**SSRI Lawyer, Karen Barth Menzies, Corrects New York Times Report**

**Antidepressant Warnings *Are* Scientifically Based and Mandated by Federal Law**

The FDA's recent warnings regarding suicidality and SSRI antidepressants were appropriate and long overdue, based on scientific evidence and the FDA's warning responsibilities to consumers as directed by the Code of Federal Regulations. The article published in the New York Times on August 6, 2005 by Gardiner Harris, titled "FDA Responds to Criticism with New Caution," asserts the erroneous thesis that the FDA simply yielded to criticism and issued invalid warnings, casting a cloud of doubt over the legitimacy of the warnings. That the FDA finally stepped up to shield consumers instead of pharmaceutical companies should be applauded, not undermined with inaccurate reporting. People died as a result of absent warnings while the SSRI antidepressants were marketed and sold as harmless.

I wrote the below letter to the New York Times to correct some of the disinformation in the article. The New York Times chose not to print it, so I am circulating my letter broadly in order to help cure some of the resulting misconceptions that will have resulted from the article.

**Op Ed Letter to Editor:**

In his article, Gardiner Harris writes: "[O]ver the last year, [the FDA] has demanded that pharmaceutical companies add tough warnings for drugs as diverse as the antidepressant Zoloft, because it might lead a small number of teenagers to become suicidal . . . In each case, according to disclosures at open hearings, the agency has acted with little or no evidence that the risks are real."

As a representative of parents who have lost one of "these small number of teenagers," I find this statement particularly offensive. It is incredible that Mr. Harris would choose the FDA's actions related to the antidepressants and children/adolescents as the Poster Child of "rash" warnings, supposedly given with "little or no evidence."

As Mr. Harris will recall, the black box warnings concerning the risk of suicidality in children taking antidepressants came over a year and a half after the issue was first raised in the UK; over a year after the UK all but banned the drugs for children and adolescents after its review of the clinical trial data found a link between the drugs and increased suicidality, as well as no benefit; several months after one of FDA's own trusted scientists observed an association between the drugs and suicidality during his review of the clinical trial data; after a several-month independent review by "the Columbia group"; after 2 FDA advisory committee meetings spanning over a 3-day period had been held at which 25 of the experts on the FDA advisory panel voted "Yes," the data presented demonstrated a causal relationship between the antidepressants, including Zoloft, and increased suicidality. (1 voted to abstain and 1 voted against.)

According to one of the advisory panel members (Dr. Thomas B. Newman), the data analyses from the antidepressants clinical trials were "striking" and "such a dramatic

result would be expected to occur by chance only 1 time in 20,000 . . . The fact that an association emerged from the meta-analysis . . . for an outcome that the sponsors of the trials were not looking for, and presumably did not wish to find, was quite convincing."

"Rash" and "little or no evidence" Mr. Harris?

Finally, Mr. Harris writes that the FDA "once avoided issuing disturbing warnings about drugs unless studies proved that a risk was certain." If true, the FDA has been ignoring Title 21 of the Code of Federal Regulations (section 201.57, in particular), which clearly states "[t]he labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved." (Emphasis added.)

Moreover, FDA regulations allow drug manufacturers to strengthen warning labels in the interest of drug safety at any time without FDA preapproval so that the warnings can be placed into effect at the earliest possible time. With respect to the antidepressants and Vioxx, drug companies have grossly failed to take the initiative, despite having in their possession far more than "reasonable evidence of an association of a serious hazard."

Drug companies are profit-driven and are loath to issue warnings about risks associated with their drugs, even those that are quite clear. It is precisely for this reason that the public is in dire need of an agency that advocates for them, not the other way around.

In the past 15-plus years, the FDA has been worse than "comatose," it has sided with industry and become an adversary to consumers. The FDA's apparent awakening (although I remain skeptical) is a good thing. If the FDA is, all of a sudden, issuing public health alerts about drug risks "even when problems are only suspected," then it would seem that it is simply getting back to its congressional mandate.

According to FDA safety expert, Dr. David Graham, the FDA's standard for establishing that a safety risk actually exists is to a 95% or greater certainty, which "is an incredibly high, almost insurmountable barrier to overcome. It's the equivalent of 'beyond a shadow of a doubt.'" Dr. Graham further explained, "in order to demonstrate a safety problem with 95% certainty, extremely large studies are often needed. And guess what. Those large studies can't be done." Dr. Graham used the following analogy to prove his point:

Imagine for a moment that you have a pistol with a barrel having 100 chambers. Now, randomly place 95 bullets into those chambers. The gun represents a drug and the bullets represent a serious safety problem. Using CDER' standard, only when you have 95 bullets or more in the gun will you agree that the gun is loaded and a safety problem exists. Let's remove 5 bullets at random. We now have 90 bullets distributed across 100 chambers. Because there is only a 90% chance that a bullet will fire when I pull the trigger, CDER would conclude that the gun is not loaded and that the drug is safe.

Mr. Harris has written a number of articles over the past few years on the topic of drug safety, and in particular, regarding antidepressants. He has increasingly been taking and running with the company party line. One wonders what Mr. Harris has against the concept of fully and accurately educating physicians about the drugs they prescribe so that patients can make informed choices about their health?

Sincerely,

Karen Barth Menzies, Esq.

Baum Hedlund

12100 Wilshire Blvd., Suite 950

Los Angeles, CA 90025

(310) 207-3233

www.baumhedlundlaw.com

*Karen Barth Menzies is a partner of the national law firm, Baum Hedlund, and heads the firm's SSRI Antidepressant Litigation Department, representing suicide victims across the country involving Zoloft or Paxil. She is Lead Counsel and member of the Plaintiffs' Steering Committee in charge of the MDL-1574 in re Paxil Products Liability Litigation handling thousands of Paxil withdrawal/dependence cases from every state. Ms. Barth Menzies has twice testified before the FDA and met with members of the House and Senate regarding the risk of antidepressant induced suicidality. Black box warnings have since been issued for children and adolescents, as well as a public health advisory concerning the suicide risk in adults. Karen was recently named one of California Lawyer magazine's, California Lawyers of the Year, one of Lawyer's Weekly USA's Lawyers of the Year and recently she was listed in The National Law Journal's "40 Under 40" for her "extraordinary achievements" and "impressive track record" for "stepping up her fight in the past few years, advocating that pharmaceutical companies should warn about the alleged risks of antidepressant drugs." She received her law degree from UC Davis and is in the Bar Register of Preeminent Lawyers; Who's Who in American Law; Who's Who in America and Southern California Super Lawyers. Baum Hedlund has been involved in SSRI-induced suicide/violence litigation since 1990 when it began a decade of litigation regarding the antidepressant, Prozac.*