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FDA's new antidepressant suicide warning for young adults gives a false perception that it's safe for older age group, says antidepressant injury lawyer Karen Barth Menzies

May 3, 2007 – Los Angeles, California - - The FDA announced on May 2 that it has asked antidepressant manufacturers to expand the current black box warnings concerning the increased risk of suicidality in children and adolescents to include young adults, but only ages 18 to 24. See http://www.fda.gov/bbs/topics/NEWS/2007/NEW01624.html

Karen Barth Menzies' statement regarding the FDA's newest suicide warning:

We are getting closer to warnings that match what the internal, unpublished data owned by the drug companies (and not entirely seen by FDA) show regarding a risk for antidepressant-induced suicidality and violence. Unfortunately, this new warning, rather than simply and accurately informing the public that this side effect can occur in some people - no matter their age, instead gives the false perception that some age groups are entirely safe while others are not.

It is unrealistic and *unwise* to think that a person is at risk the day before their 25th birthday, but then safe and no longer at risk of becoming suicidal while taking these drugs one day later. This obviously problematic interpretation was a significant concern raised by some FDA advisory committee members who met on December 13, 2006 to discuss the FDA's analysis of suicidality in adults taking antidepressants. Parsing out the data in an effort to draw lines around particular age groups appears to be designed to salvage certain markets for the drugs, nothing more.

As I stated during my public testimony before the FDA on December 13, 2006, does a drug know how old a person is? When their 25th birthday is? When a company seeks *approval* for a drug, does the FDA parse out the efficacy data by age group? Of course not. We know that breast cancer happens most often in women over 50. But, does that mean that women cannot get cancer in their 30s? No. So, why are we parsing out age groups for side effects that can happen in all age groups, whether or not it happens more often in one age group than another?

Suicidal Behavior is Higher in Patients Treated with Paroxetine (Paxil) Compared with Placebo

It is extremely misleading for the FDA to state that "scientific data" does not show an increased risk in adults older than 24. In fact, according to one antidepressant manufacturer's analysis of suicidality in adults, for "adults with MDD [Major Depressive Disorder] (all ages), the frequency of suicidal behavior was higher in patients treated with paroxetine compared with placebo. [ ] This difference was statistically significant."

How does the FDA reconcile this with the statement that the "scientific data" does not show

a risk above the age of 24? With FDA's proposed labeling, patients and their doctors will be mollified into thinking that if they are 25 years-old or older, they have nothing to worry about. As a result, more lives will be lost.

Instead of drawing age group lines, patients and healthcare providers need to be informed that this side effect can occur in some people - no matter the age - and the listed symptoms are dangerous precursors to suicidal and violent behavior. Properly educated medical professionals, patients, family members and care givers can distinguish the unusual behavior and take steps to prevent them from escalating to self-harm or harm to others.

Clinical Trial Evidence Shows Risk Since 1980's

Although the expanded warning is an improvement, it certainly is not, as the FDA's Steven Galson states, a representation of "FDA's commitment to a high level of post-marketing evaluation of drug products." In fact, the clinical trials that formed the basis of the FDA's analysis have been in existence for years. The truth is that the clinical trial evidence from 15 and 20 years ago, even before the drugs were approved, showed signals of a risk. The FDA's own medical staff raised concerns about the side effect profile of these drugs in the 1980's and 1990's, but their admonitions were ignored by their superiors.

Finally, FDA's action today continues to ignore all evidence outside of the clinical trial data created by and provided to it by antidepressant manufacturers. The FDA is *ignoring* independent analyses conducted by scientists in the field, as well as historical and foreign regulatory actions dating back over 20 years. [See Karen Barth Menzies' Comments submitted to FDA for December 13, 2006 PDAC re adult suicidality at LINK http://www.baumhedlundlaw.com/KBMFDATestimony/KBMFDAWrittenComments.htm]

5-Fold Greater Risk of Suicide in SSRI-treated Elderly Patients

In fact, the FDA's statement that antidepressants have a "protective effect" for those over the age of 65 is inconsistent with a recent study of elderly patients, which found a nearly 5-fold greater risk of suicide in SSRI-treated patients compared to patients receiving other antidepressants in the first month of treatment. [Juurlink, DN, Mamdani, MM, Kopp, A, Redelmeier, DA. The Risk of Suicide With Selective Serotonin Reuptake Inhibitors in the Elderly, The American Journal of Psychiatry (May 2006).]

I believe, w*ithout question*, drug companies and their apologists are putting a great deal of pressure on the FDA. Despite all of the controversy and exposed failures surrounding the FDA in the past few years, it appears that the FDA simply cannot muster the guts to act without industry influence. Absent this influence, there would be no reason why the FDA wouldn't insist on warnings for all ages. No doubt, drug companies are a formidable force, but the FDA must remember whose interests it is supposed to protect. If it does not, the representatives of the people, Congress, will have to step in.

About Karen Barth Menzies

For more than a decade, Baum Hedlund partner, Karen Barth Menzies, has been at the forefront of the litigation involving injuries stemming from selective serotonin reuptake inhibitors (SSRIs) such as Prozac, Paxil and Zoloft. She represents families of children and adults who have committed suicide as well as children who have suffered birth defects due to their mothers' use of antidepressants during pregnancy. Heading a team of Baum Hedlund attorneys, Karen has successfully defeated Pfizer's and the FDA's preemption arguments in a number of suicide cases, including Motus v. Pfizer and Witczak v. Pfizer. Ms. Menzies is Lead Counsel for the Plaintiffs' Steering Committee (MDL-1574) Paxil Products Liability Litigation. In addition to her court activities, she has testified about the dangers of SSRIs before the California State Assembly and three times before the Food and Drug Administration's Psychopharmacologic Drugs Advisory Committee and met with members of the House and Senate regarding the risk of antidepressant induced suicidality

and preemption issues. Ms. Menzies was named Lawyer of the Year by Lawyer's Weekly, California Lawyer of the Year by California Lawyer magazine and one of The National Law Journal's Top 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." In 2006, Karen was named a Consumer Attorney of the Year finalist by The Consumer Attorneys of California.

Baum Hedlund has the longest track-record handling SSRI-antidepressant litigation, having litigated over 3,000 antidepressant cases in the past 17 years.
