

CCHR Releases Decrypted MedWatch Reports

Contributed by Administrator
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2004-2008: 2,442 Babies with heart disease, 3,372 birth defects, 1,072 miscarriages, abortions and other deaths from psychiatric drugs

Decrypted FDA Reports Reveal 2,442 babies with heart disease, 3,372 birth defects, 1,072 miscarriages, abortions and other deaths from psychiatric drugs. Also 4,268 suicides, 2,452 other deaths, 195 homicides from psych drugs 2004-2006 alone!

Check out the decrypted MedWatch safety reports, now available to the public on reports since 2004, on CCHR's new website (<http://www.cchrint.org/psychdrugdangers/>). These decrypted reports are available nowhere else as the FDA has done little or nothing with their AERS system. So please share the information with health care providers, policy makers etc.

More importantly, please share this with people who are taking or considering taking psychiatric drugs.

The report totals reveal that between 2004-2008 the FDA's MedWatch system received pregnancy-related psychiatric drug adverse reaction reports which included 2,442 babies born with heart disease, 3,372 other birth defects, as well as 1,072 miscarriages, abortions and other deaths. Between 1-10% of actual cases ever get reported to the FDA according to their own estimates. Prenatal and Neonatal Exposure Drug Tables:
<http://www.cchrint.org/psychdrugdangers/MothersAct.html>

YouTube promotional video:

<http://www.youtube.com/watch?v=gDdA7WPgeDM&feature=Playlist&p=B9EA75455D155D89&index=1>

If you have ever made a safety report with MedWatch, you would hope that the FDA did something with that information. I personally opened the copy of my report after making it and downloading a copy of what gets sent to them from filling in the forms on their website, and found that it looked like nothing more than a bunch of garbledgook. You can see from reading this press release why that is, and how it's no different for anyone who actually requests to see the MedWatch reports from the FDA, but actually even harder to decipher. Be sure to watch the instructional video for an explanation of how to use the tables, so that you don't end up missing any of the information that you need in order to understand the FDA's labeling of different things in the reports.

Press release by CCHR:

Decrypted FDA reports reveal 4,260 suicides, 2,452 additional deaths, 195 homicides from psychiatric drugs in 2004-2006 alone

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For the first time the side effects of psychiatric drugs that have been reported to the U.S. Food and Drug Administration (FDA) by doctors, pharmacists, other health care providers and consumers have been decrypted from the FDA's MedWatch reporting system and made available to the public in an easy to search psychiatric drug side effects database and search engine. The database is provided as a free public service by the mental health watchdog, Citizens Commission on Human Rights International (CCHR). The report totals reveal that between 2004-2008 the FDA's MedWatch system received pregnancy-related psychiatric drug adverse reaction reports which included 2,442 babies

born with heart disease, 3,372 other birth defects, as well as 1,072 miscarriages, abortions and other deaths.

The database also reveals that, between 2004-2008 there were reports submitted to MedWatch including 4,895 suicides, 3,908 cases of aggression, 309 homicides and 6,945 cases of diabetes from people taking psychiatric drugs. These numbers reflect only a small percentage of the actual side effects occurring in the consumer market, as the FDA has admitted that only 1-10% of side effects are ever reported to the FDA.

The database is searchable by individual reports (for the 2004-2006 period), type of drug, age of patient, the side effect reported (suicide, homicide, heart attack, stroke, mania, etc.), and whether the drug in question carries a black box warning (the agency's strongest warning—short of banning a drug).

It is searchable by drug name and age group and includes who reported the psychiatric drug reaction (doctor, pharmacist, consumer, etc.). It also includes the top 20 reported adverse reactions to all psychiatric drugs to the FDA and combined summaries of all psychiatric drug reactions for the years 2004-2006 and 2004-2008.

Since the reform of the Prescription Drug User Fee Act (PDUFA) in 2007, ads for psychiatric and other drugs must include statements encouraging consumers to report adverse drug reactions to the FDA's MedWatch system—Adverse Events Reporting System (AERS). However, consumers or doctors attempting to access the AERS online were confounded by a system so complex that it was impossible to use. Although the FDA should have made the information collected readily accessible, it failed in that duty to the public. It took a computer programmer over 1,000 hours to decipher four years' worth of data to make this information available.

The programmer identified the main psychiatric drugs in the AERS, wading through quarterly reports of seven different reporting systems, including the drug name, demographics, adverse reactions, patient outcomes, reporting source, therapy start and end dates and the indication (diagnosis). The result: A database and search engine that unravels the 94,000 pages of codified psychiatric drug adverse reactions reported each year from 2004-2006 and 2004-2008 to the FDA's MedWatch system.

Reporting of adverse reactions to psychiatric drugs by doctors, pharmacists, other health care providers and consumers once those drugs are out in the consumer market, is fundamental to drug safety monitoring. Yet these reports have been frequently ignored or dismissed as "anecdotal" by the FDA even when serious side effects number in the thousands. The FDA approves the majority of psychiatric drugs only after Phase 2 (short term) clinical trials. However, once the drugs are out in the consumer market, the FDA is supposed to require longer clinical trials, or post-marketing studies of the drugs, however this rarely happens. Subsequently, dangerous and deadly drugs have been left without black box warnings, or on the market for far too long. The best "signal" event for the FDA to direct its resources in identifying or pulling dangerous drugs is what is happening out in the real world, with consumers and patients, not in a controlled short term clinical trial, funded by the pharmaceutical companies seeking approval for their drugs to go to market.

For years the information contained in the FDA's MedWatch reporting system has been inaccessible and therefore virtually useless for consumers and doctors. CCHR's stance has always been that consumers have the right to this information for then—and only then—can consumers have full "informed consent" regarding the risks of psychiatric drugs, and so it has provided this database as a free public service.

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