BLACK BOX" WARNINGS—THE TRUTH ABOUT SUICIDE REVEALED

CCHR: EXPOSING THE DANGERS OF ANTI-DEPRESSANTS AND OTHER PSYCHOTROPIC DRUGS—DESPITE FDA/PSYCHIATRIC-PHARMA-CEUTICAL COVER-UPS
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.144

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-Infec tive 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.145 The committees recommended that the FDA strengthened warnings about the risk of suicide ideation and attempts with antidepressants in children as soon as possible.146 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.”147

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.”148

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

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.150

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.151
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. 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. As part of the settlement, GSK agreed to create a public web site to disclose all clinical trial results, including those negative.

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. [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.

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.”
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 1993.158 30 CCHR: Exposing the Dangers of Antidepressants and Other Psychotropic Drugs

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.159 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.”160

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.”161

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
October 12: Dr. Richard Kapit, the former FDA chief safety investigator wyears 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.”162 “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.”163

September: A study titled, “Aggression, Mania, and Hypomania Induction Associated with Atomoxetine” (Straterra), 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.164 Straterra was prescribed largely to children with so-called ADHD.ho 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.”165 [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.166

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. CCHR: Exposing the Dangers of Antidepressants and Other Psychotropic Drugs 31
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.

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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 the 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. 168

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.169

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 1,000 when you amplify it to the millions, it becomes a public health issue,” Fergusson stated.17
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.171

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.172 Dr. Mark Graff, 32 CCHR: Exposing the Dangers of Antidepressants and Other Psychotropic DrugsChair 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.”173
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.174

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.175 clinical trials on possible increased suicidal behavior in adults.176
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.”177

July 21: Judge denied Pfizer’s application to dismiss Mrs. Kim Witczak’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 CCHR: Exposing the Dangers of Antidepressants and Other Psychotropic Drugs 33 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.”179
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 caused life-threatening diabetes. 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.”

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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.”

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. 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.

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.
3September 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.186

November: The FDA’s Safety Information and Adverse Event Reporting Program reported “homicidal ideation” as an adverse event of the antidepressant Effexor.187

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.188

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.189