journal articles—in essence, industry propaganda—that have infiltrated the scientific literature, undermining the integrity of medicine. But these are under court seals of confidentiality.² Industry-sponsored ghostwritten reports have unduly influenced medical practice guidelines and physicians' choice of treatments, resulting in preventable harm.

We urge the FDA to take no action on this “draft guideline for industry” that would permit distribution of medical journal articles on unapproved uses of approved drugs--until manufacturers are required to (a) identify ghostwritten journal reports (b) fully and publicly disclose all emerging safety information, and (c) waive court confidentiality orders making available all documents, depositions, transcripts and produced during discovery—so that independent scientists can verify the accuracy of the information disseminated to physicians.

The Alliance for Human Research Protection has located at least three (apparently) ghostwritten articles to which the name of Dr. Thomas Laughren, director of the FDA's Division of Psychiatry Products, CDER, is penned.

For example, in 2005, Dr. Laughren was named a co-author of the article, “Mood Disorders in the Medically Ill: Scientific Review and Recommendations,” published in *Biological Psychiatry*.³ The article promotes the unsubstantiated notion that depression accompanies practically all patients with medical illnesses—e.g., cardiovascular disease, cancer, AIDS, Alzheimer's, Parkinson's, Diabetes, Osteoporosis, Obesity, and Pain.

suicide risk in children prescribed Paxil compared to placebo. Dr. Laughren made the presentation to PDAC instead of Dr. Mosholder.¹⁴ However, it was later revealed at a Congressional hearing that Dr. Laughren had excluded from his presentation Dr. Mosholder's recommendations and the data supporting his disturbing findings.¹⁵

Two published "Consensus" reports and recommendations (2003, 2007)^{16 17} following "consensus conferences" convened by the American Academy of Child and Adolescent Psychiatry, were penned by some 46 named "authors." Disclosure statements indicate they were industry-sponsored:

"This conference was convened by the American Academy of Child and Adolescent Psychiatry and funded by Best Practice with partial financial support from unrestricted grants from the following companies: Abbott Pharmaceuticals, Bristol-Myers Squibb, GlaxoSmithKline, INC Research, Janssen Pharmaceutica, Johnson & Johnson Pharmaceutical Research and Development, Eli Lilly, Novartis, Pfizer, and Solvay Pharmaceuticals."¹⁶

"The conference on which this article is based was funded by unrestricted grants from Annie E. Casey Foundation, Bristol-Myers Squibb, Forest Research Institute, Jazz Pharmaceuticals, Otsuka Pharmaceuticals, Janssen, Eli Lilly and Company, Pfizer Laboratories, and Sanofi Synthelab."

"Conference participants agreed that Impulsive Aggression is a substantial public health and clinical concern, constitutes a key therapeutic target across multiple disorders, and can be measured with sufficient precision that pharmacological studies are warranted."¹⁷

Industry-sponsored "Consensus Conferences" such as these are convened to lend legitimacy to prescribing guidelines lacking scientific justification – most notably, Texas Medication Algorithm Project (TMAP).^{18 19} The TMAP consensus panel recommendations provided manufacturers of psychotropic drugs with a Cash Cow. Consumers, however, have been ill served by the drugs of choice have caused more harm than any clinically significant benefit.

"Impulsive Aggression" is a fabricated "symptom" concocted to legitimize the illegitimate prescribing of antipsychotics for children. Antipsychotics are the most toxic drugs in psychopharmacopaeia. A body of evidence uncovered during litigation confirmed these drugs' life-shortening risks.²⁰ In children the metabolic risks are even greater.²¹

The disclosure attached to Dr. Laughren's name in apparently ghostwritten articles states that his "contribution [sic] was made in his private capacity; no official support or endorsement by the U.S. Food and Drug Administration is intended or should be inferred."³

Whether or not Dr. Laughren is acting in his official capacity, he is a high ranking FDA official. His endorsement of industry funded propaganda masquerading as science-backed recommendations is pivotal to the good reputation of the FDA as a trustworthy, authoritative guide to science-based medicine.

and Forest Laboratories. He penned his name to a pivotal (later) discredited Forest Lab. study which was used to promote Lexapro, its new antidepressant.²² Less than six months after his appointment as president and psychiatrist in chief of McLean Hospital, Harvard's teaching hospital, in October 2005, in "an astonishing fall from grace", he was forced to resign because of admitted sexual relations with a patient. Dr. Gorman temporarily lost his license to practice in New York, and permanently in Massachusetts
<http://ahrp.blogspot.com/2007/11/cover-up-gorman-case-professional-moral.html>

- Melissa DeBello, M.D., an Associate Professor of Psychiatry and Pediatrics at the University of Cincinnati, is the lead author of a report on a pediatric trial testing AstraZeneca's antipsychotic drug, Seroquel (2002).²³ The report in the *Journal of the American Academy of Child and Adolescent Psychiatry* claimed that Seroquel (quetiapine) was "more effective" and "well tolerated" for treating adolescents with bipolar mania" than divalproex alone. However, 7 of 15 adolescents on Seroquel dropped out of the trial compared to only 1 of 15 on placebo. An investigation by Senator Charles Grassley noted that despite the lack of evidence for efficacy, the AstraZeneca funded study was used to formulate guidelines for treating bipolar disorder in adolescents with antipsychotics. Sen. Grassley also uncovered inconsistencies in Dr. DeBello's financial disclosure: he noted that AstraZeneca reported that \$238,000 had been paid to Dr. DeBello who regularly conducted "continuing medical education" courses promoting Seroquel for off-label, unapproved uses for children.
- Laurie Flynn, the Executive Director of the Columbia University TeenScreen Program since January 2001, is a named "author" in two of the ghostwritten articles. Flynn's aggressive promotion of TeenScreen, which is a market expansion gimmick for increasing the rolls of children prescribed psychotropic drugs, coincides with her cozy relations with drug companies.²⁴

Industry's corrosive influence on medicine is ubiquitous. Industry-sponsored ghostwritten articles have undermined the integrity of the scientific literature. Its brass knuckle tactics have subverted the culture in academia: stifling debate and terrorizing critics. Indeed, a Task Force Report by the Association of American Medical Colleges²⁵ has recommended that: "Academic medical centers should prohibit physicians, trainees, and students from allowing their professional presentations of any kind, oral or written, to be ghostwritten by any party, industry or otherwise."

Shouldn't FDA officials be held to at least the scholarship standards of medical students? If FDA's proposed rule change were to be adopted, ghostwritten propaganda—i.e., junk science—would be institutionalized.



Vera Hassner Sharav
President
Alliance for Human Research Protection

cc: Senate Finance Committee:

