Report on the Escalating International Warnings on Psychiatric Drugs

by

Citizens Commission on Human Rights International

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.

Sixteen such warnings were issued in the last year alone.

Following is a brief summary:

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, 2006: The Pediatric Advisory Committee for the Food and Drug Administration urged stronger warnings for ADHD drugs after hearing about hundreds of cases in which children using the drugs experienced frightening hallucinations, often involving bugs and snakes. In some cases, they felt insects crawling on their skin.[22]

In Summary

More than 19 warnings have been issued 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.

References:

[1] Transcript of Proceedings, FDA Psychopharmacological Drugs Advisory Committee, 20 Sept. 91, p. 290.
[2] "Suicidality in Children and Adolescents Being Treated With Antidepressant Medications", FDA Public Health Advisory, 15 Oct. 04.
[3] "New Warning for Strattera," FDA Talk Paper, 17 Dec. 04.
[4] "FDA Issues Public Health Advisory for Antipsychotic Drugs Used for Treatment of Behavioral Disorders in Elderly Patients," FDA Talk Paper, 11 Apr. 05.
[5] "European Medicines Agency finalises review of antidepressants in children and adolescents," European Medicines Agency Press Release, 25 Apr. 05.
[6] "Statement on Concerta and Methylphenidate," Statement posted on the FDA website, 28 June 05.
[7] "Suicidality in Adults Being Treated with Antidepressant Medications," FDA Public Health Advisory, 30 June 05.
[8] "Accompanying Statement by Joseph A. Califano, Jr., Chairman and President," *Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.,* National Center on Addiction and Substance Abuse at Columbia University, July 05, pp. i-iii.
[9] Joanna Moncrieff and Irving Kirsch, "Efficacy of Antidepressants in Adults," *British Medical Journal*, Vol. 331, 16 July 05, pp. 155-157.
[10] "Accompanying Statement by Joseph A. Califano, Jr., Chairman and President," *National Survey of American Attitudes on Substance Abuse X: Teens and Parents*, National Center on Addiction and Substance Abuse at Columbia University, Aug. 05, pp. i-ii.
[11] "Annex II," Commission Decision of 19-VIII-2005, Commission of the European Communities, 19 Aug. 05.
[12] Ivar Aursnes, *et al.*, "Suicide Attempts in Clinical Trials with Paroxetine Randomised Against Placebo," *BMC Medicine*, Vol. 3, pp. 14-18.
[13] Marian S. MacDonagh, PharmaD, and Kim Peterson, MS, "Drug Class Review on Pharmacologic Treatment for ADHD: Final Report," Oregon Health and Science University, Sept. 05, pp. 13-20.
[14] Jeffrey A. Lieberman, MD, *et al.*, "Effectiveness of Antipsychotic Drugs in Patients with Chronic Schizophrenia," *New England Journal of Medicine*, Vol. 353, No. 12, 22 Sept. 05, pp. 1209-1232.
[15] Lauren Neergaard, "FDA Commissioner Lester Crawford Resigns," *Associated Press*, 23 Sept. 05; Robert Pear and Andrew Pollack, "Leader of the F.D.A. Steps Down After a Short, Turbulent Tenure," *New York Times*, 24 Sept. 05.
[16] "Depression in Children and Young People," National Institute for Health and Clinical Excellence, Sept. 05, pp. 16, 18 and 28.
[17] "Suicidal Thinking in Children and Adolescents Being Treated with Strattera (Atomoxetine)," FDA Public Health Advisory, 29 Sept. 05.
[18] "Concluding Observations (Australia)," UN Committee on the Rights of the Child, 40th Session, 30 Sept. 05; "Concluding Observations (Denmark)," UN Committee on the Rights of the Child, 40th Session, 30 Sept. 05; "Concluding Observations (Finland)," UN Committee on the Rights of the Child, 40th Session, 30 Sept. 05.
[19] "2005 Safety Alerts for Drugs, Biologics, Medical Devises, and Dietary Supplements," FDA MedWatch, 17 Oct. 05.
[20] Lori Oliwenstein, "Study Notes Risks of Antipsychotic Drugs," *University of Southern California Public Relations*, 21 Oct. 05.
[21] Ricardo Alonso-Zaldivar, "Warning Urged for ADHD Drugs," *Los Angeles Times*, 10 Feb. 06.
[22] Ricardo Alonso-Zaldivar, "New Warning Advocated for ADHD Drugs," *Los Angeles Times*, 23 Mar. 06.