FDA Finally Adds “Addiction” to Black Box Warning on ADHD Drugs

CCHR says FDA warning is long overdue considering CDC has repeatedly warned of overdose deaths from stimulant drugs including those commonly prescribed for ADHD

While the new FDA warning is an improvement, CCHR says it does not go far enough to address the well-documented risks of stimulant drugs, and the agency is lagging in updating its warnings.

LOS ANGELES, CALIFORNIA, UNITED STATES, May 17, 2023 /EINPresswire.com/ -- The FDA has finally acknowledged ADHD drugs can cause addiction, even when used as prescribed. The agency is now requiring this information to be added to its black box warning on all stimulant drugs.[1] According to Citizens Commission on Human Rights (CCHR), the FDA’s label change regarding addiction is long overdue. The U.S. Drug Enforcement Administration (DEA) has categorized ADHD drugs as having a “high potential for abuse” (Schedule II) since 1971. Current DEA Schedule II drugs include such highly addictive drugs as morphine, oxycodone, and fentanyl.[2]

While the new FDA warning is an improvement, CCHR says it does not go far enough to address the well-documented risks of stimulant drugs, and the agency is lagging in updating its warnings. Since 1995, the DEA has also warned that ADHD drugs can cause “Psychotic episodes, violent behavior, and bizarre mannerisms,”[3]

Still, the new FDA warning on addiction should raise red flags, considering 9.5 million Americans have been prescribed ADHD drugs, including millions of children and teens.[4] It is particularly relevant considering the Centers for Disease Control and Prevention (CDC), has been reporting on stimulant overdose deaths since at least 2010, including drugs commonly prescribed for ADHD. The latest figures show that overdose deaths from stimulants have tripled in just five years—going from 10,255 deaths in 2017 up to 32,478 in 2022.[5]

The previous black box warning noted ADHD drugs had “Potential for abuse and dependence.” The new warning cites the potential for “Abuse, misuse, and addiction.” Furthermore, the FDA

> Addiction to stimulant medication is not rare; it is common. The drugs' addictive qualities are obvious. We only need to observe the many patients who are forced to periodically increase their dosage."
>
> *Dr. Richard Saul, pediatrician and neurologist*

Drug Safety Communication on the updated warning states, "Even when prescribed to treat an indicated disorder, their use can lead to misuse or abuse."[6]

This counters claims such as those made by the pharmaceutically-funded Children and Adults with Attention Deficit Disorder (CHADD), as in their 2022 statement, "Research Shows ADHD Meds Do Not Increase Substance Use Risks."

The late Dr. Richard Saul, a pediatrician and neurologist stated, "[A]ddiction to stimulant medication is not rare; it is common. The drugs' addictive qualities are obvious. We only need to observe the many patients who are forced to periodically increase their dosage…."[7]

CCHR says consumers need direct access to information on psychopharmaceutical side effects. They could access information from the FDA if only they knew where to find it.

Purportedly developed to help consumers easily understand prescription drug side effects, the FDA's Medication Guide (Med Guides) program, established in 1998, requires pharmaceutical companies to disclose any drug side effects which merit a "significant public health concern." They must also use "nontechnical, understandable language."[8] Med Guides on most brand-name psychopharmaceutical drugs are available online, unfortunately, most of the public is unaware of their existence. A cursory look at Med Guides for several brand-name ADHD drugs finds disturbing information on their known side effects. Such as:

Mental (psychiatric) problems

All patients
- new or worse behavior and thought problems
- new or worse aggressive behavior or hostility

Children and Teenagers
- new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms

Also contained within the MedGuides on various brand-name ADHD drugs is the following language:

"[DRUG-X] is a federally controlled substance (CII)* because it can be abused or lead to dependence." This language will be changed to include the factor of addiction, given the new

black box warning change.

CCHR says the FDA should be actively promoting the Med Guides to the broad public, but this is not occurring. Moreover, the Med Guides only work on desktop computers and not on mobile devices or tablets. Therefore, they aren't user-friendly, despite the fact they were enacted to make information easily available to consumers.

When a Med Guide is opened on a desktop, it automatically loads to the page containing the Med Guides section (placed somewhere within 30-40 pages of drug information). When opened on a mobile device, this function doesn't work. It simply takes the consumer to the first page—not the Med Guides section with the "easy to understand language" containing "information of significant health concern."

This is a disservice to consumers. The consumer should have access to FDA information on a drug's risk prior to the prescription being filled, not after.

This is particularly true when it comes to a drug's potential for addiction, especially when it comes to children and teens. According to IQVia (formerly IMS Health), 3,155,441 children and teens age 0-17 are prescribed ADHD drugs, with 58,000 of them aged 0-5.[9]

To reiterate, according to the Med Guides, children (and adults) are being prescribed drugs that can cause new or worse behavior or thought problems, aggression, hostility, and psychotic symptoms. They may be unaware that the FDA lists these as possible side effects.

CCHR is calling on the FDA to broadly promote the Medication Guides to the general public, given the increasing amount of overdose deaths the CDC attributes to stimulant drugs.

According to the FDA's Med Guide page, "Medication guides are FDA- approved documents that address issues that are specific to particular drugs, and can help patients avoid serious adverse events (side effects)."

CCHR says if the public is unaware of their existence, they can hardly help patients avoid serious side effects, including, but not limited to, addiction.

*CII = Schedule II drugs

Note: This is the link to the MedGuides page. Use the search box in the white section (far right) not the search box at the top right of the page in the dark blue section.

[1] "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/drugs/drug-safety-and-availability/fda-updating-warnings-improve-safe-use-prescription-stimulants-used-treat-adhd-and-other-conditions

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

[3] “Methylphenidate [A Background Paper],” U.S. Drug Enforcement Administration, Oct. 1995, pp. 4, 21

[4] https://www.cchrint.org/psychiatric-drugs/people-taking-psychiatric-drugs/

[5] “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

[6] “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/drugs/drug-safety-and-availability/fda-updating-warnings-improve-safe-use-prescription-stimulants-used-treat-adhd-and-other-conditions

[7] Richard Saul, M.D., “Doctor: ADHD Does Not Exist,” TIME Magazine, 14 Mar. 2014, https://time.com/25370/doctor-adhd-does-not-exist/

[8] 63 FR 66378 - Prescription Drug Product Labeling; Medication Guide Requirements, Federal Register Volume 63, Issue 230 (Dec. 1, 1998), Rules and Regulations, Final Rule, Office of the Federal Register, National Archives and Records Administration, https://www.govinfo.gov/content/pkg/FR-1998-12-01/pdf/98-31627.pdf

[9] https://www.cchrint.org/psychiatric-drugs/children-on-psychiatric-drugs/

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