

TESTIMONY OF Dr. Denis J. Petro
BEFORE THE PENNSYLVANIA HOUSE OF REPRESENTATIVES
COMMITTEE ON HEALTH AND HUMAN SERVICES
ON HB 1393 COMPASSIONATE USE ACT OF 2009

Good morning, Chairmen Oliver and Baker, and Members of the Committee. My name is Dr. Denis Petro. I'm writing in support of the H.B. 1393, the Compassionate Use Medical Marijuana Act.

I am a board-certified neurologist with over 25 years experience in neurology, clinical pharmacology and marijuana research, recognized world-wide as the first clinical researcher to conduct a double-blind, placebo controlled clinical trial of THC (a substance derived from marijuana) demonstrating the efficacy of marijuana in treating painful muscle spasms in patients with multiple sclerosis (*Journal of Clinical Pharmacology* 1981, 21:413-16). In the past 10 years I have written 4 book chapters (Spasticity and Chronic Pain, Seizure Disorders, and Cannabis in Multiple Sclerosis: Women's Health Concerns) on the subject of cannabis therapeutics. In 1987, I testified in the matter of Marijuana Rescheduling Petition (Docket No.86-22) at the United States Court of Appeals for the Federal Circuit (717 Madison Place, NW Washington, DC) before Judge Francis L. Young (Administrative Law Judge, U.S. Drug Enforcement Administration). In Justice Young's decision dated September 6, 1988, he repeated elements of my affidavit and direct testimony (Pages 52-53) in his decision regarding marijuana in treatment of symptoms associated with MS. As a former FDA officer and with considerable experience in neurology and drug development, I have been called on to participate as an expert in a number of cases involving drug development, drug toxicity and clinical syndromes in neurology. My qualifications have been accepted as an expert both in state and federal cases and the courts in the USA, Canada and the United Kingdom have recognized my expertise.

Marijuana is recognized by the medical community as safe and effective in the treatment of the pain and muscle spasms associated with multiple sclerosis, spinal cord injury, and CNS injury. In patients who have not obtained symptom relief with conventional therapy, marijuana offers a rational alternative at least as safe as conventional therapy without the potential for fatal overdose and addiction liability seen with opioids and dangerous drug combinations.

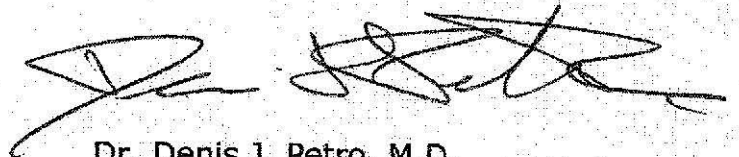
I base my opinion on the body of clinical research published in peer reviewed medical journals beginning with my original double-blind clinical trial published in 1981, which demonstrated beneficial effects of marijuana on spasticity associated with multiple sclerosis. This research was confirmed by eight subsequent independent clinical trials demonstrating the therapeutic efficacy of marijuana in patients with muscle spasms and pain. Finally, in the year 2000, a landmark study conducted in the United Kingdom entitled "Cannabinoids control spasticity and tremor in a multiple sclerosis model" (*Nature*, 2000 Mar 2;404(6773):84-7) referenced my original research and concluded that their study "provides a rationale for patients' indications of the therapeutic potential of cannabis in the control of the symptoms of multiple sclerosis". Based on this and other evidence, the drug regulatory authority of Canada (Health Canada) approved the cannabis extract Sativex® for the indication "adjunctive treatment for the symptomatic relief of neuropathic pain in multiple sclerosis in adults" in the year 2005. The neuropathic

pain seen in MS is similar to the pain associated with spinal injury. The scientific evidence demonstrates the effectiveness and safety of cannabis in treatment of chronic pain syndromes. When compared with potent opioid analgesic agents such as Vicodin, marijuana is a safe and effective therapeutic modality in treatment of patients with severe and disabling chronic pain such as in MS and in relieving cancer pain. Additional research done by the US National Institutes of Health in Bethesda demonstrated the antioxidant and neuroprotective properties of cannabinoids leading to the award of a Patent (#6,630,507) on cannabis as useful in the prevention and treatment of age-related inflammatory and autoimmune diseases and nervous system disorders such as Parkinson's disease, Alzheimer's disease and HIV dementia.

I support the passage of the HB 1393, the Compassionate Use Marijuana Act, with recognition of countless seriously ill patients with MS, spinal cord injury, AIDS, terminal cancer and other conditions made more tolerable by using medicinal marijuana. One of the most memorable patients I've had the opportunity to meet was Ms. Cheryl Miller, a resident of New Jersey, who died in 2003 after a long battle with multiple sclerosis. Her memory can be honored by passage of this Act to relieve the suffering of seriously ill patients.

Sincerely,

Dated: 18 November, 2009

A handwritten signature in black ink, appearing to read "Dr. Denis J. Petro". The signature is stylized and somewhat cursive, with a large initial "D" and "P".

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Curriculum vitae

Denis James Petro, M.D.
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Education: 1965 Bachelor of Science in Electrical Engineering
Lehigh University
Bethlehem, Pa.
1969 Master of Science in Biophysics and
Biomedical Engineering
Baylor University College of Medicine
Houston, Texas
1971 Doctorate in Medicine
Pennsylvania State University
College of Medicine
Hershey, Pa.

Medical Residency Training:

1971-2 Internal Medicine
Pennsylvania State University
Hershey Medical Center
Hershey, Pa.
1974-7 Neurology
Pennsylvania State University
Hershey Medical Center
Hershey, Pa.

Academic Appointments:

1966-8 Instructor in Biophysics and Physiology
Baylor University College of Medicine
Houston, Texas
1972-4 Adj. Assistant Professor
University of Louisville College of Medicine
Louisville, Kentucky

1976-9 Teaching Assistant in Neurology
Pennsylvania State University College of
Medicine Hershey, Pa.

1985-6 Chief Neurologic Research
Department of Neurology
Nassau County Medical Center
East Meadow, New York

Licensure:

1966 Reg. Professional Engineer (Connecticut, Texas)
1972 National Board of Medical Examiners
1972 Kentucky
1974 Pennsylvania
1979 New York
1980 American Board of Psychiatry and Neurology
2002 Maryland

National Service:

1972-4 Public Health Service
National Health Service Corps
Louisville, Kentucky
1980 Public Health Service
Refugee Resettlement Health Care
Fort Indiantown Gap, Pennsylvania

Professional Experience:

1965-6 Design Engineer, Project Apollo
Life Support Systems Division
Hamilton Standard
United Technologies, Inc.
Windsor Locks, Connecticut

Design of Oxygen supply system and decontamination system for
the Lunar Excursion Module (LEM) and Life Support System.
Design of cardiac assist device.

1966-9 National Institutes of Health
Graduate Fellowship
Physiology Department
Baylor University
College of Medicine
Houston, Texas

1969 Design Engineer, Apollo Applications
Biosatellite Program
University of California

1970 Berkeley, California
 Anesthesiology and Cardiology Fellowship
 Stanford University
 Palo Alto, California

1970-2 Consulting Engineer
 Pennsylvania State University
 College of Medicine
 Hershey, Pennsylvania

1972-4 Clinical Medicine Practice
 National Health Service Corps
 Portland Neighborhood Care Center
 Louisville, Kentucky

1972-4 Medical Director
 Planned Parenthood of Louisville
 Louisville, Kentucky

1974-7 Resident in Neurology
 Pennsylvania State University
 College of Medicine
 Hershey, Pennsylvania

1977-9 Medical Officer- Neurology
 Neuropharmacological Drug Products
 Bureau of Drugs
 Food and Drug Administration
 Rockville, Maryland

1979-81 Consultant in Neurology and Orphan Drugs
 Bureau of Drugs
 Food and Drug Administration
 Rockville, Maryland
 Chief, Health Care Systems Division
 New York State Department of Health
 New York, New York

1981-4 Associate Director/Director
 Clinical Investigation-Neuroscience
 Wyeth Laboratories
 Radnor, Pennsylvania

1984-5 Senior Medical Director
 Pfizer Pharmaceuticals
 New York, New York

1985-6 Chief, Neurologic Research
 Department of Neurology
 Nassau County Medical Center
 East Meadow, New York

1986-9 Vice President, Clinical Research
Fidia Pharmaceutical Corporation
Washington, D.C.
1989- Consulting Neurologist
Cynosure Neuroscience
2002-3 Chief of Neurology
Malcolm Grow Medical Center
Andrews Air Force Base

Professional Organizations:

American Academy of Neurology
American Heart Association- Stroke Council
Eta Kappa Nu
Tau Beta Pi

Publications:

1. Petro,D.J.: Personal telephone electrocardiogram transmitter. *Lancet* 2:1492,1973.
2. Severs,W.B., Changaris,D.G., Kapsha,J.M., Petro,D.J. and Reid,I.A.: Presence and significance of angiotensin in cerebrospinal fluid. In *Central Actions of Angiotensin and Related Hormones*. Pergamon Press, 1976.
3. Petro,D.J., Vannucci,R.C. and Kulin,H.E.: Diazoxide-diphenylhydantoin interaction. *J. Pediatrics* 84:331-2,1976.
4. Petro,D.J., Zeigler,S.B. and Ellenberger,C.: The visual evoked response in Huntington disease. *Neurology* 28:95-7, 1978.
5. Kalenak,A., Petro,D.J. and Brennan,R.W.: Migraine secondary to head trauma in wrestling- a case report. *Amer.J. Sports Medicine* 4:23-5, 1978.
6. Petro,D.J.: Use of marijuana in patients with muscle spasms and spasticity. *Psychosomatics* 21:81-2,1980.
7. Petro,D.J. and Ellenberger,C.: Delta-9 THC in treatment of spasticity. A double-blind placebo-controlled study. *J. Clin. Pharm.* 21:413-6,1981.

8. Petro,D.J.: Dezocine in "Opiate Analgesia", Clinics in Anesthesiology, 1:1 W.B.Saunders,Ltd. 1983.
9. Petro,D.J.: Cannabinoids and neurologic disease. Social Drug Use in Society. Council on Marijuana and Health, Washington, D.C. 1985.
10. Finucane,B.T., Floyd, J.B. and Petro, D.J.: Postoperative pain relief: a double-blind comparison of dezocine, butorphanol and placebo. South Med J. 79(5):548-52, 1986.
11. Petro,D.J. and Dorsey,F.: Clinical trial design considerations in neuroscience research with trophic factors. Clinical Trials, May, 1988.
12. Petro,D.J.: Research with cannabinoids in neurologic disease. Marijuana, Medicine and the Law. R.C.Randall,Ed. Galen Press, 1988.
13. Poonian,D. and Petro,D.J.: The role of a coordinating center and extramural monitoring committee in the conduct of a multicenter stroke trial. Clinical Trials,May, 1988.
14. Petro,D.J.: Medicinal Characteristics of Cannabis- Pharmacology and Toxicology. Cannabis in Medical Practice. McFarland and Co. 1997.
15. Petro,D.J.: Spasticity and Chronic Pain. Cannabis in Medical Practice. McFarland and Co. 1997.
16. Petro,D.J.: Seizure Disorders. Cannabis in Medical Practice. McFarland and Co. 1997.
17. Petro,D.J.: Treating aphasia and brain injury with bromocriptine. Arch Phys Med Rehabil. 82(11):1637, 2001.
18. Petro,D.J.: Cannabinoids in pain management. Spasticity is not the same as pain. BMJ. 323(7323):1250, 2001.
19. Petro,D.J.: Questioning the cardioprotective effect of bromocriptine treatment. Hypertension. 39(2):E16-7, 2002.

20. Petro,D.J.: Treatment of systemic lupus erythematosus with bromocriptine. *Lupus*. 11(4):266-7, 2002.
21. Petro,D.J.: Cerebral vasoconstriction and stroke after use of serotonergic drugs. *Neurology*. 59:651-2, 2002.
22. Petro,D.J.: Cannabis in multiple sclerosis: Women's health concerns. *J. Cannabis Therapeutics*. 2(3/4):161-75, 2002.

In addition to the publications listed above, many regulatory documents have been prepared including IND and NDA filings. Other documents are accessible thru the Freedom of Information Act.

Presentations:

- The Thermal Dolorimeter. AAMI Annual Mtg. Washington, D.C. 1973.
- An instrument to quantitate the strength of the deep tendon reflex AAMI Annual Mtg. New Orleans, La. 1974.
- The Audiocardiogram: an audio transduction of the EKG. AAMI Annual Mtg. New Orleans, La. 1974.
- Downbeat nystagmus and ocular bobbing. Neuro-Ophthalmologic Symposium. Scheie Institute Philadelphia, Pa. 1976.
- An analysis of the visual evoked response as a bioelectric event. AAMI Annual Mtg, Atlanta, Ga. 1976.
- Diphenylhydantoin and diazoxide interactions. Amer. College of Clin. Pharmacology. Philadelphia, Pa. 1976.
- Conference Co-Ordinator AAMI Mtg. San Francisco, CA 1977
- The use of marijuana in patients with muscle spasms and spasticity. Amer. Academy of Psychosomatic Medicine Atlanta, Ga. 1978.
- A double-blind placebo-controlled trial of Delta-9 THC in spasticity. AAAS Annual Mtg. Houston, Texas 1979.
- Ethical issues in drug research. Society for Health and Human Values. Washington, D.C. 1979.
- Delta-9 THC in the treatment of spasticity. American Academy of Neurology Annual Mtg. Toronto, Canada 1980.
- Delta-9 THC in spasticity associated with multiple sclerosis. Therapeutic Progress in Cannabinoid Research. Pfizer Biomed. Research Symposium. Groton, Connecticut 1980.

Therapeutic potential of cannabinoids in neurology. Council on Marijuana and Health. Boston, Ma. 1984.

Clinical pharmacology of dezocine- a new analgesic. Symposium on Analgesics. Miami Beach, Florida 1984.

Gangliosides in x-linked adrenoleucodystrophy and adrenomyeloneuropathy Fidia Research Symposium. Venice, Italy 1986.

Gangliosides in treatment of retinitis pigmentosa. Fidia Research Symposium. Abeno Terme, Italy 1987.

Adrenal transplantation in Parkinson Disease. Fidia Research Symposium at CINP. Munich, Germany 1987.

Pharmacologic intervention in stroke- The role of trophic factors. Fidia Research Symposium. Washington, D.C. 1987

Research design to evaluate Nerve Growth Factor (NGF) via CNS infusion. Fidia Research Symposium. Paris, France 1988.

The safety of mixed gangliosides Fidia Research Symposium. AbenoTerme, Italy 1988.

Clinical trial design in neuroscience research with trophic factors Society for Clinical Trials. San Diego, Ca. 1988.

Study design in stroke. Society for Clinical Trials. Orlando, Florida 1991.

Treatment options in spasticity

Presentations in Virginia, Pennsylvania, Florida, Texas, Arizona, Oregon and California. 1993 to 2006

FDA Major Regulatory submissions:

Analgesic-Opioid Orphan Drugs (3)

Analgesic-NSAID

Anticonvulsant

Antidepressant

Anxiolytic

FDA Device submissions:

CNS Infusion

Ophthalmologic Adjunct in Surgery

Spinal Fixation

Neurologic indications studied in clinical trials:

Alzheimer's Disease
Age-associated Memory Impairment
Amyotrophic Lateral Sclerosis
Autonomic Neuropathy of Chagas Disease
Depression
Diabetic Neuropathy
Huntington Disease
Migraine Headache
Multiple Sclerosis
Neuroprotection in coronary artery surgery
Neuroprotection in cancer chemotherapy
Peroxisomal diseases (AML, ALD)
Parkinson Disease
Retinitis Pigmentosa
Seizure Disorders
Spinal cord injury
Spinal fixation
Status Epilepticus
Stroke
Spasticity