

Ablechild appreciates the opportunity to speak to the committee about the need to enact a MedWatch Awareness Day.

Currently there are 70 million Americans prescribed mind-altering drugs, which many come with strong FDA issued adverse reaction warnings, including violent behavior and suicidal ideation.

In response to the tragic shooting incident at Sandy Hook, the State has expanded mental health services, which most certainly will include increased psychiatric drugging, making it all the more important for consumers to be aware of the FDA's adverse drug event reporting system.

The FDA's MedWatch System was instituted in 1993 and is intended to provide important information to the federal agency from health care professionals and consumers. The reporting of drug adverse events to MedWatch can prompt the FDA to act on updating safety information, make labeling changes, influence how patients receiving drug products should be monitored, and issue warnings, safety messages and even prompt drug recalls.

The MedWatch system is completely voluntary, private and there are no costs associated with its use.

Due to the lack of knowledge about the MedWatch system, the FDA acknowledges that it receives less than one percent of all adverse reactions that actually occur.

The MedWatch system is the front-line defense against products that may pose safety hazards to consumers and, in short, saves lives.

The Sandy Hook investigation revealed how the MedWatch system could have benefited Nancy Lanza had the information been provided.

Despite advising the healthcare professional at the Yale Child Study Center that Adam Lanza had experienced an adverse reaction to the antidepressant he had been prescribed, no information about reporting this adverse event to MedWatch was provided to Nancy Lanza. Nor is there any record of the healthcare provider reporting the event to MedWatch.

It is precisely this type of information that the FDA wants to know. Yet, as is seen in the case of Nancy Lanza's concerns about the drug Adam was prescribed, no one made any effort to report the adverse reaction to MedWatch.

The purpose of instituting a MedWatch Awareness Day is to provide an opportunity for Connecticut's consumers to better understand the importance of reporting adverse drug events to the FDA.

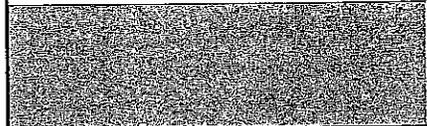
It cannot be overstated: The MedWatch System, if utilized by consumers, saves lives.

This is a public safety issue and by enacting a MedWatch Awareness Day, the State would assist in increasing knowledge about this important drug reporting system.

Thank you.



MEDWATCH Consumer Voluntary Reporting (FORM FDA 3500B)



When do I use this form?

- You were hurt or had a bad side effect (including new or worsening symptoms) after taking a drug or using a medical device or product.
- You used a drug, product, or medical device incorrectly which could have or led to unsafe use.
- You noticed a problem with the quality of the drug, product, or medical device.
- You had problems with how a drug worked after switching from one maker to another maker.

- Medical devices, including any health-related kit, test, tool, or piece of equipment (such as breast implants, pacemakers, diabetes glucose-test kits, hearing aids, breast pumps, and many others)
- Nutrition products, including vitamins and minerals, herbal remedies, infant formulas, and medical foods, such as those labeled for people with a specific disease or condition
- Cosmetics or make-up products
- Foods (including beverages and ingredients added to foods)

Don't use this form to report:

- Vaccines – report problems to the Vaccine Adverse Event Reporting System (VAERS)
- Investigational drugs or medical devices (those being studied, not yet approved) – report problems to your doctor or to the contact person listed in the clinical trial

Are there specific instructions for filling out the form?

- Fill in as much information as possible and send in the report even if you do not have all the information.
- You can fill out this form yourself or have someone fill it out for you. If you need help, you may want to talk with your health professional.
- Feel free to include or attach an image. Please do not send the products to the FDA.

Will the information I report be kept private?

The FDA recognizes that privacy is an important concern, so you should know:

- We ask only for the name and contact information of the person filling out the form in case we need more information. This information will not be given out to the public.
- Information about the problem may be shared with the company that makes the product to help them better understand the problem you are reporting, unless you request otherwise (see Section E).

How will I know the FDA has received my form?

- You will receive a reply from the FDA after we receive your report. We will personally contact you only if we need additional information.
- Your report will become part of a database so that it can be reviewed and compared to other reports by an FDA safety evaluator who will determine what steps to take.

What types of products should I use this form for?

- Drugs, including prescription or over-the-counter medicines, and biologics, such as human cells and tissues used for transplantation (for example, tendons, ligaments, and bone) and gene therapies

How can I contact the FDA if I have questions?

Toll-free line: 1-800-332-1088

www.fda.gov/reportinghelp

To report online: www.fda.gov/medwatch/report.htm

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 25 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to the address to the right:

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF EMAIL ADDRESS.

MailOnline

70 MILLION Americans are on mind-altering drugs: shock statistic which shows full extent of use of illegal and legal narcotics

- One in Five adults take prescription psychiatric drugs
- Prescription drugs are the second most common substances to be abused
- 27,000 unintentional drug overdose deaths occurred in the United States
- 250million prescriptions for anti-depressants were written in 2010
- 10 per cent of high school pupils are prescribed drugs for ADHD
- Anti-depressants have been linked to a series of school shootings

By [Tom Gardner](#)

PUBLISHED: 12:21 EST, 10 February 2014 | UPDATED: 12:10 EST, 12 February 2014

More than 70million Americans - or one in five of the population - is on mind-altering drugs, a new study reported by [WND.com](#) has found.

The shocking survey revealed that prescription drug abuse as well as illegal narcotics use has reached epidemic proportions across the country.

Nearly 50 million people are thought to have been given high-strength substances by their doctors - leading to an alarming spike in drug-related deaths.

The death of movie star of Philip Seymour Hoffman from an apparent heroin overdose again promoted the spectre of illicit substances in the country's psyche.



+3

Overdose: Philip Seymour Hoffman was found dead in his New York apartment in a suspected heroin overdose

But new research by the Centres for Disease Control and Prevention has suggested the far greater hazard is posed by over the counter prescription drugs, such as anti-depressants, sleeping pills and anxiety relief substances.

Experts have warned legal substances caused more overdose deaths than heroine and cocaine combined during the past decade, according to the U.S. report.

In 2010 more than 250 million prescriptions for antidepressants were written for Americans.



+3

Shock: More than 27,000 people died in a single years as a result of an unintentional overdose on prescription drugs

A staggering 27,000 unintentional overdoses deaths were ascribed to prescription drugs in a single year, the Centres for Disease Control and Prevention found.



+3

Experts have warned that prescription drug addiction has reached epidemic proportions

The organisation was so alarmed by the figures, its report noted, WND reports, that: 'Prescription drug abuse is the fastest growing drug problem in the United States.'

For the last decade, 'more overdose deaths have involved opioid analgesics than heroin and cocaine combined.'

It feared the rise in the rate of opioid analgesics prescriptions – drugs marketed under the brand names Norco, Vicodin, Dilaudid, Exalgo, OxyContin, Percocet, Astramorph, Avinza - was likely to drive the trend even higher in the coming years.

The dangerous implications of so many people being prescribed these powerful mind-altering substances are finally being understood.

Recent research is beginning to draw a link between a popular sleeping pill called Ambien and - called as a hypnotic drug - to a series of crimes and serious accidents.

The drug was famously thought to have been a factor in a car crash involving the-Republican Patrick Kennedy.

Research into school shootings and violence among young people is finding links with the use of anti depressants.

Four and nine million by most estimates, mostly boys – to take Ritalin or similar dangerous psycho-stimulant drugs which can have similar side effects to cocaine or the amphetamines.

19 percent of high school-age boys in the U.S. are being diagnosed with ADHD and about 10 percent are currently being prescribed drugs for it, while 10 percent of high school-age girls are being likewise diagnosed.

Dr. William Graf, a pediatric neurologist in New Haven and Yale medical professor told the New York Times: 'Those are astronomical numbers. I'm floored.'