Report on the Escalating International Warnings on Psychiatric Drugs

by

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INTRODUCTION

In 1990, the Citizens Commission on Human Rights (CCHR) asked American psychiatrists and the Food and Drug Administration (FDA) to issue warnings about the latest psychiatric drug causing violence and suicide: the antidepressant Prozac. CCHR filed complaints and provided evidence. In response, on September 20, 1991, the FDA ordered an advisory committee to hold a hearing to investigate the safety and effectiveness of antidepressant drugs. A panel of nine psychiatrists, many with financial ties to pharmaceutical companies, heard chilling testimony from medical experts as well as the victims of these drugs—and did nothing.

It wasn't until 13 years later, on October 15, 2004, that the FDA finally ordered pharmaceutical companies to add a "black box" warning to antidepressants, saying the drugs could cause suicidal thoughts and actions in children and teenagers. It took nine months for the FDA to issue another advisory, warning doctors to watch for suicidal behavior in *adults* taking antidepressants.

The FDA advisories vindicated CCHR's allegations and patient and family testimony in 1991. However millions of men, women and children were needlessly subjected to dangerous drugs for more than a decade. Now, with controversy growing over the previously undisclosed dangers of psychiatric drugs, international warnings are being issued at escalating rates, citing side effects of drug dependence, addiction, mania, hostility, aggression, psychosis, suicide and violence.

Following is a brief summary of the warnings issued since October 15, 2004:

September 20, 1991: The FDA ordered an advisory committee to hold a hearing to investigate the safety and effectiveness of antidepressant drugs. The panel's chairman, Dr. Daniel Casey, stated: "I do not find from the evidence today, that there is credible evidence to support a conclusion that antidepressant drugs cause the emergence and/or the intensification of suicidality and/or other violent behaviors."[1]

13 years later:

October 15, 2004: The FDA ordered pharmaceutical companies to add a "black box" warning to antidepressants, saying the drugs could cause suicidal thoughts and actions in children and teenagers. The agency also directed the manufacturers to print and distribute medication guides with every antidepressant prescription and to inform patients of the risks.[2]

December 17, 2004: The FDA required that a new warning be added to the packaging of the "ADHD" stimulant, Strattera, showing that the drug should be discontinued in patients who develop jaundice or liver damage. The FDA noted, "The labeling warns that severe liver damage may progress to liver failure resulting in death or the need for a liver transplant in a small percentage of patients."[3]

April 11, 2005: The FDA asked manufacturers of the atypical [new] antipsychotic drugs to add a warning to their labeling that the drugs could increase the risk of death in elderly patients suffering dementia.[4]

April 25, 2005: The European Medicines Agency scientific committee issued a statement concluding that suicide-related behavior and hostility were more frequently observed in clinical trials among children and adolescents treated with antidepressants compared to those treated with placebos.[5]

June 28, 2005: A document on the FDA website announced the identification of possible safety concerns with methylphenidate drug products. Specifically noted were psychiatric adverse events linked to Concerta, Ritalin and other drugs used to treat children diagnosed ADHD (Attention Deficit Hyperactivity Disorder) such as visual hallucinations, suicidal ideation, psychotic behavior, as well as aggression or violent behavior. The FDA announced its intention to make labeling changes and examine other stimulant drug products approved for treatment of ADHD.[6]

June 30, 2005: The FDA issued a Public Health Advisory entitled "Suicidality in Adults Being Treated with Antidepressant Medications." The advisory states that several recent scientific publications suggest the possibility of an increased risk of suicidal behavior in adults taking antidepressants and while a review of all available

data is being undertaken by the FDA, it is recommended that physicians should monitor adults who take antidepressants for suicidal tendencies.[7]

July 7, 2005: The National Center on Addiction and Substance Abuse issued a report that 15 million Americans were getting high on prescription drugs, painkillers and psychiatric drugs such Xanax, Ritalin and Adderall, abusing these drugs more than cocaine, heroin and methamphetamines combined. Some 2 .3 million teens were abusing the drugs per the report. Further, the study found that teens who abuse controlled prescription drugs were 12 times likelier to use heroin, 14 times likelier to use ecstasy and 21 times likelier to use cocaine, compared to teens who do not abuse prescription drugs.[8]

July 16, 2005: The British Medical Journal published a study by Joanna Moncrieff, senior lecturer in psychiatry at University College London, who found that antidepressants are no more effective than a placebo and do not reduce depression. The study found that trials of antidepressants with negative results are less likely to be published than those with positive results and that within published trials, negative outcomes may not be presented. Moncrieff found "no good evidence that these drugs work."[9]

August 2005: Columbia University came out with a study on the abuse of prescription drugs by teens; titled "National Survey of American Attitudes on Substance Abuse X: Teens and Parents," which found that the number of Americans who abuse controlled prescription drugs has nearly doubled between 1992 and 2003, with the number of 12-17 year olds having jumped 212%. Further, the study shows that the percentage of teens who have known someone who has abused prescription drugs jumped 86% from 2004 to 2005.[10]

August 19, 2005: The Commission of the European Communities, representing 25 countries, issued its decision to endorse and issue the strongest warning yet against child antidepressant use as recommended by Europe's Committee for Medicinal Products for Human Use (CHMP). This followed a review of clinical trials that showed the drugs cause suicidal behavior including suicide attempts and suicidal ideation, aggression, hostility and/or related behavior.[11]

August 22, 2005: A study by Norwegian researchers disclosed that Paxil (known in Norway as Paroxetine) increases suicide risk in adults. The study of more than 1,500 patients found that 7 patients taking Paxil attempted suicide compared to one suicide attempt by those on placebo. The study also says that the recommendation to not prescribe Paxil to children and adolescents should be extended to include usage by adults.[12]

September 13, 2005: The Drug Effectiveness Review Project of Oregon State University published a major study questioning the effectiveness of ADHD drugs. The researchers reviewed 2287 studies, virtually every study ever done on ADHD, and released a 731 page report which found that there is little evidence that the drugs used to treat ADHD actually work or are safe in the long term or that they help school performance.[13]

September 22, 2005: Dr. Jeffrey Lieberman of Columbia University released a federally funded study in the New England Journal of Medicine that found that 74% of the patients in the study discontinued antipsychotic medication before the end of their treatment due to inefficacy, intolerable side effects or other reasons.[14]

September 23, 2005: Lester Crawford resigned as the Commissioner of the FDA . Amongst many speculations of the reason for this resignation, *The New York Times* reported "Critics, including many in Congress, said the agency had tried to stifle one of its own scientists who had evidence that the use of antidepressants could cause children and teenagers to become more suicidal."[15]

September 28, 2005: The British National Health Service Institute for Health and Clinical Excellence released a study that details the best practice advice on the care of children and young people with depression and gives Clinical Guidelines on "Depression in Children and Young People." The Guideline specifies regular exercise, sleep and a balanced diet as the first levels of therapy and further states that antidepressants should not be used for the initial treatment of children and young people with mild depression.[16]

September 29, 2005: The FDA ordered that "black box" warnings be placed on a commonly prescribed ADHD drug, after clinical trials linked the drug to suicidal thoughts and behavior. The FDA indicated that the new warning stems from an ongoing review of all ADHD drugs and their possible association with suicide.[17]

September 30, 2005: In a landmark report, the United Nations Committee on the Rights of the Child, the world's premier children's rights body, issued a strong warning against falsely labeling youth with the psychiatric diagnosis of "Attention Deficit Hyperactivity Disorder (ADHD)" and administering powerful ADHD-drugs. In its Concluding Observations on reports by Australia, Finland and Denmark regarding their compliance to the U.N. Convention on the Rights of the Child, the Committee expressed concern that "[ADHD] and Attention Deficit Disorder (ADD) are being misdiagnosed and therefore psycho-stimulant drugs are being over-prescribed, despite growing evidence of the harmful effects of these drugs."[18]

October 17, 2005: The FDA ordered Eli Lilly & Co. to add a warning to its latest depression drug, Cymbalta, that it can cause liver damage.[19]

October 19, 2005: A University of Southern California study reinforced the earlier FDA warnings that antipsychotic drugs increase the risk of death in the elderly.[20]

February 10, 2006: An advisory committee to the FDA urged the agency to issue its most serious warning, the "black box," on drugs prescribed to treat the so-called psychiatric disorder ADHD. The recommendation followed evidence that these drugs are linked to numerous deaths and cardiovascular problems such as heart attacks and strokes.[21]

March 22-23, 2006: Two FDA advisory panels held hearings into the risk of stimulants and another new "ADHD" drug called Sparlon. Between January 2000 and June 30, 2005, the FDA had received almost 1,000 reports of kids experiencing psychosis or mania while taking the drugs. The first panel recommended stronger warnings against stimulants, emphasizing these on special handouts called "Med Guides" that doctors must give to patients with *each* prescription. The second committee recommended not to approve Sparlon, which the manufacturer, Cephalon, estimated would lose them $100 million in drug sales. [22]

March 28, 2006: The Australian Therapeutic Goods Administration announced its review of reports of 400 adverse reactions to stimulants in children taking them. CCHR had filed a Freedom of Information Act request with the TGA to obtain the reports and released this to the media that ran the story internationally.[23]

May 1, 2006: An *American Journal of Psychiatry* study revealed that elderly people prescribed antidepressants such as Prozac, Paxil, and Zoloft are almost five times more likely to commit suicide during the first month on the drugs than those given other classes of antidepressants.[24]

May 2, 2006: FDA adverse drug reaction reports linked 45 child deaths to new antipsychotic drugs. There were also more than 1,300 reports of other potentially life-threatening adverse reactions such as convulsions and low white blood cell count.[25]

May 12, 2006: GlaxoSmithKline, the manufacturer of Paxil, sent a letter to doctors warning that its antidepressant increases the risk of suicide in adults. It was the first warning of its kind by a manufacturer.[26]

July 19, 2006: The FDA said antidepressant packaging should carry warnings that they may cause a fatal lung condition in newborns whose mothers took SSRI antidepressants during pregnancy. Migraine sufferers also need to be warned that

combining migraine drugs with SSRIs could result in a life-threatening condition called serotonin syndrome.[27]

August 2006: In August, *the Archives of General Psychiatry* published a study by Mark Olfson, MD, MPH; Steven C. Marcus, PhD; David Shaffer, MD, on "Antidepressant Drug Therapy and Suicide in Severely Depressed Children and Adults." The study determined that children taking antidepressants were 1.52 times more likely to attempt suicide and 15 times ore likely to succeed in the attempt than those not taking the drugs.[28]

September 2006: A study came out in the *Public Library of Science Medicine* journal. The study was done by psychiatrist David Healy and his team of researchers. The study found that the psychiatric drug Paxil raises the risk of severe violence in a small percentage of people. The researchers looked at clinical trial data from the manufacturer of the drug, GlaxoSmithKline, and found a higher rate of hostile behavior (0.38 percent to 0.66 percent) in patients taking Paxil than in patients taking other antidepressants.[29]

October 18, 2006: The Australian Therapeutic Goods Administration (equivalent to the FDA) ordered manufacturers of "ADHD" drugs, Ritalin, Strattera and dexamphetamine to add stronger warnings to their information packaging, because of complaints that Ritalin caused headache, nausea, anorexia, somnolence and depression; Strattera caused aggression, and dexamphetamine caused agitation, tachycardia (rapid heartbeat), hypertonia (abnormally tight muscles), hyperkinesia (muscle spasm) and insomnia.[30]

November 2006: The journal Epidemiology, published a study entitled "Maternal Use of Selective Serotonin Reuptake Inhibitors and Risk of Congenital [defects from birth] Malformations." Researchers from Aarhus University in Denmark found that pregnant women who take the newer type of antidepressants, such as Prozac, are more likely to have babies with birth defects than mothers who don't take these drugs. [31]

November 6, 2006: The UK Medicines and Healthcare Products Regulatory Agency, announced that it was updating the product information for methylphenidate (Ritalin to "advise about serious cardiovascular adverse effects" and to recommend that methylphenidate not be used in children or adolescents with known serious structural cardiac abnormalities.[32]

November 27, 2006: The FDA has issued a public health advisory which warns that people receiving treatment with methadone have died and suffered life threatening side effects because of overdoses, including slow or shallow breathing and dangerous changes in heart beat that may not be felt by the patient.[33]

November 30, 2006: The obstetric (Obstetrics is the branch of medicine which deals with pregnancy and child birth) practice committee of the American College of Obstetricians and Gynecologists (Gynecologists are doctors that specialize in the female reproductive system and disorders that can occur with it) issued a statement that pregnant women and those who plan to become pregnant should avoid taking the antidepressant Paxil if possible because of the risk of birth defects.[34]

December 13, 2006: 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 who slammed the FDA for having the information 15 years ago about suicide/violence risks and failed to act. Several abuse cases that testified accused the FDA of murder, with one stating that the FDA has known for 15 years that these drugs cause suicide. This ran on national TV. The Committee voted to extend the black box warning to ages 18 to 25.[35]

February 21, 2007: The FDA directed ADHD drug manufacturers to distribute "patient-friendly" guides to consumers warning about serious psychiatric and cardiovascular problems, including stroke, heart attack, sudden death and psychotic reactions caused by ADHD drugs.

March 14, 2007: The FDA announced that all sleeping pills (also known as "sedative-hypnotic products"), including Ambien and Lunesta, can cause the dangerous side effect of "sleep-driving," which is driving while not fully awake and having no memory of doing so, and may also cause life-threatening allergic reactions. The FDA told manufacturers to write letters to doctors to notify them of the new warnings, and all prescription sleeping pills will now come with special brochures called "Medication Guides" that spell out the risks for patients in easy-to-understand language.

April 2007: The Australian Therapeutic Goods Administration issued an Adverse Reactions Bulletin stating that atypical antipsychotics may cause neuroleptic malignant syndrome (NMS). They had received 85 reports of NMS for Clozapine, 49 reports for Olanzapine (Zyprexa), 45 reports for Risperidone and there were another 46 reports for other anitpsychotics.[36]

April 25, 2007: In the UK, the National Institute for Health and Clinical Excellence (NICE) issued a warning to doctors about prescribing the antidepressant venlafaxine (Effexor), recommending its use only after two other antidepressants had been used and failed. Doctors were warned to be aware of the higher risk of fatal overdoses, cardiotoxicity, and potentially intolerable side effects in patients taking the serotonin and noradreline reuptake inhibitor. For new patients, Effexor should be considered only once two other antidepressants have been tried. In all cases, GPs must ensure hypertension is controlled before prescribing Effexor, and patients on the drug must

receive regular blood pressure checks and monitoring for cardiac dysfunction. The drug is contraindicated in patients with a high risk of serious cardiac arrhythmias and recent myocardial infarction. The MHRA warned that fatality rates in single overdose cases range from 10% (according to the drug's manufacturer) to 27% (reported to the UK ADROIT database). Fatal doses have been as low as 2 grams, involving seizure, coma, or cardiac effects. The percentage of overdoses involving more than one drug range from 57-67%. The MHRA also could not rule out drug-induced suicidality, particularly for 18-29 year-olds. Effexor may be associated with a higher rate of some side effects, such as nausea, dizziness, headache and withdrawal reactions.[37]

May 2, 2007: The FDA announced that it was extending the black box warnings on antidepressants about them causing suicide, to those 18-24 years of age ("young adults"). While the black box warnings in 2004 determined a suicide risk for those under 18 taking the drugs, the FDA Psychopharmacological Committee heard testimony in December 2006 from about 75 people who said the warning was insufficient—that people aren't suddenly no longer at risk of suicide when they turn 19. The Committee indicated that evidence existed to extend the black box warning from age 18 to 24.

In Summary

Over 80 warnings have been issued internationally on the previously undisclosed dangers of psychiatric drugs since October 2004. This comes on the heels of public awareness campaigns by watchdog organizations, independent medical doctors, patients and their families repeatedly requesting independent evaluations of clinical drug trials and accountability for the harm and loss of lives. While drug regulatory agencies such as the FDA should be accountable for failing to act sooner, it must be noted that psychiatrists have been their advisors, and have a vested interest in maintaining a multi-billion dollar psychiatric drug industry.

Psychiatric drug sales have soared in recent years based solely on psychiatry's criteria for a myriad of "mental disorders," which are simply a checklist of behaviors, emotions and attitudes. Promoting these disorders as medical conditions requiring drug treatment is misleading to the public, governments and patients.

There are no blood tests, X-rays, brain scans or any scientific/medical means by which psychiatry's diagnoses can be verified. Subsequently millions of men women and children have been wrongly diagnosed as mentally ill, and prescribed dangerous and potentially lethal psychiatric drugs.

The FDA should not be approving such drugs for mental "disorders" that cannot be medically/scientifically proven to exist.

Recommendations

1) The FDA must act in the public's interest by swiftly acting on adverse reaction reports and taking immediate action to issue warnings.

2) All treatment options should include checking for underlying medical conditions that could cause a patient's mental or emotional duress.

3) Health insurance coverage for mental health problems should only be provided on the provision that full, searching physical examinations are first undertaken to determine that no underlying untreated physical condition is causing the person's mental or emotional problems. Such examinations would be covered under existing health insurance coverage.

4) Doctors should follow the British National Health Service's Institute for Health and Clinical Excellence (NICE) medical advisory, which recommends first line treatment for mental or emotional problems involve non-harmful medical solutions, including regular sleep, exercise and nutrition.

5) *The Diagnostic and Statistical Manual of Mental Disorders (DSM)*, psychiatry's billing manual for mental disorders, is the key to false escalating mental illness statistics and psychiatric drug prescriptions and usage worldwide. Untold harm and colossal waste of mental health funds occur because of it. It is imperative that the *DSM* diagnostic system be abandoned before real mental health reform can occur.

6) Doctors and insurance companies should report all instances of patients who have been prescribed psychiatric drugs and experienced adverse effects to the FDA or their national drug regulatory agency.

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