

## GENERAL REFERENCES

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

Aaronson B, Osmond H. Psychedelics and the Future. in Aaronson B, Osmond H. (eds.). *Psychedelics- The Uses and Implications of Psychedelic Drugs*. Garden City, New York: Anchor Books, 1970: 471.

Abel E. *Marijuana: The First Twelve Thousand Years*. New York: Plenum, 1980.

Abrams D. Research Plan Portion of Public Health Service Grant Application. *Protocol: Smoked Marijuana for HIV-Associated Anorexia and Wasting*. Submitted to the National Institutes of Health, April, 1996. <http://www.maps.org/mmj/abrams2.shtml>

Abrams D. Letter to Dr. Marlene Haffner. Director, FDA Office of Orphan Product Development. September 12, 1997. <http://www.maps.org/mmj/odda/09129701.html>

Abrams D. Medical marijuana: tribulations and trials. *Journal of Psychoactive Drugs* 30 (Apr-Jun 1998) 2:163-9.

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>

Abramson H, Jarvik M, Levine A, Kaufman M and Hirsch M. Lysergic Acid Diethylamide (LSD-25): The Effects Produced by Substitution of Tap Water Placebo. *Journal of Psychology* 40 (1955): 3:367-383.

Abramson H. Lysergic Acid Diethylamide (LSD-25): XIX. As an adjunct to brief psychotherapy, with special reference to ego enhancement. *Journal of Psychology* 41 (1956): 199.

Abramson H, Hewitt M, Lennard H, Turner W, O'Neill F, Merlis S. The stablemate concept of therapy as affected by LSD in schizophrenia. *Journal of Psychology* 45 (1959): 75-84.

Adamson S, Metzner R. *Through the Gateway of the Heart*. San Francisco: Four Trees Publications, 1985.

Adamson S, Metzner R. The Nature of the MDMA Experience and its Role in Healing, Psychotherapy, and Spiritual Practice. *Revision* 10 (Spring 1988) 4:59-72.

Addicott D. Regulating Research on the Terminally Ill: A Proposal for Heightened Safeguards. *Journal of Contemporary Health Law and Policy* 15 (1999) 2:479-524.

Agency for Health Care Policy and Research. *Treatment of Depression—Newer Pharmacotherapies: Summary, Evidence Report/Technology Assessment Number 7*. Rockville, MD, Agency for Health Care Policy and Research, March 1999. AHCPR Pub. No. 99-E013. <http://www.ahcpr.gov/clinic/deprsumm.htm>

Agosti V, Ocepek-Welikson K. The efficacy of imipramine and psychotherapy in early-onset chronic depression: a reanalysis of the National Institute of Mental Health Treatment of Depression Collaborative Research Program. *Journal of Affective Disorder* 43 (May 1997) 3:181-6.

Allen J, West L. Flight from Violence: Hippies and the Green Revolution. *American Journal of Psychiatry* 125 (Sept. 1968) 3: 120-126.

Altman L. Company Developing Marijuana For Medical Uses. *New York Times* (April 10, 2000) A:8

Amberson J, McMahon B, Pinner M. A clinical trial of sanocysin in pulmonary tuberculosis. *American Review of Tuberculosis* 24 (1931): 401-435.

American Psychiatric Association, Task Force Report 14: *Electroconvulsive Therapy*. Washington, D.C.: American Psychiatric Press, 1978.

American Psychiatric Association Task Force on ECT. *The Practice of Electroconvulsive Therapy: Recommendations for Treatment, Training and Privileging*. Washington, D.C.: American Psychiatric Press, 1990.

Anderson R. What does it Mean? Anchoring Psychosocial Quality of Life Score Changes with Reference to Concurrent Changes in Reported Symptom Distress. *Drug Information Journal* 33 (1999) 2:445-453.

Angarola R, Minsk A. Regulation of Psychostimulants: How much is too much? in Schwartz H. (ed.) *Psychiatric Practice Under Fire- The Influence of Government, the Media, and Special Interests on Somatic Therapies*. Washington, D.C.: American Psychiatric Association Press, 1994: 63-84.

Annas G, Grodin M, eds. *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation*. Oxford: Oxford University Press, 1992.

Annas G, Elias S. Thalidomide and the Titanic: reconstructing the technological tragedies of the twentieth century. *American Journal of Public Health* 89 (January 1999) 1:98-101.

Anslinger H. The Psychiatric Aspects of Marijuana Intoxication. *Journal of the American Medical Association* 121 (1943): 212-213.

Archer A. Guide into Chaos: Resist It. *Journal of the American Medical Association* 227 (1974) :1397-98.

Arendsen Hein G. Dimensions of Psychotherapy. in Abramson H. (ed.) *The Use of LSD in Psychotherapy and Alcoholism*. New York: Bobbs Merrill, 1967: 561-568.

Arendsen Hein G. Selbsterfahrung and Stellungnahme eines Psychotherapeuten [Self-Experience and Statement of a Psychotherapist]. in Josuttis M, Leuner H. (eds.) *Religion und die Droge*. Stuttgart: Kohlhammer, 1972:96-108.

Arizona and California Medical Drug Use Initiatives. Hearing of the Senate Judiciary Committee, chaired by Sen. Orrin Hatch (R-UT). December 2, 1996.

Arky R. (Medical Consultant). *Physicians Desk Reference, 52nd Edition*. Montvale, NJ: Medical Economics Company. 1998: 2545.

Asher J. Whatever happened to Psychedelic Research? *APA Monitor* (November, 1975): 4-5.

Bachman J, Johnston L, O'Malley P. Explaining the recent increases in students' marijuana use: The impact of perceived risks and disapproval from 1976 through 1996. *American Journal of Public Health* 88 (1998):887-892.

Ball J, Ross A. *The Effectiveness of Methadone Maintenance Treatment: Patients, Programs, Services, and Outcomes*. New York: Springer-Verlag, 1991.

- Barber T. *Pitfalls in human research*. New York: Pergamon Press, 1976.
- Barbour J. *AP Newsfeatures*, August 10, 1992.
- Barnett G, Trsic M, Willette Robert E. (eds.) *QUASAR: Quantitative Structure-Activity Relationships of Analgesics, Narcotic Antagonists, and Hallucinogens*. NIDA Research Monograph 22. Washington, D.C., NTIS PB# 292-265/AS. 1978.
- Barrigar R. The Regulation of Psychedelic Drugs. *Psychedelic Review* 1 (1964) 4:394-441.
- Basara L, Montagne M. *Searching for Magic Bullets: Orphan Drugs, Consumer Activism, and Pharmaceutical Drug Development*. New York: Pharmaceutical Products Press- An Imprint of Haworth Press. 1994.
- Bass I, Kalb P, Berenson B. Off-Label Promotion: Is FDA's Final Guidance on Industry-Supported Scientific and Educational Programs Enforceable? *Food Drug Law Journal* 53 (1998) 2:193-212.
- Bastiaans J. The KZ Syndrome: A Thirty Year Study of the Effects on Victims of Nazi Concentration Camps. *Revista medico-chirurgicata a societatii de medici si naturalis li diu Jasi* 78 (1974): 573-578.
- Bastiaans J. Mental Liberation Facilitated by the use of Hallucinogenic Drugs. in Grinspoon L, Bakalar J. (eds.) *Psychedelic Reflections*. New York: Human Sciences Press, 1983: 143-152.
- Beck A, Rush A, Shaw B, Emery G. *Cognitive Therapy of Depression*. New York, NY: Guilford Press, 1979.
- Beck J, Rosenbaum M. *Pursuit of Ecstasy: The MDMA Experience*. Albany: State University of New York Press, 1994.
- Beck J, Azari E. FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions. *Food and Drug Law Journal* 53 (1998) 1:71-104.
- Benedict A, Saks M. The Regulation of Professional Behavior: Electroconvulsive Therapy in Massachusetts. *Journal of Psychiatry and the Law* (Summer 1987): 247-275.
- Berendes M. Formation of Typical Dynamic Stages in Psychotherapy Before and After Psychedelic Drug Intervention. *Journal of Altered States of Consciousness* 5 (1974) 4:

325-338.

Beringer K. Der Meskalinrausch (The Mescaline Inebriation). *Monogra. Gesamtgeb. Neurology and Psychiatry*49 (1927): 1-315.

Berman J, Miler R, Massman P. Cognitive therapy versus systematic desensitization: is one treatment superior? *Psychological Bulletin* 97 (1985) 451-461.

Berman R, Cappiello A, Anand A, Oren D, Heninger G, Charney D, Krystal J. Antidepressant effects of ketamine in depressed patients. *Biological Psychiatry*47 (February 15, 2000) 4:351-4.

Blatt S, Sanislow C, Zuroff D, Pilkonis P. Characteristics of effective therapists: further analyses of data from the National Institute of Mental Health Treatment of Depression Collaborative Research Program. *Journal of Consulting and Clinical Psychology*64 (December 1996) 6:1276-84.

Blood B. *The Anesthetic Revelation and The Gist of Philosophy*. Amsterdam, N.Y. [no publ.]: 1874.

Bolla K, McCann U, Ricaurte G. Memory impairment in abstinent MDMA ("ecstasy") users. *Neurology* 51 (1998): 1532-1537.

Bonny H, Savary L. *Music and Your Mind- Listening with a New Consciousness*. New York: Harper and Row, 1973.

Bonnie R, Whitebread C. The Forbidden Fruit and the Tree of Knowledge: An Inquiry into the Legal History of American Marijuana Prohibition." *Virginia Law Review* 56 (1970) 971: 1083-1149..

Bonnie R. *Marijuana Use and Criminal Sanctions*. Charlottesville, Virginia: The Michie Co.,1980.

Booth P. FDA Implementation of Standards Developed by the International Conference on Harmonisation. *Food and Drug Law Journal* 52 (1997) 2:203-223.

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>

Bothma Stephane. Search On For Ecstasy Capsules. *Business Day (Johannesburg)* November 8, 1999.

Bouso J. Proposal for a Study with MDMA and Post Traumatic Stress Disorder in Spain. *Bulletin of the Multidisciplinary Association for Psychedelic Studies* 9 (Autumn 1999) 3:11-14. <http://www.maps.org/news-letters/v09n3/09311bou.html>

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.

Box J. R.A. Fisher and the design of experiments, 1922-1926. *American Statistician* 34 (1980): 1-7.

Brady K, Pearlstein T, Asnis G, Baker D, Rothbaum B, Sikes C, Farel G. Efficacy and Safety of Sertraline Treatment of Posttraumatic Stress Disorder: A Randomized Controlled Trial. *Journal of the American Medical Association* 283 (April 12, 2000) 14:1837-1844.

Brecher E and the editors of Consumer Reports. *Licit and Illicit Drugs*. Mount Vernon, New York: Consumers Union, 1972.

Briggs J. Mescale Buttons-Physiological Effects: A Mexican Fruit with Possible Medicinal Virtues. *Medical Register* 1 (April 7, 1887): 276-77.

Brody B. When are Placebo-Controlled Trials No Longer Appropriate? *Controlled Clinical Trials* 18 (1997): 602-612.

Brown L. Director, Office of National Drug Control Policy. Letter to DEA Administrator Tom Constantine. July 5, 1994.

Buckman J. Brainwashing, LSD, and CIA: Historical and Ethical Perspective. *International Journal of Social Psychiatry* 23 (Spring 1977) 1: 8-19.

Buday P. Hints on Preparing Successful Orphan Drug Designation Requests. *Food and Drug Law Journal* 51 (1996) 1:75-84.

Bullion J. President Clinton Signs H.R. 2130 Protecting the Medical use of GHB; Scheduling of Orphan Medical's Xyrem Defined. Orphan Medical Press Release. (February 21, 2000). [http://www.orphan.com/press\\_releases\\_detail.dbm?ID=106](http://www.orphan.com/press_releases_detail.dbm?ID=106)

- Burroughs W, Ginsberg A. *The Yage Letters*. San Francisco: City Lights, 1956.
- Busch A, Johnson W. LSD 25 as an Aid in Psychotherapy (Preliminary Report of a New Drug). *Diseases of the Nervous System* 11 (1950): 241-243.
- Byock I, Merriman M. Measuring quality of life for patients with terminal illness: the Missoula-VITAS quality of life index. *Palliative Medicine* 12 (July 1999) 4:231-44.
- Calhoun S, Galloway G, Smith D. Abuse Potential of Dronabinol (Marinol). *Journal of Psychoactive Drugs* 30 (1998) 2:187-196.
- Campbell D, Stanley J. *Experimental and Quasi-Experimental Designs for Research*. Boston: Houghton Mifflin, 1963.
- Carpenter W. The Schizophrenia Ketamine Challenge Study Debate. *Biological Psychiatry* 46 (1999): 1081-1091.
- Carroll K, Rounsaville B, Gordon L, Nich C, Jatlow P, Bisighini R, Gawin F. Psychotherapy and pharmacotherapy for ambulatory cocaine abusers. *Archives of General Psychiatry* 51 (Mar 1994) 3:177-87.
- Chang A, Shiling D, Stillman R, Goldberg N, Seipp C, Barofsky I, Simon R, Rosenberg S. Delta-9-Tetrahydrocannabinol as an Antiemetic in Cancer Patients Receiving High-Dose Methotrexate. *Annals of Internal Medicine* 91 (1979): 385-425.
- Chang L, Grob C, Ernst T, Itti L, Mishkin S, Jose-Melchor R, Poland R. Effect of ecstasy [3,4-methylenedioxymethamphetamine (MDMA)] on cerebral blood flow: a co-registered SPECT and MRI study. *Psychiatry Research* 98 (Feb 2000) 1:15-28.
- Chapman C, Hill C. Prolonged morphine self-administration and addiction liability. *Cancer* 63 (1989):1636-1644.
- 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.
- Cholden L, Kurland A, Savage C. Clinical Reactions and Tolerance to LSD in Chronic Schizophrenics. *Journal of Nervous and Mental Disease* 122 (1955) 3: 211-221.

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.

Christopher W. Off-Label Prescription: Filling the Regulatory Vacuum. *Food and Drug Law Journal* 48 (1993) 2: 247-262.

Chwelos N, Blewett D, Smith C, Hoffer A. Use of d-lysergic acid diethylamide in the treatment of alcoholism. *Quarterly Journal of Studies of Alcoholism* 20 (1959): 577.

Cloud J. The Lure of Ecstasy. *Time Magazine* (June 5, 2000): 62-68.

Cocchetto D, Wallace J. Qualifications of investigators for clinical investigations conducted under and IND: A discussion paper. *Drug Information Journal* 26 (1992) 167-173.

Cohen S, Fichman L, Eisner B. Subjective reports of lysergic acid experiences in a context of psychological test performance. *American Journal of Psychiatry* 115 (1958): 30.

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

Cohen S. The Cyclic Psychedelics. *American Journal of Psychiatry* 125 (Sept 1968) 3:149-150.

Coleman P, Shellow R. Prescribing privileges for psychologists: Should only "Medicine Men" control the medicine cabinet. *Journal of Psychiatry and Law* (Fall/Winter, 1990) 269-318.

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.

Cooper J, Czechowicz D, Molinari S. (eds.) *Impact of Prescription Drug Diversion Control Systems on Medical Practice and Patient Care*. NIDA Research Monograph Series #131. Washington, D.C., NIH Publication # 93-3507, 1992.

Cooper J, Czechowicz D, Molinari S. The Impact of Prescription Drug Control Systems on Medical Practice and Patient Care: A Summary of the NIDA Technical Review. in Cooper J, Czechowicz D, Molinari S. (eds.) *Impact of Prescription Drug Diversion*



*Control Systems on Medical Practice and Patient Care*. NIDA Research Monograph Series #131. Washington, D.C., NIH Publication # 93-3507, 1992: 1-17.

Coppinger P, Peck C, Temple R. Understanding comparisons of drug introductions between the United States and the United Kingdom. *Clinical Pharmacology and Therapeutics* 46 (Aug 1989) 2:139-45.

Council on Ethical and Judicial Affairs of the American Medical Association. Direct-to-Consumer Advertisements of Prescription Drugs. *Food and Drug Law Journal* 55 (2000) 1:119-124.

Cranston J, Williams M, Nielsen N, Bezman R. Report of the Council on Scientific Affairs: Unlabeled Indications of Food and Drug Administration-Approved Drugs. *Drug Information Journal* 32 (1998) 4: 1049-1061.

Curran W. Government Regulation of the Use of Human Subjects in Medical Research: The Approaches of Two Federal Agencies. in *Experimentation with Human Subjects*, ed. P.A. Freund. New York: George Braziller, 1970: 436.

Dahlberg C, Mechaneck M, Feldstein S. LSD Research: The impact of lay publicity. *American Journal of Psychiatry* 125 (1968) 5: 137-141.

Darbyshire J. Confirmatory Trials- A New Approach? *Controlled Clinical Trials* 20 (1999): 567-568.

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.

De Amici D, Klersy C, Ramajoli F, Brustia L, Politi P. Impact of the Hawthorne effect in a longitudinal clinical study. The case of anesthesia. *Controlled Clinical Trials* 21 (Apr 2000) 2:103-14.

Dean M. A Homeopathic Origin for Placebo Controls: 'An Invaluable Gift of God.' *Alternative Therapies in Health and Medicine* 6 (March, 2000) 2:58-66

Decoster G, Buyse M. Clinical Research After Drug Approval: What is Needed and What is Not. *Drug Information Journal* 33 (1999) 2: 627-634.

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

*American Medical Association* 279 (June 17, 1998) 23:1883-8.

Delgado P, Moreno F. Different roles for serotonin in anti-obsessional drug action and the pathophysiology of obsessive-compulsive disorder. *British Journal of Psychiatry*(1998) Suppl. 35:21-5.

Delgado P, Moreno F. Hallucinogens, Serotonin and Obsessive-Compulsive Disorder. *Journal of Psychoactive Drugs*30 (October-December 1998) 4:359-366.

Denbar H, Merlis S. Therapeutic Aspects of the Mescaline-Chlorpromazine Combination. *Journal of Nervous and Mental Disease*122 (1955): 463-469.

Denbar H. Mescaline and Lysergic Acid Diethylamide: Therapeutic Implications of the Drug-Induced State. *Diseases of the Nervous System* 30 (February 1969) 2:Suppl: 23-7.

Department of Health and Human Services. *Guidance On Procedures for the Provision of Marijuana for Medical Research*. May 21, 1999. <http://www.mpp.org/hhsguide.html>

DeRubeis R, Hollon S, Evans M. Can Psychotherapies for Depression be Discriminated? A Systematic Investigation of Cognitive Therapy and Interpersonal Therapy. *Journal of Consulting and Clinical Psychology*50 (1982): 49-62.

Deyton L. National Institute of Allergy and Infectious Diseases. Letter to Dr. Donald Abrams. Notification of Scientific Review Action, Application # 1R01AI40866-01, Smoked Marijuana for HIV-Associated Anorexia and Wasting Protocol. August 22, 1996. <http://www.maps.org/mmj/abrams1.shtml>

DiMasi J, Hansen R, Grabowski H, Lasagna L. Cost of innovation in the pharmaceutical industry. *Journal of Health Economics* 10 (July 1991) 2:107-42.

DiMasi J, Seibring M, Lasagna L. New Drug Development in the United States 1963-1992. *Clinical Pharmacology and Therapeutics* 55 (June 1994) 6:609-22.

DiMasi J, Hansen R, Grabowski H, Lasagna L. Research and development costs for new drugs by therapeutic category. A study of the US pharmaceutical industry. *Pharmacoeconomics*7 (February 1995) 2:152-69.

DiMasi J, Lasagna L. The Economics of Psychotropic Drug Development. in (eds.) Bloom F, Kupfer D. *Psychopharmacology: The Fourth Generation of Progress*. New York: Raven Press, 1995: 1891 (Figure 8).

DiMasi J, Manocchia M. Initiatives to speed new drug development and regulatory review: the impact of FDA-sponsor conferences. *Drug Information Journal* 31 (1997) 3:71-88.

Doblin R. Letter to Dr. Robert Windom, Assistant Secretary of Health. February 11, 1987.

Doblin R. The Good Friday Experiment- A twenty-five year follow-up and methodological critique. *Journal of Transpersonal Psychology* 23 (1991) 1: 1-28.

Doblin R. A Comprehensive Clinical Plan for the Investigation of Marijuana's Medical Use in the Treatment of the HIV-Related Wasting Syndrome. *Bulletin of the Multidisciplinary Association for Psychedelic Studies* 5 (Summer 1994) 1: 16-17.  
<http://www.maps.org/news-letters/v05n1/05116cli.html>

Doblin R. NIDA Blocks Medical Marijuana Research. April 1995.  
<http://www.maps.org/mmj/ricklesh.html>

Doblin R. Turning Protests into Protocols: Dr. Harter's Legacy. Submitted to the NIH Expert Committee on the Medical Utility of Marijuana. February 25, 1997.  
<http://www.maps.org/mmj/022597mmj.shtml>

Doblin R. Request for Orphan Drug Designation for Smoked Marijuana in the Treatment of HIV-Associated Wasting Syndrome. April 24, 1997.  
<http://www.maps.org/mmj/odda/042497.html>

Doblin R. Letter to Dr. Marlene Haffner. Director, FDA Office of Orphan Products Development. September 24, 1997. <http://www.maps.org/mmj/odda/092497.html>

Doblin R. Letter to Dr. Marlene Haffner. Director, FDA Office of Orphan Products Development. June 9, 1998. <http://www.maps.org/mmj/odda/060998.html>

Doblin R. Letter to Dr. Marlene Haffner. Director, FDA Office of Orphan Products Development. August 25, 1998. <http://www.maps.org/mmj/odda/082598.html>

Doblin R. Dr. Leary's Concord Prison Experiment: A 34-Year Follow-up Study. *Journal of Psychoactive Drugs* 30 (1998) 4: 419-426

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

- Development. November 10, 1998. <http://www.maps.org/mmj/odda/111098.html>
- Doblin R. Letter to Dr. Marlene Haffner. Director, FDA Office of Orphan Products Development. February 19, 1999. <http://www.maps.org/mmj/odda/021699.html>
- Doblin R, Beck J, Obata K, Alioto M. Dr. Oscar Janiger's Pioneering LSD Research: A Forty Year Follow-up. *Bulletin of the Multidisciplinary Association for Psychedelic Studies* 9 (Spring 1999) 1: 7-23.
- Doblin R. Clinical Research with MDMA and MDE- A MAPS' Conference: Dead Sea, Israel. *Bulletin of the Multidisciplinary Association for Psychedelic Studies* 9 (Winter 1999 /2000) 4: 2-9. <http://www.maps.org/news-letters/v09n4/09402dob.html>
- Downey R. The antidrug mafia makes sure Washington state keeps off the grass. *Seattle Weekly*. June 15-21, 2000. <http://www.seattleweekly.com/features/0024/news-downey.shtml>
- Drayer J, Burns J. From Discovery to Market: The Development of Pharmaceuticals. *Burger's Medicinal Chemistry and Drug Discovery. Fifth Edition, Vol. 1 Principles and Practices*. ed. Manfred Wolff. NY:Wiley and Sons, 1995: 254.
- Duffett R, Lelliott P. Auditing electroconvulsive therapy. The third cycle. *British Journal of Psychiatry* 172 (May 1998): 401-5.
- Dyer C. Patients given LSD may be able to claim compensation. *British Medical Journal* 311 (Nov 4, 1995) 7014:1185-6.
- Editorial. ECT in Britain: a shameful state of affairs. *Lancet* 2 (1981): 1207-1208.
- Editorial. Dr. S Weir Mitchell's Experiments with the Mescal Button. *Journal of the American Medical Association* 28 (1897): 501-503
- Editorial. Marijuana Problems. *Journal of the American Medical Association* 127 (1945): 1129.
- Eisner B, Cohen S. Psychotherapy with lysergic acid diethylamide. *Journal of Nervous and Mental Disease* 127 (1958): 528.
- Elkin I, Parloff M, Hadley S and Autry J. NIMH Treatment of Depression Collaborative Research Program. Background and research plan. *Archives of General Psychiatry* 42 (March 1985) 3:305-16.

Elkin I, Gibbons R, Shea M, Sotsky S, Watkins J, Pilkonis P, Hedeker D. Initial severity and differential treatment outcome in the National Institute of Mental Health Treatment of Depression Collaborative Research Program. *Journal of Consulting and Clinical Psychology* 63 (October 1995) 5:841-7.

Elkin I, Pilkonis PA, Docherty JP, Sotsky SM Conceptual and methodological issues in comparative studies of psychotherapy and pharmacotherapy, I: Active ingredients and mechanisms of change. *American Journal of Psychiatry* 145 (August 1988) 8:909-17.

Elkin I, Pilkonis P, Docherty J, Sotsky S. Conceptual and methodological issues in comparative studies of psychotherapy and pharmacotherapy, II: Nature and timing of treatment effects. *American Journal of Psychiatry* 145 (September 1988) 9:1070-6.

Elkin I, Shea M, Watkins J, Imber S, Sotsky S, Collins J, Glass D, Pilkonis P, Leber W, Docherty J, et al. National Institute of Mental Health Treatment of Depression Collaborative Research Program. General effectiveness of treatments. *Archives of General Psychiatry* 46 (November 1989) 11:971-82; discussion 983.

European Council. European Council Directive 92/26/EEC Article 3, Part 3. *Official Journal of the European Communities No L 113/5*. (March 31,1992).

Everhart E, Jacob III P, Shwonek P, Baggottt M, Jones R, Mendelson J. Estimation of the Metabolic Disposition of MDMA and MDA Enantiomers in Humans. *Abstracts - College on Problems of Drug Dependence (CPDD) 1999 Annual Meeting, June 12-17, 1999*: 41.

*Facts and Comparisons*. St. Louis: Steven Hebel Publishing, January 2000.

Faden R, Beauchamp T. *A History and Theory of Informed Consent*. New York: Oxford University Press, 1986.

Farley D. Benefit Vs. Risk: How FDA Approves New Drugs. *FDA Consumer*(Special Report), January 1995. <http://www.fda.gov/fdac/special/newdrug/benefits.html>

Farnell, Josep Torrent i. Director, Spanish Agency of Medicine, (AEM-Agencia Española del Medicamento) Spanish Ministry of Health and Consumer Affairs. Letter to Jose Carlos Bouso Diaz. Reference # 447. Spanish Drug Agency Code Protocol # 99-0309. February 7, 2000. 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.

Fawcett J, Epstein P, Fiester S, Elkin I, Autry J. Clinical management--imipramine/placebo administration manual. NIMH Treatment of Depression Collaborative Research Program. *Psychopharmacology Bulletin*23 (1987) 2:309-24.

FDA Reform and the European Medicines Evaluation Agency, 108 *Harvard Law Review* 2009. (June, 1995).

Federal Regulation of Human Experimentation. Subcommittee on Health of the Committee of Labor and Public Welfare, United States Senate:U.S. Government Printing Office. NO 45-273-0, 1975.

Feng N, Vollenweider F, Minder E, Rentsch K, Grampp T, Vonderschmitt D. Development of a gas chromatography-mass spectrometry method for determination of ketamine in plasma and its application to human samples. *Therapeutic Drug Monitor*17 (Feb. 1995)1:95-100.

Fink M. Meduna and the Origins of Convulsive Therapy. *American Journal of Psychiatry* 141 (1984) 9:1034-1041.

Fink M. Training in Convulsive Therapy. *Convulsive Therapy*2 (1986) 4: 227-229.

Fink M. Impact of the Antipsychiatry Movement on the Revival of Electroconvulsive Therapy in the United States. *Electroconvulsive Therapy. Psychiatric Clinics of North America*14 (1991) 4:793-801

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

Fisher S, Greenberg R. (eds.) *The Limits of Biological Treatments for Psychological Distress*. Hillsdale, NJ: Erlbaum Associates, 1989.

Fisher S, Greeberg R. How Sound is the Double-Blind Design for Evaluating Psychotropic Drugs? *Journal of Nervous and Mental Disease* 181 (1993): 345-350.

Fishbein M. *A History of the American Medical Association, 1847-1947*. Philadelphia: Saunders, 1947.

Flieger K. Testing Drugs in People. *FDA Consumer:Special Report on New Drug Development in the United States* (January 1995).  
<http://www.fda.gov/fdac/special/newdrug/testing.html>

Fogel S, Hoffer A. The use of hypnosis to interrupt and to reproduce an LSD-25 experience. *Journal of Clinical and Experimental Psychopathology* 23 (1962): 11.

Food and Drug Administration. Approval times (in months) for NDAs and NMEs approved. Calendar years 1986 – 1999. FDA Chart.  
<http://www.fda.gov/cder/rdmt/cy99ndaap.htm>

Food and Drug Administration. Chronology of Drug Regulation in the United States: Timeline. Food and Drug Administration Center for Drug Evaluation and Research.  
<http://www.fda.gov/cder/about/history/time1.htm>

Food and Drug Administration.. *Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs (Nov. 1996, ICH)*. FDA Guidance For Industry.  
<http://www.fda.gov/cder/guidance/index.htm>

Food and Drug Administration.. *Consumer-Directed Broadcast Advertisements*. FDA Guidance For Industry. August 1999. <http://www.fda.gov/cder/guidance/1804fnl.pdf> and <http://www.fda.gov/cder/guidance/1804q&a.htm>

Food and Drug Administration. *Enforcement of the Postmarketing Adverse Drug Experience Reporting Regulations*. Guidance to FDA Field Staff. September 30, 1999.  
<http://www.fda.gov/cder/aers/chapter53.htm>

Food and Drug Administration.. Explanation of the [FDA] Office of the Commissioner Reorganization. June 18, 1999. <http://www.fda.gov/oc/reorg/june1999.html>

Food and Drug Administration. *Fast Track Drug Development Programs: Designation, Development, and Application*. FDA Guidance for Industry.  
<http://www.fda.gov/cder/guidance/2112fnl.pdf>

Food and Drug Administration. Drug Approvals List for December, 1999.  
<http://www.fda.gov/cder/da/da1299.htm>

Food and Drug Administration. Drug Abuse Advisory Committee. Transcript of the 23rd Meeting. July 14-15, 1992.

Food and Drug Administration. Medwatch "Dear Healthcare Provider" Letter. Propulsid Tablets and suspension, Jansen Pharmaceutical, April 12, 2000.

<http://www.fda.gov/medwatch/safety/2000/propul1.htm>

Food and Drug Administration. FDA Approves Zoloft for PostTraumatic Stress Disorder. *FDA Talk Paper T99-55*. December 7, 1999.

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>,

Food and Drug Administration. *Formal Dispute Resolution: Appeals Above the Division Level*. FDA Guidance for Industry. February, 2000.  
<http://www.fda.gov/cder/guidance/2740fnl.htm>

Food and Drug Administration. *Formal Meetings with Sponsors and Applicants for PDUFA Products*. FDA Guidance for Industry, Draft. February, 2000.  
<http://www.fda.gov/cder/guidance/2125fnl.htm>

Food and Drug Administration. Frequently Asked Questions Concerning Thalidomide.  
<http://www.fda.gov/cder/news/thalinfo/thalfaq.htm>

Food and Drug Administration. *Organization of an ANDA (Abbreviated New Drug Application)*. FDA Guidance to Industry. February, 1999.  
<http://www.fda.gov/cder/guidance/index.htm>

Food and Drug Administration. Pilot Drug Review Division. FDA Press Release, April 20, 1989.

Food and Drug Administration. *Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products*. FDA Guidance for Industry.  
<http://www.fda.gov/cder/guidance/1397fnl.pdf>

Food and Drug Administration. Psychopharmacologic Drugs Advisory Committee Meeting, FDA. October 8, 1999. Transcript: 29.  
<http://www.fda.gov/ohrms/dockets/ac/cder99t.htm#Psychopharmacologic%20Drugs>.

Food and Drug Administration. *Special Protocol Assessment*. FDA Guidance for Industry, Draft. December, 1999. <http://www.fda.gov/cder/guidance/2127dft.htm#I>.



Food and Drug Administration. Rezulin to be Withdrawn from the Market. FDA Press Release, March 21, 2000. <http://www.fda.gov/bbs/topics/NEWS/NEW00721.html>

Food and Drug Administration. Janssen Pharmaceutica Stops Marketing Cisapride in the US. *FDA Talk Paper*. <http://www.fda.gov/bbs/topics/ANSWERS/ANS01007.html>

Food and Drug Administration. *Submitting and Reviewing Responses to Clinical Holds*. FDA Guidance for Industry. April, 1998.

Food and Drug Administration. Thalidomide- Potential Benefits and Risks. An Open Public Scientific Workshop Sept 9-10, 1997. Executive Summary. <http://www.fda.gov/oashi/aids/thalex.html>

Food and Drug Administration. Thalidomide Information Page. <http://www.fda.gov/cder/news/thalinfo/default.htm>

Frankel M. *The times of my life and my life with the Times*. New York: Random House, 1999.

Freedman D. Problems and Prospects of Research with the Hallucinogens. in (ed.) Gamage J, Zerkin E. *Hallucinogenic Drug Research: Impact on Science and Society*. Proceedings of the First Annual Symposium of the Student Association for the Study of Hallucinogens. Beloit, Wisconsin, 1970: 1-10.

Freedman D. Editorial Note. *Archives of General Psychiatry* 46 (November 1989) 11:983.

Friedman L, Furberg C, Demets D. *The Fundamentals of Clinical Trials. 2nd Edition*. St Louis: Mosby-Year Book, 1985.

Friedman M, Woodcock J, Lumpkin M, Shuren J, Hass A, Thompson L. The safety of newly approved medicines: do recent market removals mean there is a problem? *Journal of the American Medical Association*. 281 (May 12, 1999) 18:1728-34.

Fulco C, Liverman C, Earley L (eds.) *Development of Medications for the Treatment of Opiate and Cocaine Addictions: Issues for the Government and Private Sector*. Washington, DC: Institute of Medicine, National Academy Press, 1995.

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

and brain electric activity in ecstasy users. *Neuroreport* 11 (January 17, 2000) 1:157-62.

Garcia F. Deputy Director, Office of National Drug Control Policy, Office for Demand Reduction. Letter to Dr. David Kessler, FDA Commissioner. July 5, 1994.

Gasser P. Psycholytic therapy with MDMA and LSD in Switzerland: Follow-up study on the results of Swiss research conducted during 1988-1993. *Bulletin of the Multidisciplinary Association for Psychedelic Studies* 5 (Winter 1994-95) 3: 3-7.  
<http://www.maps.org/news-letters/v05n3/05303psy.html>

Gathright A. Federal OK Needed: San Mateo County Plans Medicinal Marijuana Trial. *San Jose Mercury News*. December 26, 1999.

General Accounting Office. *FDA Drug Approval - A Lengthy Process that Delays the Availability of Important New Drugs*. General Accounting Office. Rep. No. HRD-80-64. Washington, D.C., 1980.

General Accounting Office. *Continued Vigilance Critical to Protecting Human Subjects*. Report to the Ranking Minority Member, Committee on Governmental Affairs, United States Senate. Washington, D.C., 1996.

Gershon S, Ferris S, Kennedy J, Kurts N, Overall J, Pollack, B, Reisberg B, and Whitehouse P. Methods for the Evaluation of Pharmacologic Agents in the Treatment of Cognitive and Other Deficits in Dementia. in (ed.) Prien R, Robinson D. *Clinical Evaluation of Psychotropic Drugs: Principles and Guidelines*. New York: Raven Press, 1994: 467-499.

Gerth J, Stolberg S. Drug Makers Reap Profits on Tax-Backed Research. *New York Times*(April 23, 2000): A1.

Gibbs J. First Amendment Limits on Regulating Information: An Initial Reaction to the *Washington Legal Foundation* Case. *Food and Drug Law Journal* 53 (1998) 4:597-601.

Gieringer D. *Consumer Choice and FDA Drug Regulation*. Dissertation submitted to the Department of Engineering-Economic Systems. Stanford University. May 1984.

Gieringer D. Marijuana Water Pipe and Vaporizer Study. *Bulletin of the Multidisciplinary Association for Psychedelic Studies* 6 (Summer 1996) 3: 59-63.  
<http://www.maps.org/news-letters/v06n3/06359mj1.html>

Gieringer D. Medical Cannabis Potency Testing Project. *Bulletin of the Multidisciplinary*

*Association for Psychedelic Studies* 9 (Autumn 1999) 3: 20-22.  
<http://www.maps.org/news-letters/v09n3/09320gie.html>

Gieringer D. State Suppresses Report Showing Pot Use Among California Students Leveled Off After Passage of Prop. 215. California NORML Press Release, May 27, 2000. <http://www.canorml.org/news/skagerstudy.html>

Gilman G, Vrekes R, van Gervan J, Cohen A. MDMA Study. *Neuropsychopharmacology* 21 (1999) 4:597.

Gitchel G. Existing Methods to Identify Retail Drug Diversion. in (eds.) Cooper J, Czechowicz D, Molinari S. *Impact of Prescription Drug Diversion Control Systems on Medical Practice and Patient Care*. Washington, D.C.: NIDA Research Monograph Series #131. Washington, DC, NIH Publication #93-3507. 1992: 132-140.

Glass G, Smith M, Miller T. *The Benefits of Psychotherapy*. Baltimore, MD: Johns Hopkins University Press, 1980.

Glennon R. Summary. Hallucinogens: An Update. *Hallucinogens: An Update*. NIDA Research Monograph 146. Washington, D.C., NIH Publication # 94-3872, 1994: 300-301.

Goode E. More Fuel for Debate on Prozac. *New York Times, Health and Fitness* (April 25, 2000): D7.

Gould A. Another View of Active-Controlled Trials. *Controlled Clinical Trials* 12 (1991): 474-485.

Gouzoulis E, Steiger A, Ensslin M, Kovar A, Hermle L. Sleep EEG effects of 3,4-methylenedioxyamphetamine (MDE; "eve") in healthy volunteers. *Biological Psychiatry* 32 (December 15, 1992) 12:1108-17.

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.

Gouzoulis E, von Bardeleben U, Rupp A, Kovar KA, Hermle L. Neuroendocrine and cardiovascular effects of MDE in healthy volunteers. *Neuropsychopharmacology* 8 (May 1993) 3:187-93.

Gouzoulis-Mayfrank E, Heekeren K, Thelen B, Lindenblatt H, Kovar K, Sass H, Geyer M. Effects of the hallucinogen psilocybin on habituation and prepulse inhibition of the startle reflex in humans. *Behavioral Pharmacology* 9 (November 1998) 7:561-6.

Gouzoulis-Mayfrank E, Thelen B, Habermeyer E, Kunert H, Kovar K, Lindenblatt H, Hermle L, Spitzer M, Sass H. Psychopathological, neuroendocrine and autonomic effects of 3,4-methylenedioxyethylamphetamine (MDE), psilocybin and d-methamphetamine in healthy volunteers. Results of an experimental double-blind placebo-controlled study. *Psychopharmacology* (Berl) 142 (February 1999) 1:41-50.

Gouzoulis-Mayfrank E, Schreckenberger M, Sabri O, Arning C, Thelen B, Spitzer M, Kovar KA, Hermle L, Bull U, Sass H. Neurometabolic effects of psilocybin, 3,4-methylenedioxyethylamphetamine (MDE) and d-methamphetamine in healthy volunteers. A double-blind, placebo-controlled PET study with [<sup>18</sup>F]FDG. *Neuropsychopharmacology* 120 (June 1999) 6:565-81.

Grabowski H. *Drug Regulation and Innovation- Empirical Evidence and Policy Options*. Washington, DC: American Enterprise Institute for Public Policy Research, 1976.

Grabowski H, Vernon J. *The Regulation of Pharmaceuticals- Balancing the Benefits and Risks*. Washington, D.C.: American Enterprise Institute for Public Policy Research, 1983.

Greenberg R, Bornstein R, Greenberg M, Fisher R. A Meta-Analysis of Antidepressant Outcome Under “Blinder” Conditions. *Journal of Consulting and Clinical Psychology* 60 (1992): 664-669.

Greenberg R, Fisher S. Examining Anti-depressant Effectiveness: Findings, Ambiguities, and some Vexing Puzzles. in (eds.) Fisher S, Greenberg R. *The Limits of Biological Treatments for Psychological Distress- Comparisons with Psychotherapy and Placebo*. Hillsdale, New Jersey: Lawrence Erlbaum Associates, 1989: 1-31.

Greenberg R, Fisher S. Suspended Judgement: Seeing through the Double-Masked Designs: A Commentary. *Controlled Clinical Trials* 15 (1994): 244-246.

Greer G, Tolbert R. Subjective Reports of the Effects of MDMA in a Clinical Setting. *Journal of Psychoactive Drugs* 18 (1986) 4:319-327.  
<http://www.heffter.org/SUBJREPT.HTML>

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

*Clinical, Pharmacological and Neurotoxicological Effects of the Drug MDMA*. Norwell, MA: Kluwer Academic Publishers, 1990.

Greer G, Tolbert R. A Method of Conducting Therapeutic Sessions with MDMA. *Journal of Psychoactive Drugs* 30 (1998) 4:371-379.

Grinker R. Bootlegged ecstasy. *Journal of the American Medical Association* 187 (1964): 192.

Grinspoon L, Bakalar J. *Psychedelics Reconsidered*. New York: Basic Books, 1979.

Grinspoon L, Bakalar J. *Marijuana: The Forbidden Medicine*. New Haven: Yale University Press, 1993.

Grob C, Poland R, Chang L, Ernst T. Psychobiologic effects of 3,4-methylenedioxymethamphetamine in humans: methodological considerations and preliminary observations. *Behaviour and Brain Research* 73 (1996) 1-2:103-7.

Grob C. Letter to Rick Doblin. March 15, 1999.

Grof S. *LSD Psychotherapy*. New York: Hunter House, 1980.

Grof S, Soskin R, Richards W, Kurland A. DPT as an adjunct in psychotherapy of alcoholics. *International Pharmacopsychiatry* 8 (1973) 1:104-15.

Grof S, Goodman L, Richards W, Kurland A. LSD-Assisted Psychotherapy in Patients with Terminal Cancer. *International Pharmacopsychiatry* 8 (1973) 3:129-144.

Grudzinskas C and Wright C. An 18-day Approval Becomes Reality. *Pharmaceutical Executive* 10 (October 14, 1994): 74-80.

Grudzinskas C, Wright C. An 18-day Approval Becomes Reality. *Pharmaceutical Executive* 10 (October 14, 1994): 74-80.

Guido M. Medical pot study receives support. *San Jose Mercury News*. May 16, 2000.

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

Guterman L. The Dope on Medical Marijuana. *Chronicle of Higher Education* (June 2, 2000): A21.

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

cannabis.com/project/main.html

Guy W, Gross M, Dennis H. An alternative to the double-blind procedure. *American Journal of Psychiatry* 123 (1967): 1505-1511.

Haakenson C, Akiyama T, Hallstrom A, Sather MR. Masking drug treatments in the Cardiac Arrhythmia Pilot Study (CAPS). FASHP for the CAPS Investigators. *Controlled Clinical Trials* 17 (August 1996) 4:294-303.

Haffner M. Director, FDA Office of Orphan Products Development. Letter to Rick Doblin, President, Multidisciplinary Association for Psychedelic Studies (MAPS). June 27, 1997. <http://www.maps.org/mmj/odda/06279702.html>

Haffner M. Director, FDA Office of Orphan Products Development. Letter to Rick Doblin, President, Multidisciplinary Association for Psychedelic Studies (MAPS). November 24, 1997. <http://www.maps.org/mmj/odda/11249701.html>

Haffner M. Director, FDA Office of Orphan Products Development. Letter to Rick Doblin, President, Multidisciplinary Association for Psychedelic Studies (MAPS). December 21, 1998. <http://www.maps.org/mmj/odda/12219801.html>

Haffner M. Director, FDA Office of Orphan Products Development. Letter to Rick Doblin, President, Multidisciplinary Association for Psychedelic Studies (MAPS). May 25, 1999. <http://www.maps.org/mmj/odda/05259901.html>

Haislip G. Deputy Assistant Administrator, DEA Office of Diversion Control. Letter to Dr. David Kessler, FDA Commissioner. June 8, 1994.

Halpern J. Hallucinogens, Anesthetic Agents, and Amphetamines in Year 2000. *Pharmacy News*, in press.

Harman W, McKim R, Mogar R, Fadiman J, Stolaroff M. Psychedelic Agents in Creative Problem-Solving: A Pilot Study. *Psychological Reports* 19 (1966) Monograph Supplement 2: 211-227.

Harter J. Symposium on pharmacologic and clinical control of cardiovascular drugs. Comments from the Food and Drug Administration. *American Journal of Medicine* 58 (April 1975) 4:477-8.

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

- process. *Journal of Clinical Pharmacology* 16 (October 1976) 10 Part 2:560-4.
- Harter J, Peck C. Chronobiology. Suggestions for integrating it into drug development. *Annals of the New York Academy of Sciences* 618 (1991): 563-71.
- Harter J. New Drug Approval- It's a Whole New Ballgame. *Regulatory Affairs Professional Society (RAPS) News* 1 (March 1993): 23-24.
- Hasler F, Bourquin D, Brenneisen R, Bar T, Vollenweider F. Determination of psilocin and 4-hydroxyindole-3-acetic acid in plasma by HPLC-ECD and pharmacokinetic profiles of oral and intravenous psilocybin in man. *Pharm Acta Helv* 72 (June 1997) 3:175-84.
- Hatzidimitriou G, McCann U, Ricaurte G. Altered serotonin innervation patterns in the forebrain of monkeys treated with (+/-)3,4-methylenedioxymethamphetamine seven years previously: factors influencing abnormal recovery. *Journal of Neuroscience* 19 (1999) 12:5096-107.
- Hausner M. The psychotogenic 'double-blind' model in psycholysis: Case study contribution to the sociogenic theory of schizophrenia. *Psychotherapy and Psychosomatics* 25 (1975) 1-6:26-8.
- Health Canada News Release 2000-44. May 5, 2000. Health Canada to establish source of research-grade marijuana.  
[http://www.hcsc.gc.ca/english/archives/releases/2000/2000\\_44e.htm](http://www.hcsc.gc.ca/english/archives/releases/2000/2000_44e.htm)
- Henry J. Methadone: Where are we now? *Hospital Medicine* 60 (1999) 3:161-164.
- Henry V. Off-label Prescribing. *Journal of Legal Medicine* 20 (1999): 365-383.
- Hermann R, Dorwart R, Hoover C, Brody J. Variation in ECT Use in the United States. *American Journal of Psychiatry* 152 (June 1995) 6:869-875.
- Hermann R, Ettner S, Dorwart R, Hoover C, Yeung E. Characteristics of Psychiatrists Who Perform ECT. *American Journal of Psychiatry* 155 (July 1998) 7:889-894.
- Hermle L, Funfgeld M, Oepen G, Botsch H, Borchardt D, Gouzoulis E, Fehrenbach R, Spitzer M. Mescaline-induced psychopathological, neuropsychological, and neurometabolic effects in normal subjects: experimental psychosis as a tool for psychiatric research. *Biological Psychiatry* 32 (December 1, 1992) 11:976-91.

Hermle L, Spitzer M, Borchardt D, Kovar K, Gouzoulis E. Psychological effects of MDE in normal subjects. Are entactogens a new class of psychoactive agents? *Neuropsychopharmacology* 8 (February 1993) 2:171-6.

Hermle L, Gouzoulis-Mayfrank E, Spitzer M. Blood flow and cerebral laterality in the mescaline model of psychosis. *Pharmacopsychiatry* 31 (July 1998) Suppl 2:85-91.

Higgs R. (ed.) *Hazardous to our Health- FDA Regulation of Health Care Products*. Oakland: The Independent Institute, 1995.

Hill C, O'Grady K, Elkin I. Applying the Collaborative Study Psychotherapy Rating Scale to rate therapist adherence in cognitive-behavior therapy, interpersonal therapy, and clinical management. *Journal of Consulting and Clinical Psychology* 60 (February 1992) 1:73-9.

Hoffer A, Smith C, Chwelos N, Callbeck M, Mahon M. Psychological response to d-lysergic acid diethylamide and its relationship to adrenochrome levels. *Journal of Clinical and Experimental Psychopathology* 20 (1959): 125.

Hoffer A. D-Lysergic acid diethylamide (LSD): A review of its present status. *Clinical Pharmacology and Therapeutics* 6 (March-April 1965): 183-255.

Hoffer A. A Theoretical examination of double-blind design. *Canadian Medical Association Journal* 97 (July 15, 1967) 3:123-127.

Hoffer A. Treatment of Alcoholism with Psychedelic Therapy. in (ed.) Aaronson B, Hoffer A. *Psychedelics- The Uses and Implications of Hallucinogenic Drugs*. Garden City, NY: Anchor Books, 1970: 357-365

Hoffer A. Double-Blind Studies. *Canadian Medical Association Journal* 111 (October 19, 1974) 8:752.

Hoffer A. The Double-Blind Method. *Canadian Psychiatric Association Journal* 6 (October 2, 1976): 449-450.

Hofmann A, Heim R, Brack A, Kobel H. Psilocybin, ein psychotroper Wirkstoff aus dem mexikanischen Rauschpilz *Psilocybe mexicana* Heim. [Psilocybin, a psychotropic principle from the Mexican hallucinogenic fungus *Psilocybe mexicana* Heim]. *Experientia* 14 (1958): 107.

Hofmann A, Schultes R. *Plants of the Gods*. Maidenhead, England: McGraw-Hill, 1979.



Hofmann A. *LSD- My Problem Child*. New York: McGraw-Hill, 1980.

Hofmann A. Ride Through the Sierra Mazateca in Search of the Magic Plant "Ska Maria Pastora". in *The Sacred Mushroom Seeker - Essays for R. Gordon Wasson*, ed. Thomas Riedlinger. Portland, Oregon: Discorideds Press, 1990: 115-127.

Hogel J, Gaus G. The Procedure of New Drug Application and the Philosophy of Critical Rationalism or The Limits of Quality Assurance with Good Clinical Practice. *Controlled Clinical Trials* 20 (1999): 513-519.

Hollister L. Commentary: An Approach to the Medical Marijuana Controversy. *Drug and Alcohol Dependence* 58 (2000): 3-7.

Hollon S, DeRubeis R. Placebo-Psychotherapy Combinations: Inappropriate Representations of Psychotherapy in Drug-Psychotherapy Comparative Trials. *Psychological Bulletin* 90 (1981) 3:467-477.

Hollon S, Shelton R, Loosen P. Research Considerations in Evaluating Combined Treatment. in (eds.) Beitman B, Klerman G. *Integrating Pharmacotherapy and Psychotherapy*. Washington, DC: American Psychiatric Press, 1991: 353-378.

Hollon S, DeRubeis R, Evans M, Wiemer M, Garvey M, Grove W, Tuason V. Cognitive therapy and pharmacotherapy for depression. Singly and in combination. *Archives of General Psychiatry* 49 (Oct 1992) 10:774-81.

Holmstedt B, Liljestrand G, eds. *Readings in Pharmacology*. New York: The Macmillan Company, 1963.

Holston S. An Overview of International Cooperation. *Food and Drug Law Journal* 52 (1997) 2:197-201.

Horgan C, Prottas J, Tompkins C, Wastila L, Bowden M. Summary and Conclusions of a Review of Prescription Drug Diversion Control Methods. in (eds.) Cooper J, Czechowicz D, Molinari S. *Impact of Prescription Drug Diversion Control Systems on Medical Practice and Patient Care*. Washington, D.C.: NIDA Research Monograph Series #131. Washington, DC, NIH Publication #93-3507. 1992: 206-223.

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

Prescription Drug Diversion Control. in (eds.) Cooper J, Czechowicz D, Molinari S. *Impact of Prescription Drug Diversion Control Systems on Medical Practice and Patient Care*. Washington, D.C.: NIDA Research Monograph Series #131. Washington, DC, NIH Publication #93-3507. 1992: 309--324.

Hughes P, Baldwin D, Sheehan D, Conard S, Storr C. Resident physician substance use, by specialty. *American Journal of Psychiatry* 149 (Oct 1992) 10:1348-54.

Hughes P, Storr C, Brandenburg N, Baldwin D, Anthony J, Sheehan D. Physician substance use by medical specialty. *Journal of Addictive Diseases* 18 (1999) 2:23-37.

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.

Hutt P, Merrill R. Historical Background- The Evolution of Federal Food and Drug Legislation. in *Food and Drug Law: Cases and Materials-Second Edition, University Casebook Series*. Westbury, New York: Foundation Press, 1991: 6-14.

Hutt P, Merrill, R. Prescription Drug Controlled Substances. in *Food and Drug Law: Cases and Materials-Second Edition, University Casebook Series*, Westbury, New York: Foundation Press, 1991: 535-536.

Huxley A. *The Doors of Perception*. New York: Harper, 1954.

Hyman S, Shore S. An NIMH Perspective on the Use of Placebos. *Biological Psychiatry* 47 (April 15, 2000) 8: 689-691.

Imber S, Glanz L, Elkin I, Sotsky S, Boyer J, Leber W. Ethical issues in psychotherapy research. Problems in a collaborative clinical trials study. *American Psychologist* 41 (Feb 1986) 2:137-46.

Inciardi J. *Methadone Diversion: Experiences and Issues*. NIDA Services Research Monograph Series. Washington, D.C., U.S. Government Printing Office, 1977.

International Conference on Harmonization (ICH). Efficacy guidelines. *E10: Choice of Control Group*. <http://www.ifpma.org/ich5e.html>

International Federation of Pharmaceutical Manufacturers Association. *History of the International Conference on Harmonization (ICH)*. <http://www.ifpma.org/ich8.html>

International Narcotic Control Board. *Annual Report of the International Narcotic Control Board-1998* ([http://www.incb.org/e/ind\\_ar.htm](http://www.incb.org/e/ind_ar.htm)).

International Narcotic Control Board. *Annual Report of the International Narcotic Control Board-1999* ([http://www.incb.org/e/ind\\_ar.htm](http://www.incb.org/e/ind_ar.htm)).

Isbell H. Comparison of the Reactions Induced by Psilocybin and LSD 25 in Man. *Psychopharmacologia* 1 (1959): 29-38

Isikof M.. HHS to Phase Out Marijuana Program; Officials Fear Sending 'Bad Signal' by Giving Drug to Seriously Ill. *The Washington Post*, June 22, 1991: A 14.

James W. Subjective Effects of Nitrous Oxide. *Mind*. 7(1882): 186-208.

James W. *Varieties of Religious Experience*. New York: MacMillan Publishing, 1961.

Janiger O. The use of hallucinogenic agents in psychiatry. *California Clinician* 56 (1960): 222-224, 251-259.

Janiger O, di Rios M. LSD and Creativity. *Journal of Psychedelic Drugs* 21 (1989): 129-134.

Jarrett R, Schaffer M, McIntire D, Witt-Browder A, Kraft D, Risser R. Treatment of atypical depression with cognitive therapy or phenelzine:a double-blind, placebo-controlled trial. *Archives of General Psychiatry*56 (May 1999) 5:431-7.

Johnston L, O'Malley P, Bachman J. The Monitoring the Future National Survey Results on Adolescent Drug Use- Overview of Key Findings, 1999. NIH Publication No. 00-4690, Washington, D.C. U.S. Government Printing Office, 2000: 8.  
<http://monitoringthefuture.org/pubs.html>

Joranson D. Guiding Principles of International and Federal Laws Pertaining to Medical Use and Diversion of Controlled Substances. in (eds.) Cooper J, Czechowicz D, Molinari S. *Impact of Prescription Drug Diversion Control Systems on Medical Practice and Patient Care*. NIDA Research Monograph Series #131. Washington, D.C., NIH Publication #93-3507, 1992: 18-34.

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*

*Special Interests on Somatic Therapies*. Washington, D.C.: American Psychiatric Association Press, 1994.

Joy J, Watson S, Benson J (eds.): *Marijuana and Medicine: Assessing the Science Base*. Washington, D.C.: Institute of Medicine, National Academy Press, 1999.  
<http://stills.nap.edu/books/0309071550/html>

Kaitlin K, Walsh H. Are Initiatives to Speed the New Drug Approval Process Working? *Drug Information Journal*.26 (1992): 341-349.

Kam P, Yoong F. Gamma-hydroxybutyric acid: an emerging recreational drug. *Anaesthesia* 53 (Dec 1998) 12:1195-8.

Kaplan J. *The Hardest Drug: Heroin and Public Policy*. Chicago: University of Chicago Press, 1983.

Kaptchuk T. Intentional Ignorance: A History of Blind Assessment and Placebo Controls in Medicine. *Bulletin of the History of Medicine*72 (1998): 389-433.

Karon B. Psychotherapy versus Medication for Schizophrenia: Empirical Comparisons. in (eds.) Fisher S, Greenberg R. *The Limits of Biological Treatments for Psychological Distress- Comparisons with Psychotherapy and Placebo*. Hillsdale, New Jersey: Lawrence Erlbaum Associates, 1989: 105-150.

Kast E. LSD and the dying patient. *Chicago Medical School Quarterly*26 (Summer 1966) 2:80-7.

Kast E. Attenuation of anticipation: a therapeutic use of lysergic acid diethylamide. *Psychiatric Quarterly*41 (1967): 646-657.

Kast E. A Concept of Death. in (eds.) Aaronson B, Osmond H. *Psychedelics- The Uses and Implications of Psychedelic Drugs*. Garden City, New York: Anchor Books, 1970: 366-381.

Katz E. Europe's Centralized New Drug Procedures: Is the United States Prepared to Keep Pace? 48 *Food Drug and Cosmetic Law Journal* 577 (1993): 577-587.

Katz L. NDA Days. *Regulatory Affairs*3 (1991): 209-216.

Katz J. Problems in Securing Informed Consent of Subjects in Experimental Trials of Unapproved Drugs and Devices, Testimony before the U.S. House Subcommittee on Regulation, Business Opportunities, and Technology of the Committee on Small Business, (May 23, 1994): 125-35.

Kazdin A. Comparative Outcome Studies of Psychotherapy: Methodological Issues and Strategies. *Journal of Consulting and Clinical Psychology* 54 (1986) 1:95-105.

Kazdin A, Bass D. Power to detect differences between alternative treatments in comparative psychotherapy outcome research. *Journal of Consulting and Clinical Psychology* 57 (Feb 1989) 1:138-47.

Keck P, Welge J, McElroy S, Arnold L, Strakowski S. Placebo Effect in Randomized, Controlled Studies of Acute Bipolar Mania and Depression. *Biological Psychiatry*.47 (April 15, 2000) 8: 748-755.

Kelso P. Patients sue over LSD treatment side effects. Guardian Newspaper (UK), page 2, Wednesday November 17, 1999.

Kessler D. Regulating The Prescribing of Human Drugs for Non-approved Uses under the Food, Drug and Cosmetic Act, 15 *Harvard Journal of Legislation* 693 (1978).

Kessler D. Commissioner of Food and Drug Administration. Speech to Food and Drug Institute, December 11, 1990. <http://www.fda.gov/bbs/topics/SPEECH/SPE00021.htm>

Khan A, Warner H, Brown W. Symptom Reduction and Suicide Risk in Patients Treated with Placebo in Antidepressant Trials: An Analysis of the FDA Database. *Archives of General Psychiatry* 57 (Apr 2000) 4:311-7.

King R. Narcotic Drug Laws and Enforcement Policies. *Law and Contemporary Problems* 22 (Winter 1957): 122-123.

Kitt C. National Institute of Neurological Disorders and Stroke. Letter to Dr. Ethan Russo. Notification of Scientific Review Action, Application # 1R01NS37550-01A1, Cannabis in Acute Migraine Treatment Project. January 7, 1999. <http://www.maps.org/mmj/russo2b.html>

Klein M. Research Issues Related to Development of Medications for Treatment of Cocaine Addiction. *Neurochemistry of Drugs of Abuse- Cocaine, Ibogaine and Substituted Amphetamine*, ed. by Ali S. New York: Annals of the New York Academy of Sciences. 844 (1998):75-91.

Kleiman M. Proposed Therapeutic Uses of MDMA: Risks and Benefits in Decisions about Research Approval and Approval as Medicine. *Conference on Clinical Research with MDMA and MDE*. Dead Sea, Israel. Sept 1, 1999.

<http://www.maps.org/research/mdma/israel/kleimantalk.html>

Klein D, Gittleman R, Quitkin F, Rifkin A. *Diagnosis and drug treatment of psychiatric disorders; Adults and children*. (2nd Edition). Baltimore: Williams and Wilkins, 1980.

Klerman G, Weissman M, Rounsaville B, Chevron E. *Interpersonal Psychotherapy of Depression*. New York, NY: Basic Books, 1984.

Klapheke M. Privileging for ECT. *Convulsive Therapy* 11 (1995) 1: 57-58.

Kluver H.. *Mescal: The "Divine" Plant and its Psychological Effects*. London: Kegan Paul, Trench, Trubner and Co., 1928.

Kluver H. *Mescal and Mechanisms of Hallucinations*. Chicago: University of Chicago Press, 1966

Koelle G. The Pharmacology of Mescaline and D-Lysergic Acid Diethylamide (LSD). *New England Journal of Medicine* 258 (1958) 1:25-32.

Kong D. Mental Health Body Will Review Tests-Decision Follows a Series of Reports. *Boston Globe*. January 22, 1999: A20.

Kong D. Panel Urges Review of Patient Studies. *Boston Globe* November 18, 1999.

Kong D. Drug Studies Are Questioned. *Boston Globe* December 31, 1999.

Kramer B. Use of ECT in California, 1977-1983. *American Journal of Psychiatry* 142 (October 1985) 10: 1190-1192.

Kramer B. A Teaching Guide for Electroconvulsive Therapy. *Comprehensive Psychiatry* 40 (Sept/Oct 1999) 5: 327-331.

Kramer P. *Listening to Prozac*. New York: Penguin, 1997.

Krupitsky E, Grinenko A, Karandashova G, Berkaliyev T, Moshkov K, Borodkin, Y. Metabolism of biogenic amines induced by alcoholism narcopsychotherapy with ketamine administration. *Biogenic Amines* 7 (1990): 577-582

Krupitsky E, Grinenko A, Berkaliyev T, Paley A, Petrov V, Moshkov K, Borodkin, Y. The combination of psychedelic and aversive approaches in alcoholism treatment: the affective contra-attribution method. *Alcoholism Treatment Quarterly* 9 (1992) :99-105.

Krupitsky E, Grinenko A. Ketamine Psychedelic Therapy (KPT): A Review of the results of ten years of research. *Journal of Psychoactive Drugs* 29 (1997) 2:165-183.

Krupitsky E, Burakov A, Romanova T, Strassman R, Grinenko A. Ketamine-Assisted Psychotherapy (KPT) of Heroin Addiction: Immediate Effects and Six Months Follow-up. *Bulletin of the Multidisciplinary Association for Psychedelic Studies* 9 (1999) 4:21-26. <http://www.maps.org/news-letters/v09n4/09421kru.html>

Krupitsky E. Ketamine Psychedelic Therapy in the Treatment of Heroin Addiction v04 Research Protocol <http://www.maps.org/research/ketamine/04Kheroin.html>

Krupnick J, Sotsky S, Simmens S, Moyer J, Elkin I, Watkins J, Pilkonis P. The role of the therapeutic alliance in psychotherapy and pharmacotherapy outcome: findings in the National Institute of Mental Health Treatment of Depression Collaborative Research Program. *Journal of Consulting and Clinical Psychology* 64 (June 1996) 3:532-9.

Kunz R, Oxman A. The unpredictability paradox: Review of empirical comparisons of randomized and non-randomized clinical trials. *British Medical Journal* 317 (1998): 1185-1190.

Kurland A, Unger S, Shaffer J, Savage C. Psychedelic Therapy Utilizing LSD in the Treatment of the Alcoholic Patient: A Preliminary Report. *American Journal of Psychiatry* 123 (1967) 12: 1202-1209.

Kurland A, Savage C, Pahnke W, Grof S, Olsson J. LSD in the Treatment of Alcoholics. *Pharmakopsychiatrie Neuro-Psychopharmacologie* 4 (1971) 2:84.

Kurland A. *Psychiatric Aspects of Opiate Dependence*. West Palm Beach: CRC Press, 1978.

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

*Psychoactive Drugs* 19 (October-December 1985) 4:279-90.

Kurtzweil P. Medical Possibilities for Psychedelic Drugs. *FDA Consumer* (September 1995). [http://www.fda.gov/fdac/features/795\\_psyche.html](http://www.fda.gov/fdac/features/795_psyche.html)

Langendam M, Van Brussel G, Coutinho R, Can Ameijden E. Methadone Maintenance and Cessation of Injecting Drug Use: Results from the Amsterdam Cohort Study. *Addiction*95 (2000) 4:591-600.

Larson E, Ellsworth A, Oas J. Randomized clinical trials in single patients during a 2-year period. *Journal of the American Medical Association*270 (Dec 8, 1993) 22:2708-12.

Lasagna L. The Controlled Clinical Trial. Theory and Practice. *Journal of Chronic Diseases*1 (1955): 353-367.

Lasagna L. The impact of regulation on the development of psychoactive drugs. *National Institute on Drug Abuse Research Monograph Series 27. Problems of Drug Dependence*. Proceedings of the 41st Annual Meeting. Washington, D.C: NIDA, 1979: 29-35.

Lasagna L. Clinical trials in the natural environment. *Tufts University Center for the Study of Drug Development, Reprint Series RS 8695*, 1985.

Lasagna L. Clinical trials in the natural environment. in (eds.) Stiechele C, Abshagen W, Koch-Weser J. *Drugs Between Research and Regulation*. Darmstadt: Steinfopff Verlag, 1985: 45-49.

Lasagna L. Decision Processes in Establishing the Efficacy and Safety of Psychotropic Agents. in (ed.) Prien R, Robinson D. *Clinical Evaluation of Psychotropic Drugs: Principles and Guidelines*. New York: Raven Press, 1994: 13-28.

Laska E, Klein D, Lavori P, Levine J, Robinson D. Design Issues for the Clinical Evaluation of Psychotropic Drugs. in (ed.) Prien R, Robinson D. *Clinical Evaluation of Psychotropic Drugs: Principles and Guidelines*. New York: Raven Press, 1994: 29-67.

Laughren T. Team Leader, Psychiatric Drug Products, Division of Neuropharmacological Drug Products. Memorandum. Subject: Recommendation for Approval Action. [Zoloft for PTSD] October 19, 1999.

Lavori P, Laska E, Uhlenhuth E. Statistical Issues for the Clinical Evaluation of Psychotropic Drugs. in (ed.) Prien R, Robinson D. *Clinical Evaluation of Psychotropic*



*Drugs: Principles and Guidelines*. New York: Raven Press, 1994.139-160.

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

Leary T. Newsletter #1, Research Program on Consciousness-Altering Substances, February, 1962. 13.

Leary T. Supplies. *International Federation for Internal Freedom Newsletter*1 (May 1963): 1.

Leary T, Litwin G, Metzner R. Reactions to psilocybin in a supportive environment. *Journal of Nervous and Mental Disease*137 (1963): 561-573.

Leary T, Metzner R, Presnell M, Weil G, Schwitzgebel R, Kinne S. A new behavior change pattern using psilocybin. *Psychotherapy: Theory, Research and Practice*2 (1965) 2: 61-72.

Leary T, Metzner R. Use of psychedelic drugs in prisoner rehabilitation. *British Journal of Social Psychiatry* 2 (1968): 27-51.

Leary T. The effects of consciousness-expanding drugs on prisoner rehabilitation. *Psychedelic Review*10 (1969): 20-44.

Leary T. *High Priest*. Berkeley: Ronin Press, 1984.

Lebensohn Z. The History of Electroconvulsive Therapy in the United States and Its Place in American Psychiatry: A Personal Memoir. *Comprehensive Psychiatry*40 (May/June 1999) 3:173-181.

Leber P. The placebo in clinical trials (a view from the FDA). *Psychopharmacology Bulletin*22 (1986): 30-32.

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. Director of FDA Division of Neuropharmacological Drug Products. Letter to Dr. Rick Strassman. June 14, 1988.

Leber P. Hazards of inference: The active control investigation. *Epilepsia*30 (1989)

Supplement 1: S57-S63.

Leber P. Is there an alternative to the randomized controlled trial? *Psychopharmacology Bulletin* 27 (1991): 3-8.

Leber P. Challenges to the ethicality of clinical research. *Psychopharmacology Bulletin* 32 (1996): 11-13.

Leber P, Davis C. Threats to the validity of clinical trials employing enrichment strategies for sample selection. *Controlled Clinical Trials* 19 (April 1998) 2:178-87.

Leber P. The Use of Placebo Control Groups in the Assessment of Psychiatric Drugs: An Historical Context. *Biological Psychiatry* 47 (April 15, 2000) 8: 699-706.

Lee M, Schlain B. *Acid Dreams- LSD, the CIA and the Sixties Rebellion*. New York: Grove Press, 1985.

Leinwand D, Fields G. Party's Over: Studies show drug causes brain damage. *USA Today* (April 19, 2000): A2.

Leinwand D, Fields G. Feds Crack Down on Ecstasy. *USA Today*. (April 19, 2000): A1

Leong G, Eth S. Legal and Ethical Issues in Electroconvulsive Therapy. *Psychiatric Clinics of North America*. 14 (1991) 4:1007-1020.

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

Leuner H, Holfeld H. Ergebnisse und Probleme der Psychotherapie mit Hilfe von LSD-25 und verwandten Substanzen. [Results and problems of psychotherapy assisted by LSD-25 and related substances]. *Psychiat et Neurol (Basel)* 143 (1962): 379.

Leuner H. Psychotherapy with Hallucinogens; A Clinical Report with Special Reference to the Revival of Emotional Phases of Childhood. in Crockett R, Sandison R, Walk, A (eds.) *Hallucinogenic Drugs and their Psychotherapeutic Use*. London: H.K.Lewis, 1963: 67-73.

Levine R. *Ethics and Regulation of Clinical Research-2nd Edition*. Baltimore: Urban and Schwarzenberg, 1986.

Lewin L. Uber Anhalonium lewinii. *Archiv fur Experimentelle Pathologie und*

*Pharmakologie* 24 (1888): 401-411.

Lieberman J and Aghajanian G. Editorial—Caveat Emptor: Researcher Beware. *Neuropsychopharmacology* 21 (1999) 4:471-473.

Lieberman J, Stroup S, Laska E, Volavka J, Gelenberg A, Rush J, Shear K, Carpenter W. Chapter 2- Issues in Clinical Research Design: Principles, Practices, and Controversies. in (eds.) Pincus H, Lieberman J, Ferris S. *Ethics in Psychiatric Research- A Resource Manual for Human Subjects Protection*. Washington, D.C.: American Psychiatric Association, 1999: 23-60.

Lifton R. *The Nazi Doctors: Medical Killing and the Psychology of Genocide*. New York: Basic Books, 1986

Lin G, Glennon R (eds.). *Hallucinogens: An Update. NIDA Research Monograph 146*. Washington, DC, NIH Publication # 94-3872. 1994

Lindesmith A. *The Addict and the Law*. Bloomington, Indiana University Press, 1965.

Linton H, Langs R. Placebo Reactions in a Study of Lysergic Acid Diethylamide (LSD-25). *Archives of General Psychiatry* 6 (May 1962) 5:369-383.

Lipton M. Appendix. *Psychotomimetic Drugs- Proceedings of a Workshop organized by the Pharmacology Section, Psychopharmacology Research Branch, National Institute of Mental Health, held at the University of California, Irvine, on January 25-26, 1969*. Workshop Series of Pharmacology Section, National Institute of Mental Health No 4. Efron D (ed.). New York: Raven Press, 1970: 351.

Lotsof H. Rapid method for interrupting the narcotic addiction syndrome. U.S. Patent 4,400,496. 1986.

Lotsof H. Rapid method for interrupting or attenuating the cocaine and amphetamine abuse syndrome. U.S. Patent 4,587,243. 1986.

Luborsky L, Woody G, McLellan T, O'Brien C. Can Independent Judges Recognize Different Psychotherapies? An Experience with Manual-Guided Therapies. *Journal of Consulting and Clinical Psychology* 50 (1982) 1:49-62.

Luborsky L, DeRubeis R. The Use of Psychotherapy Treatment Manuals: A Small Revolution in Psychotherapy Research Style. *Clinical Psychology Review* 4 (1985): 5-10.

Ludwig A. LSD Treatment in Alcoholism, in (ed.) Gamage J, Zerkin E. *Hallucinogenic Drug Research: Impact on Science and Society*. Proceedings of the First Annual Symposium of the Student Association for the Study of Hallucinogens. Beloit, Wisconsin, 1970: 40-47.

Lumpkin M. FDA Deputy Center Director, Center for Drug Evaluation and Research. Pragmatic Approaches to Some Current Challenges in Pharmacovigilance. Talk given at the Drug Information Association Euro2000 meeting, Nice, France. March 9, 2000. <http://www.fda.gov/cder/present/dia-nice2000/dianice2/index.htm>.

Lumpkin M. Accelerating Drug Development: Regulatory Initiatives in the US. Talk given at the Drug Information Association Euro2000 meeting, Nice, France. March 9, 2000. <http://www.fda.gov/cder/present/dia-nice2000/dianice1/sld001.htm>

Lumpkin, M. Center Reports Drug Review Statistics for 1999. *News Along the Pike* 6 (February, 2000) 2:1, 8.

Luria P, Furberg C and Wolfe S. Public Citizen's Health Research Group. Letter to FDA Documents Management Branch commenting on ICH Draft Guidance on Choice of Control Group in Clinical Trial. December 23, 1999. <http://www.citizen.org/hrg/PUBLICATIONS/1503.htm>

Lurie P, Woodcock J, Kaitin K. FDA Drug Review: The Debate over Safety, Efficacy, and Speed. *Medical Crossfire* 1 (April 15, 1999) 3:52-60.

Lyons D. The Use and Abuse of Placebo in Clinical Trials. *Drug Information Journal* 33 (1999)1: 261-264.

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

Magura S, Nwakeze P, Kang S-Y, Demsky S. Program Quality Effects on Patient Outcome during Methadone Maintenance: A Study of 17 Clinics. *Substance Use and Misuse* 34 (1999) 9:1299-1324.

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-

methylenedioxymethamphetamine (MDMA)-induced serotonin neurotoxicity and core body temperature in the rat. *Journal of Neuroscience* 18 (July 1, 1998) 13:5086-94.

Mangini M. Treatment of Alcoholism Using Psychedelic Drugs: A Review of the Program of Research. *Journal of Psychoactive Drugs* 30 (1998) 4: 381-418.

Mann L. Public Health Service, Center for Scientific Review. Summary Statement: Cannabis in Acute Migrane Treatment Project. Letter to Dr. Russo. February 1, 2000. <http://www.maps.org/mmj/russo1199/02010001.html>

Marks J. *The Search for the Manchurian Candidate*. New York: Times Books, 1979

Marshall E. NIMH to Screen Studies for Science and Human Risks. *Science*(January 22, 1999): 464-465.

Mas M, Farre M, de la Torre R, Roset P, Ortuno J, Segura J, Cami J. Cardiovascular and neuroendocrine effects and pharmacokinetics of 3, 4-methylenedioxymethamphetamine in humans. *Journal of Pharmacology and Experimental Therapeutics* 290 (Jul 199) 1:136-45.

Mash D, Kovera C, Buck B, Norenberg M, Shapshak P, Hearn L and Sanchez-Ramos J. Medication Development of Ibogaine as a Pharmacotherapy for the Treatment of Drug Dependence. Ali S. (ed.) *Neurochemistry of Drugs of Abuse- Cocaine, Ibogaine and Substituted Amphetamine. Annals of the New York Academy of Sciences* 844 (1998): 274-292.

Mason J. Assistant Secretary of Health. Letter to Mr. Dennis Peron. June 4, 1992.

Masters R, Houston J. *Varieties of Psychedelic Experience*. New York: Dell, 1966

Matthias P, Tashkin D, Marques-Magallanes J, Wilkins J, Simmons M. Effects of varying marijuana potency on deposition of tar and delta9-THC in the lung during smoking. *Pharmacology Biochemistry and Behavior*58 (Dec 1997) 4:1145-50.

Mattison N, Richard B. Postapproval Research Requested by the FDA at the time of NCE Approval, 1970-1984. *Drug Information Journal* 21 (1987): 309.

Mattocks K, Horwitz R. Placebos, Active Control Groups, and the Unpredictability Paradox. *Biological Psychiatry*47 (April 15, 2000) 8: 693-698.

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.  
December 30, 1996. <http://www.ncjrs.org/txtfiles/215rel.txt>

McCann U, Szabo Z, Scheffel U, Dannals R, Ricaurte G. Positron emission tomographic evidence of toxic effect of MDMA ("Ecstasy") on brain serotonin neurons in human beings. *Lancet* 352 (1998): 1433-37.

McCann U, Mertl M, Eligulashvili V, Ricaurte G. Cognitive performance in ( $\pm$ ) 3,4-methylenedioxymethamphetamine (MDMA, "ecstasy") users: a controlled study. *Psychopharmacology* 143 (1999): 417-425.

McClelland D. Some Social Reactions to the Psilocybin Research Project. Unpublished paper prepared for the October 8, 1961 meeting. 1-3.

McCormick C. Director of FDA's Division of Anesthetics, Critical Care and Addiction Drug Products. Letter to Richard Yensen, Ph.D.. October 28, 1997.

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. Charlie Grob. July 23, 1999.

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

McEvoy J, Keefe R. Informing Subjects of Risks and Benefits, in (ed.) Pincus H, Lieberman J, and Ferris S. *Ethics in Psychiatric Research- A Resource Manual for Human Subjects Protection*. Washington, D.C.: American Psychiatric Association, 1999: 129-157.

McLearn D. *FDA Press Release P93-19* March 18, 1993.

McNeely J, Drucker E, Hartel C, Tuchman E. Office-based methadone prescribing: acceptance by Inner-City Practitioners in New York City. *Journal of Urban Health* 77 (March 2000) 1:96-102.

Mead A. Proposition 215: A Dilemma. *Journal of Psychoactive Drugs* 30 (Apr-June 1998) 2:149-154.

Medical Marijuana Research. Letter to HHS Secretary Donna Shalala. Thirty-Five Members of Congress. November 30, 1999. <http://www.mpp.org/guidelines/ltr2.html>

Mertl M. Ecstasy and the Brain: Club Drug Rants and Raves. *Brain.Com*. April 11, 2000. [http://www.brain.com/about/article.cfm?id=9300&cat\\_id=500](http://www.brain.com/about/article.cfm?id=9300&cat_id=500)

Metzner R. Reflections on the Concord Prison Project and the Follow-up Study. *Journal of Psychoactive Drugs* 30 (1998) 4: 427-428.

Meyer G. The Food and Drug Administration Perspective on the Importance of Dialogue with Industry. *Drug Information Journal* 26 (1992): 159-161.

Meyer G. CDER's Organizational Changes. *Food and Drug Law Journal* 48 (1993) 1:43-46.

Mikuriya T. *Marijuana: Medical Papers, 1839-1972*. Oakland: Medicomp, 1973.

Miller L. Aboyu-Donia M. Rudd D. Samara B. Schmith V. Huffman C. et al. NDA Day: The Approval of a Neuromuscular Blocking Agent. *Journal of Clinical Research and Pharmacoeconomics* 6 (1992): 271-284.

Miller L. Pitfalls in the Drug Approval Process; Dose-Effect, Experimental Design, and Risk-Benefit Issues. *Drug Information Journal* 26 (1992) 2:251-260.

Miller L, Buckley J. The Interactive IND/NDA. *Drug Information Journal* 30 (1996) 3: 593-600.

Mitchell S. The Effects of Anhelonium Lewinii (the Mescal Button). *British Medical Journal* 2 (1896): 1625-1629.

Mogar R, Savage C. Personality Changes associated with Psychedelic (LSD) Therapy: A Preliminary Report. *Psychotherapy* 1 (1964): 154-162.

Monteiro M. The Work of the WHO Program on Substance Abuse and Psychedelic Drugs. *Bulletin of the Multidisciplinary Association for Psychedelic Studies* 6 (1996) 3:

2-5.

Moreno F, Delgado P. Hallucinogen-induced relief of obsessions and compulsions. *American Journal of Psychiatry* 154 (July 1997) 7:1037-8.

Morey S. NIH Consensus Panel Advocates Increased Access to Treatment for Opiate Addiction. *American Family Physician* 58 (September 1, 1998) 3:786-787.

Mulligan K. Letter to Dr. Marlene Haffner. Director, FDA Office of Orphan Product Development. September 22, 1997. <http://www.maps.org/mmj/odda/09229701.html>

Murphy A. It's Time to Make a Good Agency Better: The Food and Drug Administration Act of 1997 and the First Amendment. *Food and Drug Law Journal* 53 (1998) 4:603-625.

Naranjo C, Shulgin A, Sargent T. Evaluation of 3,4-Methylenedioxymethamphetamine (MDA) as an Adjunct to Psychotherapy. *Medicine et Pharmacologia Experimentalis* 17 (1967): 359-364.

Naranjo C. *The Healing Journey- New Approaches to Consciousness*. New York: Pantheon-Random House, 1973.

National Advisory Council on Drug Abuse. *Recommended Guidelines for the Administration of Drugs to Human Subjects*. Rockville, Maryland: NIDA, June 17, 1997. <http://www.nida.nih.gov:80/HSGuide.html>

National Bioethics Advisory Commission. *Research Involving Persons with Mental Disorders that May Affect Decisionmaking Capacity. Report and Recommendations of the National Bioethics Advisory Commission*. December 1, 1998: NIMH. Rockville, MD.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report; Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. DHEW Publication No (OS) 78-0012, Appendix I, DHEW Publication No (OS) 78-0013, Appendix II, DHEW Publication No (OS) 78-0014, Washington, D.C., 1978

National Institute on Drug Abuse. Club Drugs Take Center Stage in New National Education and Prevention Initiative by NIDA and National Partners- Initiative Includes Research Funding and Community Outreach. NIDA News Release, December 2, 1999. <http://165.112.78.61/MedAdv/99/NR-122.html>



National Institutes of Health. Effective Medical Treatment of Opiate Addiction. *NIH Consensus Statement* 15 (November 17-19, 1998) 6: 19-20.  
<http://odp.od.nih.gov/consensus/cons/mental.htm>

National Institutes of Health.. Electroconvulsive Therapy. *NIH Consensus Statement Online* 1985 Jun 10-12 [cited 2000, May 1]; 5(11):1-23.  
[http://odp.od.nih.gov/consensus/cons/051/051\\_intro.htm](http://odp.od.nih.gov/consensus/cons/051/051_intro.htm)

National Institutes of Health. *Workshop on the Medical Utility of Marijuana: Report to the Director, National Institutes of Health*. February 19-21, 1997.  
<http://www.nih.gov/news/medmarijuana/MedicalMarijuana.htm>

Nichols D. The Heffter Research Institute: New Swiss Program. *Bulletin of the Multidisciplinary Association for Psychedelic Studies*. 9 (Winter 1999/ 2000) 4: 49.  
<http://www.maps.org/news-letters/v09n4/09449hri.html>

NIH Consensus Statement: Effective Medical Treatment of Opiate Addiction. *Journal of the American Medical Association* 280 (December 8, 1998) 22:1936-1943.

Nowell R. RJR To Test Reduced-Smoke Cigarette. *AP Wire* April 20,2000.

Nunes E. Methodologic Recommendations for Cocaine Abuse Clinical Trials: A Clinician-Researcher's Perspective. in Tai B, Chiang N, Bridge P. (eds.) *Medication Development for the Treatment of Cocaine Dependence: Issues in Clinical Efficacy Trials*. NIDA Research Monograph 175. Washington, D.C., NIH Publication 97-4125, 1997:73-95

Nuremberg Military Tribunal. The Nuremberg Code on Permissible Medical Experiments. *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10. Vo. 2, Nuremberg, October 1946 - April 1949*. Washington, DC: U.S. Government Printing Office, 1949: 181-182.

O'Brien C, Jones R. Methodological issues in the evaluation of a medication for its potential benefits in enhancing psychotherapy. in Pletscher A, Ladewig D. (eds.) *50 Years of LSD- Current Status and Perspectives of Hallucinogens.- A Symposium of the Swiss Academy of Medical Sciences*. Lugana-Agno, Switzerland, Oct. 21-22, 1993. New York: Parthenon Publishing Group, 1994: 213-221.

Oepen G, Fuenfgeld M, Harrington A, Hermle L, Botsch H. Right Hemisphere involvement in mescaline-induced psychosis. *Psychiatry Research* 29 (1989): 335-336.

Office of Technology Assessment,. *Pharmaceutical R & D: Costs, Risks and Rewards*. Washington, D.C.: Office of Technology Assessment,, 1993.

Office of Inspector General. *Review of the Food and Drug Administration's Processing of a New Drug Application for Therafectin (A-15-94-00023)*. Washington, D.C.: Department of Health and Human Services, August 1995.

Office of the Inspector General. *Institutional Review Boards: Their Role in Reviewing Approved Research*. Washington, D.C.: Department of Health and Human Services, 1998.

Office of Inspector General. *Post-Marketing Studies of Prescription Drugs*. OEI-03-94--00760. Washington, D.C.: Department of Health and Human Services, May 1996.

O'Leary K, Borkovec T. Conceptual, methodological, and ethical problems of placebo groups in psychotherapy research. *American Psychologist* 33 (September 1978) 9:821-30.

O'Malley S, Foley S, Rounsaville B, Watkins J, Sotsky S, Imber S, Elkin I. Therapist competence and patient outcome in interpersonal psychotherapy of depression. *Journal of Consulting and Clinical Psychology* 56 (August 1988) 4:496-501.

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

Osmond H, Smythies J. Schizophrenia: A New Approach. *Journal of Mental Science* 98 (1952): 309-315.

Osmond H. A Review of the Clinical Effects of Psychotomimetic Agents. *Annals New York Academy of Science*. 66 (1957): 418.

Osmond H. *Predicting the Past: Memos on the Enticing Universe of Possibility*. New York: Macmillan Publishing Co., 1981: 81-82.

Ossebaard H, Maalste N. The Bastiaans Method of Drug-Assisted Therapy: A Preliminary Follow-up study with former clients. *Bulletin of the Multidisciplinary Association for Psychedelic Studies* 9 (1999) 2:3-9. <http://www.maps.org/news-letters/v09n2/09203maa.html>

Owens M. NDA Days- An update. *Regulatory Affairs* 3 (1991): 217-222.

Oxtoby A, Jones A, Robinson M. Is your “double-blind” design truly double-blind? *British Journal of Psychiatry* 155 (1989):700-701.

Pahnke Walter. *Drugs and Mysticism: An Analysis of the Relationship between Psychedelic Drugs and the Mystical Consciousness*. Unpublished doctoral thesis in the History and Philosophy of Religion submitted to Harvard University, 1963.

Pahnke W, Richards W. Implications of LSD and Experimental Mysticism. *Journal of Religion and Health* 5 (1966): 399-429.

Pahnke W, Salzman C, Katz R. Report on a Pilot Project Investigating the Psychopharmacological Effects of Psilocybin in Normal Volunteers. Self-published, November 1, 1966.

Pahnke W. The contribution of the psychology of religion to the therapeutic use of psychedelic substances. in Abramson H. (ed.) *The use of LSD in psychotherapy and alcoholism*. New York: Bobbs-Merrill, 1967: 629-49.

Pahnke W. LSD and Religious Experience. in Debold R, Leaf R (eds.) : *LSD, Man and Society*. Middletown, Conn.: Wesleyan University Press, 1967: 60-84.

Pahnke W. The Psychedelic Mystical Experience in the Human Encounter with Death. *Harvard Theological Review* 62 (1969): 1-21.

Pahnke W, Kurland A, Goodman L, Richards W. LSD-assisted psychotherapy with terminal cancer patients. *Current Psychiatric Therapies* 9 (1969): 144-52.

Pahnke W, Kurland A, Unger A, Savage C Grof S. The Experimental Use of Psychedelic (LSD) Psychotherapy. *Journal of the American Medical Association* 212 (1970) 11:1856-1863.

Pahnke W. Drugs and Mysticism. in (ed.) Aaronson B, Hoffer A. *Psychedelics- The Uses and Implications of Hallucinogenic Drugs*. Garden City, NY: Anchor Books, 1970: 145-165.

Palmer C, Rosenberger W. Ethics and Practice: Alternative Designs for Phase III Randomized Clinical Trials. *Controlled Clinical Trials* 20 (1999): 172-186.

Papac D, Foltz R. Measurement of lysergic acid diethylamide (LSD) in human plasma by gas chromatography/negative ion chemical ionization mass spectrometry. *Journal of Analytical Toxicology* 14 (1990) 3:189-90.

Parashos A. The psilocybin-induced "state of drunkenness" in normal volunteers and schizophrenics. *Behavioral Neuropsychiatry* 8(1976 Apr-1977 Mar) 1-12:83-6.

*Paraxel's Pharmaceutical R& D Statistical Sourcebook 1998*. Waltham, MA: Paraxel, 1998

Passie T. In Memoriam. *Bulletin of the Multidisciplinary Association for Psychedelic Studies* 6 (1996) 4:20-21. <http://www.maps.org/news-letters/v06n4/06408mem.html>

Passie T. *Psycholytic and Psychedelic Therapy Research 1931-1995: A Complete International Bibliography*. Hannover: Laurentius Publishers, 1997.

Peck C, Crout J. Current status of clinical pharmacology training in the United States. *Clinical Pharmacology and Therapeutics* 39 (Apr 1986) 4:451-8.

Peck C, Barr W, Benet L, Collins J, Desjardins R, Furst D, Harter J, Levy G, Ludden T, Rodman J, et al. Opportunities for integration of pharmacokinetics, pharmacodynamics, and toxicokinetics in rational drug development. *Clinical Pharmacology and Therapeutics* 51 (April 1992) 4:465-7

Peck C. Drug Development: Improving the Process. *Food and Drug Law Journal* 52 (1997) 2:163-167.

Peck J, Rabin K. (eds.) *Regulating Change—The Regulation of Foods, Drugs, Medical Devices and Cosmetics in the 1990s*. Washington, D.C.: Food and Drug Law Institute, 1989.

Pellerin C. *Trips: How Hallucinogens Work in Your Brain*. New York: Seven Stories Press, 1998.

Pereira J. *The Elements of Materia Medica and Therapeutics* Philadelphia: Lea and Blanchard, 1843.

Pilot Drug Evaluation Staff. Founders Commentary. *Pilot Drug Evaluation Staff, Internal Assessment, June 1989-December 1992, The 007 Experiment-An Approach to Change*. Rockville, Maryland, February 25, 1993.

Pletscher A, Ladewig D. (eds.) *50 Years of LSD- Current Status and Perspectives of Hallucinogens.- A Symposium of the Swiss Academy of Medical Sciences.* Lugana-Agno, Switzerland, Oct. 21-22, 1993. New York, Parthenon Publishing Group, 1994.

Pollard J. Shrouds around LSD. *Science* 154 (1966): 844.

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. *Implementing Human Research Regulations: The Adequacy and Uniformity of Federal Rules and of their Implementation.* U.S. Government Printing Office, Stock No. 040-000-00461-1. Washington, D.C., 1983.

Quitkin F, Rabkin J, Gerald J, Davis J, Klein D. Validity of clinical trials of antidepressants. *American Journal of Psychiatry* 157 (March 2000) 3:327-37.

Randall B. *Medical Use of Marijuana: Policy and Regulatory Issues.* Congressional Research Service Report for Congress. July 26, 1999. Order Code RL30274.

Randall R. *Marijuana, Medicine and the Law.* Washington, D.C.: Galen Press, 1988.

Randall R. *Marijuana, Medicine and the Law. Volume 2.* Washington, D.C.: Galen Press, 1989.

Randall R. *Marijuana and AIDS: Pot, Politics and PWAs in America.* Washington, DC: Galen Press, 1991.

Randall B and O'Leary A. *Marijuana Rx - The Patients' Fight for Medicinal Pot.* New York: Thunder's Mouth Press, 1998.

Ranga K, Krishnan R. Efficient Trial Designs to Reduce Placebo Requirements. *Biological Psychiatry* 47 (April 15, 2000) 8:724-726.

Rawson R, Hasson A, Huber A, McCann M, Ling W. A 3-Year Progress Report on the implementation of LAAM in the United States. *Addiction* 93 (1999) 4:533-540.

Reeves K. Direct-to-Consumer Broadcast Advertising: Empowering the Consumer or Manipulating a Vulnerable Population? *Food Drug Law Journal* 53 (1998) 4:661-679.

Regelman R, Hirsch R. *Studying a Study and Testing a Test: How to Read the Medical Literature. Second Edition* Boston: Little, Brown and Co., 1989.

Reid W, Keller S, Leatherman M, Mason M. ECT in Texas: 19 Months of Mandatory Reporting. *Journal of Clinical Psychiatry* 59 (January 1998) 1:8-13.

Research Plan for Marijuana for Medicinal Purposes: A Status Report. Therapeutic Products Programme, Health Canada, June 9, 1999. 1-10.

Rettig R, Yarmolinski A, eds. Federal Regulation of Methadone Treatment. Washington, DC: Institute of Medicine, National Academy Press, 1995.

Rexed B, Edmondson K, Khan I and Samsom R. *Guidelines for the Control of Narcotic and Psychotropic Substances- In the context of the international treaties*. Geneva: World Health Organization. 1984.

Reynolds C, Miller M, Pasternak R, Frank E, Perel J, Cornes C, Houck P, Mazumdar S, Dew M, Kupfer D. Treatment of bereavement-related major depressive episodes in later life: a controlled study of acute and continuation treatment with nortriptyline and interpersonal psychotherapy. *American Journal of Psychiatry* 156 (Feb 1999) 2:202-8.

Rickels K. (ed.) *Non-Specific Factors in Drug Therapy*. Springfield, Illinois: Charles C. Thomas Publishers, 1968.

Rinkel M, DeShon H, Hyde R, Solomon H. Experimental schizophrenia-like symptoms. *American Journal of Psychiatry* 108 (1952): 4572.

Rohde D. The Orphan Drug Act: An Engine of Innovation? At What Cost? *Food and Drug Law Journal* 55 (2000) 1:125-143.

Rosenbach M, Hermann R, Dorwart R. Use of Electroconvulsive Therapy in the Medicare Population Between 1987 and 1992. *Psychiatric Services* 48 (December 1997) 12:1537-1542.

Ross M, Olsen J. An expectancy-attribution model of the effects of placebos. *Psychological Review* 88 (1981): 408-437.

Rothman K, Michels K. The continuing unethical use of placebo controls. *New England Journal of Medicine* 331 (Aug 11, 1994) 6:394-8.

Rounsaville B, Chevron E, Prusoff B, Elkin I, Imber S, Sotsky S, Watkins J. The relation between specific and general dimensions of the psychotherapy process in interpersonal psychotherapy of depression. *Journal of Consulting and Clinical Psychology* 55 (Jun

1987) 3:379-84.

Russo E, Mielke J, Painter L, Hall S and Steele B. Cannabis in Acute Migraine Treatment Project. *Bulletin of the Multidisciplinary Association for Psychedelic Studies* 7 (1997) 3: 16-17. <http://www.maps.org/news-letters/v07n3/07316rus.html>

Russo E. Cannabis in acute migraine treatment project: Response to National Institutes of Health Critique. *Bulletin of the Multidisciplinary Association for Psychedelic Studies* 8 (1998) 1: 15-17. <http://www.maps.org/news-letters/v08n1/08115rus.htm>

Sallen S, Zinberg N, Frei F. Antiemetic Effect of Delta-9-Tetrahydrocannabinol in Patients Receiving Cancer Chemotherapy. *New England Journal of Medicine* 293 (1975): 785-797.

Salzman C. Controlled Research with Psychedelic Drugs. in (eds.) Hicks R, Fink P. *Psychedelic Drugs- Proceedings of a Hahnemann Medical College and Hospital Symposium, November 22-24, 1968*, New York: Grune and Stratton, 1969:23-32.

Salzman C. ECT, Research, and Professional Ambivalence. *American Journal of Psychiatry* 155 (January 1998) 1:1-2.

*Sandoz Pharmaceuticals Bibliography on Psychotomimetics 1943-1966. Annotated Bibliography on Delysid (LSD 25) (d-lysergic acid diethylamide)* Basel, Switzerland: Sandoz, 1966.

Sarett M, Cheek F, Osmond H. Reports of wives of alcoholics of effects of LSD-25 treatment of their husbands. *Archives of General Psychiatry* 14 (Feb 1966) 2:171-8.

Savage C, McCabe O. Residential psychedelic (LSD) therapy for the narcotic addict. A controlled study. *Archives of General Psychiatry* 28 (1973) 6:808-14.

Savage C, McCabe O, Kurland A, Hanlon T. LSD-assisted Psychotherapy in the Treatment of Severe Chronic Neurosis. *Journal of Altered States of Consciousness* 1 (1973) 1:31-47.

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.

Scholten W. Legal Aspects on Medicinal Use of Hemp: Historic Overview and Present Policy of the Netherlands. *Drug Information Journal* 34 (2000): 329-332.

Schreckenberger M, Gouzoulis-Mayfrank E, Sabri O, Arning C, Zimny M, Zeggel T, Wagenknecht G, Kaiser HJ, Sass H, Buell U. "Ecstasy"-induced changes of cerebral glucose metabolism and their correlation to acute psychopathology. An 18-FDG PET study. *European Journal of Nuclear Medicine* 26 (Dec. 1999) 12:1572-9.

Schulz K. Subverting randomization in controlled trials. *Journal of the American Medical Association* 274 (November 8, 1995) 18:1456-8.

Schulz K, Chalmers I, Hayes R, Altman D. Empirical evidence of bias. Dimensions of methodological quality associated with estimates of treatment effects in controlled trials. *Journal of the American Medical Association* 273 (February 1, 1995) 5:408-12.

Schuster L. FDA Panel Says Cigarettes are Addictive. *UPI Wire Service* August 2, 1994.

Serradell J, Galle B. Prescribing for Unlabeled Indications. *HMO Practice* 7 (March 1993) 1:44-7.

Shapiro C. Limiting Physician Freedom to Prescribe a Drug for any Purpose: The Need for FDA Regulation, *73 Northwestern Law Review* 801 (1979).

Shapiro H. Chair of the National Bioethics Advisory Commission. *Letter of Transmittal to the President. January 9, 1999. Research Involving Persons with Mental Disorders that May Affect Decisionmaking Capacity. Report and Recommendations of the National Bioethics Advisory Commission. December 1, 1998: NIMH, Rockville, MD.*

Shedlin M, Wallechinsky D with Salyer, S. (eds.) *Laughing Gas-Nitrous Oxide*. Berkeley: Ronin Press, 1992.

Sherwood J, Stolarof M, Harman W. The Psychedelic Experience--A New Concept in Psychotherapy. *Journal of Neuropsychiatry* 4 (1962) 2:69-80.

Shilts R. *And the Band Played On: Politics, People and the AIDS Epidemic* New York: Penguin Books, 1987.

Shulgin A. *Controlled Substances: Chemical and Legal Guide to Federal Drug Laws*. Berkeley: Ronin, 1992

Shulgin S, Shulgin A. *PIHKAL: A Chemical Love Story*. Berkeley: Transform Press, 1991.



- Sidney S, Beck J, Tekawa I, Quesenberry C, Friedman G. Marijuana use and Mortality. *American Journal of Public Health* 87 (1997) 4:585-590.
- Siegel R. Hallucinations. *Scientific American* 237 (1977): 132-140.
- Siegel R, West L. (eds.) *Hallucinations: behavior, experience, and theory*. New York: Wiley, 1975.
- Siegel R. *Fire in the brain : Clinical tales of hallucination*. New York: Dutton, 1992.
- Sinclair U. *The Jungle*. New York: Doubleday and Co., 1906.
- Skager R, Austin G. Preliminary Findings: 7th Biennial Cal. Student Substance Use Survey: Grades 7, 91, and 11, 1997-8. Sponsored by Cal. Dept of Justice, Office of the A.G., Crime and Violence Prevention Center; Cal. Dept of Education, Healthy Kids Program Office; Dept of Alcohol & Drug Programs; and Dept of Health Services, Office of AIDS. November 1998. (As of June 12, 2000, this report has not been officially released.)
- Slovenko R. The right of the mentally ill to refuse treatment revisited. *Journal of Psychiatry and Law* (Fall 1992): 407-434.
- Smart R, Storm T. The efficacy of LSD in the treatment of alcoholism. *Quarterly Journal of Studies of Alcoholism*(1964) 25: 333-338.
- Smart R, Storm T, Baker E, Solursh L. A controlled study of lysergide. *Quarterly Journal of Studies of Alcoholism* 28 (June 1967) 2:351-3.
- Smart R, Storm T, Baker E, Solursh L. A controlled study of lysergide in the treatment of alcoholism. 1. The effects on drinking behavior *Quarterly Journal of Studies of Alcoholism* 27 (September 1967) 3:469-82.
- Smith A, Traganza E, Harrison G. Studies on the effectiveness of antidepressant drugs. *Psychopharmacology Bulletin* 5 (1969): 1-53.
- Smith, Huston and Snake, Reuben. *One Nation Under God- The Triumph of the Native American Church*. Santa Fe: Clear Light Publishers, 1996.
- Snelders S. LSD en de psychiatrie in Nederland (Ph.D.-dissertation Vrije Universiteit, Amsterdam 1999).

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

Snyder S, Weingartner H, Faillace L. DOET (2,5-dimethoxy-4-ethylamphetamine) and DOM (STP) (2,5-dimethoxy-4-methylamphetamine), New Psychotropic Agents and Their Effects in Man. in Efron D. (ed.). *Psychotomimetic Drugs- Proceedings of a Workshop organized by the Pharmacology Section, Psychopharmacology Research Branch, National Institute of Mental Health, held at the University of California, Irvine, on January 25-26, 1969*. Workshop Series of Pharmacology Section, National Institute of Mental Health No 4. New York: Raven Press, 1970.

Soskin R. The use of LSD in time-limited psychotherapy. *Journal of Nervous and Mental Disease*157 (1973) 6:410-9.

Sotsky S, Glass D, Shea M, Pilkonis P, Collins J, Elkin I, Watkins J, Imber S, Leber W, Moyer J, et al. Patient predictors of response to psychotherapy and pharmacotherapy: findings in the NIMH Treatment of Depression Collaborative Research Program. *American Journal of Psychiatry* 148 (August 1991) 8:997-1008.

Spitzer M, Thimm M, Hermle L, Holzmann P, Kovar K, Heimann H, Gouzoulis-Mayfrank E, Kischka U, Schneider F. Increased activation of indirect semantic associations under psilocybin. *Biological Psychiatry*39 (June 1996) 12:1055-7.

Staff. ACTUP/NY 1988. <http://www.actupny.org/documents/cron-88.html>

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. Boston Life Sciences Announces Results of its Phase III Trial for Therafectin. *Business Wire* (September 30, 1997).

Staff. Boston Life Sciences' Drug rejected by FDA. *Boston Globe*(December 30, 1999): D7.

Staff. Boston Life Sciences to Meet With FDA On Therafectin Efficacy Issues. *Healthwire* (December 29, 1999).

Staff. Data Accrue on "Visionary" agent to interrupt addiction. *Lancet* 354 (November 27, 1999): 1883.

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

Says: Pharmacokinetics Work in Animal Models Urged by CDER Director. *F-D-C Reports Pinksheet* (February 25, 1991): 10-11.

Staff. Doctors Given Federal Threat On Marijuana. *New York Times*(December 31, 1996): A1.

Staff. Ecstasy seizures suggest drug's flow becoming epidemic. *CNN.com* (April 3, 2000). <http://robots.cnn.com/2000/US/04/03/designer.drug.deluge.ap/index.html>

Staff. FDA Anti-Inflammatory/Analgesic Drug Review Division. *Pink Sheet Trade and Government Memos* (April 3, 1989): 1.

Staff. FDA Lists Approved LSD Research Projects. *FDA Consumer*(September 1975): 24-25.

Staff. FDA OKs New Alzheimer's Option. *AP Wire Service* (April 22, 2000).

Staff. *F-D-C Reports*(February 3, 1986): 5-6.

Staff. FDLI Hears of FDA Pilot Evaluation. *Marketletter* (June 12, 1989): 24-25.

Staff. Greenwich announces negative evaluation of Therafectin. *Business Wire* (May 10, 1994).

Staff. Greenwich announces settlement of Securities Litigation. *Business Wire* (May 11, 1994).

Staff. Greenwich Pharmaceuticals makes announcement about Therafectin. *Business Wire* (January 27, 1994).

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

Staff. Greenwich Pharmaceuticals reports on status of Therafectin (amiprilose HCl). *Business Wire* (September 23, 1992).

Staff. Greenwich Pharmaceuticals submits New Drug Application for Therafectin (amiprilose HCl). *Business Wire* (January 11, 1993).

Staff. John Gamble Harter Dies, Guided Pilot Drug Program. *News Along the Pike*.(July 15, 1996): 4.

Staff. Harter to Head New FDA Analgesics, Anti-Inflammatories Division. *Pharmaceutical Manufacturers Association Newsletter*. 31 (April 3, 1989) 13: 1.

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. Pilot Group Convened Six NDA Days in 1990, More Planned. *F-D-C Reports Pinksheet* (October 22, 1990): 14-15.

Staff. NDA Days: Some Divisions Do, Some Don't. *US Regulatory Reporter* (August 1991): 3-5.

Staff. *Thalomid- Balancing the Benefits and the Risks*. Warren, New Jersey: Celgene, 1998. [http://www.celgene.com/CelgeneN2.nsf/Media/pdf/\\$FILE/Balancing.pdf](http://www.celgene.com/CelgeneN2.nsf/Media/pdf/$FILE/Balancing.pdf)

Staff. The Pilot Drug Evaluation Staff's "Interactive" Review Processes. *US Regulatory Reporter*10 (May 1994) 11: 1-5.

Staff. The Woodcock Era Begins at CDER. *US Regulatory Reporter*10 (May 1994) 11:1.

Staff. Toy Ping Tara Plans Showcase Exhibit for Women's History Month. *News Along the Pike* (February 25, 1999): 4.

Staff. Pilot Drug Staff Now Can Approve Products. *Washington Drug Letter*22 (December 24, 1990) 52.

Staff. Pilot Drug Review Division: A Profile. *US Regulatory Reporter* (March 1992): 6-8.

Staff. *Pink Sheet Trade and Government Memos*(April 3, 1989): 1.

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

Stafford, Peter. *Psychedelics Encyclopedia*.Berkeley: Ronin Publishing, 1992.

Stevens J. *Storming Heaven, LSD and the American Dream*. New York: Atlantic Monthly Press, 1987.

Stewart J, Garfinkel R, Nunes E, Donovan S, Klein D. Atypical features and treatment response in the National Institute of Mental Health Treatment of Depression Collaborative Research Program. *J Clin Psychopharmacol* 18 (December 1998) 6:429-34.

Stewart O. *Peyote Religion: A History*. Norman, Oklahoma: University of Oklahoma Press, 1987.

Stolaroff M. *The Secret Chief: Conversations With a Pioneer of the Underground Psychedelic Therapy Movement*. Charlotte, North Carolina: Multidisciplinary Association for Psychedelic Studies, 1997.

Stolberg S. FDA Adds Hurdles in Approval of Abortion Pill. *New York Times* (June 8, 2000):A18.

Stolberg, S. Study Finds Faults in Tracing of Drug Reactions. *New York Times*(December 15, 1999): A20.

Stoll W. Lysergsaure-diathyl-amid, ein Phantastikum aus der Mutterkorngruppe. [LSD, a hallucinatory agent from the ergot group] *Schweiz. Arch. Neut.* 60 (1947).

Strassman R. Adverse reactions to psychedelic drugs: A review of the literature. *Journal of Nervous and Mental Disease* 172 (1984) 10:577-95.

Strassman R. Human hallucinogenic drug research in the United States: a present-day case history and review of the process. *Journal of Psychoactive Drugs*23 (1991) 1:29-38.

Strassman R. Subjective effects of DMT and the development of the Hallucinogen Rating Scale. *Bulletin of the Multidisciplinary Association for Psychedelic Studies* 3 (Spring 1992) 2:8-12. <http://www.maps.org/news-letters/v03n2/03208dmt.html>

Strassman R, Qualls C. Dose-response study of N,N-dimethyltryptamine in humans. I. Neuroendocrine, autonomic, and cardiovascular effects. *Archives of General Psychiatry* 51 (February 1994) 2:85-97.

Strassman R, Qualls C, Uhlenhuth E, Kellner R. Dose-response study of N,N-dimethyltryptamine in humans. II. Subjective effects and preliminary results of a new rating scale. *Archives of General Psychiatry* 51 (February 1994) 2:98-108

Strassman R. Human Hallucinogenic Drug Research: Regulatory, Clinical and Scientific Issues. in Lin G, Glennon R, (eds.) *Hallucinogens: An Update*. NIDA Research

Monograph 146, Washington, D.C., NIH Publication # 94-3872. 1994: 92-123.

Strassman R. Human psychopharmacology of N,N-dimethyltryptamine. *Behaviour and Brain Research* 73 (1996) 1-2:121-4.

Strassman R, Qualls C, Berg L. Differential tolerance to biological and subjective effects of four closely spaced doses of N,N-dimethyltryptamine in humans. *Biological Psychiatry* 39 (May 1,1996) 9:784-95.

Strassman R. Issues in Psychedelic Research Introductory Comments: Psychedelic Research Panel, 1996 ITA Conference. *Bulletin of the Multidisciplinary Association for Psychedelic Studies* 7 (Winter 1996-97) 1: 22-23. <http://www.maps.org/news-letters/v07n1/07122str.html>

Survey of Pharmacy Law, 1999-2000. Chapter XXV. Dispensing Authority. Park Ridge, IL: National Association of Boards of Pharmacy, 1999.

Szara S. The hallucinogenic drugs- curse or blessing? *American Journal of Psychiatry* 123 (1967): 1513-1518.

Szara S. Are Hallucinogens Psychoheuristic? *Hallucinogens: An Update* NIDA Monograph Series # 146. Washington, D.C., NIH Publication #94-3872, 1994: 33-51.

Tancer M, Schuster C. Serotonin and Dopamine System Interactions in the Reinforcing Properties of Psychostimulants: A Research Strategy. *Bulletin of the Multidisciplinary Association for Psychedelic Studies* 7 (1997) 3:5-11. <http://www.maps.org/news-letters/v07n3/07305tan.html>

Tang A. Letter to Dr. Marlene Haffner. Director, FDA Office of Orphan Product Development. October 10, 1997. <http://www.maps.org/mmj/odda/10109701.html>

Tang A. Letter to Dr. Marlene Haffner. Director, FDA Office of Orphan Product Development. March 18, 1998. <http://www.maps.org/mmj/odda/03189801.html>

Tashkin D, Simmons M, Sherrill D, Coulson A. Heavy habitual marijuana smoking does not cause an accelerated decline in FEV1 with age. *American Journal of Respiratory and Critical Care Medicine* 155 (January 1997) 1:141-8.

Taub S. Electroconvulsive therapy, malpractice, and informed consent. *Journal of*

*Psychiatry and Law*(Spring 1987) :7-54.

Temin P. The Origin of Compulsory Drug Prescriptions. *Journal of Law and Economics*. (April 1979): 91-105.

Temin P. *Taking Your Medicine: Drug Regulation in the United States*. Cambridge: Harvard University Press, 1980.

Temple R. Difficulties in evaluating positive control trials. *Proceedings of the American Statistical Association, Biopharmaceutical Section*(1983): 1-7.

Temple R. Special study designs: early escape, enrichment, studies in non-responders. *Communications in Statistics* 23 (1994): 499-531.

Temple R. Problems in interpreting active control equivalence trials. *Accountability in Research* 4 (1996): 267-75.

Temple R. The clinical pharmacologist in drug regulation: the US perspective. *British Journal of Clinical Pharmacology* 42 (July 1996)1:73-9.

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.

Thase M, Greenhouse J, Frank E, Reynolds C, Pilkonis P, Hurley K, Grochocinski V, Kupfer D. Treatment of major depression with psychotherapy or psychotherapy-pharmacotherapy combinations. *Archives of General Psychiatry*54 (Nov 1997) 11:1009-15.

Thompson R. Side Effects and placebo amplification. *British Journal of Psychiatry*140 (1982): 64-68.

Thompson J, Neave N, Moss M, Scholey A, Wesnes K, Girdler N. Cognitive properties of sedation agents: comparison of the effects of nitrous oxide and midazolam on memory and mood. *British Dentistry Journal* (November 27, 1999) 10:557-62.

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

*Business Wire* May 22, 1992.

Tooley, Pratt. Letter to the editor. *Behavioral Science* 9 (1964) 3: 254-56.

Tufts Center for the Study of Drug Development. Clinical Development times for new drugs drop 18%, reversing 12 -yr trend. *Impact Report-Tufts Center for the Study of Drug Development* (July 1999): 1-4.

Tufts Center for the Study of Drug Development. European and U.S. approval times for new drugs are virtually identical. *Impact Report—Tufts Center for the Study of Drug Development* 1 (November 1999): 1-4.

Tyler T. Prisoners Used for Frightening Tests, New Papers Show. *Toronto Star* December 18, 1999.

United Nations. Single Convention on Narcotic Drugs. *US Treaty Series Vol. 520, US Treaties and other International Agreements. Vol. 18 Part 2, 1967: 1407-1431.*  
[http://www.incb.org/e/ind\\_conv.htm](http://www.incb.org/e/ind_conv.htm)

United Nations. Convention on Psychotropic Substances. *US Treaty Series. Vol. 1019, US Treaties and other International Agreements. Vol 32 Part 1, 1979-80: 543-571.*  
[http://www.incb.org/e/ind\\_conv.htm](http://www.incb.org/e/ind_conv.htm)

United Nations. United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. [http://www.incb.org/e/ind\\_conv.htm](http://www.incb.org/e/ind_conv.htm)

Van Dusen W, Wilson W, Miners W, Hook H. Treatment of alcoholism with lysergide. *Quarterly Journal of Studies of Alcoholism* 28 (1967) 2:295-303.

Vollenweider F, Leenders K, Scharfetter C, Antonini A, Maguire P, Missimer J, Angst J. Metabolic hyperfrontality and psychopathology in the ketamine model of psychosis using positron emission tomography (PET) and [18F]fluorodeoxyglucose (FDG). *European Neuropsychopharmacology* 7 (February 1997) 1:9-24.

Vollenweider F, Leenders K, Oye I, Hell D, Angst J. Differential psychopathology and patterns of cerebral glucose utilisation produced by (S)- and (R)-ketamine in healthy volunteers using positron emission tomography (PET). *European Neuropsychopharmacology* 7 (February 1997) 1:25-38.

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



psychopathology in the psilocybin model of psychosis. *Neuropsychopharmacology* 16 (May 1997) 5:357-72.

Vollenweider F, Gamma A, Liechti M, Huber T. Psychological and cardiovascular effects and short-term sequelae of MDMA ("ecstasy") in MDMA-naive healthy volunteers. *Neuropsychopharmacology* 19 (October 1998) 4:241-51

Vollenweider F, Vollenweider-Scherpenhuyzen M, Babler A, Vogel H, Hell D. Psilocybin induces schizophrenia-like psychosis in humans via a serotonin-2 agonist action. *Neuroreport* 9 (December 1, 1998) 17:3897-902.

Vollenweider F, Remensberger S, Hell D, Geyer M. Opposite effects of 3,4-methylenedioxymethamphetamine (MDMA) on sensorimotor gating in rats versus healthy humans. *Psychopharmacology (Berlin)* 143 (April 1999) 4:365-72.

Vollenweider F, Vontobel P, Hell D, Leenders K. 5-HT modulation of dopamine release in basal ganglia in psilocybin-induced psychosis in man--a PET study with [<sup>11</sup>C]raclopride. *Neuropsychopharmacology* 20 (May 1999) 5:424-33.

Vollenweider F, Gamma A, Liechti M, Huber T. Is A Single Dose of MDMA Harmless? *Neuropsychopharmacology* 21 (October 1999) 4: 598-600.

Vollenweider F, Vontobel P, Oye I, Hell D, Leenders K. Effects of (S)-ketamine on striatal dopamine: a [<sup>11</sup>C]raclopride PET study of a model psychosis in humans. *Journal of Psychiatric Research* 34 (Jan-Feb 2000) 1:35-43.

Wardell W, Lasagna L. *Regulation and Drug Development*. Washington, D.C. American Enterprise Institute for Public Policy Research, 1975.

Wasson G, Wasson V. *Mushrooms, Russia and History*. New York: Pantheon Press, 1957.

Wasson G. Seeking the Magic Mushroom. *Life* 42 (May 13,1958): 19.

Wechsler J. Challenging FDA Authority. *Pharmaceutical Executive* 14 (1994) 8:18-22.

Weil A. Better Than a Damn. *The Harvard Crimson* (February 20, 1962): 2.

Weil A. Alpert Defends Drugs on 'Open End.' *The Harvard Crimson* (May 27, 1963): 1,6.

- Weil A. Investigation Unlikely in Dismissal of Alpert. *The Harvard Crimson* (May 29, 1963): 1.
- Weil A, Zinberg N, Nelson J. Clinical and Psychological Effects of Marijuana in Man. *Science* 162 (1968): 1234-1242.
- Weinrich M. Provision of Methadone Treatment in Primary Care Medical Practices- Review of the Scottish Experience and Implications for US Policy. *Journal of the American Medical Association* 283 (March 8, 2000) 10:1343-1348
- Weintraub M, Singh S, Byrne L, Maharaj K, Guttmacher L. Consequences of the 1989 New York State Triplicate Benzodiazepine Prescription Regulations, in (eds.) Cooper J, Czechowicz D, Molinari S. *Impact of Prescription Drug Diversion Control Systems on Medical Practice and Patient Care*. Washington, D.C.: NIDA Research Monograph Series #131. NIH Publication #93-3507, 1992: 279-293.
- Wells D. Casenote: Conant V. McCaffrey: Physicians, Marijuana, and the First Amendment. *70 University of Colorado Law Review* 975 (Summer, 1999).
- Whitaker R, Kong D. Testing Takes Human Toll. *Boston Globe* November 15, 1998.
- Whitcomb D. The Regulation of Electroconvulsive Therapy in California: The Impact of Recent Constitutional Interpretations. *Golden Gate Law Rev* 18 (Summer 1988) 2:469-494.
- Widmer S. *Listening Into the Heart of Things: The Awakening of Love On MDMA and LSD: the Undesired Psychotherapy*. Gerolfingen, Switzerland: Basic Editions, 1995.
- Windom R. Assistant Secretary for Health. Letter to Rick Doblin. March 18, 1987.
- Wolbach A, Miner E, Isbell H. Comparison of Psilocin with Psilocybin, Mescaline and LSD 25. *Psychopharmacologia* 3 (1962): 219-223.
- Wolfe S. Director Public Citizen's Health Research Group. Letter to Dr. Janet Woodcock, Director CDER. August 25, 1998.  
<http://www.citizen.org/hrg/PUBLICATIONS/1453.htm>
- Wolfson P. Meetings at the Edge with Adam: A man for all seasons? *Journal of Psychoactive Drugs* 18 (1986) 4:329-333.

Woodcock J. FDA Director of Center for Drug Evaluation and Research. Letter to Mr. Gene Haislip, DEA Deputy Assistant Administrator, Office of Diversion Control. August 3, 1994.

Woodcock J. An FDA Perspective on the Drug Development Process. *Food and Drug Law Journal* 52 (1997) 2:145-150.

Woods J. Conclusion. *Drug and Alcohol Dependence: An International Journal on Biomedical and Psychosocial Approaches. Special issue containing papers presented at the Committee on Problems of Drug Dependence Symposium on Stimulants and Hallucinogens, (June/September, 1984)*17 (June 1986) 2-3:297-298.

World Health Organization Expert Committee. *Ataractic [tranquilizers] and Hallucinogenic Drugs in Psychiatry: Report of A Study Group*. Geneva: World Health Organization Technical Report Series 1958 #152. Geneva: World Health Organization, 1958.

World Health Organization Expert Committee on Drug Dependence. *Twenty-second report. Technical Report Series #729*. Geneva: World Health Organization, 1985.

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.

Wren C. Doctors Criticize Move Against State Measures. *New York Times* December 31, 1996.

Wren C. In the Battle Against Heroin, Scientists Enlist Heroin. *New York Times* June 6, 1999: D1.

Wright C. Acting Director, FDA Pilot Drug Evaluation Staff. Memorandum to Dr. Frank Vocci, NIDA Director of Medications Development Division, March 10, 1995. Published in Alper K. (ed.) *First International Conference on Ibogaine: Syllabus, Nov. 5 & 6, 1999*. New York University School of Medicine: 428-431.

Yager J, Kallgren D. Roles of Regulatory Project Managers in the U.S. Food and Drug Administration's Center for Drug Evaluation and Research. *Drug Information Journal* 34 (2000) 1:289-293.

Yee J. NDA Days. *Presentation at the 14th annual meeting of the Regulatory Affairs Professional Society*. October 16, 1990.

Yensen R, Di Leo F, Rhead J, Richards W, Soskin R, Turek B, Kurland A. MDA-Assisted Psychotherapy with Neurotic Outpatients: A Pilot Study. *Journal of Nervous and Mental Disease* 163 (1976) 4:233-245.

Yensen R, Dryer D. Thirty Years of LSD Research: The Spring Grove Experiment and its Sequels. in (eds.) Schlichting M, Leuner, H. *Worlds of Consciousness. Vol 5 Abstracts and Selected Papers from the 1st International Congress of the European College for the Study of Consciousness (ECSC), Gottingen, Germany, September 24-27. 1992.* Berlin: Verlag fur Wissenschaft und Bildung, 1995: 141-176.

Young F. Commissioner of FDA. Remarks before Association of Food and Drug Officials, 92nd Annual Conference, Hartford, Ct. June 23, 1988.  
<http://www.fda.gov/bbs/topics/SPEECH/SPE00008.htm>.

Zaehner R.C. *Mysticism Sacred and Profane: an inquiry into some varieties of praeter-natural experience.* Oxford: Clarendon Press, 1957.

Zhang Z, Morgenstern H, Spitz M, Tashkin D, Yu G, Marshall J, Hsu T, Schantz S. Marijuana use and increased risk of squamous cell carcinoma of the head and neck. *Cancer Epidemiological Biomarkers and Prevention* 8 (December 1999) 12:1071-8.

Zinberg N. *Drug, set and setting.* New Haven: Yale University Press, 1984.

Zinberg N. in ed. Randall R. *Cancer Treatment and Marijuana Therapy.* Washington, DC: Galen Press, 1990: 16.

Zwanzier L. Executive Secretary, FDA Drug Abuse Advisory Committee. Letter to Dr. Charles Grob. June 26, 1992.

## REFERENCES—FEDERAL REGISTER FILINGS

Administration Response to Arizona Proposition 200 and California Proposition 215. Office of National Drug Control Policy. 62 FR 6164 (February 11, 1997).

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).

Ciba-Geigy Corp. and MD Pharmaceutical, Inc.; 1986 Aggregate Production Quota, 1986 Individual Manufacturing Quotas, and 1986 Disposal Allocations for Methylphenidate. 53 FR 50591 (December 16, 1988).

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).

Delegations of Authority and Organization; Center for Drug Evaluation and Research (CDER). Final Rule. 55 FR 51687 (December 17, 1990).

Dissemination of information on unapproved/new uses for marketed drugs, biologics, and devices. Final Rule. 63 FR 64556-88 (November 20, 1998).

Expanded Availability of Investigational New Drugs Through a Parallel Track Mechanism for People With AIDS and HIV-Related Disease. 55 FR 20856 (May 21, 1990).

FDA regulation of non-approved uses. 37 FR 16,503 (August 15, 1972).

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

Federal Policy for the Protection of Human Subjects. 53 FR 45,660 and 45,665-66 (November 10, 1988).

Federal Policy for the Protection of Human Subjects. 56 FR 28,003 (June 18, 1991).

Protection of Human Subjects. FDA. 56 FR 28025 (June 18, 1991).

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).

Joint Revision of Conditions for Use of Methadone for Treating Narcotic Addicts. 45 FR 62694 (September 19, 1980).

Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration; Notice of Proposed Rule Making. 37 FR 16503 (August 15, 1972).

Levo-ALPHA-Acetyl-Methadol (LAAM) in Maintenance; Revision of Conditions for Use in the Treatment of Narcotic Addiction. 58 FR 38704 (July 20, 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 41 FR 17962 (April 29, 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 42 FR 56897 (October 28, 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. Final Rule. 57 FR 58942 (December 11, 1992).

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. 49 FR 30210 (July 27, 1984).

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

Protection of Human Subjects. FDA. 56 FR 28025 (June 18, 1991).

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 1 of the Controlled Substances Act. 51 FR 36552-36560 (October 14, 1986).

Schedules of Controlled Substances: Scheduling of 3,4-Methylenedioxymethamphetamine (MDMA) into Schedule 1 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).

Withdrawal of Proposal to Change Protocol Requirements for Researchers and Prescription Requirements for Practitioners. DEA. 51 FR 17494 (May 13, 1986).



## REFERENCES—FEDERAL LAWS, STATE CODES AND LOCAL ORDINANCES

- Anti-Drug Abuse Act of 1986. 99 P.L. 570; 100 Stat. 3207. October 27, 1986.
- Anti-Drug Abuse Act of 1988. 100 P.L. 690; 102 Stat. 4181. November 18, 1988.
- 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.
- Community Mental Health Centers Act, Biomedical Research and Research Training Amendments of 1978, 95 P.L. 622; 92 Stat. 3420. November 9, 1978.
- Controlled Substances Act of 1970. 91 P.L. 513; 84 Stat. 1236. October 27, 1970.
- Controlled Substance Analogue Enforcement Act of 1986. 99 P.L. 570, Sec. 1201-1204 ; 100 Stat. 3207-13. October 27, 1986.
- Dangerous Drug Diversion Control Amendment of 1984. 98 P.L. 473; 98 Stat. 2070, October 12, 1984.
- District of Columbia Appropriations Act. Omnibus Consolidated Appropriations Bill of 1999. Barr Amendment §171. 105 P.L. 277, 112 Stat. 2681-150. October 21, 1998.
- District of Columbia Appropriations of 1999. PL 106-113, 113 Stat. 1501; Sec. 167 (b). November 29, 1999.
- Drug Abuse Control Amendments of 1965. 89 P.L. 74; 79 Stat. 226. July 15, 1965
- Durham-Humphrey Amendment of 1951. 82 P.L. 215; 82 Cong. Ch. 578; 65 Stat. 648. October 25, 1951.

Kefauver-Harris Amendments of 1962 to the 1938 Food, Drug and Cosmetic Act. 87 P.L. 781; 76 Stat. 780. October 10, 1962.

Federal Advisory Committee Act of 1972. 92 P.L. 463; 86 Stat. 770. October 6, 1972.

Federal Food, Drug, and Cosmetic Act of 1938. 75 P.L. 717; 75 Cong. Ch. 675; 52 Stat. 1040. June 25, 1938.

Food and Drug Administration Modernization Act of 1997. 105 P.L. 115; 111 Stat. 2296. November 21, 1997.

Freedom of Information Act, Amendment of 1974. 93 P.L. 502; 88 Stat. 1561. November 21, 1974.

Harrison Narcotic Act of 1914. 63 P.L. 223; 63 Cong. Ch. 9; 38 Stat. 785. January 17, 1914.

Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 1999. 106 P.L.172; 114 Stat. 7. February 18, 2000.

Importations of Drugs and Medicines Act of 1848. 30 Cong. Ch. 70; 9 Stat. 237. June 26, 1848.

International Narcotics Control Act of 1992 102 P.L. 583; 106 Stat. 4914. November 2, 1992

International Narcotics Control Corrections Act of 1994. 103 P.L. 447; 108 Stat. 4691  
NATO Participation Act of 1994 (Title II at 108 Stat 4695). November 2, 1994

LSD and other Depressant and Stimulant Drugs, Possession Restriction. 90 P.L. 639; 82 Stat 1361. October 24, 1968.

Marijuana Tax Act of 1937. 75 P.L. 238. 75 Cong. Ch. 553; 50 Stat. 551. August 2, 1937.

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

Miller Amendment of 1948 (to Federal Food, Drug, and Cosmetic Act of 1938), 80 P.L. 749; 80 Cong. Ch. 613; 62 Stat. 582. June 24, 1948.

Narcotic Addict Treatment Act of 1974. 93 P.L. 281; 88 Stat. 124. May 14, 1974.

National Research Act of 1974. 93 P.L. 348; 88 Stat. 342. July 12, 1974.

National Security Act of 1947. 80 P.L. 253; 80 Cong. Ch. 343; 61 Stat. 495. July 26, 1947.

Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999. 105 P.L. 277; 1998 Enacted H.R. 4328; 105 Enacted H.R. 4328. October 19, 1998.

Opium, Restrictions on Importing Narcotic Drugs Import and Export Acts of 1909. 60 P.L. 221; 60 Cong. Ch. 100; 35 Stat. 614. February 9, 1909

Orphan Drug Act of 1983. 97 P.L. 414; 96 Stat 2049. January 4, 1983.

Prescription Drug User Fee Act of 1992. 102 P.L. 571; 106 Stat. 4491. October 29, 1992.

Psychotropic Substances Act of 1978. 95 P.L. 633, 92 Stat. 3768. November 10, 1978.

Pure Food and Drug Act of 1906. 59 P.L. 384; 59 Cong. Ch. 3915; 34 Stat. 768. June 30, 1906.

Sherley Amendment of 1912. 62 P.L. 301; 62 Cong. Ch. 352; 37 Stat. 416. August 23, 1912.

South Carolina Code §44-53-360. Narcotics and Controlled Substances. Prescriptions.

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

American Pharmaceutical Assn. v. Weinberger, 377 F. Supp. 824 (D.D.C. 1974), affd. sub. nom., American Pharmaceutical Assn. v. Mathews, 530 F. 2d 1054 (D.C. Cir. 1976).

Chaney v. Heckler, 718 F.2d 1174 (D.C. Cir. 1983).

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

FDA v. Brown & Williamson Tobacco Corp., 120 S. Ct. 1291 (2000).

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>).

Kuromiya v. United States, 78 F. Supp. 2d 367 (E.D. Pa. 1999).

Leary v. United States, 395 U.S. 6 (1969).

Linder v. United States, 268 U.S. 5 (1925).

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

National Org. for the Reform of Marijuana Laws v. Ingersoll, 497 F.2d 654 ( D.C. Cir. 1974).

Northern California Psychiatric Scy. v. Berkeley, 178 Cal. App. 3d 90, 223 Cal. Rptr. 609 (1986).

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).

Turner v. D.C. Bd. of Elections & Ethics, 77 F. Supp. 2d 25 (D.D.C. 1999).

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. Johnson, 221 U.S. 488 (1911).

United States v. Moore, 423 U.S. 122 (1975).

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

United States v. Randall, 104 Daily Wash. L. Rep. 2249 (Super. Ct. D.C. Nov. 24, 1976).

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

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

Washington Legal Foundation v. Friedman, Civ. No. 94-1306 slip op. (D.D.C. July 30, 1998).

Washington Legal Foundation v. Henney & Shalala, 56 F. Supp. 2d 81 (D.D.C. 1999).

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