Deaths from Marijuana v. 17 FDA-Approved Drugs
(Jan. 1, 1997 to June 30, 2005)

http://medicalmarijuana.procon.org/view.resource.php?resourceID=000145

I. Background

Much of the medical marijuana discussion has focused on the safety of marijuana compared to the safety of FDA-approved drugs. On June 24, 2005 ProCon.org sent a Freedom of Information Act (FOIA) request to the US Food and Drug Administration (FDA) to find the number of deaths caused by marijuana compared to the number of deaths caused by 17 FDA-approved drugs. Twelve of these FDA-approved drugs were chosen because they are commonly prescribed in place of medical marijuana, while the remaining five FDA-approved drugs were randomly selected because they are widely used and recognized by the general public.

We chose Jan. 1, 1997 as our starting date as it is the beginning of the first year following the Nov. 1996 approval of the first state medical marijuana laws (such as California's Proposition 215). The FDA reports we read from Sep. 13, 2005 to Oct. 14, 2005 included drug deaths "to present", which was the date each report was compiled for our request. We cut off the counting as of June 30, 2005 to provide a uniform end-date to the various reports.

On Aug. 25, 2005 the FDA sent us 12 CDs and five printed reports containing copies of their Adverse Event Reporting System (AERS) report on each drug requested. These reports included all adverse events reported to the FDA, only a portion of which included deaths. We manually counted the number of deaths reported on each drug from the FDA-supplied information.

A review of the FDA Adverse Events reports also revealed some deaths where marijuana was at least a concomitant drug (a drug also used at the time of death) in some cases. On Oct. 14, 2005 we used the Freedom of Information Act to request a copy of the adverse events reported deaths for marijuana/cannabis. We received those reports on Aug. 3, 2006 in the form of three additional CDs.

II. Cause of Death Categories & Definitions

The FDA AERS reports rely on health professionals to detect an "adverse event" and attribute that event to the drug, and then to voluntarily report that effect to either the FDA or the drug manufacturer. The drug firm, by law, must report that event to the FDA. The FDA states "ninety percent of the FDA's reports are received from drug manufacturers" on page one of its "Adverse Event Reporting System (AERS) Brief Description with Caveats of System." (PDF 2.7 MB)

Select instructions on how to report adverse events, as per the FDA's AERS Form Instructions (PDF 65 KB), are provided below:

- **Adverse Event:** Any incident where the use of a medication (drug or biologic, including HCT/P), at any dose, a medical device (including in vitro diagnostics) or a special nutritional product (e.g., dietary supplement, infant formula or medical food) is suspected to have resulted in an adverse outcome in a patient.
- **Death:** Check only if you suspect that the death was an outcome of the adverse event, and include the date if known. Do not check if:
    - The patient died while using a medical product, but there was no suspected association between the death and
    - A fetus is aborted because of a congenital anomaly (birth defect), or is miscarried

A. **Suspect Product(s):** A suspect product is one that you suspect is associated with the adverse event.

Up to two (2) suspect products may be reported on one form (#1=first suspect product, #2=second suspect product). Attach an additional form if there were more than two suspect products associated with the reported adverse event.

B. **To report:** it is not necessary to be certain of a cause/effect relationship between the adverse event and the use of the medical product(s) in question. Suspicion of an association is sufficient reason to report. Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

III. FDA Disclaimer of Information

III. FDA Disclaimer of Information

Included in the 15 CDs and five printed reports from the FDA was the following disclosure:

"The information contained in the reports has not been scientifically or otherwise verified. For any given report there is no certainty that the suspected drug caused the reaction. This is because physicians are encouraged to report suspected reactions. The event may have been related to the underlying disease for which the drug was given to concurrent drugs being taken or may have occurred by chance at the same time the suspected drug was taken.

Numbers from these data must be carefully interpreted as reported rates and not occurrence rates. True incidence rates cannot be determined from this database. Comparisons of drugs cannot be made from these data."
-- July 18, 20/05 - FDA Office of Pharmacoepidemiology and Statistical Science, "Adverse Event Reporting System (AERS) Brief Description with Caveats of System"

[**Editor's Note** - ProCon.org makes no claim that the data below reflects occurrence rates. The information is presented for our readers' benefit who may feel that the relative comparisons have value. ProCon.org attempted to find the total number of users of each of these drugs by contacting the FDA, pharmaceutical trade organizations, and the actual drug manufacturers. We either did not receive a response or were told the information was proprietary or otherwise unavailable]

IV. Summary of Deaths by Drug Classification

DRUG CLASSIFICATION	Specific Drugs per	Primary Suspect	Secondary Suspect	Total Deaths

	Category	of the Death	(Contributing to death)	Reported 1/1/97 - 6/30/05
A. MARIJUANA *also known as: Cannabis sativa L*	Marijuana Cannabis Cannabinoids	**0**	**279**	**279**
B. ANTI-EMETICS *(used to treat vomiting)*	Compazine Reglan Marinol Zofran Anzemet Kytril Tigan	**196**	429	**625**
C. ANTI-SPASMODICS *(used to treat muscle spasms)*	Baclofen Zanaflex	**118**	56	**174**
D. ANTI-PSYCHOTICS *(used to treat psychosis)*	Haldol Lithium Neurontin	**1,593**	702	**2,295**
E. OTHER POPULAR DRUGS *(used to treat various conditions including ADD, depression, narcolepsy, erectile dysfunction, and pain)*	Ritalin Wellbutrin Adderall Viagra Vioxx*	**8,101**	492	**8,593**
F. TOTALS of A-E	**Number of Drugs in Total**	**Primary Suspect of the Death**	**Secondary Suspect (Contributing to death)**	**Total Deaths Reported 1/1/97 - 6/30/05**
• **TOTAL DEATHS FROM MARIJUANA**	1	**0**	**279**	**279**
• **TOTAL DEATHS FROM 17 FDA-APPROVED DRUGS**	17	**10,008**	**1,679**	**11,687**

V. Chart of Deaths from Marijuana and 17 FDA-Approved Drugs

A. Marijuana				
	DRUG (Year Approved)	**Primary Suspect of the Death**	**Secondary Suspect (Contributing to death)**	**Total Deaths Reported 1/1/97 - 6/30/05**
1.	**Marijuana** (not approved) *also known as: Cannabis sativa L*	**0**	109	**109**
2.	**Cannabis** (not approved) *also known as: Cannabis sativa L*	**0**	78	**78**
3.	**Cannabinoids** *(unclear if these mentions include non-plant cannabinoids)*	**0**	92	**92**

Sub-Total - Anti-Emetics	**0**	279	**279**

FDA-Approved Drugs Prescribed in Place of Medical Marijuana

B. Anti-Emetics

	DRUG (Year Approved)	**Primary Suspect of the Death**	**Secondary Suspect** (Contributing to death)	**Total Deaths Reported** 1/1/97 - 6/30/05
1.	**Compazine** (1980) *also known as: Phenothiazine, prochlorperazine*	**15**	30	**45**
2.	**Reglan** (1980) *also known as: Metaclopramide, Paspertin, Primperan*	**37**	278	**315**
3.	**Marinol** (1985) *also known as: Dronabinol*	**4**	1	**5**
4.	**Zofran** (1991) *also known as: Ondansetron hydrochloride*	**79**	76	**155**
5.	**Anzemet** (1997) *also known as: Dolasetron mesylatee*	**22**	5	**27**
6.	**Kytril** (1999) *also known as: Granisetron hydrochloride*	**36**	24	**60**
7.	**Tigan** (2001) *also known as: Trimethobenzamide*	**3**	15	**18**
	Sub-Total - Anti-Emetics	**196**	429	**625**

C. Anti-Spasmodics

	DRUG (Year Approved)	**Primary Suspect of the Death**	**Secondary Suspect** (Contributing to death)	**Total Deaths Reported** 1/1/97 - 6/30/05
1.	**Baclofen** (1967) *also known as: Lioresal, 4-amino-3-(4-chlorophenyl)-butanoic acid*	**72**	33	**105**
2.	**Zanaflex** (1996) *also known as: Tizanidine hydrochloride, Sirdalud, Ternelin*	**46**	23	**69**
	Sub-Total - Anti-Spasmodics	**118**	56	**174**

D. Anti-Psychotics

	DRUG (Year Approved)	**Primary Suspect of the Death**	**Secondary Suspect** (Contributing to death)	**Total Deaths Reported** 1/1/97 - 6/30/05
1.	**Haldol** (1967)	**450**	267	**717**

	also known as: Haloperidol, Haldol Decanoate, Serenace, Halomonth			
2.	**Lithium** (1970) *also known as: Lithium Carbonate, Eskalith, Lithobid, Lithonate, Teralithe, Lithane, Hypnorex, Limas, Lithionit, Quilonum*	**175**	133	**308**
3.	**Neurontin** (1994) *also known as: Gabapentin*	**968**	302	**1,270**
Sub-Total - Anti-Psychotics		**1,593**	702	**2,295**

E. Other Well-Known and Randomly Selected FDA-Approved Drugs

	DRUG (Year Approved)	**Primary Suspect of the Death**	**Secondary Suspect** (Contributing to death)	**Total Deaths Reported** 1/1/97 - 6/30/05
1.	**Ritalin** (1955) *also known as: Methylphenidate, Concerta, Medadate, Ritaline* (used to treat ADD and ADHD)	**121**	53	**174**
2.	**Wellbutrin** (1997) *also known as: Bupropion Hydrochloride, Zyban, Zyntabac, Amfebutamone* (used to treat depression & anxiety)	**1,132**	220	**1,352**
3.	**Adderall** (1966) *also known as: Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate USP, Amphetamine Sulfate USP* (used to treat narcolepsy or to control hyperactivity in children)	**54**	12	**66**
4.	**Viagra** (1998) *also known as: Sildenafil Citrate* (used to treat erectile dysfunction)	**2,254**	40	**2,294**
5.	**Vioxx*** (1999) *also known as: Rifecixub, Arofexx* (used to treat osteoarthritis and pain)	**4,540**	167	**4,707**
Sub-Total - Other Popular Drugs		**8,101**	492	**8,593**

F. TOTALS of A-E	**Primary Suspect**	**Secondary Suspect** (Contributing to death)	**Total Deaths Reported** 1/1/97 - 6/30/05

• **TOTAL DEATHS FROM MARIJUANA**	**0**	279	**279**
• **TOTAL DEATHS FROM 17 FDA-APPROVED DRUGS**	**10,008**	1,679	**11,687**

*[**Editor's Note:** Merck, the maker of Vioxx, publicly announced its voluntary withdrawal of Vioxx from the global market on September 30, 2004. In 2005, advisory panels in both the US and Canada encouraged the return of Vioxx to the market, stating that Vioxx's benefits outweighed the risks for some patients. The FDA advisory panel voted 17-15 to allow the drug to return to the market despite being found to increase heart risk. The vote in Canada was 12-1, and the Canadian panel noted that the cardiovascular risks from Vioxx seemed to be no worse than those from ibuprofen. Notwithstanding these recommendations, Merck has not returned Vioxx to the market as of July 8, 2009.]

VI. Sources & Disagreement on Marijuana Deaths

Has marijuana caused any deaths?

General Reference *(not clearly pro or con)*

The Substance Abuse and Mental Health Services Administration's (SAMHSA) 2003 report *Mortality Data from the Drug Abuse Warning Network, 2001* (1.5 MB) stated:

"Marijuana is rarely the only drug involved in a drug abuse death. Thus ... the proportion of marijuana-induced cases labeled as 'One drug' (i.e., marijuana only) will be zero or nearly zero."
2003 - Substance Abuse and Mental Health Services Administration

PRO (Yes)	CON (No)
Thomas Geller, MD, Associate Professor of Child Neurology at the Saint Louis University Health Sciences Center, et al., wrote the following in their Apr. 4, 2004 article titled "Cerebellar Infarction in Adolescent Males Associated with Acute Marijuana Use," (560 KB) published in the journal *Pediatrics*: *"Each of the 3 cannabis-associated cases of cerebellar infarction was confirmed by biopsy (1 case) or necropsy (2 cases)... Brainstem compromise caused by cerebellar and cerebral edema led to death in the 2 fatal cases."* Apr. 4, 2004 - Thomas Geller, MD Liliana Bachs, MD, Senior Medical Officer at the Norwegian Institute of Public Health, et al., wrote the following in their Dec. 27, 2001 article titled "Acute Cardiovascular Fatalities Following	Stephen Sidney, MD, Associate Director for Clinical Research at Kaiser Permanente, wrote the following in his Sep. 20, 2003 article titled "Comparing Cannabis with Tobacco -- Again," published in the *British Medical Journal:* *"No acute lethal overdoses of cannabis are known, in contrast to several of its illegal (for example, cocaine) and legal (for example, alcohol, aspirin, acetaminophen) counterparts...* *Although the use of cannabis is not harmless, the current knowledge base does not support the assertion that it has any notable adverse public health impact in relation to mortality."* Sep. 20, 2003 - Stephen Sidney, MD Joycelyn Elders, MD, former US Surgeon General, wrote the following in her Mar. 26, 2004 editorial

Cannabis Use," published in the journal *Forensic Science International:* *"Cannabis is generally considered to be a drug with very low toxicity. In this paper, we report six cases where recent cannabis intake was associated with sudden and unexpected death. An acute cardiovascular event was the probable cause of death. In all cases, cannabis intake was documented by blood analysis... Further investigation of clinical, toxicologial and epidemiological aspects are needed to enlighten causality between cannabis intake and acute cardiovascular events."* Dec. 27, 2001 - Liliana Bachs, MD [Editor's Note: Dr. Bachs clarified the findings from her Dec. 27, 2001 study reported above in a Nov. 28, 2005 email to ProCon.org, as quoted below. *"Causality is a difficult assessment in forensic toxicology. It is often an 'exclusion diagnosis,' and so it is in our cases. I'm therefore not sure about how to classify those deaths.* *At the time I published that study I would probably not classify [the cannabis] as primary causation because it was not broadly accepted that [a death from cannabis] could occur at all. Today I see reports coming all the time that acknowledge cannabis cardiovascular risks, and the situation may be different."*]	published in the *Providence Journal:* *"Unlike many of the drugs we prescribe every day, marijuana has never been proven to cause a fatal overdose."* Mar. 26, 2004 - Joycelyn Elders, MD

VII. Full Text of All 20 FDA "Adverse Event" Reports

[Please note that some of these PDF files exceed 5 megabytes and may take several minutes to load]

1. Adderall (PDF 495 KB)
2. Anzemet (PDF 1.5 MB)
3. Baclofen (PDF 755 KB)
4. Cannabinoids (PDF 65 KB)
5. Cannabis (PDF 330 KB)
6. Compazine (PDF 1.6 MB)
7. Haldol (PDF 1.5 MB)
8. Kytril (PDF 2.2 MB)
9. Lithium (PDF 2.4 MB)
10. Marijuana (PDF 220 KB)
11. Marinol (PDF 535 KB)
12. Neurontin (PDF 6.3 MB)
13. Ritalin (PDF 1.6 MB)
14. Reglan (PDF 1.5 MB)
15. Tigan (PDF 2.4 MB)
16. Viagra (PDF 7.6 MB)
17. Vioxx (PDF 31.5 MB)
18. Wellbutrin (PDF 8.3 MB)
19. Zanaflex (PDF 6556 KB)
20. Zofran (PDF 1 MB)