GENERAL REFERENCES

Note: separate reference lists for
General References; Federal Register Filings;
Federal Laws, State Codes and Local Ordinances; Legal Cases.


Abrams D. A Prospective, Randomized Pilot Study of High, Medium or Low THC-content Smoked Marijuana on Weight Loss in Persons with HIV-related Wasting Syndrome versus Dronabinol (delta-9-tetrahydrocannabinol, Marinol, Roxane laboratories). http://www.maps.org/mmj/v6proto.html


325-338.


Borst Els (Dutch Health Minister) letter of 4 April, 2000 to Chairman of the Health Committee (vaste commissie voor Volksgezondheid, Welzijn en Sport). http://www.parlement.nl/doc/rec/hfdframe/rec001.htm


Bouso J. Informed Consent Form, Spanish Drug Agency Code Protocol # 99-0309. Administration of 3,4 methylendioxy-methamphetamine (MDMA) to Women with Chronic Post Traumatic Stress Disorder (PTSD) as a Consequence of Sexual Assault. A Dose-Finding Pilot Study. Biological Psychology and Health Department, Faculty of Psychology. Universidad Autónoma de Madrid, Hospital Psiquiátrico de Madrid.


Charney D. The Use of Placebos in Randomized Clinical Trials of Mood Disorders: Well Justified, but Improvements in Design are Indicated. *Biological Psychiatry* 47 (April 15, 2000) 8: 687-688.

Chow J. Deputy Assistant Secretary for Public Health Policy, Office of the Assistant Secretary of Health, HHS. Letter to Dale Gieringer, Coordinator of California NORML. November 30, 1992.


Cohen S. Lysergic acid diethylamide: side effects and complications. *Journal of Nervous and Mental Disease* 130 (1960).


Confirmation of Jane E. Henney to be Commissioner of the Federal Food and Drug Administration, Senator James Jeffords (R-VT). Hearing of the Senate Labor and Human Resources Committee, September 2, 1998.


Davy H. Researches, Chemical and Philosophical; Chiefly Concerning Nitrous Oxide, or Dephlogisticated Nitrous Air, and its Respiration. London: Printed for J. Johnson by Biggs and Cottle, Bristol, 1800.


Dehlendorf C, Wolfe S. Physicians disciplined for sex-related offenses. Journal of the


Doblin R. Letter to Dr. Marlene Haffner. Director, FDA Office of Orphan Products


Finkel M. Phase IV Testing: FDA Viewpoint and Expectations. 33 *Food Drug and Cosmetic Law* 181 (1978)


384
Food and Drug Administration. FDA Approves Zoloft for PostTraumatic Stress Disorder. 

Food and Drug Administration. FDA Issues Approvable Letter to Celgene for Thalidomide. 
*FDA Talk Paper T97-44.* September 22, 1997
http://www.fda.gov/bbs/topics/ANSWERS/ANS00820.html

Food and Drug Administration. Janssen Pharmaceutical Stops Marketing Cisapride in the US. 
*FDA Talk Paper T00-14.* March 23, 2000
http://www.fda.gov/bbs/topics/ANSWERS/ANS01007.html

http://www.fda.gov/cder/guidance/2740fnl.htm

http://www.fda.gov/cder/guidance/2125fnl.htm

Food and Drug Administration. Frequently Asked Questions Concerning Thalidomide.

http://www.fda.gov/cder/guidance/index.htm


http://www.fda.gov/ohrms/dockets/ac/cder99t.htm#Psychopharmacologic%20Drugs.


Gamma A, Frei E, Lehmann D, Pascual-Marqui R, Hell D, Vollenweider F. Mood state


Gouzoulis E, Borchardt D, Hermle L. A case of toxic psychosis induced by 'eve' (3,4-methylene-dioxyethylam-phetamine). *Archives of General Psychiatry* 50 (January 1993) 1:75.


Greer G, Tolbert R. The therapeutic use of MDMA. in Peroutka S (ed.) *Ecstasy: The*


Gust S. E-mail message to Dr. Russo. December 6, 1999.


Guy G. UK Medicinal Cannabis Project: http://www.medicinal-


Harter J. Application of pharmacokinetic data to clinical trials during the IND/NDA


Horgan C, Prottas J, Tompkins C, Wastila L, Bowden M. A Research Agenda for


Hutt P. Regulation of the Practice of Medicine under the Pure Food and Drug Laws. Speech presented at the 72nd Annual Conference of the Association of Food and Drug Officials of the United States, June 19, 1968.


Joranson D, Gilson A. Controlled Substances, Medical Practice and the Law. in Schwartz H. (ed.) *Psychiatric Practice Under Fire- The Influence of Government, the Media, and


398


Kurland A. LSD in the supportive care of the terminally ill cancer patient. *Journal of*


Leary T. Letter to Dr. Carl Henze, Sandoz Laboratory, Medical Department, Hanover, New Jersey. November 14, 1961.


Leber P. Director of FDA Division of Neuropharmacological Drug Products. Letter to Dr. Francisco Di Leo re IND# 27,281. March 5, 1987.


Leber P. Hazards of inference: The active control investigation. Epilepsia30 (1989)
Supplement 1: S57-S63.


Leshner A. Director of NIDA. Letter to Dr. Donald Abrams. April 19, 1995 http://www.maps.org/mmj/leshner.html


Lewin L. Uber Anhalonium lewinii. *Archiv fur Experimentelle Pathologie und
Pharmakologie 24 (1888): 401-411.


Macfarlane A. British Home Office, letter of November 16, 1998 to Dr. Geoffrey Guy, President of GW Pharmaceuticals.


Malberg J, Sabol K, Seiden L. Co-administration of MDMA with drugs that protect against MDMA neurotoxicity produces different effects on body temperature in the rat. Pharmacology and Experimental Therapeutics 278 (July 1996) 1:258-67.

Malberg J, Seiden L. Small changes in ambient temperature cause large changes in 3,4-


McCaffry B. Director of the Office of National Drug Control Policy. The Administration’s
Response to the Passage of California Proposition 215 and Arizona Proposition.


McCormick C. Director of FDA’s Division of Anesthetics, Critical Care and Addiction Drug Products. Letter to Dr. Francisco Moreno. Sept 17, 1998.

McCormick C. Director of FDA’s Division of Anesthetics, Critical Care and Addiction Drug Products. Letter to Dr. Grob. March 18, 1999.


McCormick C. Director of FDA Division of Anesthetics, Critical Care and Addiction Drug Products. Letter to Dr. Ethan Russo. September 21, 1999.


Organization of Government Programs Related to LSD. Senate Subcommittee on Executive Reorganization Hearing, May 24-26, 1966.


Scheer R. Reefer Madness, ‘90s Style: The war on drugs has been a dismal failure and its escalation to fight marijuana is lunacy. Los Angeles Times December 31, 1996: A7.


417


Sneyd R. House approves methadone treatment plan. *Associated Press* (May 1, 2000).


Staff. Adolor Corporation Appoints Two Executives; Dr. Curtis Wright to Lead Clinical and Regulatory Affairs; Peter J. Schied Named CFO. *PR Newswire*. (September 29, 1997).


Staff. Data Dredging was Key to Toradol, Lodine, Duragesic Approvals, FDA’s Harter


Staff. Greenwich Pharmaceuticals receives "not approvable" letter from FDA. *Business Wire* (September 13, 1993).


Staff. Keep your NDA’s 'lean' to cut drug development time. *Medical Marketing & Media*26 (February 1991) 2: 34.

Staff. NDA Days Have Been Held By Two FDA Groups Outside of Pilot Drug Evaluation


Staff. Results of study confirm the Therapeutic potential of Therafectin (amiprilose HC1) as a treatment for Rheumatoid Arthritis. *Business Wire*(March 8, 1990).


Taub S. Electroconvulsive therapy, malpractice, and informed consent. *Journal of*
Psychiatry and Law (Spring 1987): 7-54.


Temple R. When Are Clinical Trials of a Given Agent vs Placebo No Longer Appropriate or Feasible? *Controlled Clinical Trials* 18 (1997): 613-620.

Temple R. Associate Director for Medical Policy, CDER/FDA. Clinical Trial Considerations with Marijuana. Slides shown at the NIH Workshop on the Medical Utility of Marijuana, Bethesda, MD. February 19-21, 1997.


Thompson E. Chairman, President and CEO of Greenwich Pharmaceuticals. Statement.


Vollenweider F, Leenders K, Scharfetter C, Maguire P, Stadelmann O, Angst J. Positron emission tomography and fluorodeoxyglucose studies of metabolic hyperfrontality and


Wells D. Casenote: Conant V. McCaffrey: Physicians, Marijuana, and the First Amendment. 70 *University of Colorado Law Review* 975 (Summer, 1999).


http://www.citizen.org/hrg/PUBLICATIONS/1453.htm


World Medical Assembly. *Declaration of Helsinki*. Adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, revised by the 29th World Medical Assembly, Tokyo, Japan, 1975.


REFERENCES—FEDERAL REGISTER FILINGS


Advisory Committee Meetings. FDA. 41 FR 52148 (November 26, 1976).

Changes in Protocol Requirements for Researchers and Prescription Requirements for Practitioners. DEA. 50 FR 42184 (October 18, 1985).


Conditions for the Use of Methadone; Intent To Propose Revisions to Regulations and Request for Comments. 48 FR 41049 (September 13, 1983).

Controlled Substances; Proposed Aggregate Production Quotas for 1986. 50 FR 40070 (October 1, 1985).


FDA regulation of non-approved uses. 40 FR 15,393 (April 7, 1975).


Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Treatment
Use and Sale. 52 FR 19466 (May 22, 1987).

Investigational New Drug, Antibiotic, and Biological Product Regulations; Procedures for Drugs Intended To Treat Life-Threatening and Severely Debilitating Illnesses. 53 FR 41516 (October 21, 1988).

Investigational New Drug, Antibiotic, and Biological Product Applications; Clinical Hold and Termination. 57 FR 13244 (April 15, 1992)

Investigational New Drugs; Procedure to Monitor Clinical Hold Process; Meeting of Review Committee and Request for Submissions. 56 FR 49894 (October 2, 1991).

Investigational New Drugs; Procedure to Monitor Clinical Hold Process; Meeting of Review Committee and Request for Submissions, 58 FR 32537 (June 10, 1993).


Medical Use of Byproduct Material, Nuclear Regulatory Commission. 50 FR 30616 (July 26, 1985).

Methadone in Maintenance and Detoxification; Joint Proposed Revision of Conditions for Use. 52 FR 37046 (October 2, 1987).

Methadone in Maintenance Treatment of Narcotic Addicts; Joint Proposed Revision of Conditions for Use. 54 FR 8973 (March 2, 1989).

Methadone in Maintenance Treatment of Narcotic Addicts; Joint Proposed Revision of Conditions for Use. 54 FR 8973 (March 2, 1989).

Methadone in Maintenance Treatment of Narcotic Addicts; Proposed Interim Maintenance Treatment; Public Hearing. 54 FR 50226 (December 4, 1989).
Methadone in Maintenance Treatment of Narcotic Addicts; Joint Revision of Conditions for Use; Interim Maintenance Treatment; Human Immunodeficiency Virus Disease Counseling/ 58 FR 495 (January 6, 1993).

Narcotic drugs in maintenance and detoxification treatment of narcotic dependence. 37 FR 6940 (April 6, 1972)

Narcotic drugs in maintenance and detoxification treatment of narcotic dependence. 37 FR 26790 (December 15, 1972)

Narcotic drugs in maintenance and detoxification treatment of narcotic dependence 41 FR 28261 (July 9, 1976).


Narcotic drugs in maintenance and detoxification treatment of narcotic dependence 42 FR 46698 (September 16, 1977).


Narcotic drugs in maintenance and detoxification treatment of narcotic dependence; repeal of current regulations and proposal to adopt new regulations. 64 FR 39810 (July 22, 1999).


New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval. Revision. 64 FR 402 (January 5, 1999).

Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction; Conditions for the Use of Partial Agonists Treatment Medications in the Office-Based Treatment of Opiate Addiction. 65 FR 125895 (May 4, 2000).

Procedures for Drugs Intended to Treat Life-Threatening or Severely Debilitating Illnesses. 53 FR 41516 (October 21, 1988).

Proposed Placement of 3,4-Methylenedioxymethamphetamine Into Schedule I Hearing. 49 FR 50732 (December 31, 1984).


Rejection of NORML Petition to Reschedule Marijuana into Schedule II. Bureau of Narcotic and Dangerous Drugs. 37 FR 18093 (September 1, 1972).

Revised Training and Experience Criteria for Nuclear Medicine Physicians. 47 FR 3228 (January 22, 1982).

Revised Training and Experience Criteria for Nuclear Medicine Physicians. 47 FR 54376 (December 2, 1982).

Schedules of Controlled Substances: Scheduling of 3,4-Methylenedioxymethamphetamine (MDMA) into Schedule I of the Controlled Substances Act. 51 FR 36552-36560 (October 14, 1986).

Schedules of Controlled Substances: Scheduling of 3,4-Methylenedioxymethamphetamine (MDMA) into Schedule I of the Controlled Substances Act. 53 FR 5156 (February 22, 1988).

Schedules of Controlled Substances: Rescheduling of the Food and Drug Administration Approved Product Containing Synthetic Dronabinol in Sesame Oil Encapsulated in Soft Gelatin Capsule from Schedule II to Schedule III. 64 FR 35928 (July 2, 1999).

REFERENCES—FEDERAL LAWS, STATE CODES AND LOCAL ORDINANCES


Berkeley City Ordinance 5504. Prohibiting the administration of electric shock treatment.

California Business & Professional Code § 2904. Excluded services.

California Health & Safety Code §11480. Research as to marijuana and hallucinogenic drugs; Research Advisory Panel; Membership; Proceedings.

California Welfare & Institutions Code §5326.15. Quarterly reports of doctor or facility administering convulsive treatments or psychosurgery

California Welfare & Institutions Code §5326.2. Information for informed consent.


Massachusetts Mental Health Regulation 181 (effective May 1, 1973). Reports.
(Repealed, no reporting requirements at present.)


South Carolina Code §38-71-275. Insurance coverage for certain drugs not to be excluded from policy definitions.

Texas Health & Safety Code §578.003. Consent to Therapy.

Texas Health & Safety Code §578.007. Reports.
REFERENCES—LEGAL CASES


Dent v. West Virginia, 129 U.S. 114 (1889).


Grinspoon v. DEA, 828 F.2d 881 (1st Cir. 1988).

In the Matter of MDMA Scheduling, Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of ALJ, No. 84-48 (Young, ALJ) (May 22, 1986) (http://www.mninter.net/~publish/mdma.htm).


Melanson v. United States, 256 F. 783 (5th Cir. 1919).


Oakshette v. United States, 260 F. 830 (5th Cir. 1919).

Thompson v. United States, 258 F. 196 (8th Cir. 1919).

Trader v. United States, 260 F. 923 (3d Cir. 1919).

United States v. Carlson et. al., 87 F.3d 440 (11th Cir. 1996).

United States v. Evers, 643 F.2d 1043 (5th Cir. 1981).


United States v. Oakland Cannabis Buyers’ Cooperative, 190 F. 3d 1109 (9th Cir. 1999).


United States v. Rosenberg, 515 F. 2d 190 (9th Cir. 1975).

United States v. Smith, No. 99-10477, (9th Cir. 2000).


Workin v. United States, 260 F. 137 (2d Cir. 1919).