ORIGINAL

IN THE UNITED STATES COURT OF FEDERAL CLAIMS OFFICE OF SPECIAL MASTERS

F-11 [20] AUS 0 8 2007 H-200 8 2007

N RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER, OR A SIMILAR NEURODEVELOPMENTAL DISORDER,

Various Petitioners,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

PSC'S UNOPPOSED MOTION FOR LEAVE TO DESIGNATE ADDITIONAL EXPERT WITNESS DR. JAMES WOODS, PH.D.

AUTISM MASTER FILE

Special Master George Hastings

MOTION

The Petitioners' Steering Committee seeks leave of the Special Masters to designate an additional expert witness--Dr. James Woods, Ph.D.--in the Omnibus Autism Proceeding. The PSC anticipates that Dr. Woods will submit a report relevant to the theory that thimerosal itself, notwithstanding any exposure to the MMR vaccine, is a substantial contributing cause of neurodevelopmental injuries, including autism. Dr. Woods' report would be filed on August 31, 2007 along with the other general causation expert reports in the "thimerosal only" test cases. A copy of Dr. Woods' *curriculum vitae* and bibliography are attached as an exhibit to this motion.

The PSC would have designated Dr. Woods earlier, but the PSC only recently became aware of Dr. Woods' work in the course of the PSC's review of the medical literature relied upon by others of our experts. Having identified Dr. Woods' body of work as relevant to issues of causation in these omnibus cases, the PSC contacted Dr. Woods and discussed the substance of his research with him. Following those conversations, Dr. Woods only agreed to serve as an expert witness on the PSC's behalf within the past 3 weeks. Thus, the PSC seeks leave to designate Dr. Woods and file an expert report that he will prepare. The PSC notified

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respondent's counsel of the intent to add this witness on July 24, 2007. Respondent does not object to the additional designation and report.

The PSC represents that moving to designate Dr. Woods at this time is not for delay or any other improper purpose, but for the reasons described above. The PSC further represents that it will have no objection if respondent seeks additional time, if necessary, in order to respond to this designation.

ADDITIONAL INFORMATION RE EXPERT WITNESSES

The PSC also takes this opportunity to inform the Special Masters that the following witnesses designated in February 2006 as potential experts in the omnibus proceeding will *not* appear as witnesses and will *not* submit expert reports for use in the "thimerosal only" test cases:

Dr. James Adams, Ph.D.

Dr. Jeffrey Bradstreet, MD

Dr. Eric Gershwin, MD

Dr. Phillippe Grandjean, Ph.D.

Dr. Robert Hirsch, Ph.D.

Dr. Arthur Krigsman, MD

Dr. Andrew Wakefield, MD

Dr. Harland Austin and Cathy Lally have already submitted a report in the omnibus proceeding regarding their reanalysis of the Verstraeten, et al. *Pediatrics* journal article pursuant to the Special Master's Order, and therefore will not file any additional report regarding general causation. The PSC reserves the right to submit rebuttal testimony if needed from either Dr. Austin or Ms. Lally.

The PSC informed respondent on July 24, 2007 that the witnesses listed above would not file reports. The PSC trusts that this information will assist everyone in focusing their review of the scientific literature and prioritizing their hearing preparation resources.

DATED this 7th day of August, 2007.

WILLIAMS LOVE O'LEARY & POWERS P.C.

By:

Michael L. Williams Thomas B. Powers

Counsel for Petitioners' Steering Committee 9755 S.W. Barnes Road, Suite 450 Portland, Oregon 97204 Tel: (503) 295-2924 Fax: (503) 295-3720

CURRICULUM VITAE

JAMES S. WOODS

Professor, Department of Environmental and Occupational Health Sciences School of Public Health and Community Medicine Box 354695 University of Washington, Seattle, Washington 98105 (206) 685-3443

EDUCATION

1962	Princeton University, Princeton, New Jersey, AB, (Chemistry)
1968	University of Washington, Seattle, MS, (Pharmacology)
1970	University of Washington, Seattle, PhD, (Pharmacology)
1978	University of North Carolina, Chapel Hill, MPH, (Epidemiology)

PROFESSIONAL POSITIONS

1987-present	Professor , Department of Environmental and Occupational Health Sciences, School of Public Health and Community Medicine, University of Washington
1978-2006	Senior Health Research Leader, Environmental and Occupational Health Research Program, Battelle Centers for Public Health Research and Evaluation, Seattle, Washington
1982-1987	Research Associate Professor, Department of Environmental Health, School of Public Health and Community Medicine, University of Washington
1979-1982	Affiliate Associate Professor, Department of Environmental Health, School of Public Health and Community Medicine, University of Washington



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1974-1978	Curriculum Vitae
1974-1970	Head, Biochemical Toxicology Section, Laboratory of Environmental Toxicology, National Institute of Environmental Health Sciences,
	Total of Stational institute of Environmental Health Sciences,
	National Institutes of Health, Research Triangle Park, North Carolina
1972-1974	Staff Fellow/Senior Staff Fellow, Environmental Toxicology Branch, National Institute of Environmental Health Sciences, National Institutes of Health, Research Triangle Park, North Carolina
1970-1972	Research Associate, Department of Pharmacology, Yale University School of Medicine, New Haven, Connecticut
1966-1970	Public Health Service Predoctoral Trainee , Department of Pharmacology, School of Medicine, University of Washington

James S. Woods

MILITARY SERVICE

1962-1966 Commissioned Officer, US Navy

FELLOWSHIPS, AWARDS, HONORS

Institutional Recipient, Colgate-Palmolive Visiting Professorship, 1998
Professional Achievement Award, Battelle Seattle Research Center, 1991
American Cancer Society Research Fellowship, Yale University, 1970-1972
American Men and Women of Science, 1978-present
Men of Achievement, 1985-present
USPHS Toxicology Training Grant, University of Washington, 1966-1970
USNROTC Scholarship, Princeton University, 1958-1962
Who's Who in America, 1996-present

PROFESSIONAL ORGANIZATIONS

American Association for the Advancement of Science

American Association for Cancer Research

American College of Epidemiology

American Society for Pharmacology and Experimental Therapeutics (Emeritis)

Pacific Northwest Association of Toxicologists (Founding President)

Sigma Xi

Society for Epidemiologic Research

Society for Experimental Biology and Medicine

Society for Free Radical Biology and Medicine (formerly Oxygen Society)

Society of Toxicology

Western Pharmacology Society

PROFESSIONAL CERTIFICATION

Diplomate, American Board of Toxicology, 1986-Present

PROFESSIONAL ACTIVITIES

Research Interests

- 1. Molecular toxicology of metals; metal effects on porphyrin metabolism and heme biosynthesis; cellular adaptive responses to metal-induced oxidative stress.
- 2. Ecogenetics of mercury toxicity; genetic susceptibility to mercury neurotoxicity; role of mercury autism and genetic polymorphisms in autism and other developmental disorders
- 3. Occupational and environmental epidemiology of metal exposure; metals as risk factors in chronic renal and neurologic diseases; porphyrins as biomarkers of metal exposure in human subjects.

Current Research

- 1. Molecular mechanisms of mercury toxicity; signaling transduction pathways involved in mercury-induced gene expression and cell injury.
- 2. Neurobehavioral toxicity of mercury in children; genetic polymorphisms that alter the risk of mercury on neurological functions; role of mercury and other metals in the etiology of autism and autistic spectrum disorders in children.
- 3. Urinary porphyrin profiles as biomarkers of mercury exposure and toxicity in adults and children.

Community, National and International Activities

- **Invited Speaker**, DAN! (Defeat Autism Now) Conference, Garden grove, CA, October 12-14, 2007.
- Invited Speaker, Regional Symposium on the Health Effects of Metals in South Asia, Shimla, India, May 31-June 3, 2005.
- Invited Speaker, Fifth Princess Chulabhorn International Conference: Evolving Genetics and its Global Impact, Bangkok, Thailand, August 16-20, 2004.
- Invited Reviewer, Oakridge Institute for Science and Education, Review of alternative approaches for deriving a reference dose for barium compounds, June, 2004.

- Invited Reviewer, U.S. Civilian Research and Development Foundation, Review of proposal for evaluation of health risks from exposure to heavy metals in an East Kazakhstan population, April, 2004.
- Invited Speaker and Session Chair, International Conference on Biomarkers for Toxicology and Molecular Epidemiology, Atlanta, GA, March 15-17, 2004.
- Adjunct Professor, Institute of Environmental and Human Health, Texas Tech University, 1998-present.
- Reviewer, NIEHS Special Emphasis Group, P30 ES01908 Duke University Marine and Freshwater Biomedical Center, June 2000.
- Reviewer, NRC Committee Report on The Toxicological Effects of Mercury, May, 2000.
- Member, Metals Bioavailability Task Force, National Environmental Policy Institute, 1998-1999.
- Ad Hoc Reviewer, Alcohol and Toxicology Study Section I, Division of Research Grants, National Institutes of Health, September, 1997
- Member, Scientific Committee, Session Chair and Invited Speaker, International Conference on Human Health Effects of Mercury Exposure, Torshavn, Faroe Islands, June, 1997.
- Councilor, American Board of Toxicology, 1994-1995, Secretary, 1995-96. Chairman of Examination Committee, 1995-96. Vice President, 1996-97. President, 1997-98.
- Councilor, Metals Specialty Section, Society of Toxicology, 1994-1996.
- Member, Scientific Program Committee and Invited Keynote Speaker, 5th COMTOX Symposium on The Clinical Chemistry and Toxicology of Metals, Vancouver, BC, July, 1995.
- Adjunct Professor, Department of Environmental Toxicology, Clemson University, 1993-1998.
- Secretary and Resident Agent, International Congress of Toxicology-VII, 1992-1995. Member, NIEHS Special Review Committee for RPF92-03, Molecular Interventions for Environmentally-induced Disease Prevention. 1993.
- Member, Editorial Boards, <u>Toxicology and Applied Pharmacology</u>, 1984-1989; <u>Journal of Toxicology and Environmental Health</u>, 1990-1999; <u>Fundamental and Applied Toxicology</u>, 1993-1998; <u>Toxicological Sciences</u>, 1998-2000.
- Trustee, Seattle Biomedical Research Institute, 1989-present; Member, Executive Committee, 1992-1995. Chairman, Planning Committee, 1992-1995.
- Councilor, Society of Toxicology, 1990-1992.
- Member, Veterans Administration National Advisory Committee on Health-Related Effects of Herbicides, 1987-1990.
- Member, Task Force on Environmental Cancer and Heart and Lung Disease, Workshop on the Effects of Pesticides on Human Health, Working Group on Carcinogenicity, 1988.
- Session Chairman, 1986 Gordon Conference, Chemistry and Biology of Pyrroles Founding President, Pacific Northwest Chapter, Society of Toxicology, 1985; Councilor, 1986-1987
- Founding President, Pacific Northwest Association of Toxicologists, 1984 Chairman, Committee on Public Communications, Society of Toxicology, 1984-1987

- **Chairman**, Advisory Committee, NOAA-NCI Interagency Study to investigate the etiology of tumors in bottom-dwelling marine fish, 1984-1987
- Member, Toxic Substances Task Group, Eagle Harbor ad hoc Advisory Committee, Division of Health, Washington State, Department of Social and Health Services, 1984-1986
- Member, Seattle City Light, Lake Union Steam Plant PCB Citizens Advisory Committee, 1984-1986
- Reviewer, Special Study Section, Division of Research Grants, NIH, 1983
- Member, Steering Committee, Puget Sound Council of Governments, Puget Sound Water Quality Conference, 1983-1984
- Member, Communications Task Group, Society of Toxicology, 1983-1984 Liaison, Society of Toxicology and Society for Epidemiologic Research, 1982-present
- Chairman, Science Council; Member, Board of Directors, Pacific Science Center, 1981-1988
- Chairman, Nominating Committee, Metals Specialty Section, Society of 1981-1982

 Member, Ad hoc Advisory Committee to Review Effects of Chemical Contaminants in Puget Sound, Washington State Department of Fisheries, 1981-1984
- Member, Executive Committee, American Industrial Hygiene Association Biological Monitoring Program, 1979-1985
- Member, Panel on evaluation of hazards associated with maritime personnel exposed to cargo vapors, Board on Toxicology and Environmental Health Hazards, Assembly of Life Sciences, National Research Council, National Academy of Sciences, 1978-1981
- Invited Participant, International Conference on Hepatotoxicity Due to Drugs and Chemicals, Fogarty International Center for Advanced Study in the Health Sciences, Bethesda, Maryland, 1977
- Member, Program Committee, Society of Toxicology, 1977-1980
- Member, Advisory Panel, Resource Conservation and Recovery Act of 1976, Hazardous Waste Management Division, Office of Solid Waste, EPA, 1976-1977
- Member, Toxicology Information Subcommittee, DHEW Committee to Coordinate Toxicology and Related Programs, National Library of Medicine, 1975-1977
- **Invited Participant**, First International Conference on Porphyrins in Human Disease, Freiburg, Germany, 1975
- Organizer and Chairman, EPA/NIEHS Joint Conference on Human Health Effects of New Approaches to Insect Pest Control, Research Triangle Park, NC, 1975
- Project Officer, NIEHS Contract, Evaluation of chronic toxicity of vinyl chloride and vinylidene chloride, 1974-1978.

BIBLIOGRAPHY JAMES S. WOODS

Research Papers in Refereed Journals

- 1. **Woods JS,** Lee IP, Dixon RL. Asparagine incorporation into the DNA of hepatic and 6C3HED murine lymphosarcoma cells. Cancer Res 1970; 30:1210-1211.
- 2. **Woods JS,** Dixon RL. Neonatal differences in the induction of hepatic delta-aminolevulinic acid synthetase. Biochem Pharmacol 1970; 19:1951-1954
- 3. **Woods JS,** Dixon RL. Perinatal differences in delta-aminolevulinic acid synthetase activity. Life Sci 1970; 9:711-719.
- 4. **Woods JS,** Handschumacher RE. Hepatic homeostasis of plasma L-asparagine. Amer J Physiol 1971; 221(6):1785-1790.
- 5. **Woods JS,** Dixon RL. Studies of the perinatal differences in the activity of hepatic delta-aminolevulinic acid synthetase. Biochem Pharmacol 1972; 21:1735-1944.
- 6. Hovarth C, Sardi A, **Woods JS.** L-asparaginase tubes: kinetic behavior and application in physiological studies. J Appl Physiol 1973; 34:181-187.
- 7. **Woods JS.** Handschumacher RE. Hepatic regulation of plasma L-asparagine. Amer J Pysiol 1973; 224:740-745.
- 8. **Woods JS.** Studies of the effects of 2,3,7,8-tetrachlorodibenzo-p-dioxin on mammalian hepatic delta-aminolevulinic acid synthetase. Environ Health Perspect 1973; 5:221-225.
- 9. **Woods JS.** Studies on the role of heme in the regulation of delta-aminolevulinic acid synthetase during fetal hepatic development. Molec Pharmacol 1974; 10:389-397.
- 10. **Woods JS.** Studies on the pharmacology of methaqualone: induction of mammalian hepatic δ-aminolevulinic acid synthetase. Proc Soc Exp Biol Med 1974; 146:367-372.
- 11. Murthy VV, **Woods JS.** Solubilization and partial purification of mitochondrial delta-aminolevulinic acid synthetase from fetal rat liver. Biochem Biophys Acta 1974: 350:240-246.
- 12. **Woods JS**, Murthy VV. Delta-aminolevulinic acid synthetase from fetal rat liver: studies on the partially purified enzyme. Molec Pharmacol 1975; 11:70-78.

- 13. **Woods JS**. Developmental aspects of hepatic heme biosynthetic capability and hematotoxicity. Biochem Pharmacol 1976; 25:2147-2152.
- 14. **Woods JS**. Heme regulation of cytochrome oxidase synthesis in fetal rat liver. Molec Pharmacol 1977; 13:50-59.
- 15. Fowler BA, **Woods JS**. The transplacental toxicity of methyl mercury to fetal rat liver: morphometric and biochemical studies. Lab Invest 1977; 36:122-130.
- 16. **Woods JS**, Fowler BA. Renal porphyrinuria during chronic methyl mercury exposure. J Lab Clin Med 1977; 90:266-273.
- 17. Fowler BA, **Woods JS**, Schiller CM. The ultrastructural and biochemical effects of prolonged oral arsenic exposure on liver mitochondria of rats. Environ Health Perspect 1977; 19:197-204.
- 18. Schiller CM, Fowler BA, **Woods JS**. Arsenic effects on pyruvate dehydrogenase activation. Environ Health Perspec 1977; 19:205-208
- 19. **Woods JS**, Fowler BA. Effects of chronic arsenic exposure on hematopoietic function in adult mammalian liver. Environ Health Perspec 1977; 19:209-214.
- 20. Fowler BA, **Woods JS**. Ultrastructural and biochemical changes in renal mitochondria following chronic oral methyl mercury exposure: the relationship to renal function. Exptl Molec Pathol 1977; 27:403-412.
- 21. Lee CC, Bhandari JC, Winston JM, House WB, Peters PJ, Dixon RL, **Woods JS**. Inhalation toxicity of vinyl chloride and vinylidene chloride. Environ Health Perspect 1977; 21:25-32.
- Woods JS, Carver GT. Action of cobalt chloride on the biosynthesis, degradation and utilization of heme in fetal rat liver. Drug Metab Dispos 1977; 5:487-492.
- Woods JS, Fowler BA. Altered regulation of mammalian hepatic heme biosynthesis and urinary porphyrin excretion during prolonged exposure to sodium arsenate. Toxicol Appl Pharmacol 1978; 43:361-371.
- 24. Lee CC, Bhandari JC, Winston JM, House WB, Dixon RL, **Woods JS**. Carcinogenicity of vinyl chloride and vinylidene chloride. J Toxicol Environ Health 1978; 4:15-30.
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- 26. Kitchin KT, **Woods JS**. 2,3,7,8-Tetrachlorodibenzo-p-dioxin induction of aryl hydrocarbon hydroxylase in female rat liver. Evidence for de novo synthesis of cytochrome P448. Molec Pharmacol 1978; 14:890-899.

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- 30. **Woods JS**, Carver GT, Fowler BA. Altered regulation of hepatic heme metabolism by indium chloride. Toxicol Appl Pharmacol 1979; 49:455-461.
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- Fowler BA, Kimmel CA, **Woods JS**, McConnell EE, Grant LD. Chronic low level lead toxicity in the rat. III. An integrated assessment of long term toxicity with special reference to the kidney. Toxicol Appl Pharmacol 1980; 56:59-77.
- 34. Kardish RM, **Woods JS**. Measurement of heme biosynthetic enzymes in mammalian tissues: I. Uroporphyrinogen decarboxylase. J Appl Biochem 1980; 2:159-167.
- 35. Kardish RM, **Woods JS**. Measurement of heme biosynthetic enzymes in mammalian tissues: II. Coproporphyrinogen oxidase. J Appl Biochem 1980; 2:168-174.
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- 39. Fowler BA, **Woods JS**, Davidian NM, Squibb KS. Alteration of hepatic mitochondrial aldehyde dehydrogenase activity by sodium arsenate: the relationship to mitochondrial-microsomal oxidative interactions. Exptl Molec Pathol 1982; 37:351-357.
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- 41. Fowler BA, Kardish RM, **Woods JS**. Alteration of hepatic microsomal structure and function by indium chloride: ultrastructural morphometric and biochemical studies. Lab Invest 1983; 48:471-478.
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- 54. **Woods JS**, Polissar L. Non-Hodgkins lymphoma among phenoxy herbicide-exposed farm workers in Western Washington State. Chemosphere 1989; 18: 401-406.
- 55. **Woods JS**. Mechanisms of metal-induced alterations of cellular heme metabolism. Comm Toxicol 1989; 3: 3-25.
- Woods JS, Southern MR. Studies on the etiology of trace metal-induced porphyria: effects of porphyrinogenic metals on coporporphyrinogen oxidase in rat liver and kidney. Tox Appl Pharmacol 1989; 97: 183-190.
- 57. Kulander BG, Polissar L, Yang C, **Woods JS**. Grading soft tissue sarcoma: necrosis as a determinant of survival. Modern Pathol 1989; 2: 205-208.
- 58. **Woods JS**, Calas CA. Iron stimulation of free radical-mediated uroporphyrinogen oxidation by hepatic and renal mitochondria. Biochem Biophys Res Commun 1989; 160: 101-108.
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- 63. Lund BO, Miller DM, **Woods JS**. Mercury-induced H₂O₂ production and lipid peroxidation in vitro in rat kidney mitochondria. Biochem Pharmacol 1991; 42:S181-S187.
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- 65. Bowers MA, Aicher LD, Davis HA, **Woods JS**. Quantitative determination of porphyrins in rat and human urine and evaluation of urinary porphyrin profiles during mercury and lead exposures. J Lab Clin Med 1992; 120:272-281.
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- 67. **Woods JS**, Davis HA, Baer, RP. Enhancement of gamma-glutamylcysteine synthetase mRNA in rat kidney by methyl mercury. Arch Biochem Biophys 1992; 296: 350-353.
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- 79. **Woods JS**. Altered porphyrin metabolism as a biomarker of mercury exposure and toxicity. Canad J Physiol Pharmacol 1996; 74:210-215.
- 80. Kushleika J, Checkoway H, **Woods JS**, Moon J-D, Smith-Weller T, Franklin GM, Swanson PD. Selegiline (L-Deprenyl) mediates increased lymphocyte cytosolic and mitochondrial superoxide dismutase activities in Parkinson's disease. Ann Neurol 1996; 39:378-381.
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8/3/07

CERTIFICATE OF SERVICE

I hereby certify that on August 7, 2007, I served the foregoing PSC'S UNOPPOSED MOTION

FOR LEAVE TO DESIGNATE ADDITIONAL EXPERT WITNESS DR. JAMES

WOODS, PH.D. on the following individual(s):

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By United Parcel Service, next business day delivery.

Petitioners specifically authorize the Court and the Office of Special Masters to post this document, and any attachments or exhibits thereto, on the Court/OSM website, expressly waiving any confidentiality as to the contents of these materials. Petitioners expressly wish to publicly disclose this filing in any other forum designated by the Court or the OSM.

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Of Attorneys for Petitioners' Steering Committee

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