

CCHR:  
EXPOSING THE DANGERS  
OF ANTIDEPRESSANTS AND  
OTHER PSYCHOTROPIC DRUGS—  
DESPITE FDA/PsYCHIATRIC-  
PHARMACEUTICAL COVER-UPS

VESTED INTERESTS INVENTING  
“CHEMICAL IMBALANCE” THEORY TO SELL DRUGS





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# INTRODUCTION: THE ASSAULT ON CONSUMER PROTECTION

*Preamble: In the interests of consumer protection, this report is a history of the cover-up of antidepressant risks and CCHR's vigilant exposure of this and other dangerous psychotropic drugs. Parents, whistleblowers and legislators are also among the many that saw the need to warn others about these drugs and how vested interest groups fought to ensure consumers didn't know the truth. This is a resource document for anyone who wants to know the facts. The report tracks key events spanning 20 years and is a resource for those wanting the facts.*

How far would a multi-billion dollar industry go to protect its interests when threatened with publicity of its knowledge that its products could cause suicide, violence and death? What would it do to silence those that knew the truth and exposed it? Why would a government agency allow such an industry to get away with this, especially at the potential risk of millions of people's lives that they were sworn to protect?

Consider that fraud involves intentional deception or deliberate misrepresentation to secure money, rights, property or privilege. In general terms, fraud means dishonest dealings, cheating or trickery, most often involving money. This is a report on how millions of consumers in the United States and around the world were deceived about medications that they were told corrected a "chemical imbalance" in the brain that doesn't exist. Pharmaceutical manufacturers used the theory to conduct clinical drug trials to produce drugs to treat the "imbalance."

They manufactured drugs for "disorders" catalogued in psychiatry's *Diagnostic and Statistical Manual of Mental Disorders* (DSM) that has never stood the test of science. As a 2006 study determined, 56% of those psychiatrists determining what disorders were included in the DSM were pharmaceutical funded. Based on the DSM, more than \$100 billion of taxpayers' money is expended every year on psychiatric services in the United States, and billions more around the world.

Spurious claims about mental disorders being caused by "chemical imbalances" or "neurobiological dysfunction" are used to convince the U.S. Food and Drug Administration to approve drugs to "treat" them. The agency doesn't require scientific proof of the veracity of these claims. In 2006, FDA Commissioner Dr. Andrew C. von Eschenbach wrote that the FDA relies merely upon the "agreement of those we consider experts" to determine what a "disease" is and the fact that there "are no laboratory tests, to diagnose" mental disorders, for example, "Attention Deficit Hyperactivity Disorder" (ADHD), does not mean that it is not a neurobiological disease.

Imagine a heart surgeon diagnosing a heart defect and performing by-pass surgery without any physical confirmation of irregularity, or an oncologist diagnosing cancer and prescribing chemotherapy based on the "general agreement" that cancer exists but never verifying it with physical tests.

John Read, senior lecturer in psychology at Auckland University in New Zealand stated that "Making lists of behaviors, applying medical-sounding labels to people who engage in them, and then using the presence of those behaviors to prove they have the illness in question is scientifically meaningless. It tells us nothing about causes or solutions. It does, however, create the reassuring feeling that something medical is going on."<sup>1</sup>

While in general medicine medications are developed for existing diseases, in psychiatry

the business is seeking new disorders for existing drugs. Kelly Patricia O'Meara, an award-winning journalist, author and former Congressional staff pointed out, "Drug companies pull a mental disorder out of the DSM hat and get FDA approval to use an already existing drug to treat it. Well-known psychiatrists are enlisted to publicly affirm the disorder as a social problem...Voila! Confirmed psychiatric ill and magic pill."<sup>2</sup>

### Drug Sales vs Consumer Protection

Selective Serotonin Reuptake Inhibitor (SSRI) antidepressants—even *before* they first reached the market in the late 1980s—were known to cause suicide, aggression and other violent behavior. Two years before the FDA approved Prozac there was evidence that the rate of suicide with the drug was more than five times greater than with an existing antidepressant on the market. Two months before the drug was approved, there was evidence of 15 suicides linked to it. Another 12 deaths were also known of. Despite the startling fatalities, the FDA approved the drug on December 29, 1987.

When the Citizens Commission on Human Rights (CCHR) and concerned medical professionals exposed the clear evidence of suicide risk, psychiatry and its pharmaceutical cohorts—protected by the FDA—mounted a well-funded campaign to silence it...especially CCHR. CCHR's disclosure of the potential deadly effects and coverage of this in just one *Wall Street Journal* article led to stock nose diving, with more than \$600 million lost in a single day.

CCHR's exposure of the potentially lethal side effects was so that consumers were given *all* the known information—and if the risks were substantial enough, to remove the drug from the market. It was primarily a consumer protection issue. After all, in 1989, the FDA had recalled the natural amino acid L-tryptophan after being linked to two deaths. L-tryptophan, which acts on serotonin as allegedly Prozac does *unnaturally*, had been in use for years without incident. Despite the fact that the deaths were traced to a single tainted batch, the FDA withdrew L-tryptophan. Why couldn't it do the same with an antidepressant that had 27 deaths linked to it at the time? It had also removed an antidepressant from the market, Merital, because of fatal strokes. But there was much more at stake with Prozac, a best seller within a year of going on the market and sales reaching \$1 billion in 1991.

Steven Gerber, securities analyst with Bateman Eichler told the *Los Angeles Times* in 2002, the sales would have been "substantially higher" were it not for CCHR's campaign.<sup>3</sup>

In 2003, a former executive of the manufacturer of Prozac told The *Hartford Courant* that at the height of the controversy CCHR was generating, the company had an FDA official defending it against exposure of risks in the media, advocating that the antidepressant's risk of suicide was merely a "public relations problem."

Psychiatrists and the American Psychiatric Association—the latter relying upon pharmaceutical funding to survive—preferred consumers didn't have all the facts. In August 1991, the APA issued a press release supporting the FDA's decision not to remove Prozac from the market, claiming that it had "demonstrated its relative safety and effectiveness" and that "depression," not Prozac caused suicide. At the time, more adverse reactions regarding Prozac had been reported to the FDA than any other drug on the market. Since then, an estimated 63,000 people have committed suicide while taking this type of antidepressant.

In 1996, when confronted by a series of CCHR publications mailed to several million



individuals and groups and available to millions more on the Internet, the APA acknowledged the problem of CCHR in a memo dated July 15. It stated: "Their web sites and linked sites are getting more daily 'hits' than ours and, possibly, more than all mental health/psychiatry web sites totaled." It then detailed a list of proposed retaliatory responses.

As this report shows, despite this, CCHR continued to expose the fraud of the "chemical imbalance in the brain" mantra, the dangers of not just antidepressants but also other psychiatric drugs, and the monopoly that psychiatry had on what "treatments" people with mental health problems were supposed to use. It was a 14-year battle, with more and more people recognizing and exposing antidepressant risks, before the FDA finally ordered "black box" warnings that SSRI antidepressants could cause suicide in children and adolescents.

In 2005, the APA's president, Stephen Sharfstein and other psychiatrists were forced to admit there is no lab test to prove a chemical imbalance in the brain causing *any* "mental disorder." The marketing hoax was finally exposed but by then 30 million Americans were taking the drugs. In January 2008, the *New England Journal of Medicine* vindicated CCHR when a study it published revealed the effectiveness of antidepressants had been exaggerated and that many negative studies of the drugs were never published. In fact, the drugs are no more effective than taking placebo (dummy pill).

The following report details the history of the cover-up and the tactics taken by psychiatrists to misdirect consumers and legislators about both the science of their "disorders" and the dangers of the drugs used to treat them. Many of the documents relating to the FDA, CCHR obtained through Freedom of Information Act (FOIA) requests in 1992-1993. Additionally, doctors testifying in civil suits involving antidepressants had access to internal pharmaceutical company documents that were eventually made public.

Sincerely,

Jan Eastgate  
International President

# CHAPTER ONE: PRE-PROZAC APPROVAL

**1978:** Although this information would not be made known until 200 lawsuits were filed in relation to the new antidepressant, Prozac, in the 1990s, the manufacturer, Eli Lilly's own documents showed that as early as 1978-10 years before its approval in the U.S.—that in some patients, Prozac induced agitation, psychosis, akathisia [from Greek *a* – meaning “without” or “not” and *kathisia* meaning “sitting” that can be accompanied by violent outbursts] and restlessness—which can be precursors of suicide: “There have been a fairly large number of reports of adverse reactions... Another depressed patient developed psychosis... Akathisia and restlessness were reported in some patients... Some patients have converted from severe depression to agitation within a few days; in one case the agitation was marked and the patient had to be taken off [the] drug...” As a precautionary measure, the company added tranquilizers (benzodiazepines) “to control future agitation” in future pre-marketing trials.<sup>4</sup>

Three placebo-controlled studies were provided for the FDA to approve Prozac, the first SSRI (Selective Serotonin Reuptake Inhibitor) antidepressant. One demonstrated no effect, while the second, called Protocol 27, where Prozac was compared to imipramine (an older antidepressant) and placebo, found Prozac to be inferior in effectiveness. The third study, involving only 11 people and only five weeks in duration, found a positive result. The manufacturer, Eli Lilly, determined the score was two to one in favor of Prozac.<sup>5</sup>

**September 13, 1984:** Dr. Frances O. Kelsey, Director of Division of Scientific Investigations, Office of Compliance at the FDA, wrote to some of the investigators on Protocol 27, citing violations in the clinical trials.

**November 13, 1984:** Tony DeCicco, FDA Consumer Safety Officer, recorded the minutes of an in-house FDA meeting that discussed Prozac and stated: “This agency has discovered a flaw in the experimental design and execution of the fluoxetine [Prozac] studies” and that the way the studies were conducted could lead to “a biased comparison.”

**November 13, 1984:** In a FDA Memorandum, it stated, “This Agency must inform Lilly early on, that we have problems with their analysis because of the large number of dropouts.” Dr. David Graham, an epidemiologist with the FDA stated, “The firm’s analysis of suicidality does not resolve the issue.” According to this same document, even “Lilly acknowledged that its clinical trials were not designed to study this and that the quality and specificity of data to be gleaned from these trial to address suicidality were poor...” Dr. Graham concluded that “because of apparent large-scale under reporting, the firm’s analysis cannot be considered as proving that fluoxetine and violent behavior are unrelated.”<sup>6</sup>

**March 1985:** An FDA memo showed that J. Hillary Lee, the FDA’s Efficacy Reviewer for Prozac, expressed concerns over Eli Lilly instructing their investigating physicians not to include symptoms of depression manifesting in their patients during their clinical trials as adverse reactions. In the review of Protocol 27, for example, Lee analyzed six studies that comprised this it and determined that one could not be included; one demonstrated that Prozac was only slightly more effective than placebo, while four studies showed it to be no more effective than placebo.

**March 29, 1985:** An Eli Lilly memo admitted a rate of suicide for Prozac to be 5.6 times higher than for the older tricyclic antidepressant, imipramine.<sup>7</sup> “The benefits vs. risks



considerations for fluoxetine [Prozac] currently does not fall clearly in favor of the benefits. Therefore, it is of greatest importance that it be determined whether there is a particular subgroup of patients who respond better to fluoxetine (Prozac) than to imipramine, so that higher incidence of suicide attempts may be tolerable.”<sup>8</sup>

German authorities expressed concern about Prozac causing akathisia and suicide.<sup>9</sup>

**May 1985:** A memo by the FDA’s Safety Reviewer Richard Kapit stated, “It is fluoxetine’s particular profile of adverse side effects which may perhaps, in the future give rise to the greatest clinical liabilities in the use of this medication to treat depression.”<sup>10</sup>

**March 23, 1986:** Dr. Kapit’s review of the Prozac New Drug Application (NDA) found additional adverse reactions that the manufacturer had not submitted. These “involved the onset of an unreported psychotic episode,” “may exacerbate certain depressive symptoms” and “potential risks include intensification of the vegetative signs and symptoms of depression.”<sup>11</sup> There were 10 reports of psychotic episodes, 2 reports of completed suicides, 13 attempted suicides, 4 seizures—including in a healthy volunteer, and 4 reports of movement disorders.<sup>12</sup>

## 1987

The German BGA, the country’s FDA equivalent, refused to approve Prozac based on Lilly’s studies showing that previously non-suicidal patients who took the drug had a *fivefold higher rate of suicides and suicide attempts* than those taking older antidepressants, and a threefold higher rate than those taking placebos.

**May:** The American Psychiatric Association updated its *Diagnostic and Statistical Manual*, adding another 29 “mental disorders” bringing the total to 253. The DSM-II, published in 1980, added 61 new disorders. Since its 1994 edition, there has been a 256% increase in antipsychotic and antidepressant drug sales.

**September 14:** An FDA “Safety Update Segment 3” report on adverse reactions, deaths and potentially serious events recorded 5,620 patients treated with fluoxetine in the U.S. and 7,948 on the worldwide database. There were 13 deaths reported worldwide, attributing them mostly to physical conditions, of which 8 deaths were “apparent suicides.”<sup>13</sup>

**December 17:** In a memo, the FDA’s Consumer Safety Officer Arthur K. Yellin noted, “Lilly representatives advised that they very intentionally wished to refrain from promoting this aspect [anorexia] of Prozac at this time” that the FDA agreed to.<sup>14</sup> A memo from Dr. Kapit of the same date, references 4 cardiac-related deaths, “30 cases of mania, hypomania, or manic psychosis reported. Twenty of these cases were discontinued as a result of these adverse effects... There were 18 patients who took overdoses of fluoxetine, less than 1000 mg....”<sup>15</sup>

**December 29:** The FDA approved Prozac for the market.

**December 30:** The FDA’s Neuropharmacological Drug Division, under the leadership of psychiatrist Paul Leber, approved Prozac for the market.<sup>16</sup> By October 1989, there were 5,740 adverse reactions reported to the FDA. As CCHR would report, in contrast the antidepressant Elavil, which had been on the market for 20 years, accumulated 2,923 adverse reaction reports as of November 1989—nearly twice as many reports on Prozac as there were on Elavil in less than one-tenth of the time.<sup>17</sup>

# CHAPTER TWO: DENYING CONSUMERS THE TRUTH

## 1988

**January 20:** Memo by FDA's Safety Reviewer Richard Kapit said that he had contacted the clinical research division of Eli Lilly about four unreported seizures suffered by people taking fluoxetine. Kapit said it was an error that it was not reported.<sup>18</sup>

## 1989

**September 14:** Joseph Wesbecker of Louisville, Kentucky, while under the influence of Prozac, gunned down 8 co-workers and wounded 12 others before killing himself at the Standard Gravure printing plant. Three days prior, Wesbecker's psychiatrist described him as exhibiting an "increased level of agitation and anger," adding, "Plan—Discontinue Prozac which may be cause."

**September:** A published medical report estimated that between 10% and 25% of Prozac users experienced akathisia, making it a "common" side effect, while Eli Lilly's product information only acknowledged that the condition occurs in less than 1%.<sup>19</sup> (Akathisia: *a*, without; *kathisia*, sitting; an inability to keep still, a severe restlessness that can cause agitation and psychosis.)

**October-November:** The coroner's inquest into the Wesbecker killings was held, at which CCHR testified about psychiatric drugs causing violence. Coroner Dr. Richard Greathouse determined that Wesbecker had a "high therapeutic level" of Prozac in his blood. The jury ruled that "the effects of the drugs...may have been a contributory factor" to the rampage. Dr. Greathouse stated, "...Prozac in certain individuals has caused a violent hostile type of reaction."<sup>20</sup>

## 1990

CCHR did hundreds of media interviews throughout 1990 about the dangers of the new antidepressant and how it could drive users to commit murder.

**January 30:** Eli Lilly letter to sales representatives gave them a "heads up" on the upcoming Dr. Martin Teicher study (see next entry), stating, "Because these issues (suicide) are not part of our current marketing plan, you should not initiate discussions on these articles...."<sup>21</sup>

**February:** Medical studies reported violent and suicidal reactions in people taking Prozac. Dr. Martin Teicher from Harvard Medical School described how Prozac could generate "intense, violent suicidal thoughts" in a significant portion of persons taking it.<sup>22</sup>

**February 7:** In a memo, Leigh Thompson, group vice president of Lilly Research Laboratories, stated, "Anything that happens in the UK can threaten this drug in the U.S. and worldwide. We are now expending enormous efforts fending off attacks because of (1) relationship to murder and (2) inducing suicidal ideation."<sup>23</sup> Further, "I'm concerned about reports I get re UK attitude toward Prozac safety...I hope Patrick (a Lilly medical director in Britain) realizes that Lilly can go down the tubes if we lose Prozac and just one [adverse reaction] event in the UK can cost us that."<sup>24</sup> Thompson also said that although the FDA's Paul Leber is "a fan of Prozac and believes a lot of this is garbage [suicidal reactions], he is clearly a political creature and will need to respond to pressures."<sup>25</sup> [See July 30, 1990 entry]



**March:** CCHR met with Chief Counsel and Staff Director of the U.S. Congressional Subcommittee on Oversight and Investigations, providing research on antidepressants causing violence and suicide and requesting an investigation.

**May 4:** Max W. Talbott Ph.D., Lilly Regulatory Affairs Associate, told the FDA that following phone conversations with the agency over Prozac causing violent, aggressive acts, Lilly would submit a summary of its findings but ultimately claimed that Prozac did not cause such behavior.

**May 15:** The Prozac Survivors Support Group (PSSG) formed to expose the risk of antidepressants.

**May 29:** Eli Lilly changed its Prozac product information sheet to add the term “suicidal ideation” in the small print of the section dealing with post-marketing reports.<sup>26</sup>

**July 17:** Prozac victim Ronda Hala filed the first lawsuit to charge that Prozac could drive someone intensely suicidal and self-destructive.<sup>27</sup> She suffered acute *akathisia*, a drug-induced nervous restlessness associated with violent behavior. She said it caused her to mutilate herself, gouge her flesh with any sharp instrument she could lay her hands on: screws, scissors, shower hooks, carpet tacks, razors, and pens. “I had to hurt,” Hala told *Newsweek*. “You sit down and every nerve in your body has to move. You feel like you’re going to jump right out of your skin.”<sup>28</sup>

**July 18:** Dr. Leigh Thompson spoke with the principal FDA regulator, Paul Leber (director of the FDA’s Neuropharmacological Drug Division) at 6:15 in the morning about the issue of suicide and Prozac and the desirability for study data to complement anticipated testimony from “experts on suicide” so that would match chronologies. Another memo of the same date showed the strategy was to conduct studies to put a “cap on the frequency of suicidal ideation.” When two members of the media called Leber about the possible risk of suicide with Prozac, his response was, “I trashed the idea.”<sup>29</sup>

**July 18:** *The Wall Street Journal* reported that CCHR was collecting reports of Prozac adverse reactions.

**July 30:** Paul Leber of the FDA told *TIME* magazine: “Even if we got several hundred reports involving suicide and Prozac, we wouldn’t be alarmed...Depressed people commit suicide.”

**July:** An Eli Lilly executive circulated an internal memo stating that Paul Leber as dismissing press coverage of suicide concerns as “trivial.” In another memo Lilly’s Leigh Thompson recommended that Lilly rent space in a building next to Leber’s Washington office so secure communication about Prozac to the FDA could be ensured. Thompson spoke to Leber as often as three times a week during the controversy that CCHR was generating. “Paul Leber was our defender against all of the attacks in the media,” Thompson said. “The Scientologists were really after us and the simplest thing for [the FDA] to do would have been to pull it off the market—and they didn’t.”<sup>30</sup>

**July 24:** CCHR petitioned the Chairman of the U.S. House of Representative’s Subcommittee on Oversight and Investigations to remove Prozac from the market because of its risks. *The Wall Street Journal* reported this on July 27, 1990.

**July 31:** The FDA issued a “Talk Paper” defending Prozac and said the agency had no reported cases of (“intense, violent suicidal thoughts”) similar to those described by Dr. Martin Teicher in his study. [See February 1990 entry]

**August 3:** An internal Eli Lilly letter to sales representatives advised them how to answer questions about Prozac causing suicidal ideation, stating, “You should not initiate discussion on these issues” but if asked, “reassure the healthcare professional that no causal relationship has been established between suicidal ideation and Prozac therapy.”<sup>31</sup> [Letter was not released until 1999 in a civil suit.]

**August 8:** CCHR responded to the FDA’s “Talk Paper” to FDA Commissioner James S. Benson demanding that consumers know the truth: “In the last eight months, the number of voluntary reports to the FDA of suicide attempts by people taking Prozac had increased 372%...The FDA is now allowing Americans to die with the perverted defense that people who take Prozac are ‘depressed’....the FDA uses this to disguise the fact that people become suicidal while taking Prozac and then kill themselves, and in too many reported cases kill others....” It provided comparisons: In **31 months**, over 9,973 adverse reports on Prozac had been reported to the FDA while over a **20-year** period, 6,343 reports of adverse reactions on Valium had been reported and 2,923 reports on the antidepressant drug Elavil (Prozac’s prime competitor).<sup>32</sup>

**August 9:** CCHR presented further submissions to members of Congress calling for action to be taken.

**August 31:** Eli Lilly sends a “Dear Doctor” letter assuring the doctors that there is no “causal relationship between Prozac and suicidality.”<sup>33</sup>

**September 11:** Dr. David Graham, section chief of the FDA’s Epidemiology [determining causes, distribution and controlling spread of diseases] Branch, wrote that he had reviewed data from the clinical trials for Prozac and found that they “were not designed for the prospective evaluation of suicidality.” He said, “Treatment-emergent [i.e., new] suicidality was more frequent among” patients taking Prozac than among those receiving, older, tricyclic antidepressants. Graham noted, “...the firm’s analysis cannot be considered as proving that Prozac and violent behavior are unrelated.”<sup>34</sup> The FDA ignored his concerns.

**September 12:** A Leigh Thompson (Eli Lilly) memo indicated that Paul Leber (FDA) was under pressure within the FDA to add a warning to Prozac’s product information before the FDA could hold a hearing on the matter of suicidality.<sup>35</sup>

**September 14:** Dr. Thompson also told Eli Lilly’s Board of Directors that suicide and acts of violence were, in all probability, causally related to the patients’ underlying mental disorder, while Lilly staff were concerned that the issue was never studied during the clinical trials.<sup>36</sup> In another memo, John Heiligenstein of Eli Lilly told Thompson, “We feel caution should be exercised in a statement that ‘suicidality and hostile acts in patients taking Prozac reflect the patient’s disorder and not a causal relationship to Prozac...Postmarketing reports are increasingly fuzzy and we have assigned “Yes, reasonably related” on several reports’...’You may want to note that trials were not intended to address issue of suicidality.”<sup>37</sup>

**September 25:** FDA Meeting Minutes written by Paul A. David, Consumer Safety Officer, to FDA members and Eli Lilly executives about post marketing safety



experience with Prozac, in which it was stated that suicidal behavior was of concern. Leigh Thompson from Eli Lilly said there was no “correlation between suicide and Prozac.” It was recommended that Lilly hold a symposium on suicidality with the National Institute of Mental Health.<sup>38</sup> Essentially it ignored Dr. Graham’s findings of September 11.<sup>39</sup>

**October 2:** A Leigh Thompson memo to Lilly employee Robert Zerbe regarding the prospective suicidality symposium noted, “Then the question is what to do with the ‘big’ numbers on suicidality. If the report numbers are shown next to those for nausea, they seem small.”<sup>40</sup>

**October:** Thomas Donnelly, an executive from the then SmithKline Beecham (now GlaxoSmithKline), manufacturer of the antidepressant Paxil (paroxetine), circulated a memo recounting a telephone conversation with the FDA official, Dr. Martin Brecher, who was performing the government’s study of Paxil’s safety and requested information on any potential suicide risk. He said that Brecher and the FDA did not “see it as a real issue” and instead considered the concerns a “public relations problem.”<sup>41</sup>

**October 11:** CCHR submitted a Citizen’s Petition to the FDA outlining the evidence showing that Prozac drove persons violently insane and called for withdrawal of the drug from the market to protect consumers. In an addendum dated November 1, CCHR submitted that the antidepressant was also addictive.

**November 13:** Eli Lilly requested that its company in Germany change the adverse drug event “suicidal ideation” to say “depression” when reporting to the BGA (German equivalent to the FDA). A memo from Claude Bouchy of Lilly in Germany responded, “I do not think I could explain to a BGA, a judge, to a reporter or even to my family why we would do this, especially on the sensitive issue of suicide and suicidal ideation.”<sup>42</sup> [Letter not released until 1999 during a civil suit.] In another memo, Leigh Thompson wrote, “I’d suggest that we (1) protect Prozac....”<sup>43</sup>

During the year, a study conducted at the University of Pittsburgh Medical School was also published documenting a new drug, “Lovan” as effective for weight reduction. Lovan was fluoxetine — triple strength Prozac marketed a weight loss pill.<sup>44</sup> If approved the drug would have reaped Eli Lilly \$55 million in 1991. In 1994, Lilly withdrew its New Drug Application in the United States for Lovan.<sup>45</sup>

# CHAPTER THREE:

## THE CONFLICTS OF INTEREST INCREASE

1991

**January 10:** Illinois Chief Judge William A. Lewis wrote of having sentenced a Larry Walters to probation for the second degree murder of his father saying that the father was on Prozac which possibly caused him to go on an extremely violent rampage resulting in his son killing him in self defense.

**January 31:** Dr. Thomas Kurt of the FDA's Southwest Region alerted the FDA headquarters in a memo about "Ten Deaths While on Prozac (fluoxetine) in Dallas County in One Year."<sup>46</sup>

**February 7:** Three medical doctors reported in *The New England Journal of Medicine* patients "in whom suicidal ideation and fluoxetine [Prozac] treatment were strongly associated." A 58-year-old man "was started on fluoxetine (20 mg/day). Three days later he had violent suicidal thoughts and tried to hang himself with a rope. The fluoxetine was discontinued, with a complete disappearance of suicidal ideation four days later."<sup>47</sup>

**March 29:** Dr. Thomas Laughren, head of the Psychiatric Drug Products Division of the FDA wrote a memo clarifying the question of suicidality in association with Prozac and acknowledged that the issue was raised by CCHR in its Citizens Petition where there were occurrences of depression/suicidal ideation in *non-depressed* individuals being treated with the drug. He recommended that the product information sheet for Prozac include a statement about suicidal thoughts.<sup>48</sup>

**March:** Robert A. King, M.D., and others of Yale University School of Medicine published a study in the *Journal of the American Academy of Child and Adolescent Psychiatry* regarding the emergence of intense self-injurious behavior found in six adolescents aged 10 to 17 years old taking Prozac.<sup>49</sup>

**April 1:** Leigh Thompson defended reports that Prozac caused violence, blaming the reaction instead on mental illness.<sup>50</sup> With Prozac sales reaching \$1 billion, the drug was protected, despite the risks to individual and public safety.<sup>51</sup> [See September 14, 1990 entry]

**April 15:** Memo to Leigh Thompson about upcoming TV appearance on 20/20, headed "MESSAGE GOALS—Whatever questions you are asked or direction the interview [sic] take, the three points that we want to establish are: (2) 'It's in the disease, not the drug.'... 'If pressed, or as a postscript to the above, then make the point that absolutely no evidence indicates that PROZAC as a cause of such behavior [suicide and violence]....'"<sup>52</sup>

**May:** Alan Gelberg, Acting Chief of the Surveillance & Data Processing Branch of the FDA, stated: "Since marketed in 1988, by Eli Lilly, Prozac (fluoxetine) has had the highest number of adverse event reports submitted to the FDA National Adverse Drug Reaction Reporting (ADR) System database. The database dates back to 1969. In 1990, Prozac had the largest number of reports." [By September 15, 1993, the FDA ADR Database had logged over 28,600 adverse reaction reports on Prozac.]<sup>53</sup>

**May:** Dr. William Wirshing, a UCLA psychiatrist, reported to the annual meeting of the American Psychiatric Association (APA) that five patients appeared to have



developed *akathisia* from Prozac. Dr. Wirshing believed the akathisia had “led them all to contemplate suicide.”<sup>54</sup>

**May 9:** The national ABC TV show Prime Time ran a story on Prozac, titled, “What made them do it?” in which Leigh Thompson denied that the drug could cause suicide or violence.

**June 3:** CCHR wrote to FDA Commissioner Dr. David Kessler about Prozac having more ADRs than any other drug. Since December 1989, more than 3,000 people had reported to CCHR alone adverse reactions associated with Prozac, including suicidal thoughts and behaviors, hostility, violence, self-mutilation, agitation, and psychosis. CCHR had also recorded that persons taking the drug had murdered more than 34 people. [See June 2, 1993 entry re: Kessler’s admission that only 1% of adverse reactions were reported to the FDA.]

**June 18:** Eli Lilly’s Leigh Thompson told The Indianapolis News that there were “scientific” ways to determine if a patient was likely to kill him or herself and that the company was working with NIMH and the FDA on developing a suicide assessment scale.<sup>55</sup> [See September 25, 1990 entry.] However, all suicide assessments are based on subjective, not scientific-based questions.

**July 26:** The FDA denied CCHR’s Citizens Petition, claiming that Prozac was safe and effective and “we do not believe there is evidence that Prozac causes suicidality or other violent thinking or behavior.”<sup>56</sup> However, it agreed to “convene a meeting of its Psychopharmacological Drugs Advisory Committee [PDAC] to consider the issue of suicidality associated with antidepressant drugs, including Prozac.”

**August 7:** CCHR wrote to Dr. Louis W. Sullivan, Secretary of the Department of Health and Human Services requesting an investigation into why the FDA had dismissed the ADRs on Prozac and why its “Talk Paper” was released to Eli Lilly and other psychiatric trade organizations in advance of its public release to prepare a response, while the same opportunity was not given CCHR.<sup>57</sup>

**August 8:** FDA “Minutes of Meeting re: Prozac” written by Paul A. David, R.Ph., Consumer Safety Officer. Meeting was sponsored by Eli Lilly and attended by FDA officials Dr. Paul Leber, Dr. Thomas Laughren, Dr. C. Arnello and Paul David to discuss the upcoming PDAC hearing on September 20. Dr. Leber said the hearing was to provide “full public scrutiny” and Commission discussion about the allegations of violence and suicide linked to antidepressants. Leber wanted it stressed that because of the high number of all adverse reactions reported on Prozac (15,000), that there should be a presentation on the limitations of Spontaneous Reporting System (SRS) to the FDA. Dr. C. Anello disagreed. The memo stated, “In view of the importance attached by critics of Prozac to the volume of reports received, Dr. Leber urged Dr. Arnello to reconsider, but agreement on this issue was not reached.” The SRS’s Department of Epidemiology and Surveillance (DES) was urged to review all reports of completed suicide but it was decided in advance of the PDAC hearing that, “the review would most likely lead to a conclusion that the information was inadequate to support such an assessment, but substantiation of this point would be useful.”<sup>58</sup>

**August 23:** CCHR filed a complaint with FDA Commissioner Dr. David A. Kessler about the FDA planning to only hold a one-hour hearing to review the concerns about

Prozac and requested the PDAC hearing be extended to a full day. [Subsequently extended to one day]

**September 10:** CCHR wrote Dr. Kessler about the conflicts of interest in the upcoming PDAC hearing detailing the financial links between its psychiatric members and drug manufacturers, including Eli Lilly, Sandoz, SmithKline Beecham, Merck, Bristol Meyers Squibb and Pfizer. Nine out of 10 panel members had financial conflicts regarding antidepressants, with 8 being psychiatrists, those most likely to make a living by prescribing antidepressants. This included Dr. David Dunner who had financial interests totaling a half million dollars. CCHR found that Dunner's conflict of interest waiver with the FDA failed to disclose two pending grants worth \$250,000 from two pharmaceutical companies and that he had a series of engagements to speak at a series of seminars funded by Eli Lilly. He had also received more than \$4 million in research grants from antidepressant manufacturers in the 8 years preceding the FDA hearing. The tenth panel member was a psychologist in the department of psychiatry at the University of Pittsburgh who was also a member of the Scientific Council of the National Alliance for Research on Schizophrenia and Depression, an organization heavily backed by drug companies.<sup>59</sup>

**September 20:** The FDA's PDAC held a hearing into antidepressants causing suicidal ideation/behavior in patients and whether a package insert should warn the drug could cause suicidal behavior. CCHR presented evidence along with dozens of antidepressant victims. The evidence given by patients and their families to the FDA hearing was dismissed as anecdotal. Dr. Martin Teicher, who had slides that showed how Prozac could cause suicidality, was denied the right to present this evidence. Psychiatrists representing Eli Lilly made half of the formal presentations on the agenda, even though the FDA's memo on the potential conflicts of interest said that the committee would not be dealing with or reviewing any specific drug or sponsor (manufacturer). Psychiatrists warned PDAC that any changes in Prozac labeling would undermine the public's confidence in psychiatric drugs.<sup>60</sup> The committee voted unanimously that antidepressants did not cause suicide and violent behavior. [Dr. David Dunner—see above entry—while not participating in the actual vote, was an advisory member.]

**October 3:** Dr. Robert Temple, Director of the Office of Drug Evaluation and Research, Department of Health and Human Services responded to CCHR's letter of August 7, and, not surprising, supported the findings of the PDAC hearing, which he had attended. Documents later obtained through the Freedom of Information Act revealed that Lilly's clinical studies that were presented to the 1991 FDA hearing were known to be "inadequate."<sup>61</sup> Dr. Temple was senior to the Division of Neuropharmacological Drug Products, headed by Paul Leber. In 1984, Dr. Temple had approved another antidepressant, Merital, for use, but six months later the drug was withdrawn from the market because of fatal strokes and hemolytic anemia—the excessive destruction (for example by chemical poisoning) of red blood cells. The manufacturer was criminally prosecuted for failing to report deaths and adverse reactions.<sup>62</sup> Temple later testified before a Congressional hearing that the FDA knew the drug had risks, but he believed the "benefits" outweighed these. "Most, marketed antidepressant drugs are known to be associated with multiple risks, some of them quite serious and also potentially fatal."

**October:** In the U.S., "National Depression Screening Day" began as an annual October event, funded with a grant from Eli Lilly. Thousands of sites in hospitals,



corporations and universities around the country provided free “depression” screening that involved people answering a subjective questionnaire lasting less than 5 minutes. They then watched a video on how “treatable” depression was.<sup>63</sup>

**December:** In a Harvard Medical School study, published in *The Journal of Clinical Psychiatry*, the researchers noted, three “depressed” inpatients that had attempted suicide while taking Prozac, were recommenced on the drug. In each case, they developed akathisia and commented that it was the same syndrome that precipitated their earlier suicide attempt. They again developed suicidal ideation, which abated only when they were discontinued on Prozac.<sup>64</sup>

# CHAPTER FOUR: USING FREEDOM OF INFORMATION TO ACCESS THE FACTS

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## 1992

**January:** The FDA approved Zoloft for the market.

**March 22:** CCHR filed a complaint with F. Gary Davis, General Counsel for the Office of Government Ethics about the conflicts of interest in the FDA PDAC committee panel and requested an investigation.

**May 18:** Linda Little, Inspector, Criminal Investigations Division responded that the matter had been referred to the Washington Field Office for investigation.

**June 23:** CCHR filed an FOIA request with the FDA for copies of all records, notes, electronic in format or other information in the custody or control of the FDA concerning Prozac, including all applications made by the manufacturer, its studies, and all information submitted in support of the application, all internal memoranda, reports, letters, phone call memoranda, records etc., all information given the FDA on adverse reactions relating to the drug.

**July 9:** The Center for Drug Evaluation and Research responded to the FOIA releasing several thousand pages of documents, although the bulk of this was made up of the adverse reactions. The other internal memoranda barely scratched the surface of CCHR's request. The FDA claimed that it was not required by law to release certain of the documents being sought by CCHR.

**July 28:** CCHR appealed the FDA's denial of documents, but the agency failed to respond to the appeal in a timely manner.

**August 7:** CCHR received a letter from Mr. John P. Dempster, Director, Compliance Branch, Department of Health & Human Services, stating that in relation to the Prozac request, "certain material has been deleted from the record(s) furnished to you...."

**August 21:** A Los Angeles Federal judge ordered GSK to stop advertising Paxil as not habit forming.<sup>65</sup> GSK appealed and on September 4, the FDA presented a brief to the court in which it urged the court to reconsider the injunction. In June 2003, however, GSK removed product information labels stating that Paxil was not habit-forming.<sup>66</sup>

**October:** CCHR filed a suit to get full disclosure of the documents.

**December 9:** The National Academy of Science's Institute of Medicine published the results of its study of FDA advisory committees and called for the FDA to take steps to avoid conflicts of interest associated with its advisory committee members. It referenced the PDAC hearing into Prozac and PDAC members that had received \$760,790 in grants from drug companies.<sup>67</sup>

**December:** The SSRI antidepressant Paxil introduced to the United States.<sup>68</sup>

## 1993

**March 1:** The FDA changed its Spontaneous Reporting System entries on adverse reactions (ADRs) to delete all medical reporters' comments about the patient. Where once consumers could be informed that a drug caused a suicidal or violent reaction



in someone with no history of such behavior, this information was to be deleted. For example, a June 20, 1991 ADR report showed a 15-year-old girl hospitalized for an attempted suicide (overdose) after being on Prozac for a month and specified that she, "...did not have a history of suicidal thoughts prior to Prozac." Further, "Prozac was dc'd [discontinued] and pt [patient] fully recovered." However, the same entry after the change in the reporting system omitted this crucial information. The same ADR, dated September 15, 1993, stated only that there was a suicide attempt and hospitalization.<sup>69</sup>

**May:** A study published in the *Journal of The American Medical Association* reported that of 128 pregnancies where the mother took Prozac during the first trimester, the risk of miscarriage was 14.8% compared to 7.8% in mothers not exposed to fluoxetine or tricyclic antidepressants. There were 19 spontaneous abortions and 13 anomalies (abnormalities), including heart and small intestine defects in the group whose mothers used Prozac. One baby was born with clubfeet, and a second with a congenital dislocation of the hip. In comparison, there were 10 spontaneous abortions and 4 anomalies in the control group.<sup>70</sup>

**May 25:** CCHR filed a complaint with Brian Mitchell, Principal Deputy Inspector General of Health and Human Services about the flaws in the FDA approval of Prozac that CCHR had evidence of from the documents it had received through its FOIA request. Further, the ADRs had revealed over 1,300 deaths.

**June 2:** FDA Commissioner David Kessler reported in *The Journal of the American Medical Association*, "Although the FDA receives many adverse event reports, these probably represent only a fraction of the serious adverse events encountered by providers.... Only about 1% of serious events are reported to the FDA...."<sup>71</sup> Therefore, the ADRs for Prozac were likely to be 100 times greater.

**July 26:** CCHR wrote to Congressman Dan Schaefer regarding the FDA's questionable procedures in approving Prozac, including FDA having prior knowledge of clinical trial deaths. CCHR requested an "unbiased look" into the matter.

**August:** The FDA ADRs that CCHR received for Prozac between 1988 and August 1993 revealed physicians had reported 28,564 adverse reactions, including 659 infants and youths between the ages of 1 and 18 who suffered 1,332 adverse reactions and 34 children and adolescents between the ages of 5 and 18 that died, including two 5-year-olds that had committed suicide. At least 83 children between the ages of 4 and 18 had attempted suicide.<sup>72</sup> [June 2, 1993 entry shows this potentially represented only 1% of the actual number of ADRs.]

**November 2:** CCHR filed a complaint to FDA Commissioner David Kessler about Prozac being advertised through a Business Wire to treat conditions for which it was not FDA approved, violating federal regulations for "Prescription Drug Advertising."

**November 10:** In the *Journal of the American Medical Association*, Eli Lilly reported that there was a 15.9% risk of spontaneous abortion in women taking Prozac during pregnancy and 3.4% risk of perinatal (around birth) malformations. Its database recorded 1,103 women taking Prozac during pregnancy.<sup>73</sup>

**December 13:** CCHR filed a complaint with the Inspector General of the Dept of Health and Human Services along with an analysis of the adverse reactions of Prozac, requesting action to be taken against the FDA's failure to protect consumers.<sup>74</sup>

## 1994

During the year, Pfizer paid for the development of "Prime MD," a checklist of symptoms based on the DSM that physicians checked off to supposedly identify anxiety, depression, substance abuse and other disorders in order to make a "diagnosis" in an average of 8 minutes. Professors Herb Kutchins and Stuart A. Kirk, author of *Making Us Crazy*, called it "the Alaskan pipeline for the pharmaceuticals, a method of gaining direct access to an immense new market."<sup>75</sup> The fourth edition of the DSM was released with an emphasis on a "biological" basis for mental disorders, despite no evidence to support this, making it easier for drugs to be approved for "treatment" of them. Yet, DSM-IV contained this "Cautionary Statement" to conceal the fact that the 1,000 experts used in the development of the manual could not define what a mental disorder is and could not provide scientific support for one: "The specific diagnostic criteria for each mental disorder are offered as guidelines for making diagnoses, because it has been demonstrated that the use of such criteria enhances agreement among clinicians and investigators...These diagnostic criteria...reflect a consensus of current formulations of evolving knowledge in our field." In other words, it was a consensus of opinions, not medical fact.<sup>76</sup>

A study by Dr. David Healy of the Department of Psychological Medicine, North Wales Hospital, entitled, "The Fluoxetine and Suicide Controversy: A Review of the Evidence" confirmed that Prozac "may lead to the emergence of suicidal ideation."<sup>77</sup>

**January 14:** The Inspector General of Health and Human Services responded to CCHR stating that it did not have the expertise to investigate the FDA.<sup>78</sup> Instead, the complaint was referred to Dr. Robert Temple, Director of the Office of the FDA's Drug Evaluation and one of the officials, who had already endorsed the September 20, 1991 PDAC hearing findings that there was nothing wrong with Prozac and was one of the original FDA members that *originally approved Prozac for the market as safe*. [See October 3, 1991 entry.]

**March 15:** Dr. Temple's response to CCHR merely reiterated that there was nothing wrong with Prozac.<sup>79</sup>

**March 26:** FDA Safety Reviewer, Andrew Mosholder, M.D., presented evidence to the FDA PDAC hearing into Prozac that during the clinical trials of a drug for "bulimia" (an "eating disorder") *7 people died, 4 by suicide*. No autopsies were conducted in the Eli Lilly-controlled studies. In their package information for Prozac, the manufacturer reported that 9% of patients during the clinical trials developed anorexia. In a New Drug Application report obtained under the Freedom of Information Act, this side effect was noted as "significant." According to the ADRs, at least 20 children suffered anorexia or weight loss, with the majority of these aged between 13 and 18. Despite this, the PDAC recommended that Prozac be approved for the treatment of bulimia.<sup>80</sup>

**May:** CCHR produced a White Paper titled "CHILD ABUSE WITH PROZAC" that outlined the ADRs showing children attempting or committing suicide while taking Prozac and that the drug should not be approved for pediatric use. This was sent to



the FDA and various Congressional committees. Further, it reported that the FDA had received ADRs showing birth defects in babies born to women taking Prozac during pregnancy. There were 17 reports of babies being born with a congenital anomaly (abnormalities). Of these, 2 died and 13 were hospitalized. There were four infant deaths in relation to Prozac where the mother had either taken Prozac during or before pregnancy: 1 was stillborn, a 6-month-old died after having been prematurely born and 2 died from congenital deformities. Another 4-month-old baby was reported as suffering “drug dependence, dystonia (movement disorder), overdose and convulsions.” A newborn suffered drug withdrawal symptoms within 24 hours of delivery.

**May:** The APA updated its *Diagnostic and Statistical Manual*, adding 21 new “mental disorders” bringing the total to 374—a goldmine of new “disorders” for which new psychiatric drugs could be developed. By 1994, there were 32 childhood “psychiatric disorders” for which antidepressants, stimulants and antipsychotics could be prescribed. The DSM-IV listed 1,000 consultants that could not agree on a definitive definition of mental disorder.<sup>81</sup>

**May 20:** In the *Psychiatric News*, Donald Klein, professor of psychiatry at Columbia University commented on the lack of studies into the potentially damaging effects of antidepressants in the Prozac group, stating, “I think the industry is concerned about the possibility of finding long-term risks.”<sup>82</sup>

**December:** Twenty-seven survivors of Joseph Wesbecker’s killing rampage and family members of his deceased victims sued Eli Lilly contending that it knew about the propensity for Prozac to cause violence. This gave attorneys and experts access to Lilly’s internal memos. With 150 lawsuits filed by 1994 in relation to the antidepressant, the Wesbecker trial was crucial for Eli Lilly to win. Plaintiffs argued that there was a history of reckless disregard toward consumers, particularly about another drug Oraflex that had led to 100 deaths. (Oraflex was taken off the market and Eli Lilly pled guilty to 25 counts of mislabeling side effects.) The company did not want the internal records involving Oraflex made public during the Wesbecker trial.<sup>83</sup> Lilly won the case, but was later forced to admit that it had made a secret settlement with the plaintiffs during the trial, which meant the verdict was invalid.<sup>84</sup> The judge in the trial fought for an investigation and in 1997, Lilly agreed to a verdict being changed from a victory to “dismissed as settled.”<sup>85</sup> The psychiatrist that had treated Wesbecker had softened his earlier testimony to the Coroner linking Prozac to his behavior, after he had been approached to review Lilly’s own material—highlighted to emphasize their views—for which he was paid \$200 an hour.<sup>86</sup>

# CHAPTER FIVE: COVERING UP WITHDRAWAL SYMPTOMS

## 1995

IMS America reported that the number of times doctors in the U.S. recommended prescribed or refilled prescriptions for Prozac for children ages 6 to 12 doubled from 1995 to 1996. Commenting on the massive increase three years later, Dr. Thomas Laughren from the FDA's psychiatric drug productions division was unconcerned, "It's only alarming in the sense that it's a practice that's ongoing in the absence of research data to support the use of antidepressants in children." Laughren was part of an FDA group working on rules that would require manufacturers to *conduct more studies into the effects of drugs like Prozac on children*.<sup>87</sup> [See May 1994 entry on the DSM and inclusion of childhood mental disorders.] Between 1995 and 1999, the use of antidepressants would increase 580% in the under 6 population and 151% in the 7-12 age group.<sup>88</sup>

More medical studies were published confirming the violence/suicide links to SSRI antidepressants. Nine Australian psychiatrists reported that patients had slashed themselves or become preoccupied with violence while taking SSRIs. "I didn't want to die, I just felt like tearing my flesh to pieces," one patient told the psychiatrists.<sup>89</sup> In *Lancet*, the British medical journal, Dr. Miki Bloch reported on patients who became suicidal and homicidal after stopping an antidepressant, with one man having thoughts of harming "his own children."

A study, "Antidepressants and Suicide" by Dr. Hershel Jick, determined, "The results indicate that only fluoxetine [Prozac] has a rate [of suicide] that seems to be substantially higher than that of other antidepressants."<sup>90</sup>

**August:** A study by Dr. Junji Ichikawa at Case Western Research University School of Medicine and published in the *European Journal of Pharmacology*, reported that Prozac produced a 57% drop in dopamine [chemical/hormone] in the involuntary motor system. "Boosted beyond ordinary levels, elevated serotonin could trigger a dangerous backlash, a compensatory drop in dopamine, resulting in the drugs' most severe neurological side effects. This is like squeezing one end of a balloon only to have it pop out elsewhere. Of course, this kind of secondary, indirect effect on other neurotransmitters renders the drugs not 'selective' at all."<sup>91</sup>

## 1996

At a drug company-funded closed-door conference, the withdrawal effects from the SSRIs were renamed as "antidepressant discontinuation syndrome" to avoid the negative connotations of addiction.<sup>92</sup> Psychiatrists began using the term in medical papers and to patients. In the following year, the group of experts that attended this symposium published eight papers marketing "antidepressant discontinuation syndrome."<sup>93</sup>

An FDA memo raised the possibility that Zoloft might cause children and teenagers to become suicidal.<sup>94</sup> FDA researcher Dr. James F. Knudsen wrote to an executive at Pfizer that "there appears to be an increased frequency of reports of suicidality in the pediatric/adolescent patients exposed to" Zoloft in clinical trials.<sup>95</sup>



## 1997

The FDA approved the antidepressant Luvox for children diagnosed with “Obsessive Compulsive Disorder.” Yet during the clinical trials for the drug, 4% of those taking Luvox developed mania, described as a “form of psychosis characterized by exalted feelings, delusions of grandeur...and overproduction of ideas.”<sup>96</sup> [See April 1999 entry, Columbine school massacre.]

Internal GlaxoSmithKline documents (revealed publicly in 2004) showed that in some clinical studies, the number of people taking Paxil who experienced *withdrawal* symptoms was as high as 42%. Documents directed sales reps to minimize concerns about “discontinuation” and to avoid using the word “withdrawal.” Forced to testify before Congress in October 2004, manufacturer representatives admitted their own studies showed as many as 25% of people taking Paxil experience withdrawal symptoms. Yet the drug packaging only reported a risk of 2%.<sup>97</sup>

The FDA approved Direct to Consumer marketing (TV, Magazine ads, etc.) that dramatically influenced prescription trends and drug sales. Psychotropic drug prescriptions for adolescents aged 14 to 18 years increased by 250% between 1994 (pre DTC) and 2001, with the bulk of the increase from 1999 onward.<sup>98</sup> The money that went to DTC advertising would be staggering, rising from \$791 million in 1996 to \$2.4 billion in 2000 and \$4 billion in 2004.<sup>99</sup>

**November:** In the *Archives of General Psychiatry*, Lewis Judd of the department of psychiatry at the University of California and past director of NIMH, described depression as “a disease of the brain,” forwarding the psychiatric-pharmaceutical marketing line that would convince millions to take mind-altering drugs to correct “chemical imbalances” in the brain that simply didn’t exist.<sup>100</sup>

## 1998

Minnesota psychiatrist Frank Abuzzhab, a lead investigator in one of four placebo controlled studies for Prozac that Lilly submitted to the FDA to win approval, was found guilty by the Minnesota Board of Medical Practice of “recklessly” entering patients into psychiatric drug trials, falsifying their records, and fabricating positive drug responses in an investigation. He would call the patient’s diagnosis one thing in the chart, then put the person on a drug and change the diagnosis to fit the criteria for the study.<sup>101</sup>

**1998-2002:** SmithKline Beecham, now GlaxoSmithKline, conducted clinical trials for its SSRI antidepressant, Paxil. Studies of more than 1,000 patients under the age of 18 showed that 3.4% of those taking Paxil or recently stopped, had attempted suicide or thought more about it. That compared with 1.2% of the children who were taking placebo.<sup>102</sup>

An internal GSK document from 1998 (made public in 2004) concluded that, in light of the mixed efficacy outcomes from one study, No. 329, and the entirely negative results of another study No. 377, GSK’s “target” was “[o] effectively manage the dissemination of these data *in order to minimize any potential negative commercial impact.*” 3

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**October:** CCHR began writing a series of publications and reporting on its website that the antidepressant marketing claim that the drugs corrected a chemical imbalance in the brain was fraudulent and misleading to consumers. The booklets, which by 2004 comprised 20 issues, also exposed the dangers psychiatric drugs posed, the misinformation psychiatrists were spreading about the effectiveness of these drugs and cited many medical experts that debunked the chemical imbalance theory.

**November 16-18:** The National Institutes of Health held a two-day hearing into the validity of Attention Deficit Hyperactivity Disorder (ADHD), which was being promoted as a “neurobiological” disorder. CCHR and medical experts saw this as yet another example of pharmaceutical-psychiatric false marketing to sell drugs, similar to the “chemical imbalance” theory invented to sell SSRI antidepressants. CCHR and experts testified to this effect during the hearing. NIH’s concluded, “We don’t have an independent, valid test for ADHD; there are no data to indicate that ADHD is due to a brain malfunction...and finally, after years of clinical research and experience with ADHD, our knowledge about the cause or causes of ADHD remains speculative.”<sup>103</sup> NIH panel member Mark Vonnegut, M.D. stated: “The diagnosis is a mess.”<sup>104</sup> Despite this, the FDA continued to allow stimulant manufacturers to advertise that ADHD was a neurobiological condition.



## CHAPTER SIX: PSYCHIATRIC DRUGS CAUSE SCHOOL VIOLENCE & DEATH

*Between 1988 when Prozac was approved and 2006, there were 46 incidents of school violence involving 48 children and adolescents. Of these, 38% were reported in media, websites or books to be taking psychiatric drugs or were withdrawing from them at the time of their shooting spree. The relationship of psychiatric drugs in the remaining incidents of violence has not been publicly disclosed or the person's records are sealed. Frequently, antidepressants were implicated.*

### 1999

**April:** In Idaho, 15-year-old Shawn Cooper fired two shotgun rounds in his school, narrowly missing students. He was taking a prescribed SSRI antidepressant and Ritalin.

**April:** Eric Harris and Dylan Klebold went on a shooting spree in their Columbine, Colorado school, killing 13 and wounding 23. CCHR and others pressured to have the Coroner re-test the teens' blood for psychiatric drugs. The Coroner subsequently confirmed that Harris' blood contained a therapeutic dose of the SSRI antidepressant, Luvox. Clinical trials showed that 4% of children taking the drug experienced mania, a condition known to result in violent behavior. Colorado State Rep. Penn Pfiffner, chaired a hearing on the possible connection of violent behavior and psychotropic drugs, stating, "There is enough coincidence and enough professional opinion from legitimate scientists to cause us to raise the issue and to ask further questions." "If we're only interested in debating gun laws and metal detectors," said Pfiffner, "then we as legislators aren't doing our job."<sup>105</sup>

**May:** CCHR produced a White Paper *Psychiatry and The Creation of Senseless Violence* detailing examples of psychiatric-drug induced crime and medical studies proving that such drugs precipitate murderous acts. More than 10,000 copies of the report were distributed to legislators, educators and media in the U.S.

**May:** Kelly Patricia O'Meara, a former Congressional staff who was writing for *Washington Times' Insight Magazine* wrote a story based on CCHR's and her own research, titled "Guns and Doses." It showed the common link between high-school shootings and psychiatric drugs.

**June:** The national TV show 20/20 ran a story on the dangers of antidepressants and how the "science" behind the studies showing their safety was inaccurate and misrepresented. A follow-up program on antidepressant withdrawal confirmed SSRI antidepressants were potentially addictive, with severe withdrawal effects.

**July:** Pennsylvania State Representative LeAnna Washington held a Hearing into "Psychiatric Drugs and Their Effects on Children" at which CCHR testified about the violence-inducing nature of these drugs.

**July:** The FDA approved repackaged version of Prozac called Sarafem to treat "premenstrual dysphoric disorder" (PMDD), was protected until 2007. The FDA had approved Sarafem for a condition that didn't even exist in the DSM.<sup>106</sup> Lilly agreed to pay \$90 million for this patented new Prozac molecule to reduce certain side effects of the original Prozac, including "nervousness, anxiety, insomnia, inner restlessness, suicidal thoughts, self-mutilation and manic behavior."<sup>107</sup> [See December 18, 2003 entry]

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**August:** The National Foundation of Women Legislators annual congress was held in Los Angeles where CCHR presented a round-table conference on psychiatric drugs and violence. Copies of CCHR's *Psychiatry and the Creation of Senseless Violence* report were distributed to legislators.

**October:** CCHR, along with medical experts and educators testified before a hearing of the Colorado State Board of Education, providing evidence and medical studies on psychiatric drugs and violence, especially in relation to school shootings.

**October 4:** *The Boston Globe* reported that Dr. Martin Keller, professor and chairman of the department of psychiatry at Brown University, had numerous articles advocating long-term use of antidepressants—especially Zoloft—published in medical journals. While appearing to be impartial, Keller had earned \$842,000 in 1998, more than half of which was from pharmaceutical companies. He received \$218,000 from Zoloft's manufacturer.<sup>108</sup>

**November 9:** Responding to CCHR's report, *Psychiatry and the Creation of Senseless Violence*, a Colorado state legislator organized an Ad hoc government hearing into psychiatric drugs and violence. CCHR and medical experts presented evidence on this.

**November 11:** The Colorado State Board of Education passed a Resolution calling for teachers to use academic solutions for behavioral and educational problems in the classroom instead of psychiatric drugs. The Board recognized that "there are documented incidences of highly negative consequences in which psychiatric prescription drugs have been utilized for what are essentially problems of discipline...."

**November 4:** Dr. David Healy wrote to the UK Medicines Control Agency [FDA equivalent] about the risk of suicide in people taking Prozac.<sup>109</sup>

**December:** CCHR presented its evidence on psychotropic drugs and violence to the National Caucus of Black State Legislators that passed a resolution calling for a federal investigation into the use of these drugs in children.

## 2000

*The American Journal of Epidemiology* published two studies that demonstrated that Paxil presented a 720% increase in risk of breast cancer in females.<sup>110</sup>

**February:** The Australian Therapeutic Goods Administration (TGA) published an Adverse Drug Reactions Bulletin reporting that psychiatric drugs cause nightmares and specifically mentioned Prozac, Zoloft, Paxil and Celexa.<sup>111</sup>

**March 1:** Matthew Smith, aged 14, died of a heart attack after being prescribed Ritalin for several years. A Michigan coroner determined that his heart showed clear signs of the small blood vessel damage caused by stimulants, concluding that he had died from the long-term use of Ritalin. Matthew was forced onto the drug through his school, with the parents threatened with charges of medical and education neglect if they refused to put him on the drug.<sup>112</sup> Psychiatrists at the time dismissed the coroner's findings. [See January 5, 2006 entry on warnings the FDA eventually issued, more than 40 years after Ritalin had been on the market.]



**August 19:** A suit was filed in San Jose, California under the “Business and Professions Code” alleging that GlaxoSmithKline had failed to warn the public about the dangers of Paxil withdrawal effects. GSK resolved the suit in January 2002; the results, including any settlement by GSK, were not announced.<sup>113</sup>

An analysis of new antipsychotic drugs (FDA approved only a few years earlier) involving 12,000 patients found “no clear evidence that atypical [new] antipsychotics are more effective or are better tolerated than conventional antipsychotics.” Dr. John Geddes from Oxford University reviewed 52 independent clinical trials in a study paid for by the British government with the results published in *The British Medical Journal*.<sup>114</sup>

**September 29:** A U.S. House Education Subcommittee held a hearing on psychiatric drug use in children. CCHR worked with parents and medical experts who testified before the Subcommittee. One parent, Mrs. Patricia Weathers, testified that antidepressants made her son psychotic.

## 2001

**February 14:** The FDA finally issued a warning about Paxil’s withdrawal effects, including “dizziness, sensory disturbances (e.g., electric shock sensations), agitation, anxiety, nausea and sweating...Similar events have been reported for other selective serotonin reuptake inhibitors.”<sup>115</sup>

**April 4:** Dr. Healy wrote again to the UK Medicine’s Control Agency about evidence of antidepressants, in particular Paxil and Zoloft, causing suicide.<sup>116</sup>

Dr. Joseph Glenmullen, Harvard Medical School psychiatrist, published *Prozac Backlash*, exposing the dangerous effects of SSRI antidepressants, stating: “In recent years, the danger of long-term side effects emerged in association with Prozac-type drugs, making it imperative to minimize one’s exposure to them. Neurological disorders including disfiguring facial and whole body tics, indicating potential brain damage, are an increasing concern with patients on drugs.”<sup>117</sup> “Withdrawal syndromes” were estimated to affect up to 50% of patients; sexual dysfunction affected 60%, adding, “Here is evidence that they may affect a ‘chemical lobotomy’ by destroying the nerve endings in the brain.”<sup>118</sup>

**May 25:** An Australian judge blamed an SSRI for turning a peaceful, law abiding man, David Hawkins, into a violent killer. Judge Barry O’Keefe of the New South Wales Supreme Court said that had Mr. Hawkins not taken the antidepressant, “it is overwhelmingly probable that Mrs. Hawkins would not have been killed....”

**June:** A Wyoming jury awarded \$8 million to the relatives of a man, Donald Schell, who went on a shooting rampage after taking Paxil and killed his wife, daughter, granddaughter and himself. The jury determined that the drug was 80% responsible for the killing spree.

**June:** The BBC in the UK ran an expose on Paxil causing addiction and withdrawal symptoms. Dr. Healy reported that clinical drug trials showed that healthy subjects suffered withdrawal symptoms after only taking the drug for a few weeks.<sup>119</sup>

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**August:** The patent for Prozac expired.<sup>120</sup>

**August:** Dr. Frank J. Ayd, the psychopharmacologist that helped develop neuroleptics (antipsychotic drugs) in the 1950s and 60s, presented findings of his review of literature for atypical (new) antipsychotics. He determined that there was a “startling” association between initiation of treatment with Eli Lilly’s Zyprexa and new-onset of diabetes in adolescents.<sup>121</sup>

**November:** Researchers at the FDA’s Center for Drug Evaluation Center and Dr. P. Maurali Doraisewamy of Duke University confirmed Dr. Ayd’s findings that there was a causal association between Zyprexa and diabetes—10 times higher than in the general population.<sup>122</sup>

**December 14:** GlaxoSmithKline and the FDA strengthened Paxil’s label in regard to withdrawal effects, however using the drug industry-invented term “discontinuation” syndrome instead of the negative connotation, *withdrawal*. In the Precautions section of the new label, GSK cited clinical trial data confirming the existence of several withdrawal symptoms, including abnormal dreams, paresthesia (abnormal sensations; electric shock sensations), and dizziness, agitation, anxiety, nausea and sweating.<sup>123</sup>



# CHAPTER 7: WHISTLEBLOWERS SPEAK OUT

## 2002

**May:** An FDA official Dr. Andrew Mosholder reviewed information GlaxoSmithKline had previously submitted to the FDA for approval of Paxil and noted that children given the drug suffered more emotional “lability” (vulnerability) than those given placebos.<sup>124</sup> He provided his review to the FDA who would not allow him to release it. Several years later Dr. Mosholder blows the whistle on the dangers of these drugs.

**May:** International media ran on a study by Stanford University physician Randall Stafford that found that despite thousands of studies, hundreds of millions of prescriptions and tens of billions of dollars in drug sales, sugar pills were just as effective as or even better than antidepressants. Seattle psychiatrist Arif Khan also reviewed 96 antidepressant trials between 1979 and 1996, finding that in 52% of them, the effect of the antidepressant could not be distinguished from that of placebo. Andrew Leuchter, a professor of psychiatry at UCLA commented, “We have this fallacy of success, but we don’t know in any individual why they get better.”<sup>125</sup>

**June 3:** Article in the *Washington Times’ Insight Magazine*, titled “Money and Madness” reported how the APA, National Institute of Mental Health were asked how many disorders that are listed in the DSM-IV are curable, what documented diagnostic, physical abnormality had been found in schizophrenia, ADHD and depression. And what diagnostic tests were available and utilized to detect a chemical imbalance? The APA would not respond and NIMH referred the journalist to the U.S. Surgeon General’s 1999 report on mental health. This report, while claiming that mental illnesses accounted for 15% of the “overall burden of disease” in the country, there was no mention of any diagnostic test or physical proof to confirm this.<sup>126</sup>

**October 13:** In Britain, the BBC aired the results of its investigation into what it called “The Secrets of Seroxat Paxil,” showing psychiatrists had known all along that people could get hooked on the antidepressant. They could also suffer serious withdrawal symptoms.

**September 2:** CCHR testified before the U.S. Government Reform Committee inquiry into “Over-Diagnosis of Attention Deficit Hyperactivity Disorders—Are We Over-Medicating Our Children?” and called for national and state legislation to stop children being forced onto stimulants and antidepressants in schools. They provided statistics on school violence linked to psychiatric drugs.

**September:** Until his resignation in late 2004, FDA Chief Counsel, Daniel Troy was another defender of the pharmaceutical industry, filing legal briefs on behalf of his former clients such as Pfizer, Inc. (maker of Zoloft). In 2002, Pfizer contacted Troy requesting the government get involved in a private lawsuit, arguing that, even though Pfizer never sought to strengthen Zoloft’s warning label concerning suicidality, any warning, no matter how worded, suggesting a link between Zoloft and suicidality would have been false and misleading, would have misbranded the drug, and the FDA would have rejected any effort by Pfizer to use such a warning. Troy’s brief claimed that Pfizer would have been liable for publishing a label that was false and misleading if it had issued the warning advocated by the plaintiff in that case.<sup>127</sup>

**October:** A study conducted by Arif Khan, medical director of the Northwest Clinical Research Center in Bellevue, Washington and adjunct professor of psychiatry at Duke

University School of Medicine, revealed startling numbers of suicides committed and suicides attempted in the clinical trials for SSRI antidepressants—numbers that for years had been hidden. Examining the clinical trial data that had been presented to the FDA, Kahn found while people with a history of suicide are excluded that nearly 4% of SSRI drug-trial participants attempted suicide within the following year. The FDA's Thomas Laughren negated the findings as irrelevant because the clinical trials "were not designed to influence suicide." Laughren further announced that "the drug is not approved for the treatment of suicide. They are approved for the treatment of depression."<sup>128</sup> Laughren had been involved in discussions with Eli Lilly and FDA officials on this issue in 1991. [See Entry August 8.]

**November:** Douglas Kennedy of FOX National News in the U.S. produced a three-part series on prescribed psychotropic drugs causing violence and exposed how confidential drug company records showed Paxil was 8 times more likely to cause individuals to commit suicide than if taking a placebo. Further, 7 out of the last 12 school shooters had been on these types of drugs or withdrawing from them prior to committing acts of violence.

In 2002, a Duke University study determined there was a link between Eli Lilly's antipsychotic drug, Zyprexa, and diabetes after documenting nearly 300 cases of diabetes in people using the drug. The British Medical Control Agency and the Japanese Health and Welfare Ministry warned about diabetes risks amongst Zyprexa patients.<sup>129</sup>

## 2003

FDA official Dr. Andrew Mosholder reviewed 22 studies and found that children given antidepressants were nearly twice as likely to become suicidal as those given placebos. His FDA bosses, however, disagreed with his findings, kept his recommendations secret and initiated a new analysis by Columbia University. However, Columbia's findings released in 2004 supported Mosholder's conclusions.<sup>130</sup>

**March:** A GlaxoSmithKline memo on the suicide risk in children taking Paxil stated, "It would be unacceptable to include a statement that efficacy has not been demonstrated, as this would undermine the profile of paroxetine."<sup>131</sup>

**March:** The U.S. Child Medication Safety Act was introduced into the U.S. House of Representatives, prohibiting school personnel from coercing parents into putting their child on psychiatric drugs as a requisite for educational services. CCHR worked with parents and doctors to get this safeguard legislated.

**May:** GlaxoSmithKline submitted a new report to the FDA showing that children given Paxil were more likely to become suicidal than those given placebos and did not improve their "depression" any better than the placebo.<sup>132</sup>

**June 10:** Britain's Department of Health recommended that Seroxat (Paxil) not be used to treat depression in those under the age of 18, stating, "It has become clear that the benefits of Seroxat in children, for the treatment of depressive illness, do not outweigh these risks."<sup>133</sup>



**June 19:** The FDA said that it was reviewing reports of increased risk of suicidal thinking and suicide attempts in children and adolescents using Paxil.<sup>134</sup>

**July:** A Finnish study published in *The Archives of General Psychiatry* found that infants whose mothers took SSRIs during pregnancy could suffer neurological problems during their first week of life. The symptoms included tremors, restlessness and rigidity. Previous studies had shown that pregnant women taking SSRIs during the third trimester of pregnancy could experience neurological symptoms such as irritability, constant crying, convulsions and eating and sleeping disorders.<sup>135</sup>

**August 22:** Wyeth Pharmaceuticals, the makers of the antidepressant Effexor, issued a warning to U.S. doctors that the drug could cause hostility, suicidal ideation and self-harm in patients under the age of 18.<sup>136</sup>

**September:** The FDA requested the makers of six new antipsychotic drugs, including Zyprexa, add a caution to their labeling language about the potential risk of diabetes and blood-sugar abnormalities.<sup>137</sup>

**September 21:** *The Hartford Courant* exposed how antidepressant makers and the FDA had covered up information about antidepressant risks and that Eli Lilly executives worked closely with Paul Leber, head of the FDA's Neuropharmaceutical Drug Division in the 1990s to deflect media attention away from the fact that antidepressants could cause suicide and violence that CCHR was exposing at the time.<sup>138</sup> [See July/October 1990 entries.]

**September:** A GlaxoSmithKline memo updated concerns over Paxil causing a high incidence of suicide and hostility but instructed sales representatives in bold letters not to "discuss the contents" with doctors. GSK agreed to disclose the memo to settle the lawsuit filed against it by the New York attorney general, who accused the company of fraud for concealing the negative results.<sup>139</sup>

**September:** The FDA determined that Eli Lilly's antipsychotic drug Zyprexa required labeling changes as a result of a multi-year review. The labeling warned of diabetes risks.<sup>140</sup>

**October:** The Irish Medical Board (FDA equivalent) prohibited GlaxoSmithKline from claiming that Paroxetine (Paxil) corrected a chemical imbalance.<sup>141</sup>

**December 10:** The British Medicines and Healthcare Products Regulatory Agency prohibited the use of six more antidepressants on children less than 18 years of age because of suicidal ideation. The FDA responded by stating it would investigate this further.<sup>142</sup>

**December 18:** Eli Lilly sent a "Dear Healthcare Professional" letter to all physicians in the UK, headed, "Prozac—No longer authorized for treatment of Pre-menstrual Dysphoric Disorder (PMDD)," and said the reason for withdrawing Prozac as a treatment for this was because PMDD is not a well-established disease entity across Europe. It is not listed in the International Classification of Diseases (ICD) and remains only a research diagnosis in the American Psychiatric Association's DSM-IV classification.<sup>143</sup>

# CHAPTER 8: “BLACK BOX” WARNINGS — THE TRUTH ABOUT SUICIDE REVEALED

2004

**January 5:** A memo by Dr. Thomas Laughren, of the FDA’s Division of Psychiatric Products, said 12 of 15 studies involving children treated for “major depression” showed no efficacy when comparing the antidepressants to placebo. He indicated there was the potential for increased risk of suicide attempts and/or suicide-related behavior in five out of seven antidepressants tested in pediatric clinical trials.<sup>144</sup>

**February 1:** The *San Francisco Chronicle* ran an article revealing that FDA medical officer Dr. Andrew Mosholder had been asked by the agency to perform a safety analysis of antidepressants after reports emerged in June 2003 of high rates of suicidal behavior among children enrolled in clinical trials for SSRI antidepressants. Mosholder was to have presented his report at the February 2, 2004 FDA advisory committee hearing on antidepressants causing suicide in children and teens but FDA officials barred him from testifying.

**February 2:** The FDA advisory committee hearing on antidepressants was held comprising the Psychopharmacologic Drugs Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee. FDA official Dr. Andrew Mosholder testified that adverse reaction events had been reported to the FDA regarding children being prescribed SSRIs that indicated, “...there were a total of 524 case reports, of which 110 were death reports.” There were 7 completed suicides and 67 attempted suicides.<sup>145</sup> The committees recommended that the FDA strengthened warnings about the risk of suicide ideation and attempts with antidepressants in children as soon as possible.<sup>146</sup> The committee heard from over 60 people during the meeting’s public hearing, of which many were parents of children who had committed or attempted suicide or homicide after a short time on antidepressants. The parent testimony was very similar to the “anecdotal” evidence presented in the 1991 FDA hearing that CCHR had obtained and, like the 1991 hearing, psychiatrists claimed that the suicidal and other effects were caused by the person’s “mental illness.” However, the advisory committee recommended warnings against the drugs. CCHR assisted several parents that testified.

**March 22:** The FDA issued an advisory that it had requested 10 antidepressant manufacturers to include in their labeling a warning recommending close observation of adult and pediatric patients taking antidepressants for worsening depression or the emergence of suicidality. Further, “Anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia (severe restlessness), hypomania, and mania, have been reported in adult and pediatric patients being treated with antidepressants... both psychiatric and non-psychiatric.”<sup>147</sup>

**March 24:** The U.S. House Energy and Commerce Subcommittee on Oversight and Investigations chaired by Texas Representative Joe Barton sent a letter to the FDA stating that they were now “examining issues surrounding the safety and efficacy of antidepressants in the pediatric/adolescent population” and requested all “written analyses, data, correspondence and background information of clinical trials involving depressed children.”<sup>148</sup>

**April 3:** Children 5 years old and *younger* had become the fastest-growing segment of the non-adult population prescribed antidepressants.<sup>149</sup>



**April 19:** The first nationwide class action suit was filed against a pharmaceutical company over its antipsychotic drug Zyprexa that was linked to dangerous adverse effects including diabetes, hyperglycemia, and pancreatitis.<sup>150</sup>

**May 20:** Mrs. Kim Witczak filed a wrongful death lawsuit against Pfizer in the County of Hennepin District Court, Fourth Judicial District, in Minneapolis, Minnesota claiming that Zoloft caused her husband, "Woody," to experience severe side effects that caused him to commit suicide. He had been prescribed Zoloft to help him sleep and had no prior bouts with depression, Witczak contended. The key to the case was whether Pfizer gave adequate warning that use of Zoloft could lead to suicidal tendencies.<sup>151</sup>

**June:** The New York attorney general Robert Spitzer sued GlaxoSmithKline, alleging "persistent fraud" in suppressing research showing suicide risk from Paxil to those under 18. The company settled the case in August 2004 for \$2.5 million.<sup>152</sup> In the documents made public as a result of this case, three GSK placebo-controlled studies failed to show that Paxil was more effective than placebo.<sup>153</sup> As part of the settlement, GSK agreed to create a public web site to disclose all clinical trial results, including those negative.<sup>154</sup>

**July:** Pfizer attempted to dismiss Witczak's suit against Zoloft claiming that because the FDA had not required it to add a warning for suicidality for *adults* taking the drug. Showing its collusion with the drug industry, FDA's chief counsel Daniel Troy joined Pfizer in this application.<sup>155</sup> [See September 2002 Daniel Troy entry.]

**August 20:** Columbia University's analysis of studies of pediatric antidepressant use, commissioned by the FDA, found that antidepressants were likely to lead children to become suicidal.<sup>156</sup>

**August 25:** Pfizer updated Zoloft prescribing information to warn of suicidal behavior. It also advised "families and caregivers of patients being treated with antidepressants" to be alert to the "need to monitor patients for the emergence of agitation, irritability... as well as the emergence of suicidality, and to report such symptoms immediately to health care providers."

**September 9:** The U.S. House Energy and Commerce Subcommittee on Oversight and Investigations chaired by Texas Rep. Joe Barton held the first of several hearings focusing on the use of antidepressants in children and adolescents and the FDA's decision not to disclose study results showing that the drugs may cause children to become acutely suicidal and were no more effective than sugar placebo. The FDA was accused of "stonewalling, slow rolling and plain incompetence."<sup>157</sup> Rep. Barton said that the FDA deliberately refused to turn over e-mails, memos and other documents to the Subcommittee that had been requested. He held up a copy of an e-mail from an FDA official instructing others in the agency not to unearth the documents. The Subcommittee stated they would push the FDA and the drug industry to make more information public about clinical trials of antidepressants including possible legislation requiring public disclosure of such to be submitted in both the House and Senate. It was confirmed that they knowingly withheld the damaging information about the drugs from the public—the precise stonewalling that CCHR had faced when trying to get the FDA to release its documents on antidepressants in 1993.<sup>158</sup>

**September 13 & 14:** The FDA's Psychopharmacological Drugs and Pediatric Advisory Committees held hearings to discuss whether to call for stronger warning labels on antidepressants and report the findings of a study the FDA had contracted with Columbia University to look into whether antidepressants caused suicidal behavior in children. CCHR assisted several people that testified before the hearings.<sup>159</sup> The committees recommended that the FDA require antidepressant makers to place the FDA's strongest "black box warning" on packaging information. Testimony about Zoloft also concentrated on the drug's lack of proven efficacy in treating "depression."<sup>160</sup>

**September:** The FDA's Paul Leber told *The Denver Post*, "Second generation antidepressants were approved by regulatory process that requires limited proof of efficacy and safety."<sup>161</sup>

**September 24:** The U.S. House Energy and Commerce Committee held a hearing where FDA officials were called to answer allegations that they had suppressed documents showing that antidepressants could cause suicide in children. Congressmen noted that with no benefit to recommend them and a risk for suicidal behavior, the members said they could not understand why the agency did not ban the drugs—which CCHR had called for 14 years earlier. Dr. Robert Temple, head of the FDA's medical affairs, responded that just because the trials had failed they shouldn't discard the drug not working! "More than 50 percent of all trials in adults fail, too," he said. "We don't know why."<sup>162</sup> "There is something terribly rotten at the FDA," said Rep. Peter Deutsch (D-Fla.). "No agency charged with protecting public health should have behaved with such indifference."<sup>163</sup>

**September:** A study titled, "Aggression, Mania, and Hypomania Induction Associated with Atomoxetine" (Strattera), published in *Pediatrics*, the journal of the American Academy of Pediatrics, revealed that 33% of the patients reviewed exhibited extreme irritability, aggression, mania or hypomania.<sup>164</sup> Strattera was prescribed largely to children with so-called ADHD.

**October 12:** Dr. Richard Kapit, the former FDA chief safety investigator who investigated Prozac, Paxil and Zoloft before the drugs were allowed on the U.S. market, testified in a murder case linked to Zoloft that he always suspected in some patients the drugs could cause mania, a condition that can lead to violence. "In the psychiatric profession, antidepressants have always been thought to cause manic episodes," Kapit said. "Now, we have hard data to back up what everyone sort of believed."<sup>165</sup> [See March 1985 and March 23, 1986 entries.]

**October 15:** The FDA ordered pharmaceutical companies to add a "black box" warning to antidepressants alerting that they could cause suicidal thoughts and actions in some children and teenagers. Dr. Robert Temple of the FDA, that had approved Prozac for the market in 1987, had defended it following the 1991 FDA Hearing that CCHR helped instigate, was quoted in the *British Medical Journal* as saying he found it "interesting and persuasive" that all drugs, including Prozac, showed the same trend toward increased suicidality.<sup>166</sup>

**December 3:** The Prohibition on Mandatory Medication Amendment of the Individuals with Disabilities Education Act (IDEA) law was enacted banning school personnel forcing parents to administer psychotropic drugs to their children as a requisite for their education—a safeguard that CCHR had been seeking since 2002.



**December 4:** ABC (U.S.) national TV show, *Prime Time*, exposed how pharmaceutical records for 62% of patients in clinical trials taking the antidepressant Paxil experienced withdrawal symptoms.

## 2005

**January 4:** The office of U.S. Rep. Maurice Hinchey provided CNN copies of Eli Lilly documents that showed the company had data when Prozac was approved in 1987 that ADRs were far more likely to list suicide and violence than reports for other antidepressants. One of the documents reported 14,198 adverse effects, of which a Lilly official indicated 3.7% were suicide attempts, yet the rate was far higher for any of four other commonly used antidepressants. Further, 2.3% of the adverse reactions concerned psychotic depression, more than double the next-highest rate of patients using any other antidepressant. And 1.6% involved incidents of hostility—more than double the rate reported on any other commonly used antidepressants.<sup>168</sup>

**January 13:** The Louisiana Attorney General filed a lawsuit against Eli Lilly alleging unfair trade practices by fraudulently misrepresenting to doctors and public that Zyprexa was safe and more effective than alternate drugs on the market and promoting off-label use of the drug in children and for non-approved uses.<sup>169</sup>

**February 17:** An analysis of hundreds of studies involving 87,650 patients taking antidepressants showed that adults were more than twice as likely to attempt suicide as patients given sugar pills—and had been known for 15 years, when CCHR and others first raised this. The study, published in the current issue of the *British Medical Journal*, was conducted by epidemiologist Dean Fergusson and colleagues at the Ottawa Health Research Institute and included scientists from McGill University. “The biggest concern is these drugs are widely prescribed. There are millions of people on the drugs, so even a risk of one in a 1,000 when you amplify it to the millions, it becomes a public health issue,” Fergusson stated.<sup>170</sup>

**April 11:** The FDA issued a Public Health Advisory regarding the use of antipsychotic drugs in elderly patients with dementia, stating the drugs can cause an increase in death rates and manufacturers would be required to place a boxed warning in their packaging information.<sup>171</sup>

**May:** More than 100 doctors and medical professionals, including medical advisory board members of CCHR, signed a joint letter to the FDA Commissioner, Dr. Lester Crawford, calling for stronger warnings on antidepressants and other psychotropic drugs labeling. The doctors also indicated that psychiatrists and advertisements that claimed antidepressants corrected a chemical imbalance in the brain was fraudulent and should be investigated.

**June:** International media ran on criticism of psychiatrists misleading consumers about the dangers of antidepressants and stimulants and how there was no scientific evidence that a “chemical imbalance” existed for antidepressants to “correct.” There was also criticism about prescribing antidepressants to pregnant women because of the risk of fetal damage. [See September 27, 2005 entry that substantiated this risk.] In the wake of the unrelenting exposure on July 1, Dr. Steven Sharfstein, president of the American Psychiatric Association was forced to publicly admit that there is “no clean cut lab test” to determine a chemical imbalance in the brain.<sup>172</sup> Dr. Mark Graff,

Chair of Public Affairs of the APA said that this theory was “probably drug industry derived... We don’t have tests because to do it, you’d probably have to take a chunk of brain out of someone—not a good idea.”<sup>173</sup>

**June 29:** In an interview on national TV Dr. Nada Stotland, APA Vice President misled both the interviewer and audience by claiming, “We have brain pictures of people who have depression and people who don’t. You can see the difference in their brain images. You can see when they are treated successfully, either with medication or with psychotherapy or both, their brain returns to normal.” However, an October 18 *New York Times* story reported, “After almost 30 years, researchers have not developed any standardized tool for diagnosing or treating psychiatric disorders based on imaging studies.” Further, the U.S. Surgeon General’s 1999 definitive report on “mental illness” had stated: “The precise causes (etiology) of mental disorders are not known” and that there is no definitive lesion, laboratory test, or abnormality in brain tissue that can identify [a mental] illness.”

**June 30:** The FDA issued a Public Health Advisory entitled, “Suicidality in Adults Being Treated with Antidepressant Medications” stating that several recent scientific publications suggest the possibility of an increased risk of suicidal behavior in *adults* taking antidepressants.<sup>174</sup>

**June 30:** The FDA issued an “Alert for Healthcare Professionals” on the new antidepressant Cymbalta, concluding that suicidal thinking or behavior may increase in pediatric patients treated with any type of antidepressant. The FDA issued this warning despite not having approved the drug’s use in children.<sup>175</sup> clinical trials on possible increased suicidal behavior in adults.<sup>176</sup>

**July 5:** CCHR wrote to Jan N. Johannessen, Executive Secretary, Senior Science Policy Analyst, Office of Science and Health Coordination, FDA regarding the need for stronger warnings against stimulants and requesting action to be taken against manufacturers making false claims that “ADHD” was a neurobiological disorder when there was no scientific/physical evidence to substantiate this. For example, on May 6, 2004, the manufacturer of Adderall had issued a PR Newswire, definitively stating, “ADHD is a neurobiological disorder.” No action was taken.

**July 5:** The FDA issued another advisory to healthcare professionals, stating: “FDA has concluded that suicidal thinking or behavior may increase in pediatric patients treated with any type of antidepressant, especially early in treatment. Increases in suicidal thinking or behavior due to drug can be expected in about 1 out of 50 treated pediatric patients.”

**July 16:** The *British Medical Journal* published a study, “Efficacy of antidepressants in adults,” by Joanna Moncrieff, senior lecturer in psychiatry at University College London, and Irving Kirsch, who found that antidepressants were no more effective than placebo and do not reduce depression. Moncrieff found “no good evidence that these drugs work.”<sup>177</sup>

**July 21:** Judge denied Pfizer’s application to dismiss Mrs. Kim Witzak’s wrongful death suit. Pfizer had asserted that FDA regulations pre-empted stronger failure-to-warn state laws—if the FDA did not issue specific drug warnings, then states could not



expect pharmaceutical companies to do so, even when they had evidence of serious adverse reactions. U.S. District Judge James Rosenbaum ruled that FDA warning standards were minimum standards. He also said the mass marketing of prescription drugs in print and on television has created a new appeal for these medicines that creates an environment that “calls out for enhanced consumer protection.”<sup>179</sup>

**July 22:** Eli Lilly, the manufacturer of the antipsychotic drug, Zyprexa, agreed to pay \$690 million to settle more than 8,000 claims against the drug alleging it can potentially cause life-threatening diabetes.<sup>180</sup> By 2008, the suits had increased to 30,000 with a payout of \$1.2 billion. [See January 30, 2008 entry]

**August 19:** The Commission of the European Communities, representing 25 countries, issued the strongest warning yet against child antidepressant use as recommended by Europe’s Committee for Medicinal Products for Human Use (CHMP). A review of clinical trials had shown the drugs caused suicidal behavior including “suicide attempts and suicidal ideation, aggression, hostility (predominantly aggression, oppositional behavior and anger) and/or related behavior.”

**August 22:** Norwegian researchers published their study of more than 1,500 patients, entitled, “Suicide attempts in clinical trials with paroxetine [Paxil] randomized against placebo” in the *BMC Medicine* that found paroxetine was 7 times more likely to induce suicide than those taking placebo. “The data strongly suggests that the use of SSRIs is connected with an increased intensity and suicide attempts per year.”<sup>181</sup>

**September:** The Evidence-based Practice Center of Oregon Health & Science University published a report in which 2,287 studies—virtually every study ever conducted on ADHD drugs—were reviewed. This determined that no trials have shown the effectiveness of these drugs and that there was a lack of evidence that they could affect “academic performance, risky behaviors, social achievements, etc.”<sup>182</sup>

**September 22:** Dr. Jeffrey Lieberman of Columbia University and other researchers released a federally funded study in the *New England Journal of Medicine* that determined that the newer antipsychotic drugs were no more effective or safer than an older antipsychotic. One of the newer drugs was Zyprexa and after 18 months, 64% of the patients taking this had stopped, most often because it was not well tolerated and caused sleepiness, weight gain or neurological symptoms like stiffness and tremors.<sup>183</sup> Of the 1,493 patients who participated, 74% discontinued their antipsychotic drug before the end of their treatment due to inefficacy, intolerable side effects or other reasons.<sup>184</sup>

**September 27:** The FDA and GlaxoSmithKline issued a warning that pregnant women taking Paxil or other antidepressants during their first trimester of pregnancy were at risk of giving birth to babies suffering major congenital [defect at birth] and cardiovascular [heart] malformations. There were also been reports of premature births in pregnant women exposed to SSRIs, including Paxil.<sup>185</sup>

**September 29:** The FDA issued a Public Health Advisory directing a revision in the labeling of the antidepressant Strattera (prescribed as a stimulant for so-called “ADHD”) to include both a boxed warning and additional warning statements that alerted health care providers to an increased risk of suicidal thinking in children and adolescents being treated with the drug.<sup>186</sup>

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**November:** The FDA's Safety Information and Adverse Event Reporting Program reported "**homicidal ideation**" as an adverse event of the antidepressant Effexor.<sup>187</sup>

**November:** CCHR sent copies of media exposing how antidepressants caused violence and suicide to 400,000 doctors in the U.S. Another letter sent to 100,000 doctors reminded them of their responsibility to report drug adverse reactions to the FDA using its "MedWatch" reporting form.

**November 8:** U.S. District Judge Samuel Der-Yeghiayan found against Pfizer in a lawsuit about Zoloft. The widow of a man, Donald Zikis who died from suicide while taking Zoloft, argued that Pfizer had failed to properly warn users of the drug's dangerous side effects. The court rejected Pfizer's assertion that had it added warnings to its label, "it might mislead physicians about the risks entailed in prescribing a drug, thereby over-detering its use." The judge disagreed and pointed out that the company can add any warning, precaution or adverse reaction without the prior FDA approval.<sup>188</sup>

**December:** A study published in *PLoS Medicine* (Public Library of Science) determined that neuroscientific research had failed to confirm any chemical abnormality in the brain requiring antidepressants to correct. Neuroscientific research, the report said, had failed to confirm any serotonin abnormality in the brain.<sup>189</sup>



## CHAPTER 9: THE FDA IS UNRAVELED

2006

**January 5:** The FDA said that it had received reports of sudden deaths, strokes, heart attacks and hypertension (high blood pressure) in both children and adults taking “ADHD” stimulants such as Ritalin, Adderall and Celexa. The FDA asked its Drug Safety and Risk Management advisory committee to examine the potential of cardiovascular (heart) risks of the drugs.<sup>190</sup> Ritalin had been on the market for more than 40 years, without psychiatrists or the FDA acting to warn parents of these risks.

**February:** The Alaska Attorney General’s office filed suit against Eli Lilly for illegal marketing of Zyprexa for off-label conditions. The suit also alleged that the company knew about the drug’s potential diabetic and hyperglycemic side effects and sought reimbursement and penalties.<sup>191</sup> West Virginia filed a similar suit on February 28.

**February 6:** A study published in the *Archives of Pediatrics and Adolescent Medicine* determined that nearly one-third of newborn infants whose mothers took SSRI antidepressants during pregnancy experienced withdrawal symptoms that included high-pitched crying, tremors and disturbed sleep.<sup>193</sup>

**February 9:** The FDA’s Drug Safety and Risk Management Advisory Committee held a hearing into stimulant drug risks. CCHR assisted several parents that testified and who urged that the strongest “black box” warning be issued.<sup>194</sup> The advisory panel voted in favor of the “black box” warning, recommending this to the FDA. The FDA approved stronger warnings, but not a “black box.” CCHR presented information to members of Congress on the dangers of these drugs that it had investigated since the 1980s.

**March:** A study published in *The New England Journal of Medicine* reported use of SSRIs during the second half of pregnancy could be associated with a rare but life-threatening condition where the infant does not receive sufficient oxygen in the blood and required intensive-care treatment to survive. According to the study, babies born with this condition were six times more likely than healthy babies to have been exposed to SSRIs.<sup>195</sup>

**March 22:** An FDA advisory panel held a hearing into the risk of stimulants prescribed for the treatment of “ADHD.” Evidence revealed that from January 2000 to June 30, 2005, the FDA had received almost 1,000 reports of kids experiencing psychosis or mania while taking stimulants. The panel recommended increasing the warnings about the drug dangers, emphasizing these on special handouts called “Med Guides” that doctors must give to patients with *each* prescription.

**April 12:** CCHR wrote to FDA Commissioner Dr. Andrew C. von Eschenbach calling for stronger warnings against stimulants and raised concerns about advertisements that made claims that ADHD was a “neurobiological disorder” which was false and misleading and, therefore, in violation of Section 202.1 of Title 21 of the Code of Federal Regulations. It provided examples of pharmaceutical company advertising and a Netherlands court decision that had prohibited ADHD being advertised as a brain-based disorder. CCHR requested an investigation into this misrepresentation in psychotropic drug advertising.

**April 24:** The Government Accounting Office (GAO), a government oversight agency, issued the findings of its investigation into the FDA, stating, “FDA lacks a clear and effective process for making decisions about, and providing management oversight of, postmarket drug safety issues.” It was incapable of properly monitoring adverse drug reactions once it had approved the drug.<sup>196</sup> The pharmaceutical industry did not support any increased requirements for safety studies after a drug was approved.<sup>197</sup>

**May 12:** GlaxoSmithKline and the FDA warned doctors that Paxil increases the risk of suicide in young adults.<sup>198</sup>

**May:** A study published in the journal *Psychotherapy and Psychosomatics* revealed the pharmaceutical company influence on the DSM, with 56% of all DSM committee members having financial interests in drug companies. For so-called mood disorders (“depression” and “bipolar”) and “schizophrenia/psychotic” disorders, 100% of the panel members had undisclosed financial involvements with drug companies.<sup>199</sup>

**June 30:** An Alaska Supreme Court ruling determined, “Given the nature and potentially devastating impact of psychotropic medications...we now similarly hold that the right to refuse to take psychotropic drugs is fundamental.” Recognizing the risks of these drugs, the court stated: “Psychotropic drugs ‘affect the mind, behavior, intellectual functions, perception, moods, and emotion’ and are known to cause a number of potentially devastating side effects.... Courts have observed that ‘the likelihood [that psychotropic drugs will cause] at least some temporary side effects appears to be undisputed and many have noted that the drugs may—most infamously—cause Parkinsonian syndrome (disease of the nerves causing tremor, muscle weakness, shuffling walk) and tardive dyskinesia” (*tardive*, late and *dyskinesia*, abnormal movement of muscles).<sup>200</sup>

**July 24:** The state of Mississippi filed a lawsuit against Eli Lilly, alleging improper sales and marketing of Zyprexa. Civil penalties, punitive damages and litigation costs were sought.<sup>201</sup>

**August 21:** Senator Charles Grassley (R-IA) issued statements and national media criticizing the FDA for “quietly” requiring ADHD drug manufacturers to add warnings to their products, but not making the public aware that these new warnings would be required.

**September 11:** In a study, published in the journal *Public Library of Science Medicine*, Dr. David Healy and colleagues determined that SSRI antidepressants could increase the risk of violence in people taking them. They looked specifically at Paxil and concluded the drug raised the risk of **severe violence** in some people. The findings were based in part on clinical trial data GSK submitted to the UK’s Committee on Safety of Medicines Expert Working Group. The study stated: “In paroxetine clinical trials, **aggression** and **violence** were commonly coded under the rubric of hostility. This coding term includes **homicide, homicidal acts, and homicidal ideation** as well as aggressive events and ‘conduct disorders,’ but no homicides were reported from these trials....”<sup>202</sup>

**September 18:** FDA Commissioner Dr. Andrew C. von Eschenbach responded to CCHR’s letters commencing April 12, stating, “You asked about steps or regulations FDA is taking to inform drug manufacturers that claim that there is a neurobiological, physical abnormality, or chemical imbalance cause for any mental disorder is false and



misleading advertising...." However, while no evidence to support the following, the Commissioner wrote, "*The fact that there are no laboratory tests to diagnose ADHD does not mean that ADHD is not a genuine disease (one that might be called a neurobiological disease)... So FDA thinks that referencing ADHD as a neurobiological disorder can be supported.*"

**October:** Congressman Dan Burton sent a letter to members of Congress (a copy of which had been given the FDA) alerting them to the results of a survey showing 9 out of 10 Americans were unaware that they had the right to report a drug adverse reaction to the FDA. Congressman Burton demanded that the FDA mandate drug companies to advise consumers to report adverse effects (ADRs) to Medwatch.

**December 13:** The FDA held a hearing into the relationship between antidepressants and suicide in those 18-25 years of age ("young adults"). The FDA Psychopharmacological Committee heard testimony from about 75 people, including a CCHR representative, who said the FDA had the information 15 years ago when CCHR obtained the 1991 FDA Hearing into Prozac causing suicide and violence, but had failed to act. This time the committee voted to extend the black box warning on antidepressants to age 24.

**November 27:** The New Mexico Attorney General filed a lawsuit against Eli Lilly alleging the company promoted the drug for off-label uses (such as in children and in elderly for dementia, as well as for non-approved indication such as irritability, sleep disturbances and anxiety).<sup>203</sup>

**November 29:** Acting FDA Commissioner Dr. Andrew C. von Eschenbach responded to CCHR's query about how psychotropic drug advertising can be allowed to make claims that mental disorders are "neurobiological" or the result of a chemical imbalance when there were no replicable scientific studies to support this. Dr. von Eschenbach wrote, "Regarding the issue of how FDA makes a judgment that any particular clinical entity is a 'disease,'...we, generally, rely on the experts within the clinical, academic, and government communities who treat and study these entities. There is virtually unanimous agreement among those we consider experts in ADHD, bipolar disorder, and schizophrenia that these are legitimate diseases...." He could not direct CCHR to any specific evidence of this.

**December 17 & 21:** Articles appearing in *The New York Times* disclosed that Eli Lilly had engaged in a decade-long effort to play down the health risks of Zyprexa and had actively marketed Zyprexa for illegal off-label uses.<sup>204</sup>

## 2007

*Throughout 2006 and 2007, CCHR, along with many concerned parents, doctors, healthcare groups and whistleblowers worked to ensure that legislation governing the FDA would provide safeguard and consumer protections. This included full disclosure of all clinical drug trial results and the right for consumers to report drug adverse reactions to the FDA.*

*Cases of violent crimes compiled by the International Coalition for Drug Awareness also recorded more than 950 acts of violence over an eight-year period, committed by people of all ages taking SSRI antidepressants. This includes 362 murders; 45 attempted murders; over 100 acts of violence and assault, including 13 school shootings; 5 bomb threats or bombings; 24 acts of arson; 21 robberies; 3 pilots who crashed their planes; and more than 350 suicides and suicide attempts.*

**February 21:** The FDA directed “ADHD” drug manufacturers to distribute “patient-friendly” guides to consumers that stimulants could cause serious psychiatric and cardiovascular problems, including stroke, heart attack, sudden death and psychotic reactions.

**February 26:** The Pennsylvania Governor’s office filed a suit against Eli Lilly, Janssen and AstraZeneca, alleging they had fraudulently marketed their antipsychotic drugs (Zyprexa, Risperdal and Seroquel, respectively) and owed the state for prescription costs and harm to patients.<sup>205</sup>

**March 22:** The House Energy and Commerce Committee’s subcommittee on oversight and investigations held a hearing into the FDA and drug safety, at which FDA commissioner Dr. Andrew von Eschenbach appeared. The FDA’s treatment of whistleblowers had long been of concern to members of Congress, stemming in part from allegations the agency had retaliated against employees who spoke out about safety issues with the now-withdrawn painkiller Vioxx and antidepressants.<sup>206</sup>

**April 25:** The FDA announced it was investigating whether the manufacturer of Zyprexa had provided it with accurate data about the side effects of the antipsychotic drug. This was based on a February 2000 document provided to the FDA in which the manufacturer admitted that it had found that patients taking Zyprexa in clinical trials were three and a half times more likely to develop high blood sugar as those who did not take the drug. That document was not submitted to the agency, while a few months later, the company provided data that only showed almost no difference in blood sugar between patients who took Zyprexa and those who did not.<sup>207</sup>

**April:** Over 350 lawsuits were filed in April against AstraZeneca Pharmaceuticals after the FDA ordered a change in the labeling of its antipsychotic drug, Seroquel, to warn users about an increased risk of diabetes. Further, Seroquel was linked to pancreatitis (an inflammation of the pancreas), hyperglycemia, and Neuroleptic Malignant Syndrome, a potentially fatal syndrome with symptoms that include irregular heartbeat, fever, and stiff muscles. It could also increase the risk of death in seniors who had dementia-related mental problems, a condition that Seroquel has not been approved to treat.<sup>208</sup>

**April 26 2007:** The national consumer protection group, Public Citizen, secured an improved settlement for the parents of thousands of children prescribed the antidepressant Paxil. The class action suit had sought economic damages against the manufacturer, GSK, alleging the company had misled parents by not disclosing that the drug was dangerous and ineffective when taken by children younger than 18. GSK agreed to put \$63.8 million into a settlement fund for victims and attorneys fees.<sup>209</sup>

**March 7:** The state of Montana sued Eli Lilly for marketing Zyprexa for off-label purposes and alleged Lilly owed the state for drug costs and the harm patients have suffered from use of the drug and as a result of its marketing the drug to sedate nursing home patients, and giving kickbacks to doctors.<sup>210</sup>

**May 2:** The FDA officially extended the age group for the black box warning about antidepressant inducing suicide from 18 to 24.<sup>211</sup>

**July:** CCHR obtained documents from the Australian Therapeutic Goods Administration regarding antidepressant adverse reactions. Children under 10 years



old taking the drugs had suffered 129 side effects, while those 10 to 19 years old had experienced 1,149 reported side effects. There were at least two suicides and one death due to heart failure in the 10 to 19 age group. Other adverse reactions included: convulsions, hallucinations, deafness and paralysis.

**September:** Legislation reforming the FDA was passed, providing consumer rights and clinical drug trial transparency. For CCHR, this had been a 17-year battle to correct the collusion between psychiatrists, pharmaceutical companies and the FDA. To protect psychiatric interests, consumers had been denied vital information about drug risks, their evidence of serious adverse reactions were dismissed as “anecdotal” and false advertising, misleading claims and fraudulent assertions that “chemical imbalances” existed had been allowed to flourish in the media and in medical journals. Some of the changes to the FDA legislation include:

- Drug ads to carry a conspicuous notice: “You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.”
- Drug companies required to publicly post all results of their drug clinical trials on the Internet, including the negative. They could no longer selectively choose what they want consumers to know.
- If any drug maker submitted false information on a clinical trial, the FDA would post a notice stating: “The entry for this clinical trial was found to be false or misleading and therefore not in compliance with the law.”
- The FDA was mandated to monitor drug advertisements and if they are false or misleading, fine drug makers up to \$10 million.

# CHAPTER 10: VINDICATION & THE NEXT STEP

2008

**January:** A *New England Journal of Medicine* study reported that makers of SSRI antidepressants never published the results of about a third of the drug trials that they conducted to get government approval, misleading people about the drugs' effectiveness. The *published* studies showed while about 50% of people taking the drugs reported significant relief, 40% taking placebo did too. Further, when factoring in all the unpublished studies, the antidepressants were about as "effective" as taking placebo. Researchers also found that 37 of 38 trials that the FDA had reviewed as having positive results were published in journals, while of the 36 trials that the agency viewed as *failed* or *unconvincing*, only 14 of these were published.<sup>212</sup>

**January 30:** Eli Lilly and federal prosecutors discussed a settlement of a criminal and civil investigation into the company's marketing of Zyprexa that could result in Lilly paying more than \$1 billion—the largest fine ever paid by a drug company for breaking federal laws that govern how drugs can be promoted. Part of the agreement would include Lilly pleading guilty to a misdemeanor *criminal* charge.<sup>213</sup> The company had already paid out \$1.2 billion to settle 30,000 civil lawsuits against it over Zyprexa.

## THE UNDERLYING PROBLEM: DIAGNOSTIC FRAUD

CCHR, along with many other like-minded individuals, groups and whistleblowers, tenaciously spoke out about the serious risks associated with antidepressants and other FDA-approved psychiatric drugs for more than 14 years, before the FDA—also under Congressional pressure—acted.

Psychiatrist's ability to convince drug companies and governments to pour billions of dollars into its practices is based upon a fraudulent diagnostic criteria catalogued in the *Diagnostic and Statistical Manual of Mental Disorders*. Psychiatrists package various behavior and emotional characteristics and categorize them as a "disease" or "disorder" for which drugs can be manufactured to "treat." Carl Elliot, a bioethicist at the University of Minnesota, says: "The way to sell drugs is to sell psychiatric illness."<sup>214</sup>

Professors Herb Kutchins and Stuart A. Kirk have conducted extensive research into the DSM, and in their book, *Making Us Crazy: The Psychiatric Bible and the Creation of Mental Disorders*, they summarized it this way: "...DSM's definition of mental disorders is flawed, the claims of validity and reliability of the manual as a whole shaky, and the causes of most mental disorders are unknown...no manual should be foisted on clinicians or the public and used for purposes of [insurance] reimbursement unless there is substantial evidence for its reliability and validity." DSM is notoriously unreliable. Further, "psychiatrists and other mental health professionals benefit from DSM's unrelenting expansion of domain, its attempts to sweep all manner of personal troubles under the medical umbrella and to rationalize its moves on the basis of research and science."<sup>215</sup>

Even Dr. Robert Spitzer, the main architect of DSM told *The New Yorker* in 2005, "To say that we've solved the reliability problem is just not true...if you're in a situation with a general clinician it's certainly not very good. There's still a real problem, and it's not clear how to solve the problem."<sup>216</sup>



That problem will never be solved as long as there are pharmaceutical dollars influencing the APA. In 2006, Dr. Irwin Savodnik, an assistant clinical professor of psychiatry at the University of California, Los Angeles, was quoted in *The Chicago Tribune* stating, “The very vocabulary of psychiatry is now defined at all levels by the pharmaceutical industry.”<sup>217</sup>

Reported in 2007, 19 of the 27 members of the APA task force, determining what “mental disorders” are to be included in DSM-V due to be published in 2012, have financial ties to pharmaceutical companies.<sup>218</sup>

Crime comes in many forms. This includes “organized crime” and the idea of syndicate bosses running networks of lesser criminals around the country who commit the deeds that bring the racketeers their profits. When syndicate’s corruption is out in the open, official and public outcry and action usually bring about some social and legal restraint. Yet today, we have operating out in the open—plain for all who will look to see—a syndicate that continues to perpetuate the fraud that all life’s problems are caused by a disorder defined only by them. From reading and writing disorder, fidgeting, stuttering, jet lag and coffee use disorder to self-defeating personality and the all encompassing “Phase of Life Problem,” this is the DSM. Yet because it is couched in terms of “mental health care” and “science,” the outcry by those who see it is fought.

Still, the deepening reliance upon DSM in many social sectors is under increasing attack because of psychiatry’s Achilles heel: it lacks any scientific validity. Jeffrey A. Schaler, Ph.D., lecturer at the American University in Washington, D.C., says, “[T]he notion of scientific validity, though not an act, is related to fraud. Validity refers to the extent to which something represents or measures what it purports to represent or measure. When diagnostic measures do not represent what they purport to represent, we say that the measure lacks validity. If a business transaction or trade rested on such a lack of validity, we might say [this] was an instrumental in a commitment of fraud. The DSM-IV, published by the American Psychiatric Association...is notorious for low scientific validity.”<sup>219</sup>

Yet the FDA relies upon this fraudulent document to approve all psychiatric drugs. There are no physical tests, including brain scans or MRIs, that can prove the existence of any mental disorder. Canadian psychologist Tana Dineen points out, “Unlike medical diagnoses that convey a probable cause, appropriate treatment and likely prognosis,” psychiatric disorders are “terms arrived at through peer consensus”—literally, a vote by APA committee members—and designed largely for billing purposes.<sup>220</sup>

The FDA is failing in its duty and to fully inform of all the risks associated with psychotropic drugs and that they are approved and prescribed for conditions that cannot be scientifically or medically verified. The FDA should issue regulations requiring pharmaceutical companies to cease referring to any mental disorder as potentially caused by a chemical imbalance or any neurobiological or other physical condition.

In this way, other organizations that receive substantial grants and funds from pharmaceutical companies will also be put on notice not to promote mental disorders as such and to warn about the very real risks of the drugs prescribed to treat them.

# RECOMMENDATIONS

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1. Investigate the failure of the FDA to take action against false advertising that contain claims that a mental disorder is neurobiological or the result of a chemical imbalance in the brain. Issue regulations that prohibit such fraudulent claims.
2. None of the 374 mental disorders in the DSM should be eligible for insurance coverage without replicable scientific, physical validation.
3. Government, criminal, educational, judicial and other social agencies should not rely on the DSM and no legislation should use this as a basis for determining the mental state, competency, educational standard or rights of any individual.
4. General practitioners, pediatricians and neurologists should not use DSM for diagnosing patients' conditions. No physician, pediatrician, neurologist etc. should rely upon the DSM to diagnose patients.
5. Establish or increase the number of psychiatric fraud investigation units to recover funds that are embezzled through the mental health system because of the DSM.



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