

ORIGINAL

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

JAN 10 2007

OSM
U.S. COURT OF
FEDERAL CLAIMS

IN 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.

**PETITIONERS' ADDITIONAL EXPERT
DESIGNATIONS**

AUTISM MASTER FILE

Special Master George Hastings

Petitioners hereby designate three additional expert witnesses who may be called upon to submit expert reports and testimony in support of petitioners' case for general causation in the Omnibus Autism Proceeding. The *curricula vitae* of the experts are attached as PSC Exhibits 92, 93, and 94. The three additional experts are:

1. H. Vasken Asposhian, Ph.D.
2. Vera S. Byers, M.D., Ph.D.
3. Marcel Kinsbourne, M.D.

DATED this 9th day of January, 2007

WILLIAMS LOVE O'LEARY CRAINE & POWERS P.C.

By: 

Thomas B. Powers
Counsel for Petitioners' Steering Committee
Williams Love O'Leary Craine & Powers, P.C.
9755 S.W. Barnes Road, Suite 450
Portland, Oregon 97225-6681
(503) 295-2924 tel.
(503) 295-3720 fax

November, 2006

CURRICULUM VITAE

H. Vasken Aposhian, PhD
Professor of Molecular and Cellular Biology
Professor of Pharmacology
University of Arizona

Place of Birth: Providence, RI

Education

B.S. Brown University, 1948 (Chemistry)

M.S. University of Rochester, 1950 (Physiological Chemistry)

Ph.D. University of Rochester, 1953 (Physiological Chemistry)

Advanced Training:

Department of Biochemistry, Stanford University School of Medicine (with Nobel Laureate Dr. Arthur Kornberg), 1959-1962

Department of Biology, Massachusetts Institute of Technology (with Dr. Paul Schimmel) -- six-month sabbatical, January 1-June 30, 1983

Department of Biology, University of California, San Diego -- six-month sabbatical as Visiting Scholar, June 1-December 30, 1990

Positions Held

- 1954-56 Instructor, Department of Pharmacology, Vanderbilt University School of Medicine
- 1956-59 Assistant Professor, Department of Pharmacology, Vanderbilt University School of Medicine
- 1959-62 USPHS Senior Research Fellow, Department of Biochemistry, Stanford University School of Medicine
- 1962-67 Associate Professor, Department of Microbiology, Tufts University School of Medicine
- 1966-75 Professor, Department of Cell Biology and Pharmacology, University of Maryland School of Medicine. (As Head of Department, 1966-72)
- 1975-present **Professor, Department of Pharmacology, College of Medicine, University of Arizona**
- 1975-83 Professor, Department of Cellular and Developmental Biology, College of Liberal Arts, University of Arizona. (Head of Department, 1975-79)
- 1983 Visiting Professor, Department of Biology, Massachusetts Institute of Technology (January 1, 1983-June 30, 1983)
- 1983-present **Professor, Department of Molecular and Cellular Biology, Faculty of Science, University of Arizona**

Research Interests

1. Metal toxicity and mechanisms of intoxication of arsenic, mercury, lead, and manganese, polymorphisms involved.
2. Biological chelation: Use of DMPS as a challenge test for mercury, arsenic and lead.
3. Arsenic detoxification and intoxication: molecular mechanisms.
4. DNA and gene delivery systems for mammalian cells and intact animals.
5. Pseudovirions.
6. Autism

Professional Societies

Society for Toxicology
American College of Toxicology
American Society of Biological Chemistry and Molecular Biology
American Society of Microbiology
American Society for the Advancement of Science, Fellow
New York Academy of Sciences
American Society for Pharmacology and Experimental Therapeutics (resigned 1976)
American Academy of Microbiology
American Association of University Professors

Awards or Honors

1959-64	USPHS Senior Research Fellowship (resigned 1962)
1959	Jane Coffin Child Fellowship (declined)
1972	Sigma Xi Annual Award for Scientific Achievement, Maryland Chapter
1974	Student Council Award for Excellence in Teaching, University of Maryland School of Medicine
1977	Invited Guest, Soviet Academy of Science, June, 1977
1977	Invited Lecturer, Al-Hazen Research Institute, Baghdad, Iraq, May, 1977
1981	Invited Speaker, Korean Biochemical Society
1985	National Academy of Science (U.S.) - Soviet Union Academy of Science Exchange Fellow for September, 1985, in Soviet Union
1985	Official Guest of Peoples' Republic of China, Academy of Science, Lecture Tour, October, 1985
1996	Official Guest of Peoples' Republic of China, Academy of Science, Evaluation of arsenic problem in Guizhou Province, November, 1996
1998	Official Guest of Peoples' Republic of China, Academy of Science, Evaluation of arsenic problem Autonomous Region of Inner Mongolia, November, 1996
1999	Official Guest of Peoples' Republic of China, Academy of Science, Treatment of Arsenic problem in Guizhou Province.

National Service (only a few are listed)

- 1970-78 Member of ad hoc committees for cancer programs and cancer construction programs of the National Cancer Institute.
- 1971 Consultant to National Cancer Institute Planning Session, Airlie Conference Center.
- 1972 Advisor on gene technology to U.S. Senator J.V. Tunney.
U.S. Environmental Protection Agency, Mercury Advisory Committee.
- 1971-73 American Cancer Society, Maryland Division - Member, Board of Directors.
- 1971-72 American Cancer Society, Maryland Division -Chairman Grants Committee.
- 1989- Consultant For Various Multinational Pharmaceutical, Consumer-Goods And Life Science Companies – Confidential.
- 1990 Lecturer - Continuing Education Committee, Society of Toxicology.
- 1990-94 Member of various ad hoc study sections, National Institutes of Health especially for the National Institute for Environmental Health Sciences.
- 1993 Councilor - Metal Section, Society of Toxicology.
- 1993 Super Fund - Agenda Workshop for Biodiversity Toxicology of Children, for the National Institute for Environmental Health Sciences.
- 1995 WAARF Arsenic Research Priority Planning Meeting,-- Mechanisms Section Chairman.
- 1995 WAARF Arsenic Grant Application Study Section.
- 1997-98 National Research Council, Committee on Toxicology, Subcommittee on Arsenic in Drinking Water, member.
- 1997 EPA Working Committee on Arsenic Carcinogenesis.
- 1998 NIEHS Methylmercury evaluation group.
- 1998 Mercury toxicity. Presentation to Committee On Government Reform, House of Representatives, Congress of the United States
- 1998 Cure Autism Now, Research Grant Committee
- 1999-2000 National Research Council, Committee on Toxicology, Committee on Mercury Toxicity, member.
- 2004 Presentation to Vaccine Committee of IOM entitled: *A Toxicologist's View of Autism and Thimerosal*
- 2005-2006 EPA, Arsenic Study Committee

International Service

- Present Research and Scientific Evaluations of Arsenic, Mercury and Other Toxic Chemicals for National Governments.
- 1992 Metal Toxicology Workshop for Physicians, Taipei Veterans Hospital Center, Taiwan.
- 1993 Superfund Workshop, Campagne de Madonna, Italy.
- 1993 Mercury Levels in Mexican Dental and Tampico Factory workers.

1994 German Government Metal Toxicology Workshop.
 1994 Arsenic Toxicity in Chile.
 1994 Hg Toxicity in Denmark.
 1996 Arsenic toxicity in China.
 1998 Arsenic toxicity in Inner Mongolia.
 1999 Arsenic toxicity in China.
 1999 Arsenic toxicity in Romania
 2000 Lead, cadmium and arsenic toxicity in children in Torreon, Mexico
 2003 WHO workshop on Child Health in Southeast Asia (Bangladesh)
 2003 US-Japan meeting on arsenic (by invitation only)
 2004 Arsenic toxicity in rural elevated Argentina
 2006 International Conference of Chelating Agents, Advisory Board

University of Arizona Service

1976-79 University Advisory Committee on Promotion and Tenure.
 1975-79 Biomedical Support Research Grants Committee.
 1975-77 Executive Committee, Cancer Center.
 1976-77;
 1979 Search Committee, Biochemistry Head.
 1977-85 University Committee to review DNA recombinant research.
 1978 Toxicology Program - Member of Executive Committee.
 1979-85 Graduate Council - Chairman, Student Affairs Subcommittee; Petitions Subcommittee.
 1987 Toxicology Faculty Search Committee, College of Pharmacy.
 1988 Molecular and Cellular Biology Faculty Search Committee, College of Arts and Sciences.
 1991-95 Chairman, Biomedical Group for Superfund Center.
 1992 Member of committee to review College of Medicine Molecular and Cellular Biology course.
 1993 Chairman of committee for five-year review of Department Head.
 1994 Environmental Quality Committee.
 1995 Medical School Neurosciences Review Committee.
 1995 Chairman, Departmental Promotion and Tenure Committee.
 1998 College of Science, Promotion and Tenure Committee.

State of Arizona Service

1989-92 Commissioner, Structural Pest Control Commission, State of Arizona.

Present Grant Support

NIEHS Superfund Project, \$181,000 per year. *In vivo* and *in vitro* metabolism of arsenic.
 Autism Research Institute, \$40,000 per year. Autism Biomarkers.

Other

Paid consultant at various times for various multinational pharmaceutical or consumer product companies.

Bibliography

(Does not include abstracts of papers presented at international or national meetings or seminars and lectures given at various institutions.)

Chowdhury UK, Zakharyan RA, Hernandez A, Avram MD, Kopplin MJ, and Aposhian HV. Glutathione-S-transferase-omega [MMA(V) reductase] knockout mice: Enzyme and arsenic species concentrations in tissues after arsenate administration. *Clin Res Toxicol* 216:446-447 (2006).

Aposhian HV and Aposhian MM Arsenic Toxicology: Five Questions. *Chem Res Toxicol* 19:1-15 (2006).

Zakharyan RA, Tsapraillis G, Chowdhury UK, Hernandez A, and Aposhian HV. Interactions of Sodium Selenite, Glutathione, Arsenic Species and Omega Class Human Glutathione Transferase. *Chem Res Toxicol* 18:1287-1295 (2005).

Aposhian HV, Zakharyan RA, Avram MD, Sampayo-Reyes A, and Wollenberg M L. A review of the enzymology of arsenic metabolism and a new potential role of hydrogen peroxide in the detoxication of the trivalent arsenic species. *Toxicol and Applied Pharmacol* 198:327-335 (2004).

Marnell LL, Garcia-Vargas GG, Chowdhury UK, Zakharyan RA, Walsh B, Avram, MD, Kopplin MJ, Cebrian ME, Silbergeld EK, and Aposhian HV. Polymorphisms in the human monomethylarsonic acid (MMA V) reductase/hGSTO1 gene and changes in urinary arsenic profiles. *Chem Res Toxicol* 16:1507-1513 (2003).

Aposhian HV, Zakharyan RA, Healy SM, Wildfang E, Petrick JS, Sampayo-Reyes A, Boar PG, Carter DE, Guha Mazumder DN, and Aposhian MM. Enzymology and toxicity of inorganic arsenic. In *Arsenic Exposure and Health Effects V: Proceedings of the Fifth International Conference on Arsenic Exposure and Health Effects* (2002), pgs. 225-240, Editors: Chappell, Abernathy, Calderon, Thomas, Elsevier Science Ltd. Oxford (2003).

Carter DE, Aposhian HV, and Gandolfi AJ. The metabolism of inorganic arsenic oxides, gallium arsenide, and arsine: a toxicochemical review. *Toxicol and Applied Pharmacol* 193:309-334 (2003).

Aposhian HV, Zakharyan RA, Avram MD, Kopplin MJ, and Wollenberg ML. Oxidation and detoxification of trivalent arsenic species. *Toxicol and Applied Pharmacol* 193:1-8 (2003).

Aposhian HV, Morgan DL, Queen HLS, Maiorino RM, and Aposhian MM. Vitamin C, Glutathione nor Lipoic Acid Did Not Decrease Brain or Kidney Mercury in Rats Exposed to Mercury Vapor. *Clinical Toxicol* 41:339-347 (2003).

Loffredo CA, Aposhian HV, Cebrian ME, Yamauchi H, and Silbergeld EK. Variability in human metabolism of arsenic. *Environ Res* 92:85-91 (2003).

Bhumasamudram J, Aposhian HV, Mash EA. An efficient synthesis of sodium dimethylarsinate-¹⁴C. *J LabelCompd Radiopharm* 46:373-377 (2003).

Aposhian HV. Elemental, mercuric and organic mercury: biological interactions and dilemmas. *PowerPlant Chem* 4:557-561 (2002).

Radabaugh TR, Sampayo-Reyes A, Zakharyan RA, and Aposhian HV. Arsenate reductase II. Purine nucleoside phosphorylase in the presence of dihydrolipoic acid is a route for reduction of arsenate to arsenite in mammalian systems. *Chem Res Toxicol* 15:692-680 (2002).

Liu J, Zheng B, Aposhian HV, Zhou Y, Chen M-L, Waalkes MP. Chronic arsenic poisoning from burning high arsenic containing coal in Guizhou, China. *Environ Health Perspect* 110:119-122 (2002).

Gong Z, Jiang G, Cullen WR, Aposhian HV, and Le XC. Determination of arsenic metabolic complex excreted in human urine after administration of sodium 2,3-dimercapto-1-propane sulfonate. *Chem Res Toxicol* 15:1318-1323 (2002).

Wildfang E, Radabaugh TR, and Aposhian HV. Enzymatic methylation of arsenic compounds. IX. Liver arsenite methyltransferase and arsenate reductase activities in primates. *Toxicol* 168:213-221 (2001).

Zakharyan RA, Sampayo-Reyes A, Healy SM, Tsaprailis G, Board PG, Liebler DC, and Aposhian, HV. Human monomethylarsonic acid (MMAV) reductase is a member of the glutathione-S-transferase superfamily *Chem Res Toxicol* 14:1051-1057 (2001).

Petrick JS, Jagadish B, Mash EA, and Aposhian HV. Monomethylarsonous Acid (MMAIII) and Arsenite: LD50 in Hamsters and In Vitro Inhibition of Pyruvate Dehydrogenase. *Chem Res Toxicol* 14:651-656 (2001).

Aposhian HV and Aposhian MM. Arsenic mobilization by DMPS. In *Arsenic Exposure and Health Effects: Proceedings of the Fourth International Conference (2000) on Arsenic Exposure*. pg 397-406. Editors: Chappell, Abernathy, and Calderon. Elsevier Science Ltd.Oxford (2001).

Aposhian HV, Gurzau ES, Le XC, Gurzau A, Zakharyan RA, Cullen WR, Healy SM, Gonzalez-Ramirez D, Morgan DL, Sampayo-Reyes A, Wildfang E, Radabaugh TR, Petrick JS, Mash EA, Aavula RB, and Aposhian MM. The discovery, importance and significance of monomethylarsonous acid (MMAIII) in urine of humans exposed to inorganic arsenic. In *Arsenic Exposure and Health Effects: Proceedings of the Fourth International Conference (2000) on Arsenic Exposure*. Editors: Chappell, Abernathy, and Calderon. Elsevier Science Ltd.Oxford (2001).

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Sampayo-Reyes A, Zakharyan RA, Healy SM, and Aposhian HV. Monomethylarsonic acid reductase and monomethylarsonous acid in hamster tissue. *Chem Res Toxicol* 11:1181-1186 (2000).

Petrick JS, Ayala-Fierro F, Cullen WR, Carter DE, and Aposhian HV. Monomethylarsonous Acid (MMAIII) is More Toxic than Arsenite in Chang Human Hepatocytes. *Toxicol Appl Pharmacol* 163:203-207 (2000).

Aposhian HV, Gurzau ES, Le XC, Gurzau A, Healy SM, Lu X, Ma M, Yip L, Zakharyan RA, Maiorino RM, Dart RC, Tircus MG, Gonzalez-Ramirez D, Morgan DL, Avram D, and Aposhian MM. Occurrence of Monomethylarsonous acid (MMA^{III}) in Urine of Humans Exposed to Inorganic Arsenic. *Chem Res Toxicol* 13:693-697 (2000).

Le XC, Ma M, Lu X, Cullen WR, Aposhian HV, and Zheng B. Determination of monomethylarsonous acid, a key arsenic methylation intermediate, in human urine. *Environ Health Perspect* 108:1015-1018 (2000).

Gailer JG, George GN, Pickering IJ, Prince RC, Ringwald SC, Pemberton JE, Glass RS, Younis HS, DeYoung DW, and Aposhian HV. A metabolic link between arsenite and selenite: The seleno-bis(S-glutathionyl) arsinium ion. *J Am Chem Soc* 122:4637-4639 (2000).

Aposhian HV, Zheng B, Aposhian MM, Le XC, Cebrian ME, Cullen W, Zakharyan RA, Ma M, Dart RC, Cheng Z, Andrewes P, Yip L, O'Malley GF, Maiorino RM, Van Voorhies W, Healy SM, and Titcomb A. DMPS-arsenic challenge test: II. Modulation of arsenic species, including monomethylarsonous acid (MMA^{III}), excreted in human urine. *Toxicol Appl Pharmacol* 164:74-83 (2000).

Radabaugh TR and Aposhian H. Enzymatic Reduction of Arsenic Compounds in Mammalian Systems: Reduction of Arsenate to Arsenite by Human Liver Arsenate Reductase, *Chem Res Toxicol* 13:26-30 (2000)

Zakharyan RA and Aposhian H V. Enzymatic Reduction of Arsenic Compounds in Mammalian Systems: The Rate Limiting Enzyme of Rabbit Liver Arsenic Biotransformation is MMA^V Reductase. *Chem Res Toxicol* 12:1278-1283 (1999).

Aposhian HV, Zakharyan RA, Wildfang EK, Healy SM, Gailer J, Radabaugh TR, Bogdan GM, Powell LA, and Aposhian MM. How is inorganic arsenic detoxified? In *Arsenic Exposure and Health Effects: Proceedings of the Third International Conference on Arsenic Exposure and Health Effects*, July 12-15, 1998, San Diego, California, pgs. 289-297, Editors: Chappell WR, Abernathy CO, and Calderon RL. Elsevier Science Ltd. Oxford (1999).

Bogdan GM, Goud GN, Sampayo-Reyes A, Porath J, Aposhian MM, and Aposhian HV. Arsenic binding proteins of mammalian systems: II. Purification of a 450 kDa arsenite-binding protein from rabbit liver. Submitted.

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Zakharyan RA and Aposhian HV. Arsenite methylation by methylvitamin B₁₂ and glutathione does not require an enzyme. *Toxicol Appl Pharmacol* 154:287-291 (1999).

Zakharyan RA, Ayala-Fierro F, Cullen WR, Carter DE, and Aposhian HV. Enzymatic methylation of arsenic compounds: VII - MMA^{III} is the substrate for MMA methyltransferase of rabbit liver and human hepatocytes. *Toxicol Appl Pharmacol* 158:9-15, (1999).

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Wildfang E, Zakharyan RA, and Aposhian HV. Enzymatic methylation of arsenic compounds: VI. Arsenite and methylarsonic acid methyltransferase kinetics. *Toxicol Appl Pharmacol* 152:366-375 (1998).

Aposhian HV. Enzymatic methylation of arsenic species and other new approaches to arsenic toxicity. *Annu Rev Pharmacol Toxicol* 37:397-419 (1997).

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Aposhian HV. Mobilization of mercury and arsenic in humans by sodium 2,3-dimercapto-1 propane sulfonate (DMPS). *Environ Health Perspect* 106:1017-1025 (1998).

Cianciola ME, Echeverria D, Martin MD, Aposhian HV, and Woods JS. Epidemiologic assessment of measures used to indicate low-level exposure to mercury vapor (Hg⁰). *J Toxicol Environ Health* 52:19-33 (1997).

Aposhian HV. Enzymatic methylation of arsenic species and other new approaches to arsenic toxicity. *Annu Rev Pharmacol Toxicol* 37:397-419 (1997).

Aposhian HV, Zakharyan RA, Wu Y, Healy S, and Aposhian MM. Enzymatic methylation of arsenic compounds: II. An overview. In Abernethy C, Calderon R, and Chappell W, eds., *Human Health II*, London: Chapman & Hall (1997).

Healy S, Zakharyan RA, and Aposhian HV. Enzymatic methylation of arsenic compounds: IV. In vitro and in vivo deficiency of the methylation of arsenite and monomethylarsonic acid in the guinea pig. *Mutation Res* 386:229-239 (1997).

Aposhian HV, Arroyo A, Cebrian ME, Del Razo LM, Hurlbut KM, Dart RC, Gonzalez-Ramirez D, Kreppel H, Speisky H, Smith A, Gonsebatt ME, Ostrosky-Wegman P, and Aposhian MM. DMPS-Arsenic challenge test: I. Increased Urinary Excretion of Monomethylarsonic acid in humans given dimercaptopropane sulfonate. *J Pharmacol Exp Ther* 282:192-200 (1997).

Aposhian MM, Maiorino RM, Xu Z, and Aposhian HV. Sodium 2,3-dimercapto-1-propanesulfonate (DMPS) treatment does not redistribute lead or mercury to the brain of rats. *Toxicol* 109:49-55 (1996).

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Aposhian HV. Arsenic toxicology: Does methylation of arsenic species have an evolutionary significance? In Collery, P., Corbella, J., Domingo, J. L., and Etienne, J.-C., Llobet, J. M., eds. *Metal Ions in Biology and Medicine*, vol. 4, Proceedings of the Fourth International Symposium on Metal Ions in Biology and Medicine held in Barcelona (Catalonia) Spain, May 19-22, pp. 399-401, (1996).

Maiorino RM, Gonzalez-Ramirez D, Zuniga-Charles M, Xu Z, Hurlbut KM, Aposhian MM, Dart RC, Woods JS, Ostrosky-Wegman P, Gonsebatt ME, and Aposhian HV. Sodium 2,3-dimercaptopropane-1-sulfonate challenge test for mercury in humans. III. Urinary mercury after exposure to mercurous chloride. *J Pharm Exp Ther* 227:938-944 (1996).

Aposhian MM, Maiorino RM, Xu Z, and Aposhian HV. Sodium 2,3-dimercapto-1-propanesulfonate treatment does not redistribute mercury or lead to the brain of rats. In Collery P, Corbella J, Domingo JL, Etienne J-C, and Llobet JM, eds. *Metal Ions in*

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Aposhian HV. Neurotoxicity of metals: the new challenges: Introductory remarks. *Toxicol* 97:1-2 (1995).

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Zakharyan R, Wu Y, Bogdan GM, and Aposhian HV. Enzymatic methylation of arsenic compounds: I. Assay and partial purification of arsenic methyltransferases from rabbit liver. *Chem Res Toxicol* 8:1029-1038 (1995).

Bogdan GM, Sampayo-Reyes A, and Aposhian HV. Arsenic binding proteins of mammalian systems: I. Isolation of three arsenite-binding proteins of rabbit liver. *Toxicol* 93:175-193 (1994).

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Hurlbut KM, Maiorino RM, Mayersohn M, Dart RC, Bruce DC, and Aposhian HV. Determination and metabolism of dithiol chelating agents XVI. Pharmacokinetics of 2,3-Dimercapto-1-propanesulfonate after intravenous administration to human volunteers. *J Pharmacol Exp Ther* 268:662-668 (1994).

Maiorino RM, Aposhian MM, Xu Z, Li Y, Polt RL, and Aposhian HV. Determination and metabolism of dithiol chelating agents. XV. The meso-2,3-dimercaptosuccinic acid-cysteine (1:2) mixed disulfide, a major urinary metabolite of DMSA in the human, increases the urinary excretion of lead in the rat. *J Pharmacol Exp Ther* 267:1221-1226 (1993).

Aposhian HV, Levine DJ, Rivera M, and Fernando Q. Determination and metabolism of dithiol chelating agents: The zinc chelate of the dimethyl ester of meso-2,3-dimercaptosuccinic acid increases biliary excretion of cadmium and platinum. *Chem Res Toxicol* 6:208-214 (1993).

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Aposhian HV, Pointer NS, and Aposhian MM. Reversal of the inhibitory activity of chlorpromazine by calcium. *Proc Soc Exp Biol Med* 100:512 (1959).

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Kochakian CD and Aposhian HV. The in vitro metabolism of 3-17-androstenediol of liver and kidney. *Arch Biochem Biophys* 37:442 (1952).

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Curriculum Vitae

VERA S. BYERS, M.D., Ph.D.
775 771 9075
vbyersmd@aol.com

Internist, and basic and clinical immunologist with extensive experience in development of biologic drugs in autoimmune disease, allergic disease, and cancer

Medical Toxicologist with hands-on experience in assessing medical damage to over 3000 patients over the past 15 years

Basic and clinical research included cancer and tumor immunology, bone marrow transplantation, immunodermatology, allergy and autoimmune diseases particularly rheumatoid arthritis, multiple sclerosis, HIV disease, and pharmacotoxicology and Immunotoxicology.

Over 300 articles and abstracts published in peer reviewed medical journals, most recently in bone marrow transplantation, tumor immunology and immunotherapy, and allergy.

Extensive experience with FDA, and with corporate and academic presentations.

One of the founders of the field of human tumor immunotherapy

Serves on the editorial board of two leading cancer journals, and maintains ties with the academic and biotechnology communities in the US and Europe.

Experience with multiple sclerosis and other demyelinating diseases:

Developed clinical trials using the immunotoxin H65-RTA for demyelinating diseases, 1989

Identified emerging research using T cell receptor proteins as vaccines for demyelinating diseases including multiple sclerosis, developed by Vandembark et al. in Oregon. Persuaded Xoma Corp. to license the technology in 1991, and designed the clinical trials, and developed laboratory assays to prove its efficacy in vivo.

At Connetive Therapeutic Corp, redesigned the clinical trials using the TCR vaccine cocktail composed of V α 5.1 and V β 8. From 1996-1997 wrote and submitted to the FDA, the clinical trials testing the clinical efficacy of the vaccine. Supervised the laboratory assays to check the surrogate efficacy. Won FDA approval for the trials and ran them from 1997 to 1998. Wrote the final study report for the FDA in 1999.

PRESENT POSITIONS

President of Immunology Inc.

Job responsibilities:

Consulting Medical Director for Pharmaceutical Companies

- Preclinical and clinical consultant

- Design Phase I, II, III clinical trials in autoimmune diseases and cancer
- File INDs (over 30 to date)
 - Design and implement supporting toxicology studies (over 20 to date)
 - Design and direct preclinical IND supporting studies
- Select clinical sites and principal investigators, run the clinical trials
- Author the clinical reports or scientific publications (over 300 scientific papers and abstracts)
- File PLAs or BLAs and defend the filing– lead author for 2 reports to date, part of clinical team for 2 additional ones.
- Present data at national and international scientific meetings and grand rounds
- Clients have included: Icos Corp., Eli Lilly Co., Connetics Corp., Allergene Corp., Immunex Corp. Orphan Biomedical

Areas of expertise:

Diseases: Have designed and run trials in:

Cancer Immunology: multiple phase I/II studies, typically with 10 centers, 30 – 50 patients, principally colon, breast cancer, renal cell cancer, malignant melanoma, leukemia and lymphoma

Atopic Dermatitis: 60 sites, 600 patients

Bone Marrow Transplantation: 33 sites, 150 patients

Autoimmune diseases: Rheumatoid arthritis, diabetes, ulcerative colitis, multiple sclerosis, typically 10 centers, 100 patient studies.

HIV disease: Two 100 patient phase III studies, five sites.

Erectile dysfunction: 10 centers, 200 patients.

Drugs: Expertise is primarily in biologics, monoclonal antibodies, cytokines, and peptide vaccines.

Monoclonal antibodies: Developed a large number of monoclonal antibodies with specificity ranging from tumor antigens to allergens. Supervised preclinical development of >50 of them, filed INDs on about 15 different ones. Managed clinical trials using monoclonal antibodies in graft vs. host disease, transplantation rejection, ovarian, breast, renal, and colorectal cancer, leukemia and lymphoma, and about 15 different autoimmune diseases.

Cytokines: Gamma-interferon, GM-CSF, TNFR:Fc.

Medical toxicologist

- Design, supervise, and run epidemiologic studies on populations exposed to carcinogenic environmental chemicals
- Write reports, serve as expert medical witness, publish papers in peer reviewed journals.
- Responsible for the class certification of the largest class of plaintiffs exposed to toxic waste sites
- Private practice (Immunology Inc. Medical Group) includes patients exposed to pesticides, herbicides, other environmental toxins and carcinogens
- Experience with a wide variety of chemicals including TCE, PCE, Benzene, Formaldehyde

Recent Clients:

Consulting Medical Director:

1998 - 2000: Immunex Corp: Medical director on the team responsible for filing the BLA for for Enbrel in methotrexate resistant rheumatoid arthritis, and as initial therapy for rheumatoid arthritis.

1999 - 2000: Abgenix Corp.: Medical director for development of monoclonal antibody ABX-CBL for therapy for GvHD. Currently, analyzing the completed Phase I/II study, writing the study report, and the manuscript. Designing and implementing the protocol for the Phase III pivotal study (selecting and site visiting sites, establishing DSMB, working with the CRO to manage the study, serving as the Abgenix medical monitor for the study).

1999 - 2001: ICOS Corp, and Eli Lilly: Developing Platelet Activating Factor Hydrolase in sepsis, and IC351, a phosphodiesterase inhibitor, for erectile dysfunction.

Analyzing results of a Phase IIb study investigating effect of platelet activating factor acid hydrolyzase on patients with severe sepsis. Analyzed and wrote the ISS, investigator brochure, and clinical study report supporting the Phase III study.

1996-1998: Connetics Corp. Designed and ran a 100 patient vaccine study using peptide therapy in multiple sclerosis.

Ran a 600 patient clinical study examining the effect of IFN-gamma in Atopic Dermatitis

Medical toxicology: Developing screening program for 1 million+ people potentially exposed to toxic chemicals from the old Boeing plant in LA.

Private practice: From 1984-1997, partner in Immunology Inc. Medical Practice, San Francisco, specializing in HIV disease, allergy, immunology, tumor immunotherapy, chronic fatigue syndrome.

Academic positions:

University of California, San Francisco

Adjunct Professor of Immunodermatology
San Francisco, CA
1974 - present

Nottingham University School of Medicine

Special Lecturer in Tumor Immunology
Nottingham University Faculty of Medicine
Nottingham, England
1986 to present

Previous positions

Allergene Corporation

1991-1993
President and co-founder

Developed monoclonal antibodies for use in controlling allergic diseases

In-licensed peptides for use in HIV disease, and asthma. Designed and implemented protocols for clinical trials.

XOMA, 1984-1991

Director of Clinical Immunology, 1984-1989:

Invented four immunotoxins. Supervised their preclinical and clinical development. Defended the INDs before the FDA. Filed the PLA for use of one of them in graft vs. host disease.

Assembled a clinical team to design and run trials of one of the immunotoxins in 10 autoimmune diseases including organ transplantation.

Director of Corporate Development, 1989-1991: Out-licensed one of the Immunotoxins, H65-RTA to a corporate partner (Ortho Biotechnology).

Experience in England and Italy identifying new biological drugs at various stages of development, developing preclinical and clinical profiles for potential in-licensing, as well as developing due diligence profiles for potential corporate partners.

Abbott Laboratory

Chicago, Ill

Bench Chemist 1970 - 1972

Research on molecular evolution
Research on anti-coagulant from snake venom

ACADEMIC POSITIONS:

Assistant Professor of Immunology
Department of Dermatology

University of California, San Francisco
January 1976 - July 1985
Basic and Clinical Research in immunodermatology and tumor immunology, supported
by USPHS-NIH-NIAID and NCI Research Grants

Research Associate

Department of Dermatology
University of California, San Francisco
Supported by USPHS-NIH-NIAID Research Grants
January 1975 - January 1976

Postdoctoral Fellow

Department of Medicine
University of California, San Francisco
1971-1974
Clinical Immunology

EDUCATION

MEDICAL SCHOOL:

University of California at San Francisco
August 1977 - June 1981
M.D., June 1981

RESIDENCY:

Internal Medicine, University of California San Francisco
1981-1984

BOARD CERTIFICATION:

Diplomate, American Board of Internal Medicine
1984

GRADUATE SCHOOL:

University of California at Los Angeles
M.A. in Microbiology, January 1967
PH.D. in Immunology, December 1969

POSTDOCTORAL FELLOWSHIPS

Protein Chemistry, Abbott Laboratory, Dr. E. Margoliash and U. Mich. Dr. Henry Lardy, 1969-

1971

Clinical Immunology, UCSF, Dr. Hugh Fudenberg, 1971-1973

COLLEGE:

University of California at Los Angeles
B.A. in Bacteriology, January 1965

ORGANIZATIONS:

American Academy of Allergy - Fellow
American Society for Cancer Research - Member
American Association of Immunologists - Member
American Medical Association - Member
California Medical Society - Member
San Francisco Medical Society - Member

EDITORIAL BOARDS:

Cancer Immunology and Immunotherapy, March 1983 - present
Cancer Drugs, 1991 - present

PATENTS:

Ribosomal Inhibiting Protein-Immunoglobulin Conjugates with Specificity for Tumor Cell Surface Antigens, and Mixtures Thereof. P.J. Scannon, R.W. Baldwin, V.S. Byers. United States Patent 4,916,213; April 10, 1990.

Hepatic Blocking Agents. V.S. Byers, R.W. Baldwin.
European Patent ,889,062,972; December 12, 1990.

Novel Methods for treatment of retroviral infections. U.S. Pat Docket No. L018-1 June 2, 2992.

BIBLIOGRAPHY OF VERA S. BYERS, M.D., PH.D.

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2. Byers, V.S. and Sercarz, E.E.: The XYZ scheme of immunocyte maturation. IV. Exhaustion of memory cells. *J. Exp. Med.* 127: 307, 1968.
3. Byers, V.S. and Sercarz, E.E.: The XYZ scheme of immunocyte maturation. Paralysis of memory cells. *J. Exp. Med.* 128:715, 1968.
4. Byers, V.S. and Sercarz, E.E.: In vitro unresponsiveness induced by antibody or antigen; sequence of sensitive events. *In Prague Symposium, Developmental Aspects of Immunity.* 1969.
5. Byers, V.S. and Sercarz, E.E.: Induction and reversal of immune paralysis in vitro. *J. Exp. Med.* 132:845, 1970.
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8. Goodman, J.W., Roelants, G., and Byers, V.S.: RNA-antigen complexes and the testing of a possible mode of action. *Ann. Rev. N.Y. Acad. Sci.* 1972.
9. Fudenberg, H.H., Byers, V.S., Levin, A.S., and Hackett, A.J.: Additional evidence for viral etiology of certain human tumors. *In Fundamental Aspects of Neoplasia*, A.A. Gotlib, ed. Springer-Verlog, New York, 1974.
10. Fudenberg, H.H., Levin, A.S., Spittler, L.E., Wybran, J.E., and Byers, V.S.: Therapeutic uses of transfer factor. *Hospital Practice* 9:2, 1974.
11. Levin, A.S., Spittler, L.E., Fudenberg, H.H., Byers, V.S., and Wybran, J.E.: Transfer factor therapy: current status. *So. Med. J.* (invited review), 1974.
12. Fudenberg, H.H., Byers, V.S., Levin, A.S., and Hackett, A.J.: Immunologic evidence for a viral etiology of certain malignant tumors. *Ann. N.Y. Acad. Sci.* 1974.
13. Levin, A.S., Byers, V.S., Fudenberg, H.H., and Wybran, J.E.: Immunologic parameters for monitoring immunotherapy with tumor-specific transfer factor. *Trans. Assoc. Am. Phys.* 87:153, 1975.

14. Carter, J.B., Ponce, B., Byers, V.S., Levin, A.S., and Fudenberg, H.H.: Circadian rhythms of human lymphocytes. *J. Allergy and Infect. Dis.* 56:191, 1975.
15. Byers, V.S., Levin, A.S., Hackett, A.J., and Fudenberg, H.H.: Tumor Specific cell-mediated immunity in household contacts of cancer patients. *J. Clin. Invest.* 55:500, 1975.
16. Levin, A.S., Byers, V.S., Fudenberg, H.H., Hackett, A.J., Johnston, J.O. and Wybran, J.E.: Osteogenic Sarcoma: Immunologic parameters before and during therapy with tumor specific transfer factor. *J. Clin. Invest.* 55:487, 1975.
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18. Fudenberg, H.H., Byers, V.S., Levin, A.S., and Hackett, A.J.: Evidence for viral etiology of human hypernephroma and osteosarcoma. *Perspectives in Virology. (Gustav Stern Symposium)* 9:153, 1975.
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20. Levin, A.S., Byers, V.S., Hackett, A.J., Johnston, J.O., and LeCam, L.M.: Tumor specific transfer factor therapy in osteogenic sarcoma. *Immunotherapy in Cancer. Proceedings of ITR-Chicago*, 1975.
21. Fisher, G.L., Byers, V.S., Shifrine, M., and Levin, A.S.: Copper and zinc levels in serum from human patients with sarcomas. *Cancer* 37:356, 1976.
22. Dollbaum, C.M., Smith, H.S., and Byers, V.: In-vitro characterization of human tumor cell lines. *J. Cell. Biol.* 70:329, 1976.
23. Kaplan, M.A., Byers, V.S., Levin, A.S., German, D., Fudenberg, H.H., and LeCam, L.M.: Circadian rhythm of stimulated lymphocyte blastogenesis. A 24 hour cycle in the mixed leukocyte culture reaction and SKSD stimulation. *J. Allergy Clin. Immunol.* 58:180, 1976.
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25. Byers, V.S. and Levin, A.S.: Tumor immunology. *In Basic and Clinical Immunology* J. Caldwell, H.H. Fudenberg, D. Stites, and A.C. Wang eds. Lange Books, Los Altos Ca, 1976.

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28. Byers, V.S., LeCam, L.M., Levin, A.S., Stone, W.H., and Hackett, A.J.: Identification of human populations with high incidence of cellular immunity against breast carcinoma. *Cancer Immunol. Immunother.* 2:163, 1977.
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CURRICULUM VITAE

10/18/2005

Name Marcel Kinsbourne
Home Address 158 Cambridge Street, Winchester, MA 01890
Telephone (781) 729-8201 **Fax** (781) 756-0236
Email kinsbourne@aol.com

Education

1952 B.A. Christ Church, Oxford University, England
1955 B.M., B.Ch. Oxford University Medical School, England
1956 M.A. Oxford University, England
1963 D.M. Oxford University, England
1967 M.D. State of North Carolina

Postdoctoral Training

1955-1956 House Physician, Lewisham Hospital, London, England
1956 House Surgeon, New End Hospital, London, England
1956-1957 Senior House Officer, Neurosurgery, Metropolitan Regional Neurosurgical Centre, Blackheath, England
1957 Medical Registrar, Chest Diseases, Preston Hall Hospital, Kent, England
1957-1958 House Physician, Paediatrics, Hospital for Sick Children, Great Ormond Street, London, England
1958-1959 Junior Assistant Resident, Pediatrics, Bellevue Hospital, New York
1959-1960 Assistant House Physician, Neurology, National Hospital, Queen Square, London, England
1960-1962 Registrar, Neurology, Hospital for Sick Children, Great Ormond Street, London, England
1962 Registrar, Neurology, United Oxford Hospitals, England
1962-1964 Senior Registrar, Neurology, United Oxford Hospitals, England

Medical Licensure

1955 United Kingdom
1967 State of North Carolina
1976 Medical Council of Canada
1980 Commonwealth of Massachusetts
1999 Commonwealth of Virginia

Medical Certification

1957 Member of the Royal College of Physicians (London)
1966 Educational Commission for Foreign Medical Graduates
1968 American Board of Pediatrics

Academic and Hospital Appointments

1964-1967 University Lecturer in Experimental Psychology, Oxford University, Oxford, England
1966-1967 Fellow of New College, Oxford University, Oxford, England

Academic and Hospital Appointments (Continued)

- 1967-1974 Associate Professor in Pediatrics, Associate Professor in Neurology, Duke University Medical Center, Durham, N.C.
- 1972-1974 Senior Research Associate, Center for the Study of Aging and Human Development, Duke University, Durham, N.C.
- 1974-1979 Professor of Psychology, University of Waterloo, Waterloo, Ontario
- 1974-1980 Professor of Pediatrics (Neurology), University of Toronto, Toronto, Ontario
- 1974-1980 Senior Staff Physician, Hospital for Sick Children, Toronto, Ontario
- 1975-1985 Professor of Psychology, University of Toronto, Toronto, Ontario
- 1976- Senior Fellow, Center for the Study of Aging and Human Development, Duke University, Durham, N.C.
- 1976-1980 Member, Institute of Medical Sciences, University of Toronto, Toronto, Ontario
- 1981-1991 Director, Behavioral Neurology Department, Eunice Kennedy Shriver Center, Waltham, MA
- 1981-1991 Lecturer in Neurology, Harvard Medical School, Boston, MA
- 1981-1991 Clinical Associate in Neurology, Massachusetts General Hospital, Boston, MA
- 1982-1988 Adjunct Professor of Linguistics and Cognitive Science, Brandeis University, Waltham, MA
- 1982- Adjunct Professor of Occupational Therapy, Boston University, Boston, MA
- 1987- Affiliate Professor of Psychology, Clark University, Worcester, MA
Adjunct Professor of Neurology, Graduate School, Division of Medical and Dental Sciences, Boston University School of Medicine, Boston, MA
- 1991-1992 Director, Behavioral Neurology Unit, Sargent College of Allied Health Professions, Boston University, Boston, MA
- 1992- Research Professor, Center for Cognitive Studies, Tufts University, Medford, MA
- 1995- Professor of Psychology, New School University, New York, NY

Awards and Honors

- 1949 State Scholarship, Oxford University
- 1950 Henderson Scholarship in Anatomy, Christ Church, Oxford University
- 1952 University Entrance Scholarship, Guy's Hospital, London, England
- 1955 Beaney Prize in Pathology, Guy's Hospital, London, England
- 1958-1959 Fulbright Traveling Scholarship
- 1961 Queen Square Prize in Neurology
- 1975 James Arthur Lectureship on Evolution of the Brain: The American Museum of Natural History, New York
- 1990 Visiting Resident Scholar, Rockefeller Foundation, Bellagio Study Center,

Administrative Assignments

- 1966-1967 Secretary, Sub-Faculty of Psychology, Oxford University
- 1967-1972 Chief, Division of Pediatric Neurology, Duke University
- 1968-1974 Member of Operating Committee, Duke University Neuroscience

- Research Training Program
- 1968-1975 Member of Steering Committee, Duke University Center for Study of Aging and Human Development
- 1974-1977 Director of Learning Clinic, Hospital for Sick Children, Toronto
- 1975-1979 Policy Advisor, Communicative Disorders Branch, National Institute for Neurological Diseases and Stroke
- 1978-1979 Member of Advisory Committee, Women's Studies Programme, University of Toronto
- 1992-1993 Full Member, Neuropsychology Committee, Max-Planck-Gesellschaft, Germany
- 1997- Chair, Institutional Review Board, New School University
- 1998- Member of Neuroscientific Advisory Panel, New York Psychoanalytic Institute

Editorial Boards (Current)

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Editorial Boards (Previous)

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 Developmental Neuropsychology
 Developmental Psychology
 Development and Psychopathology
 Exceptionality
 Human Development
 Journal of Clinical Neuropsychology
 Journal of Communication Disorders
 Learning and Individual Differences
 Reading Research Quarterly
 Remedial and Special Education
 Semiotic Inquiry
 Topics in Learning Disabilities

Professional Societies

Academy of Aphasia
American Neurological Association
American Psychological Association
 Division 3 (Experimental)
 Division 6 (Physiological); Fellow
 Division 20 (Aging)
American Psychological Society; Fellow
Association Costaricense de Pediatria; Honorary Life Member
Association of Educational Therapists; Advisory Board
Attention Deficit Information Network, Inc.; Professional Advisory Board (previous)
Child Neurology Society
Experimental Psychology Society; Member of Executive Committee, 1963-1965
Gerontological Society; Fellow (previous)
International Academy for Research on Learning Disabilities; Member of Development
 Committee 1978-1980; Membership Chairman 1978-1980
International Association for the Study of Attention and Performance (past); Member,
 Advisory Council 1976-1984 (previous)
International Neuropsychological Society; Membership; Membership Chairman 1972-
 1975; Member, Executive Committee 1976-1980; Chairman of Program
Committee,
 1977; President, 1977-1978
International Neuropsychology Symposium
Multidisciplinary Academy of Clinical Education (previous)
Massachusetts Medical Society
Professional Group for ADD and Related Disorders
Society for Neuroscience
Society for Pediatric Research; Chairman, Behavioral Pediatrics
 Section, 1972
Society for Philosophy and Psychology; Member of Executive Board;
 President, 1996-1997
Society for Research in Child Development
Society for Research in Child and Adolescent Psychopathology

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CERTIFICATE OF SERVICE

I hereby certify that on January 9, 2007, I served the foregoing **PETITIONERS'**
ADDITIONAL EXPERT DESIGNATIONS on the following individual(s):

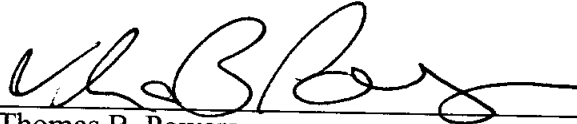
John Fabry, Esq.
Williams Bailey Law Firm, LLP
8441 Gulf Freeway, Suite 600
Houston, TX 77017-5001

Vincent Matanoski, Esq.
Mark Raby, Esq.
US Department of Justice
Torts Branch, Civil Division
1425 New York Avenue NW
Suite 3100
Washington DC, 20005

Ghada Anis, Esq.
Petitioners' Steering Committee
The Kim Law Firm
4309 Yoakum Blvd, Suite 2000
Houston, TX 77006

By United Parcel Service, next day delivery.

WILLIAMS LOVE O'LEARY CRAINE & POWERS, P.C.



Thomas B. Powers
Of Attorneys for Petitioners' Steering Committee

cc: George Hastings
U.S. Court of Federal Claims
Office of the Special Master
1440 New York Avenue, NW
Suite 200
Washington, D.C. 20005