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Mrs. Kennedy's 6th Grade Class Is Dead

"Mrs. Kennedy's entire 6th grade class is dead!"

The words simply didn't register with Principal Jones. His secretary repeated. "Sir, they're dead. All 23 students."

Immediate thoughts flashed through the Principal's head. Twenty-three students. Eegad. That's worse than Columbine. How did it happen? Terrorists. Surely it was terrorists. Al-Qaida. These were followed instantaneously by hopes for revenge. "Thank God for the Patriot Act" he thought. "Attorney General Ashcroft and the FBI will root out these bastards. Wherever they are. Whatever it takes. Wiretaps. Arrests. Searches. Civil rights be damned. These monsters will pay."

"No wait, they're not just here on our soil. Some foreign terrorist group ordered this madness. Doesn't matter where they are," he thought. "They can't run and they can't hide. We'll root them out and send in the Marines. They will surely pay!"

Only two seconds had passed since Mrs. Miller spoke the words. But it seemed like an eternity to Principal Jones. Then reality set back in. There were 980 other students in his elementary school. He had to act fast. He had to protect the living. "How did it happen?" he asked.

"Suicide, sir" she said. His mind flashed back to the Jonestown tragedy. It hit him like a brick. Someone had poisoned his 6th graders. "What were they taking?" he asked. "Zoloft, sir."

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To some, this story will sound like sensationalized fiction. Trial lawyer hype. A “hoax.” The notion that all 1003 students in Principal Jones’s school would be taking Zoloft, and that 23 of them in one class would all commit suicide simultaneously is, of course, fictional. And obviously it has been chosen for graphic illustrative purposes. But the phenomenon of Zoloft-induced suicidality is real, and the magnitude of this risk is, indeed, 2-3%. Or at least that’s what the FDA now says.

On Monday and Tuesday of this week, i.e., September 13-14, 2004, I sat in Washington and heard reports, testimony, debate and, ultimately two decisions, from the FDA and its two Advisory Committees. **“Causality has been established.”** More than once I heard Bob Temple and Tom Laughren of the FDA mouth these words. “The risk is approximately 2-3%.” People need to know. At the end of the day, with obvious encouragement from Dr. Temple himself, the Committees voted 15:8 in favor of

BLACK BOX WARNINGS.

Mrs. Kennedy’s Sixth Grade Class is an example. And, much as I would like to take credit for this example, it is not mine. The example was chosen by GSK’s Head of European Psychiatry, Dr. Alastair Benbow, in an interview with the BBC. During his April 1, 2004, deposition, I asked him about it. Here are my questions and **his** answers:

- Q. (Mr. VICKERY) Let’s use a hypothetical. Let’s say there were a school, an ordinary school of a thousand schoolchildren. How prevalent would this phenomenon of emergent suicidality on paroxetine [Paxil] be within that school?
- A. (Dr. BENBOW) Of the order of a class size of, say, 20-25. . . . Just so we get it clear, the numbers that we were talking about in the paediatric population, I don’t know how the size of the schools are in the US, but we were talking about more than a thousand patients and **only 20-25 children**, just to put that in context.

Q. You are well aware, of course, of where I got the example of the school?

A. I believe so, yes.

Q. That was **your example** that you chose to use in a public interview earlier, right?

A. Yes.

Dr. Benbow agreed that this was “a small but important signal.” However, he hastened to add that he did “not believe it is causally associated” with Paxil. Instead, he blamed the treatment emergent suicidality on the “disease” of depression. But then, of course, that has been the company line for Big Pharma since this issue first caught the public eye in February of 1990. This week, finally, after more than 14 years, the FDA has set the record straight. Big Pharma is wrong. **“Causality has been established.”**

Who’s Hoaxing Whom?

For the last nine years our tiny little law firm in Houston, Texas, has been saying that the SSRI drugs do trigger suicidality, and, in some cases, homicidality, for a “small vulnerable subpopulation” of patients. We have been seeking justice for the victims’ families. Big Pharma has fought us every step of the way. Even after a Wyoming jury concluded on June 6, 2001, that “Paxil can cause some people to become homicidal and/or suicidal,” GSK maintained its public stance that their drug was totally safe for all people. Dr. Benbow’s sound bite, i.e., “it’s the disease (of depression), not the drug” is a familiar echo from the past.¹

¹ Depression is, of course, a risk factor for suicide. That’s common sense and common knowledge. However, Big Pharma has grossly exaggerated that risk. The figure that they commonly use is 15%. According to them, 15% of depressed patients will kill themselves at some point in their lives. The figure is repeated time and again as if it were Holy Writ. But where did it originate? The 15% figure comes out of a two-page, 1970 article by Guze and Robins in the British Journal of Psychiatry. They describe earlier European research with **hospitalized** patients. (None of the SSRI drugs have ever shown efficacy in this group of patients.) Now, why on Earth would a depressed person be hospitalized? Guess why? One obvious reason is that they were suicidal already. Although depression is unquestionably a risk factor for suicide, in fact, the risk for primary care depression is slightly less than three times higher than the background risk in the population as a whole, and, even at that, less than 1%. What the FDA has now found is that, for those taking SSRI drugs, it is 2-3%, which is several multiples of the “normal” risk for a person with primary care depression.

How did this happen? Who originated this obvious PR ploy? Who spun this web?

The answer to those questions is revealed in candid but hostile answers which I got in an October 30, 2000 deposition from Mitch Daniels, former Vice President of Eli Lilly, chief architect of his company's PR response to the Prozac/suicide issue, and current GOP candidate for Governor of Indiana. According to Lilly's Daniels, it was a "hoax" perpetrated by the Church of Scientology. And we, the perennially "greedy trial lawyers" were their willing accomplices. Or perhaps they were ours. (For the record, I am Episcopalian and both my partner Paul Waldner and my co-counsel/colleague Karen Barth Menzies are Catholic.)

On August 22nd of last year (2003), Wyeth issued a "Dear Doctor" letter which was mailed out to tens of thousands of physicians in this country. The letter warned about the increased risk of suicide and hostility for children and adolescents taking Effexor.

Eli Lilly had ample data in 1990 to justify such a letter, not just for the risk in children, but adults as well. But instead of mailing out thousands of "Dear Doctor" letters to alert the prescribing physicians about this small but lethal risk, in August 1991 Lilly chose instead to spend \$49,000 buying 700,000 reprints of a derogatory Wall St. Journal article about the Church of Scientology and to mail those out to physicians.

Who's hoaxing whom? You tell me. When I asked him what he meant when he branded this whole issue as a "hoax," Lilly's Mitch Daniels told me that "a hoax is a trick played by someone in contradiction of the facts." The **fact** is that **"causality has now been established."** The fact is that this assessment is based on a reanalysis of data that the drug companies have had for years. SO, who's been tricking whom?

While you ponder the answer to that question, I will tell you that Big Pharma's Spin Doctors continue their work, even to this day. On July 26, 2004, in anticipation of the September 13-14th hearings, Pfizer submitted a 39-page "brief" to the FDA and its Advisory Panels. Instead of confining itself to the science, Pfizer continued with

Lilly's practice of finger pointing and name calling. It belittled Dr. David Healy, the courageous Irish neuro-psychopharmacologist who has done more to increase public awareness of this problem than anyone as a person "primarily known for his work as a medical historian." It accused him of "unscientific rhetoric." It acknowledged that, in the *Miller* case, at Pfizer's behest, the trial judge kept Dr. Healy from answering legitimate questions posed by independent experts, but, even then, it spun this "fact" stating that the court had merely "precluded him from springing new 'reanalyses'" on poor, unsuspecting Pfizer. It ended its 39 page anti-Healy diatribe with a precatory statement that it hoped that the FDA could distinguish "fact from fiction."

Well, Pfizer got its wish. Like Dr. Healy, the FDA and its Advisory Committees also did their own "reanalysis" of Pfizer's data. And, in spite of Pfizer's attacks, they did sort "fact from fiction," concluding that "**causality has now been established**" and voting in favor of a **black box warning** for the Zoloft label.

At the same time Pfizer was blasting Dr. Healy in public it was trying to assuage its own people in private. In an internal memo dated September 9, 2004, Pfizer assured its employees that "each time" the FDA has looked into the issue, it "concluded that there was no scientific basis for a warning that SSRIs . . . cause suicide." For further reassurance and emphasis, Pfizer answered the rhetorical question, "*Why is all of this negative media attention flaring up?*" with bold print and a colored background, all inside a big **black box**, as follows:

Much of the media attention around this issue is being fueled by a couple of contingent-fee personal injury lawyers who have filed numerous lawsuits against a number of SSRI manufacturers over the past decade.

Attacking Dr. Healy and trial lawyers like me is one thing. But even that isn't enough for Pfizer. To protect Zoloft's market share and maintain its super-profits Pfizer has even stooped to attack the children who have taken its pills. In its July 26, 2004, submission to the FDA, it attacked Matt Miller, a 13-year old boy who hanged himself one week after he started taking Zoloft, with a long list of slanted statements which it claimed were "undisputed facts." Other critical facts, like the fact that Matt's grandmother described his behavior on the night before he died as being "like he wanted to jump out of his skin" were omitted by Pfizer.

Meanwhile, in South Carolina, Pfizer has been trying to help a prosecutor send a 12-year old boy to prison for life for something that happened while he was taking Zoloft. In January 2002 one of its lawyers wrote a letter to an expert witness for the prosecution, enclosing certain carefully selected, self-serving documents which tout the total safety of Zoloft. But, in 2004, when my colleague Karen Barth Menzies and I entered the case for young Christopher Pittman and subpoenaed our own list of documents from Pfizer – internal, **UNPUBLISHED**, Zoloft-incriminating documents – Pfizer's lawyers responded that these were "irrelevant" and "confidential." Pfizer asked the judge, not only to "quash" the current subpoena, which it claimed would pose an "onerous burden" and "require Pfizer to incur considerable expense," but also to "order the defense not to issue to Pfizer any future subpoenas."

Pfizer also told the judge in a pleading filed on dated June 1, 2004 that "there is no indication that the use of Zoloft **permanently** destroyed Christopher Pittman's ability to know right from wrong, and so any evidence of his use of Zoloft or any documents relating to Zoloft in Pfizer's possession would be irrelevant to the matters to be tried." Permanently? But, wait a minute Pfizer. What if Zoloft caused a **temporary**, involuntary intoxication? What if this drug, which was prescribed off-label, triggered a momentary psychotic break with reality? Isn't that relevant?

So, whatcha think? Why doesn't Pfizer want the court and jury to see its dirty laundry? Is Pfizer trying to hide something? If not, why all the "confidentiality" business? Is this a "trick by someone in contradiction of the facts"? Is the largest

pharmaceutical company in the world perpetrating a hoax? And, meanwhile, what's the deal with that cute little blue squiggly Zoloft creature that has invaded all of our television sets?²

Consider the facts, and then you tell me. But as you ponder them, remember what the FDA has now said. In spite of Pfizer's vehement protests to the contrary, "**causality has now been established.**"

Andy Vickery
September 17, 2004

"Oh, what tangled webs we weave
When first we practice to deceive"

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² Hopefully, that little sucker's days are numbered. In future ads, his journey across the screen would have to end with a bump of his little head against a big **BLACK BOX WARNING**.