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Sham Peer Review

Dr. Huntoon has masterfully dissected the beast of sham peer review.[1] It is terrifying that it works so perfectly. The ultimate end point of this process is to destroy the targeted independent physician financially and professionally. It is a form of pro-rated genocide. While it is done piece by piece rather than in a wholesale fashion, it is not much different from the Jewish Holocaust, Armenian genocide, or the Serbian ethnic cleansing of Kosovars.

The important question is why the process is applied and why it is not opposed on a massive scale. In my opinion, just like historic examples of genocide, a very specific and widely accepted Zeitgeist supports the current persecution of independent physicians. The ruling oligarchy in Turkey used anti-Armenian sentiment to assert its power and enrich itself. Only a few intellectuals protested; the majority of the intellectual elite and general populace applauded the injustice perpetrated by the state.

Currently the U.S. oligarchy was shaken a little by the discontent displayed by many constituents at town hall meetings this summer. We should not deceive ourselves, however, because the masses still believe that private independent physicians (not rotten politicians) are our misfortune—just as in von Treitschke's catchy phrase: "*Die Juden sind unser Unglück!"*

The German nation paid dearly for its anti-Semitic folly. German soldiers were slaughtered, cities were carpet bombed, thousands (if not millions) of German women were raped by Eurasian barbarians. In due time the U.S. and all of the Western world will pay a price for the misguided current Zeitgesit.

Walter P. Borg, M.D.

[1] Huntoon LR. Tactics characteristic of sham peer review. *J Am Phys Surg* 2009;14:64-66.

Transparency Needed in Psychopharmaceutical Trials

We thank the journal for publishing a critical review of the potential benefits and risks of Selective Serotonin Reuptake Inhibitor (SSRI) drugs,[1] focusing on the controversial issues of SSRI-associated suicidality and violence. This material is rarely discussed so frankly in the medical literature.

Kauffman notes that "early findings of severe adverse effects by SSRI makers came to light *only after the class was established*" [emphasis added]. He cites SSRI whistleblower David Healy, noting that "much of the evidence for suicide and murder (associated with use of SSRIs) came from the efforts of journalists and lawyers." [2,3] These statements characterize, we believe accurately, a sad state of affairs. The foundation of rational risk-benefit analysis for one of the most frequently prescribed classes of medication is revealed to be shaky, at best, because the manufacturers have withheld critical information.

Commitment to transparency in reporting hard data from clinical trials, including post-marketing surveys of adverse events, is lacking. Kauffman makes a credible argument that FDA and potential prescribers are receiving only highly selected servings of available information. For example, only 27% of the data from studies of the effects on volunteers of the SSRIs fluoxetine, paroxetine, and sertraline have been reported, either to FDA or in the peer-reviewed literature. Of the unpublished clinical trials presented to the FDA before the approval of fluoxetine, only half demonstrated benefit, and in the case of sertraline, only one of five showed benefit.[3]

Suppression of data that might raise concerns about potential for suicide or violent behavior, or raise fundamental doubts about efficacy, is unacceptable. Lack of full disclosure creates the clear impression of conflict of interest even when there may not be any.

Honest, open discussion of data from all stages of clinical testing should allow physicians to ask the hard questions and make well-informed decisions. However, full disclosure is only a minimum basic requirement. There is an urgent need to establish durable criteria for clinical significance in drug trials. Controlled clinical trials of SSRIs (and other psychopharmaceuticals) too often produce efficacy results that reach conventional levels of statistical significance but lack practical clinical significance.[4] Without full disclosure of risks and consensus on what constitutes clinically significant efficacy, the much-anticipated era of "evidence-based psychiatry" is not likely to materialize.

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[1] Kauffman, JM. Selective serotonin reuptake inhibitor (SSRI) drugs: more risks than benefits? *J Am Phys Surg* 2009;14:7-12.
[2] Healy D. One flew over the conflict of interest nest. *World Psychiatry* 2007;6(1):26–27.
[3] Dept. Health and Human Services. Public Health Service. Psychopharmacologic Drugs Advisory Committee 33rd meeting, Nov 19, 1990. Available at: www.healyprozac.com/PDAC/PDAC-Zoloft%20Nov%2090.pdf. Accessed Nov 11, 2009.
[4] Kirsch I, Moore TJ, Scoboria A, et al. The emperor's new drugs: an analysis of antidepressant medication data submitted to the US Food and Drug Administration. *Prevention & Treatment* 2002;5(1):23-33.