Patients, Not the FDA, Have Been Leaders in Exposing Psychiatric Drug Side Effects

LOS ANGELES, CALIFORNIA, UNITED STATES, May 31, 2023 /EINPresswire.com/ -- Citizens Commission on Human Rights (CCHR), the leading mental health industry watchdog, criticizes the Food and Drug Administration (FDA) for its long-standing disregard for patients' reporting psychiatric drug side effects, and for delaying critical warnings about psychiatric drug risks for years.

In 1991, patients and experts testified before the FDA on the link between antidepressants and suicidality. It would take the FDA 13 years to admit they were right and issue a black box warning. CCHR says to this day FDA continues to devalue patients' first-hand reports

A case in point: concerns regarding antidepressant adverse effects emerged in the early 1990s when medical studies reported instances of violent and suicidal reactions among patients taking these drugs. Dr. Martin Teicher from Harvard Medical School, was among them, publishing a study on how one of the first SSRI antidepressants could cause "intense, violent suicidal thoughts" in a substantial number of patients.[1] CCHR began receiving increasing numbers of reports of people becoming suicidal once prescribed the drug, who also reported their side effects to the FDA. In 1990, CCHR submitted a Citizen's Petition to the FDA outlining the evidence of the drug's risks.

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>
> *Toby Watson, psychologist*

In 1991, the FDA finally responded by holding a public hearing on the antidepressant. Dozens of distraught patients gave testimony before the FDA's Psychopharmacological Drugs Advisory Committee, having become violent and/or suicidal after being prescribed the drug. Other family members testified about loved ones who had committed suicide under the influence of the antidepressant.[2]

Prior to the hearing, CCHR had written to the FDA Commissioner, raising concerns about the conflicts of interest of many of the panel members to major pharmaceutical companies. It turns out CCHR's concerns were well-founded, and despite all the evidence given before the 1991 FDA panel, they unanimously concluded that antidepressants did not cause suicide or violent behavior, disregarding the mounting concerns raised by patients and experts. CCHR's footage of that hearing documents the harrowing public testimony and the conflicts of interest of the FDA's voting panel members—and is available here.

Fast forward to 13 years later: Prompted by the FDA's British counterpart, the Medicines and Healthcare products Regulatory Agency (MHRA), issuing a warning on the risk of suicidal behaviors among adolescents being prescribed SSRI antidepressants, the FDA finally held its second hearing on antidepressants and suicide.[3]

In September 2004, the FDA's Psychopharmacological Drugs and Pediatric Advisory Committees held new hearings on whether antidepressants caused suicidal behavior in children.[4]

One of many grieving parents testifying of their children committing suicide after being prescribed SSRI antidepressants was Mathy Milling Downing, whose 12-year-old daughter, Candace, tragically took her own life four days after starting on an antidepressant. At the FDA hearing, Mathy passionately confronted the committee, stating, "The blood of these children is on your hands. To continue to blame the victim rather than the drug is wrong."[5]

Finally, on October 15, 2004, after years of mounting evidence and public pressure, and likely due to the fact that Britain had acted first, the FDA admitted the link between antidepressant drugs and suicide, issuing its most severe warning, the black box, on all antidepressants.[6]

Psychiatric drug side effects have long been a cause for concern among patients. Many have reported suffering from debilitating and even life-threatening effects. Despite this, the FDA has consistently been slow to respond, failing to adequately protect the public's well-being.

Another example of patients' reports being ignored by the FDA, is that over an 8-year period, the FDA's MedWatch received 700 overdose reports from ADHD drugs. The U.S. Drug Enforcement Administration (DEA) has categorized ADHD drugs as having a "high potential for abuse" (Schedule II) since 1971.[7] The Centers for Disease Control and Prevention has been reporting on stimulant overdose deaths for years, with the latest figures showing stimulant overdose deaths tripled between 2017 and 2022.[8]

And yet it took until 2023 for the FDA to finally issue its black box warning on all ADHD drugs causing addiction. Even when taken as prescribed.[9]

Another drug side effect amassing a growing number of reports from consumers is sexual dysfunction from antidepressants.

There is also a growing number of patient advocacy groups raising awareness about the debilitating sexual dysfunction experienced by those taking SSRI antidepressants. One such group is the PSSD Network, "a collaborative group of volunteers who have been directly (or indirectly) affected by Post-SSRI Sexual Dysfunction." Their website features dozens of victims of PSSD sufferers, men, and women, holding handwritten signs detailing their personal experience with devastating SSRI side effects, including permanent disability, with one describing the condition as "hell on earth."

In 2018, nearly two dozen doctors submitted a petition to the FDA requesting that warnings be included on all SSRI and SNRI product labels regarding adverse sexual side effects. The request also called for adding a black box warning about prolonged symptom persistence even after stopping the drugs.[10] But it wasn't until September 2021 that the FDA acted, and even then, they only required that the drugs include that the drugs may cause symptoms of sexual dysfunction among the long list of side effects in the drug package inserts—which are usually 20-30 pages long.[11]

They are still awaiting the black box warning, and their concerns are backed by a growing number of published research. A 2022 article, "Diagnosing Long-Term Sexual Dysfunction from SSRIs," published in Psychology Today, reported, "Multiple studies find the drugs 'may cause sexual dysfunction in 40 to 65 percent of individuals' prescribed them."[12]

It is crucial for doctors and regulatory bodies like the FDA to prioritize patient well-being over the interests of the pharmaceutical industry. The FDA's delay in issuing timely warnings regarding psychiatric drug side effects has put countless individuals at risk. CCHR says that ultimately, it is the patients who suffer the most from these side effects, and it is imperative that their concerns and experiences are heard and taken seriously.

Psychologist Toby Watson emphasized the importance of healthcare professionals listening to patients, "I encourage doctors to believe patients who report debilitating side effects from psychiatric drugs. Historically, it's patients who've been right about nearly all drug side effects decades before the FDA finally issues a 'black box' warning. I would also like to remind doctors the oath to 'do no harm' was meant for their patients, not the pharmaceutical industry."

[1] Martin H. Teicher, M.D., Ph.D., et al., "Emergence of Intense Suicidal Preoccupation During Fluoxetine Treatment," The American Journal of Psychiatry, Feb. 1990

[2] Psychopharmacological Drugs Advisory Committee, FDA, 20 Sept. 1991, Hearing Transcript

[3] Dien Ho, PhD, "Antidepressants and the FDA's Black-Box Warning: Determining a Rational Public Policy in the Absence of Sufficient Evidence," Virtual Mentor, 2012;14(6):483-488, https://journalofethics.ama-assn.org/article/antidepressants-and-fdas-black-box-warning-determining-rational-public-policy-absence-sufficient/2012-06

[4] Elizabeth Shogren, “Suicide Risk to Children Affirmed,” Los Angeles Times, 14 Sept. 2004

[5] Joint Meeting of the CDER Psychopharmacologic Drugs Advisory Committee and the FDA Pediatric Advisory Committee, 13 Sept. 2004, Hearing Transcript

[6] https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/suicidality-children-and-adolescents-being-treated-antidepressant-medications

[7] “Methylphenidate [A Background Paper],” U.S. Drug Enforcement Administration, Oct. 1995, p. 16; https://www.deadiversion.usdoj.gov/schedules/orangebook/orangebook.pdf, p. 15

[8] “Provisional Drug Overdose Death Counts,” National Vital Statistics System, Centers for Disease Control and Prevention, https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm; https://www.cdc.gov/drugoverdose/deaths/other-drugs.html#psychostimulants

[9] “FDA updating warnings to improve safe use of prescription stimulants used to treat ADHD and other conditions,” Food and Drug Administration, 11 May 2023, https://www.fda.gov/media/168066/download

[10] “Citizen petition: Sexual side effects of SSRIs and SNRIs,” International Journal of Risk & Safety in Medicine, 2018;29(3-4):135-147. doi: 10.3233/JRS-180745, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6004927/

[11] Denise Myshko, “FDA Requires New Labeling for Antidepressants,” Formulary Watch, 4 Oct. 2021, https://www.formularywatch.com/view/fda-requires-new-labeling-for-antidepressants

[12] Christopher Lane Ph.D., “Diagnosing Long-Term Sexual Dysfunction from SSRIs,” Psychology Today, 20 Jan. 2022, https://www.psychologytoday.com/us/blog/side-effects/202201/diagnosing-long-term-sexual-dysfunction-ssris

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