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Evelyn Pringle: SSRI Pushers under Fire

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SSRI Pushers under Fire

By Evelyn Pringle

Throughout the 1990's, most doctors who attended conferences, medical seminars and other events were not aware that the so-called "key opinion leaders" encouraging them to prescribe the new generation of antidepressants for everything under the sun, including to children as young as infants, were nothing more than highly paid drug pushers for Big Pharma.

For years, the research that showed SSRI antidepressants (selective serotonin reuptake inhibitors) were dangerous and practically useless was kept hidden, while the studies published and presented to potential prescribers painted a glowing picture of success. These days, a person would be hard pressed to find someone who does not have a family member or friend labeled mentally ill and taking drugs like Prozac, Paxil, Zoloft, Lexapro and Celexa, or their chemical cousins Effexor, Cymbalta and Wellbutrin.

About once a year, a new round of headlines about all the money made by the SSRI pushers comes and goes; but nothing really ever seemed to stick, until now.

The Senate Finance Committee, with the ranking Republican, Senator Charles Grassley, leading the charge, is investigating GlaxoSmithKline regarding new revelations in a report filed in litigation showing that the company manipulated the numbers on adverse events related to suicidality in clinical trials back in 1989, to make it appear that Paxil did not increase the risk of patients experiencing suicidal behavior when, in fact, trial subjects on Paxil were eight times more likely to attempt or commit suicide than patients taking placebos.

Quite a few of the top pushers are also under investigation by the Committee due to revelations that millions of dollars has changed hands between the SSRI makers and the academics who signed off on some of the most fraudulently reported research in the history of modern medicine. A full list of names is easy to compile by scanning the literature on SSRI studies conducted on children. The same names appear repeatedly.

In alphabetical order, the Fortune 500 team of SSRI pushers, at a minimum, includes Drs Joseph Biederman, David Brent, Jeffrey Bridge, Daniel Casey, David Dunner, Graham Emslie, Daniel Geller, Robert Gibbons, Frederick Goodwin, M http://www.dailymail.co.uk/health/article-434241/Why-trust-new-wonder-drugs.htmlartin Keller, Andrew Leon, John Mann, John March, Charles Nemeroff, John Rush, Neal Ryan, David Shaffer, and Karen Wagner.

Truth Buried in Litigation Graveyard

On February 6, 2007, the world famous historian on psycho-pharmacology, Dr David Healy, published a commentary entitled, "Why you should never trust new wonder drugs," in the UK's Daily Mail stating:

"Ten years ago, I sat faced with boxes and boxes that contained a dirty secret. Inside were thousands of confidential internal company documents about Prozac."

"The secret they revealed was that public statements about the safety of the drug were a lie; that the company knew Prozac was responsible for a raised risk of suicide and was only slightly more effective than a placebo."

Several years later, Dr Healy recounts, he was faced with the secrets of Paxil. "No one outside the two companies, and few within them," he writes, "knew what those boxes contained; I saw them because I was an expert witness in a court case."

"Documents prised out of companies by American court cases," he says, "have become the main way we have of discovering the truth about some of our best-selling drugs."

"The scientific literature, the very place doctors would look for a warning," he writes, "contained barely a hint of problems."

"What's more, no one seems likely ever to have to answer for what appears to be fraud," he points out.

"In other organizations when evidence of disregard for public safety emerges, heads roll," Dr Healy said. "But there have been no resignations following these drug disasters - barely a flicker of embarrassment."

The UK's medicines "watchdog," the British Medicines and Healthcare Products Regulatory Agency, he reports, "has never taken any action against the academics who make fraudulent claims in ghostwritten articles, nor doctors working for the companies who repeat such claims, even when they have been shown to be untrue."

"And no one in Britain," he points out, "has any means of finding out why their husband or child might have died."

Seven years before Dr Healy wrote this commentary, in a Prozac case for which he served as an expert witness, the plaintiff's legal team learned that Eli Lilly had withheld evidence in a jury trial when the May 7, 2007 Boston Globe reported that Lilly had agreed to pay $20 million for the rights to a patent on a new version of Prozac that would reduce "akathisia," the very side effect long believed to increase the risk of suicidal behavior, three months before the trial began.

While testifying under oath, Lilly researcher, Gary Tollefson, had told the jury, "there is absolutely no medically sound evidence of an association between any antidepressant medicine, including Prozac, and the induction of suicidal ideation or violence."

When in fact, the wording in the patent for the new formula stated "fluoxetine (Prozac) produces a state of inner restlessness (akathisia), which is one of its more significant side effects," and the "adverse effects which are decreased by administering the R(-) isomer of fluoxetine include but are not limited to headaches, nervousness, anxiety, insomnia, inner restlessness (akathisia), suicidal thoughts and self mutilation."

Patients who lived to talk about a failed suicide attempt have described the SSRI-induced akathisia, as being so unbearable that their only option for relief seemed to be death.

America's Most Wanted

Dr Daniel Casey was a major player in the SSRI drug-push and useful in many ways to the companies promoting the drugs. He was the chairman of the very first FDA advisory committee that met in 1991, to decide whether a warning about the increased risk of suicide should be added to the label of Prozac, the first SSRI approved in the US, and voted it down. He was also the chairman of the advisory panel that voted to approve Zoloft for Pfizer later that same year.

Bob Sorenson was a sales representative for Pfizer for 21 years. He moved to Oregon shortly before Zoloft was approved. During the first week at his new location, Pfizer's chief of marketing at the time told him he needed to start calling on a doctor by the name of Dr Daniel Casey at the V.A. in Portland because he was very important to the company.

Dr Casey worked at the V.A., but never treated patients for depression, Mr Sorenson says. "His expertise [was] psychotropic drugs and experimentation."

The chief of marketing said he was interested in finding out what Dr Casey thought of the company's new drug, Zoloft. The company tried to call on him that day, but Dr Casey was not in. Mr Sorenson called on him later in the week and learned that Dr Casey was the lead investigator on Zoloft, which was up for approval by the FDA advisory committee Dr Casey chaired.

"He said I shouldn't be there, but I did ask how it looks for the drug and he said very well," Mr Sorenson recalls.

Dr Casey ended up making a ton of money from Zoloft. "He told me personally one time that he made enough from Pfizer in one year to purchase two cars," Mr Sorenson reports.

Dr Casey became a member of Pfizer's Advisory Board for Zoloft, which meant "all expense paid trips," including honorariums, to anywhere Pfizer wanted him to advise, at any location in the world, Mr Sorenson explains.

"Many speakers were sought out that would only give lectures that put Zoloft in a positive light," he notes, "there was no room for a balanced lecture."

"Dr Casey later became one of the most sought after speakers for the Pfizer promotion of Zoloft," he says, "the reps loved him because of his positioning of Zoloft."

Mr Sorenson was often told to take information to speakers, "including Dr Casey, to have them add the information to their lectures," he reports. "I look back at it now and see how wrong it was," he states.

"As far as the suicide issue," Mr Sorenson says, "the standard company line was that parents and doctors should be monitoring these kids because after being on Zoloft they finally feel good enough that they can carry out their suicide tendencies."

"Another tactic was to blame Paxil and Effexor," he recalls, "it was those drugs that caused suicidal tendencies, not Zoloft."

"Finally," he notes, "the statement was made that if they didn't take Zoloft, they probably would have committed suicide anyway."

Sales reps would practice and rehearse these statements at sales meetings to be able to respond to concerns or objections raised by Doctors about Zoloft's relationship to suicidality, he says. "There would be contests as to who could detail the drug the best with objections," he recalls.

Pfizer was able to get rid of employees and still keep them quiet, he says, by offering severance packages of up to a year's salary, while forcing them to sign a confidentiality agreement, in which they promised not to sue, or speak adversely about Pfizer, as part of the deal.

Many people were so surprised at being terminated that they felt forced to sign because Pfizer kept the pressure on, he explains. They feared they wouldn't find another job before financial problems set in, but regretted signing the agreement later, he says.

Mr Sorenson did not sign an agreement when he was fired. His young son had developed cancer, but Pfizer expected him to continue to attend out-of-town meetings and refused to believe that his son was terminally ill, he recalls. After 20 years with the company, Mr Sorenson was let go when he insisted that he needed to remain near his dying son and distraught wife. The Sorenson's son passed away on April 1, 2005.

Going rate for Legal Drug Pushers

SEC filings for Cypress Bioscience provide a good source for estimating how much money legal drug pushers can make each year, from each company, because the names of several appear in these filings. According to its website, “Cypress Bioscience is committed to developing and commercializing pharmaceutical products and personalized medicine laboratory services that allow physicians to serve unmet medical needs.”

Drs Martin Keller and Charles Nemeroff, two of the most prolific depression-mongers, have served on the company’s board of directors, on its scientific advisory board and as consultants for this company. Under their 2004 Consulting Agreements, Cypress was required to pay them $50,000 per year for services rendered up to and including “two days per fiscal quarter.” In addition, the company could request additional services at a rate of $5,000 per day.

During 2003, Dr Nemeroff was paid $19,000 for additional services under his agreement, and Dr Keller was paid an extra $18,000. But they were only making $2,000 per day that year. As members of the Psychopharmacology Advisory Board, Dr Nemeroff earned $19,000 and Dr Keller $18,000 in 2003.

For their service as directors of the company in 2002, they each received $24,000. They were also offered stock options regularly. Cypress is only company. A bio on Dr Keller in a July 25, 2002 agenda for an annual meeting states that he is also a consultant to, "Bristol-Myers Squibb, Eli Lilly, Forest Laboratories, Janssen, Merck, Inc, Organon, Otsuka Pharmacia/Upjohn, Pharmastar, Pfizer, Inc. and Wyeth-Ayerst Laboratories."

It also shows he serves on the scientific advisory boards of, "Bristol-Myers Squibb, Cephalon, Cyberonics, Inc., Eli Lilly, Forest Laboratories, Merck, Inc, Mitsubishi, Organon, Pfizer, Sepracor, Scirex, SmithKline Beecham, Somerse, Vela Pharmaceuticals and Wyeth-Ayerst."

Dr David Dunner and a few more of the usual suspects appear in the Cypress SEC filings as advisory board members as well.

Dr Nemeroff's role in the prostitution of research is legendary. In April 2004, Shannon Brownlee, author of, "Overtreated," wrote an article in the Washington Monthly entitled, "Doctors Without Borders," after he was caught failing to disclose his financial ties to the companies whose treatments he promoted in a paper in Nature Neuroscience, and noted:

"With financial ties to nearly two dozen drug and biotech companies, Dr. Charles B. Nemeroff may hold some sort of record among academic clinicians for the most conflicts of interest.

"A psychiatrist, a prominent researcher, and chairman of the department of psychiatry and behavioral science at Emory University in Atlanta, Nemeroff receives funding for his academic research from Eli Lilly, AstraZeneca, Pfizer, Wyeth-Ayerst--indeed from virtually every pharmaceutical house that manufactures a drug to treat mental illness.

"He also serves as a consultant to drug and biotech companies, owns their stocks, and is a member of several speakers' bureaus, delivering talks--for a fee--to other physicians on behalf of the companies' products."

Dr Nemeroff stood to "reap as much as $1 million in stock" from just one company that manufactured one of the products in his Nature Neuroscience paper, she noted.

"But the drug industry's most powerful means of boosting the bottom line is funding research," Ms Brownlee writes, "which allows companies to control, or at least influence, a great deal of what gets published in the medical journals, effectively turning supposedly objective science into a marketing tool."

She notes how companies are able to routinely delay or prevent the publication of data and specifically how the majority of studies which found antidepressants to be no better than placebos, "never saw print in medical journals."

In conclusion, she states, "I'm struck more than anything by the apparent lack of shame among clinicians when it comes to this issue."

Two years later, on July 19, 2006, the Wall Street Journal reported that the journal, Neuropsychopharmacology, published by the American College of Neuropsychopharmacology (ACNP), planned to publish a correction of a favorable review of a new depression treatment device because it failed to list the ties of the eight academic authors to the device maker, Cyberonics, including lead author Dr Nemeroff, the editor of Neuropsychopharmacology at that time. The FDA had approved the VNS device in July 2005 over the objections of "more than 20" FDA scientists, Bloomberg reported a day earlier on July 18, 2006.

"This is about as classic an example as you'll ever find of conflict of interest and manipulation by thought leaders who are beholden to corporations," Dr Bernard Carroll, a member of the ACNP, told Bloomberg. "This article is a piece of a slick, skillfully coordinated PR campaign directed by the corporation," he said.

Ten days before the Wall Street Journal article, Cyberonics had sponsored a little noticed symposium on treatment-resistant depression at the annual Collegium Internationale Neuro-Psychopharmacologicum Meeting. The main presenters at the July 9, 2006 event were Drs Nemeroff, Dunner, and Keller (the lead author of the infamous Paxil “Study 329” on adolescents).

"In recent years, new treatment modalities have emerged, among them, the only FDA-approved treatment option specifically designed for this patient population, VNS Therapy," Dr Dunner stated in a press release for the event.

Dr Dunner was one of the authors vouching for the new device in the Neuropsychopharmacology paper. However, a “stamp of approval” from this guy should be taken with a grain of salt. Back in March 1995, he also vouched for Paxil as lead author of a study titled, "Reduction of suicidal thoughts with paroxetine in comparison with reference antidepressants and placebo," in the journal of European Neuropsychopharmacology. However, he later admitted that he never reviewed any of the actual data from that study.

Dr Nemeroff apparently learned nothing from the public embarrassment of the previous scandals. Last week, he was forced to step down as Chair of Emory's psychiatry department. According to a December 23, 2008 posting by Ed Silverman, on the popular blog, Pharmalot:

"Under pressure from a US Senate Finance Committee investigation, renowned psychiatrist Charles Nemeroff is giving up the post he held for 17 years and must follow new restrictions on his outside activities, according to an Emory University statement."

"Emory's own investigation found Nemeroff received more than $800,000 from Glaxo, which paid Nemeroff more than any other drugmaker, but he never reported the fees. There were more than 250 speaking engagements between 2000 and 2006."

"Moreover, Emory will not submit any National Institutes of Health grant or other sponsored grant or contract requests in which Nemeroff is listed as an investigator or has any other role for a period of at least two years," Pharmalot reports.

All total, Dr Nemeroff earned more than $2.8 million from drug companies between 2000 and 2007, but failed to disclose at least $1.2 million to Emory, according to the Senator.

Dr Keller's disclosure records are under investigation as well He also appears center stage in a new book by former Boston Globe reporter, Alison Bass, called, "Side Effects: A Prosecutor, a Whistleblower, and a Bestselling Antidepressant on Trial," The book contains a treasure trove of insider revelations with specifics on Dr Keller's endless conflicts of interest, along with other academics on the take. However, Ms Bass first broke the Keller story back on October 4, 1999, in the Globe, when she reported that he was forced to forfeit "hundreds of thousands of dollars" in state grant money in 1998.

She explained how in the same year that Dr Keller authored a review article in "Biological Psychiatry," and concluded that the newer antidepressants Zoloft, Bristol-Meyer's Serzone, and Wyeth's Effexor were more effective, he received $77,400 in personal income and $1.2 million in research funding from Bristol-Myers, as well as $8,785 in personal income from Wyeth.

In "Side Effects," she notes that Dr Keller did not report any income to the IRS from Glaxo for 1998, but says he did receive money from the Paxil maker, and also earned $62,500 from Celexa maker Forest Labs that year.

Dr Keller published 3 studies, "with colleagues," in the Journal of the American Medical Association and the Journal of Clinical Psychiatry, touting the efficacy of Zoloft in 1998, and received $218,000 in personal income and more than $3 million in research funding from Pfizer the same year, Ms Bass reports.

The "colleagues," referred to include the all-time champion of child drugging, Dr Joseph Biederman, the main promoter of the bogus epidemic of childhood bipolar disorder. He too is under investigation for taking $1.6 million from drug companies between 2000 and 2007, and only disclosing a fraction of that amount to Harvard. On December 30, 2008, Harvard's teaching hospital, Massachusetts General announced that Dr Biederman was no longer participating in

several industry-funded trials and had agreed to “not to participate in any outside activities that are paid for or sponsored by industry, such as consulting activities or speaking engagements.”

In most of the SSRI trials conducted on children, "colleagues," will also include Dr Graham Emslie of Prozac fame, and the Zoloft Czar, Dr Karen Wagner, both from the University of Texas.

Back in April 2004, the British Medical Journal published a paper by a research team led by Dr Jon Jureidini, head of the department of psychological medicine at Women's and Children's Hospital in Australia, after a review of the clinical trial data on the safety and efficacy of antidepressant use with children. The review included the published trials, along with some unpublished data made public by the Committee on Safety of Medicines in the UK.

The Australian team was extremely critical of the published papers on the major trials of Prozac, Paxil and Zoloft, with Emslie, Wagner and Keller listed as lead authors. "In discussing their own data," the team wrote, "the authors of all of the four larger studies have exaggerated the benefits, downplayed the harms, or both."

"It is vital," they wrote, "that authors, reviewers, and editors ensure that published interpretations of data are more reasonable and balanced than is the case in the industry-dominated literature on childhood antidepressants."

Seven months later, the New York Times ran a report by Barry Meier on November 29, 2004, throwing another spotlight on the trail of corruption within the SSRI research factories, and zeroed in on Dr Wagner. He noted that, from 1998 to 2001, she was one of several researchers participating in more than a dozen industry-funded pediatric trials of antidepressants and other drugs, and that some of the results were published, but many were not.

In her Zoloft study, Dr Wagner acknowledged that she had received "research support" from several drug makers including Pfizer, which paid $80,000 to the center in connection with the test, Mr Meier reports. But she did not state that she received “sizable payments” from Pfizer for work related to the study, he says.

The same month that patients were first recruited for the Zoloft trial, in a financial filing with the school in December 1992, Dr Wagner reported that she received more than $10,000 from Pfizer, with no further details. A lawyer for the school told Meier that Dr Wagner said Pfizer had paid her $20,500 during the course of the Zoloft trial. But records for payments she received in speaking and consulting fees could not be located.

In September, Dr Wagner’s name was added to the Senator Grassley’s investigative roster, along with Dr John Rush. Between 2000 and 2005, Glaxo alone paid Dr Wagner $160,404, but only $600 was disclosed to the University, according to the Senator. She was also paid over $11,000 in 2002, by Eli Lilly, and that money was not disclosed either. Lilly paid Dr Rush $17,802 in 2001, but he only reported $3,000, Senator Grassley said.

Dr Emslie's financial trail to the drug makers gained media attention last summer due to his prominent role in the "Texas Children's Medication Algorithm Project," and the creation of a drug formularies for children. He was chairman of the panel that wrote guidelines instructing doctors to prescribe SSRIs off-label to kids for depression in 1998. On August 18, 2008, the Dallas Morning News ran the headline: "Conflict of interest fears halt children's mental health project."

"A state mental health plan naming the preferred psychiatric drugs for children has been quietly put on hold over fears drug companies may have given researchers consulting contracts, speakers fees or other perks to help get their products on the list," the News reported. University disclosure forms indicate that Dr Emslie "has made at least $130,000 in drug company speakers fees and consulting contracts since 2002," the paper noted.

In discussing the investigation of Dr Wagner on the Senate floor, Dr Grassley pointed out that she was a co-author on Paxil Study 329. In 2001, when the study was published, Glaxo "reported paying her $18,255," he said. "Study 329 was cited in a New York case where GlaxoSmithKline was charged with 'repeated and persistent fraud,'" the Senator added.

Dr Emslie was also a co-author on the Paxil study and a check of the full list for 329, reveals that 5 of the co-authors appear with Dr Emslie on the guidelines for the "Children's Medication Algorithm Project," including Karen Wagner, Boris Birmaher, Barbara Geller, Neil Ryan and Michael Strober. Dr Rush's name is also on the Texas guidelines but he moved to Singapore last August.