# Fred David Ledley, M.D.

# curriculum vitae

Center for Integration of Science and Industry
Departments of Natural & Applied Sciences, Management
Bentley University

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#### **CURRENT POSITIONS**

Director, Center for Integration of Science and Industry, Bentley University, 2012-present. Professor, Department of Natural and Applied Sciences, Bentley University. Waltham, MA, 2005-present. Department Chair, 2005-2011.

Professor, Department of Management, 2012-present.

Member, Board Chair, National Biomedical Research Foundation. Waltham, MA<sup>1</sup>

#### **PREVIOUS POSITIONS**

2002-2004	Founder and Chairman, Mygenome, Inc. Needham, MA
2000-2002	Co-founder, Chief Scientific Officer, Director, Framingham Genomic
	Medicine, Framingham, MA
1999-2000	Acting Medical Director/Consultant GENEMEDICINE, Burlingame, CA
1996-1999	President, Director, Chief Operating Officer (1996), Chief Executive Officer
	(1997-1999), VARIAGENICS, INC., (Nasdaq:VGNX) Cambridge MA.
1993-1996	Scientific Co-founder, Vice President, Research & Development,
	GENEMEDICINE, INC. (Nasdaq:GMED) The Woodlands, TX.
1985-1992	Assistant Investigator, Howard Hughes Medical Institute. Houston, TX.
1988-1995	Associate Professor (tenured), Department of Cell Biology, Baylor College
	of Medicine, Houston, TX. Associate Professor, Department of Pediatrics,
	Texas Children's Hospital, Baylor College of Medicine, Houston, TX.
1985-1988	Assistant Professor, Department of Cell Biology, Baylor College of Medicine,
	Houston, TX.

#### **EDUCATION**

M.D. Georgetown University School of Medicine, 1978

B.S. University of Maryland (College Park), 1974;

Citation in General Honors, Academic Honors (Cum Laude)

#### **RESEARCH AND CLINICAL TRAINING**

<sup>1</sup> Member 1980-present, Board of Directors, 1980-present, Board Chair 2005-present.

#### Postdoctoral research

Dr. Savio Woo, Department of Cell Biology. Baylor College of Medicine, Howard Hughes Medical Institute Post-Doctoral Fellow.

1981-1983 Dr. David Baltimore, Center for Cancer Research, Massachusetts Institute of Technology. American Cancer Society Post Doctoral Fellowship.

# Clinical training

1981-1983 Research Fellow in Genetics, Clinical Fellow Medicine (Pediatrics), Children's Hospital; Clinical Fellow in Pediatrics, Harvard Medical School; Recipient of Charles A. Janeway Scholarship (1981-1983).

1978-1981 Internship and Residency (PL-1, PL-2, PL-3) in Medicine (Pediatrics), Children's Hospital; Clinical Fellow in Pediatrics, Harvard Medical School

# Graduate and undergraduate research

1975-1978 Student Research with Dr. Leonard Kohn, National Institute of Arthritis Metabolism and Digestive Diseases, National Institutes of Health; Dr. Caroline Hardegree, Food and Drug Administration

1972-1974 Summer Research with Dr. Margaret Dayhoff on Atlas of Protein Sequence and Structure; Dr. Robert Ledley on Computer applications in Medicine, National Biomedical Research Foundation, Georgetown University

# PROFESSIONAL ACTIVITIES (selected)

Fellow, American Association for the Advancement of Science, 2013

Member: "Committee on Preparing the Next Generation of Policy Makers for Science-Based Decisions" National Academy of Sciences, 2014-present

Board of Overseers, Children's Hospital, Boston, 2000-2003

Massachusetts Biotechnology Council, Board of Directors, 1998-2001

Advisory Committee on Predictive Medicine, National Institute Child Health and Human Development (NICHD), 1999-2000

Advisor to National Children's Study, NICHD, 2000-2003

Biotechnology Industry Organization, Regulatory Affairs Committee, Government Affairs Committee, Bioethics Committee, 1994-2001

Council of Society for Pediatric Research (elected), 1993–1997

Genetics Advisory Committee, American Academy of Pediatrics, 1993

National Advisory Panel, "Conference on Genetics, Religion, and Ethics"; Institute of Religion, Institute for Human Genetics, Baylor College of Medicine, 1991-1992 Co-chair of Houston study group, 1990-1993

National Advisory Committee, Protein Identification Resource (PIR), National Biomedical Research Foundation, Georgetown University, 1989-2000

### at Bentley University/academic (selected since 2005)

Advisory Board: Dan & Jeanne Valente Center for Arts & Sciences, 2005-2008, 2012-present

Institutional Review Board, 2008-present

Bentley Safety Committee, 2010-present

Global Business Ethics Teaching Workshop, Bentley University, May, 2010

Academic Affairs Strategic Planning, 2005-2011

TIME Magazine/Bentley Leadership Forum Organizing Committee, 2007-2010

# at Bentley University/diversity

Spiritual Life Advisory Committee, 2005-present

Bentley Diversity Retreat, May, 2011

Diversity Curriculum Taskforce, 2009

ALLY 2007-present (support for LGBTQ students) ALLY workshop, 2007

### at Baylor College of Medicine (selected 1983-1993)

Scientific Advisory Committee, General Clinical Research Center, Texas Children's Hospital, 1987-1993

Recombinant DNA Safety Committee, Baylor College of Medicine, 1990-1993

Radiation Safety Committee, Baylor College of Medicine, 1989-1993

Biosafety Committee, Texas Children's Hospital, 1992-1993

Graduate Education Committee, Department of Cell Biology (directed department graduate program), Baylor College of Medicine, 1986-1990

# **COURSES TAUGHT (at Bentley University)**

Human Biology (NASC 110) Department of Natural and Applied Science. Undergraduate course in human biology designed for business students.

Innovating the Future (NASE 398, experimental) Department of Natural and Applied Sciences. Undergraduate course on emerging science and the impact of disruptive innovations on business and management. 2007-present

Management of Technology (MG 646) Department of Management, Graduate course on strategies and techniques for technology management. 2010-present

Valente Seminar: Seminar course focused on textual analysis and critical thinkings.

Readings included Adam DeTocqueville <u>Democracy in America</u> and Michael Sandel <u>Democracy's Discontent: America in Search of a Public Philosoph.</u> Fall 2013

# PRESENTATIONS AND WORKSHOPS (selected since 2010)

- "Ownership and Sharing of Synthetic Biology: Setting the Patent Framework for Innovation in Synthetic Biology, A Workshop." National Academy of Sciences/Imperial College, London, UK, July 2013.
- "Development of a Science Course for Professional Schools." National Academy of Sciences, 2012-2014.
- "Conducting Impactful Cross-Cultural Research: A Workshop on Scientific Mindfulness" Annual Meeting of the Academy of Management Meetings, Orlando, FL, August 2013.
- "Data analytics and technology life cycles in biopharmaceutical development." Big Data and Analytics in Pharma conference, Philadelphia PA, June 2013.
- "Quality management in educational organizations; building from the ground up" for

- the AAC&U, Network for Academic Renewal conference: "General Education and Assessment: A Sea Change in Student Learning." Boston, MA, February, 2013 with Dr. James Salsbury, Bentley University.
- "The "Sputnik Moment"—then and now." AAC&U National meeting: "Shared futures/difficult choices, reclaiming a Democratic Vision for College Learning, Global Engagement, and Success." Washington, D.C., January 25-28, 2012 with Dr. Roger Launius, Smithsonian Institution, George Fishman, Bentley University.
- "Bridging the Boundary between Science and Industry through Education" Third International Conference on Science and Society, Catholic University, Washington DC, August, 2011.
- "Innovation and Design: Making Room in a Crowded Curriculum for the Big Questions" for the AAC&U conference: "Arts & Humanities: Toward a Flourishing State?" Providence, RI, November, 2011 with Drs. Maureen Goldman and Gesa Kirsch, Bentley University.
- "Making Science Work" Department of Biology, University of Massachusetts, Lowell, February, 2011.
- "Engaging Science Continued: What institutions are doing to advance STEM learning" AAC&U National Meeting, Washington, DC, January 2010.

# **MEDICAL LICENSE**

State of Maryland, 1978-present State of Texas, 1985-1996 (voluntarily discontinued in 1996 on moving to Massachusetts)

# **PUBLICATIONS**

- 1. **Ledley, F.D.,** Wilson, J.B. (1974) Computer analysis of ultrasound cardiograms. Computers in Biology and Medicine 4:27-41.
- 2. Mullin, B.R., Lee, G., **Ledley, F.D.**, Winand, R.J., Kohn, L.D. (1976) Thyrotropin interactions with human fat cell membrane preparations and the finding of a soluble thyrotropin binding component. *Biochemical and Biophysical Research Communications* 69:55-62.
- 3. Mullin, B.R., Fishman, P.H., Lee, G., Aloj, S.M., **Ledley, F.D.**, Winand, R.J., Kohn, L.D., Brady, R.O. (1976) Thyrotropin-ganglioside interactions and their relationship to the structure and function of thyrotropin receptors. *Proceedings of the National Academy of Science USA* 73:842-846. www.ncbi.nlm.nih.gov/pmc/articles/PMC336015/pdf/pnas00672-0184.pdf
- 4. **Ledley, F.D.**, Mullin, B.R., Lee, G., Aloj, S.M., Fishman, P.H., Hunt, L.T., Dayhoff, M.O., Kohn, L.D. (1976) Sequence similarity between cholera toxin and the glycoprotein hormones: implications for structure activity relationships and the mechanism of action. *Biochemical Biophysical Research Communications* 69:852-859.
- 5. Meldolesi, M.F., Fishman., P.H., Aloj, S.M., **Ledley, F.D.**, Lee, G., Bradley, R.M., Brady, R.O., Kohn, L.D. (1977) Separation of the glycoprotein and ganglioside components of thyrotropin receptor activity in plasma membranes. *Biochemical Biophysical Research Communications* 75:581-588.
- 6. Kohn, L.D., Lee, G., Grollman, E.F., Ledley, F.D., Mullin, B.R., Friedman, R.M., Aloj,

- S.M., Meldolesi, M.F., Mullin, B.R. (1977) Membrane glycolipid and their relationship to the structure and function of cell surface receptors for glycoprotein hormones, bacterial toxins, and interferon. In: Harmon, R.E. Cell surface carbohydrate chemistry. Academic Press, San Francisco.
- 7. **Ledley, F.D.**, Lee, G., Kohn, L.D., Habig, W.H., Hardegree, M.D. (1977) Tetanus toxin interactions with thyroid plasma membranes: implications for the structure and function of tetanus toxin receptors and potential pathophysiological significance. *Journal of Biological Chemistry* 252:4029-4055. www.jbc.org/content/252/12/4049.full.pdf
- 8. Habig, W.H., **Ledley, F.D.**, Grollman, E.F., Meldolesi, M.F., Aloj, S.M., Hardegree, M.C., Kohn, L.D. (1978) Tetanus toxin interactions with the thyroid: decreased toxin binding to membranes from a thyroid tumor with a thyrotropin receptor defect and *in vivo* stimulation of thyroid function. *Endocrinology* 102:844-851.
- 9. Hunt, L.T., **Ledley, F.D.**, Dayhoff, M.O. (1979) Hormones and active peptides. In: Dayhoff, M.O. (ed.): Atlas of Protein Sequence and Structure, Vol. 5, supplement 3. National Biomedical Research Foundation, Washington, D.C.
- Kohn, L.D., Consiglio, E., DeWolf, M.J.S., Grollman, E.F., Ledley, F.D., Lee, G., Morris, N.P. (1980) Thyrotropin receptors and gangliosides. In: Svennerholm, L., Mardel, P., Dreyfus, H., Urban, P.F. (eds): Structure and Function of Gangliosides, Advances in Experimental Medicine, Vol. 125, Plenum Press, New York. pp. 487-504.
- 11. **Ledley, F.D.** (1982) Evolution and the human tail, a case report. The New England Journal of Medicine 306:1212-1215. [also correspondence: 307:1089-1090.]
- 12. **Ledley, F.D.** (1983) Recombinant DNA and the Copernican world view. *Perspectives in Biology and Medicine* 26:245-260.
- 13. Wang, J.Y.J., **Ledley, F.D.**, Goff, S., Lee, R., Groner, Y., Baltimore, D. (1984) The mouse c-abl locus: Molecular cloning and characterization. *Cell* 36:349-356.
- Ledley, F.D. (1984) Metabolic disease. In: Graef, J.W., Cone, T.E. (eds): Manual of Pediatric Therapeutics, third edition, Little, Brown and Company, Boston. pp. 341-350.
- 15. **Ledley, F.D.**, Levy, H.L., Shih, V.E., Benjamin, R., Mahoney, M.J. (1984) Benign methylmalonic aciduria. *New England Journal of Medicine* 311:1015-1018.
- 16. DiLella, A.G., **Ledley, F.D.**, Rey, F., Munich, A., Woo, S.L.C. (1985) Detection of phenylalanine hydroxylase messenger RNA in PKU liver biopsy samples from patients with phenylketonuria. *Lancet* 19:160-161.
- 17. Kwok, S.C.M., **Ledley, F.D.**, DiLella, A.G., Robson, K.J.H., Woo, S.L.C. (1985) Nucleotide sequence of a full-length cDNA clone and amino acid sequence of human phenylalanine hydroxylase. *Biochemistry* 24:556-561.
- 18. **Ledley, F.D.**, Grenett, H.E., DiLella, A.G., Kwok, S.C.M., Woo, S.L.C. (1985) Gene transfer and expression of human phenylalanine hydroxylase. Science 228:77-79. www.sciencemag.org/content/228/4695/77.full.pdf
- 19. Woo, S.L.C., Güttler, F., **Ledley, F.D.**, Lidsky, A.S., Kwok, S.C.M., DiLella, A.G., and Robson, K.J.H. (1985) The human phenylalanine hydroxylase gene. In: Berg, K. (ed.) Vol. 177 *Medical Genetics Past, Present, Future*. Alan R. Liss, New York. pp. 123-138.
- 20. **Ledley, F.D.**, Woo, S.L.C., Güttler, F. (1985) Cloning and expression of the human phenylalanine hydroxylase gene. In: Bickel, H., Wachtel, U.: *Inherited Diseases of Amino Acid Metabolism*. Georg Thieme Verlag, Stuttgart, New York. pp. 37-50.

- 21. DiLella, A.G., **Ledley, F.D.**, Woo, S.L.C. (1985) Prenatal Diagnosis and Carrier Detection of Phenylketonuria by Gene Mapping. In: H. Koprowski, S. Ferrone, and A. Albertini (eds) *Biotechnology in Diagnostics*. Elsevier Science Publishers, Rome, Italy. pp. 295-307.
- 22. **Ledley, F.D.**, DiLella, A.G., Kwok, S.C.M. Woo, S.L.C. (1985) Homology between phenylalanine and tyrosine hydroxylases reveals common structural and functional domains. *Biochemistry* 24:3389-3394.
- 23. Lidsky, A., **Ledley, F.D.**, DiLella, A.G., Kwok, S.C.M., Daiger, S.P., Robson, K.J.H., Woo, S.L.C. (1985) Extensive restriction site polymorphisms in the human phenylalanine hydroxylase locus and application in prenatal diagnosis of phenylketonuria. *American Journal of Human Genetics* 37:619-634. www.ncbi.nlm.nih.gov/pmc/articles/PMC1684630/pdf/ajhg00159-0005.pdf
- 24. **Ledley, F.D.**, DiLella, A.G., Woo, S.L.C. (1985) Molecular biology of phenylalanine hydroxylase and phenylketonuria. *Trends in Genetics* 1:309-313.
- 25. **Ledley, F.D.**, Grenett, H.E., McGinnis-Shelnutt, M., Woo, S.L.C. (1986) Retroviral mediated gene transfer of human phenylalanine hydroxylase into NIH3T3 and hepatoma cells. *Proceedings of the National Academy of Sciences*, 83:409-413. www.pnas.org/content/83/2/409.full.pdf
- 26. **Ledley, F.D.**, DiLella, A.G., Woo, S.L.C. (1986) Molecular biology of phenylalanine hydroxylase and phenylketonuria. In: Y. Tsukata (ed) The Ninth International Symposium on Brain Sciences. *Molecular Genetics in Developmental Neurobiology*. Japan Scientific Societies Press (JSSP), Tokyo, Japan. pp. 201-214.
- 27. DiLella, A.G., Kwok, S.C.M., **Ledley, F.D.**, Marvit, J., Woo, S.L.C. (1986) Molecular structure and polymorphic map of the human phenylalanine hydroxylase gene. *Biochemistry* 25:743-749.
- 28. **Ledley, F.D.**, Levy, H., Woo, S.L.C. (1986) Molecular analysis of the inheritance of phenylketonuria and mild hyperphenylalaninemia in families with both disorders. *New England Journal of Medicine* 314:1276-1280.
- 29. **Ledley, F.D.**, Woo, S.L.C. (1986) Molecular basis of alpha<sub>1</sub>-antitrypsin deficiency and its potential therapy by gene transfer. *Journal of Inherited and Metabolic Disease* 9(suppl 1):85-91.
- 30. **Ledley, F.D.** (1987) Somatic gene therapy for human disease: background and prospects (Part I). *Journal of Pediatrics* 110:1-8. *ibid* (Part II). *Journal of Pediatrics* 110:167-174.
- 31. Güttler, F., Lidsky, A.S., **Ledley, F.D.**, DiLella, A.G., Sullivan, S.E., Woo, S.L.C. (1987) Correlation between polymorphic DNA haplotypes at phenylalanine hydroxylase locus and clinical phenotypes of phenylketonuria. *Journal of Pediatrics* 110:68-71.
- 32. **Ledley, F.D.**, Woo, S.L.C. (1987) P-chlorophenylalanine does not inhibit production of recombinant human phenylalanine hydroxylase in NIH3T3 cells or *E. Coli. Biochemical and Biophysical Research Communications* 142:302-308.
- 33. **Ledley, F.D.**, Grenett, H.E., Woo, S.L.C. (1987) Biochemical characterization of recombinant human phenylalanine hydroxylase produced in *E. Coli. Journal of Biological Chemistry* 262:2228-2233.
- 34. **Ledley, F.D.**, Hahn, T., Woo, S.L.C. (1987) Selection for phenylalanine hydroxylase activity in cells transformed with recombinant retrovirus. *Somatic Cell and Molecular Genetics* 13:145-154.

- 35. Lockyer, J., Cook, R.G., Milstein, S., Kaufman, S., Woo, S.L.C., **Ledley, F.D.** (1987) Structure and expression of human dihydropteridine reductase. *Proceedings of the National Academy of Science USA* 84:3329-3333. www.pnas.org/content/84/10/3329.full.pdf
- 36. **Ledley, F.D.** (1987) Somatic gene therapy for human disease: a problem of eugenics? *Trends in Genetics* 3:112-115.
- 37. Marvitt, J., DiLella, A.G., Brayton, K., **Ledley, F.D.**, Robson, K.J., Woo, S.L.C. (1987) GT to AT transition at a splice donor site causes skipping of the preceding exon in phenylketonuria. *Nucleic Acids Research* 15:5613-5628.
- 38. **Ledley, F.D.**, Darlington, G.J., Hahn, T., Woo, S.L.C. (1987) Retroviral gene transfer into primary hepatocytes: implications for genetic therapy of liver specific functions. *Proceedings of the National Academy of Science USA* 84:5335-5339. www.pnas.org/content/84/15/5335.full.pdf
- 39. **Ledley, F.D.**, Grenett, H.E., Bartos, D.P., van Tuinen, P., Ledbetter, D.H., Woo, S.L.C. (1987) Assignment of human tryptophan hydroxylase locus to chromosome 11: gene duplication and translocation in evolution of the aromatic amino acid hydroxylases. *Somatic Cell and Molecular Genetics* 13:575-580.
- 40. Grenett, H.E., **Ledley, F.D.**, Reed, L.L., Woo, S.L.C. (1987) Full length cDNA for rabbit tryptophan hydroxylase: functional domains and evolution of aromatic amino acid hydroxylases. *Proceedings of the National Academy of Science USA* 84:5530-5534. www.pnas.org/content/84/16/5530.full.pdf
- 41. Güttler, F., DiLella, A.G., **Ledley, F.D.**, Lidsky, A.S., Kwok, S.C., Marvit, J., Woo, S. (1987) Molecular Biology of Phenylketonuria. *European Journal of Pediatrics* 146(sup1):5-11.
- 42. MacDonald, M.E., Anderson, M.A., Lockyer, J.L., Milstein, S., Hobbs, W.J., Faryniarz, A.G., Kaufman, S., **Ledley, F.D.**, Woo, S.L.C., Gusella, J.F. (1987) Physical and Genetic Localization of the quinonoid dihydropteridine reductase gene (QDPR) on the short arm of chromosome-4. *Somatic Cell and Molecular Genetics* 13:569-574.
- 43. **Ledley, F.D.**, Grenett, H.E., Bartos, D.P., Woo, S.L.C. (1987) Retroviral mediated transfer and expression of human alpha<sub>1</sub>-antitrypsin in cultured cells. *Gene* 61:113-118.
- 44. Bao, J.J., Sifers, R.N., Kidd, V.J., **Ledley, F.D.**, Woo, S.L.C. (1987) Molecular evolution of serpins: homologous structure of the human alpha<sub>1</sub>-antichymotrypsin and alpha<sub>1</sub>-antitrypsin genes. *Biochemistry* 26:7755-7759.
- 45. Woo, S.L.C., DiLella, A.G., Marvit, J., **Ledley, F.D**. (1987) Molecular Basis of Phenylketonuria and recombinant DNA strategies for therapy. *Enzyme* 38:207-213.
- 46. **Ledley, F.D.**, Grenett, H.E., Woo, S.L.C. (1987) Structure of aromatic amino acid hydroxylases. In: S. Kaufman (ed.) *Amino Acids in Health and Disease: New Perspectives*. UCLA symposia on molecular and cellular biology New Series V. 55. Alan R. Liss, New York. pp.267-284.
- 47. **Ledley, F.D.** Woo, S.L.C. (1987) Prospects for somatic gene therapy of phenylketonuria. In: S. Kaufman (ed.) Amino Acids in Health and Disease, New Perspectives. UCLA symposia on molecular and cellular biology New Series V. 55. Alan R. Liss, New York. pp. 565-580.
- 48. Woo, S.L.C., DiLella, A.G., Marvit, J., Ledley, F.D. (1987) Molecular basis of

- phenylketonuria and potential somatic gene therapy. Cold Spring Harbor Symposium in Quantitative Biology 51:395-401.
- 49. McDonald, J.D., Cotton, R.G., Jennings, I., **Ledley, F.**, Woo, S.L.C., Bode, V.C. (1988) Biochemical defect of the hph-1 mouse mutant is a deficiency of GTP-cyclohydrolase activity. *Journal of Neurochemistry* 50:655-657.
- 50. **Ledley, F.D.**, Lumetta, M.R., Zoghbi, H.Y., VanTuinen, P., Ledbetter, S.A., Ledbetter, D.H. (1988) Mapping of human methylmalonyl CoA mutase (MUT) locus on chromosome 6. *American Journal of Human Genetics* 42:839-846. www.ncbi.nlm.nih.gov/pmc/articles/PMC1715214/pdf/ajhg00129-0047.pdf
- 51. **Ledley, F.D.** Woo, S.L.C. (1988) Reconsidering the genetics of phenylketonuria. In: Wurtman, R.J. and Ritter-Walker, E. (eds) *Dietary Phenylalanine and Brain Function*. *Birkhauser*, Boston/Basel. pp. 228-237.
- 52. **Ledley, F.D.**, Lumetta, M., Nguyen, P.N., Kolhouse, J.F., Allen, R.A. (1988) Molecular cloning of L-methylmalonyl CoA mutase: gene transfer and analysis of mut cell lines. *Proceedings of National Academy of Science* 85:3518-21. www.pnas.org/content/85/10/3518.full.pdf
- 53. **Ledley, F.D.**, Ledbetter, S.A., Ledbetter, D.H., Woo, S.L.C. (1988) Localization of mouse phenylalanine hydroxylase locus on chromosome 10. *Cytogenetics and Cell Genetics* 47:125-126.
- 54. **Ledley, F.D.**, Koch, R., Beaudet, A., O'Brien, W., Bartos, D., Woo, S.L.C. (1988) Phenylalanine hydroxylase expression in the liver of a fetus with phenylketonuria. *Journal of Pediatrics* 113:463-467. [letter: **Ledley, F.D.** (1989) Genetic Counseling and the Outcome of Phenylketonuria. *Journal of Pediatrics* 114:684-685.]
- 55. Zoghbi, H., O'Brien, W.E., **Ledley, F.D.** (1988) Linkage relationships of the human methylmalonyl CoA mutase to the HLA and D6S4 loci on chromosome 6. *Genomics* 3:396-398.
- 56. Jansen, R., Kalousek, F., Fenton, W., Rosenberg, L.E., **Ledley, F.D.** (1989) Cloning of full-length methylmalonyl-CoA mutase from a cDNA library using the polymerase chain reaction. *Genomics* 4:198-205.
- 57. Peng, H., Armentano, D., Graham, L., **Ledley, F.D.**, Woo, S.L.C. (1988) Retroviral-mediated gene transfer and expression of human phenylalanine hydroxylase in primary mouse hepatocytes. *Proceedings of the National Academy of Sciences USA* 85:8146-8150. www.pnas.org/content/85/21/8146.full.pdf
- 58. Cheng, S.V., Martin, G.R., Nadeau, J.H., Haines, J.L., Bucan, M., Kozak, C.A., MacDonald, M.E., Lockyer, J.L., **Ledley, F.D.**, Woo, S.L.C., Lehrach, H., Gilliam, T.C., Gusella, J.F. (1989) Synteny on mouse chromosome 5 of human loci linked to Huntington's Disease. *Genomics* 4:419-426.
- 59. Jansen, R., **Ledley, F.D.** (1989) Production of high specific activity DNA probes by the polymerase chain reaction. *Gene Analysis Techniques* 6:79-83.
- 60. **Ledley, F.D.** (1989) Human gene therapy In: Jacobson, G.K., Jolly S.O. (eds) *Biotechnology, a comprehensive treatise*, Vol 7b. VCH Verlagsgesellschaft. Weinheim, pp. 399-461.
- 61. Armentano, D., Peng, H., MacKenzie-Graham, L., Seh, M., Shen, R-F., **Ledley, F.D.**, Darlington, G.J., Woo, S.L.C. (1989) Retroviral-mediated gene transfer of human PAH into mouse primary hepatocytes. In: A.L. Beaudet, R. Mulligan, I.M. Verma (eds) Gene Transfer and Gene Therapy. Alan R. Liss, New York. pp. 355-363.

- 62. **Ledley, F.D.** (1989) Molecular Genetic Studies in Methylmalonic acidemia. UCLA symposium on gene transfer in animals. In: A.L. Beaudet, R. Mulligan, I.M. Verma (eds) Gene Transfer and Gene Therapy. Alan R. Liss, New York. pp. 335-344.
- 63. **Ledley, F.D.** (1990) Prospects for somatic gene therapy in the management of inborn errors of metabolism. In: Fernandes, J., Bremer, H.J., Saudubray, J.M. (eds): *Inherited metabolic disease. Diagnosis and treatment*. Springer-Verlag pp. 671-680.
- 64. Sifers, R.N., **Ledley, F.D.**, Reed-Fourquet, L., Ledbetter, D.H., Ledbetter, S.A., Woo, S.L.C. (1990) Complete cDNA sequence and chromosomal localization of mouse alpha<sub>1</sub>-antitrypsin. *Genomics* 6:100-104.
- 65. **Ledley, F.D.**, Grenett, H.E., Dunbar, B.S. Woo, S.L.C. (1990) Mouse phenylalanine hydroxylase: homology and divergence from human phenylalanine hydroxylase. *The Biochemical Journal* 267:399-406. www.ncbi.nlm.nih.gov/pmc/articles/PMC1131302/pdf/biochemj00185-0123.pdf
- 66. **Ledley, F.D.**, Crane, A.M., Lumetta, M. (1990) Heterogenous alleles and expression of methylmalonyl CoA mutase in mut methylmalonic acidemia. *American Journal of Human Genetics* 46:539-547. www.ncbi.nlm.nih.gov/pmc/articles/PMC1683614/pdf/ajhg00100-0137.pdf
- 67. Threadgill, D.W., Wilkemeyer, M.F., Womack J.E., **Ledley, F.D.** (1990) Localization of the murine methylmalonyl CoA mutase (*Mut*) locus on chromosome 17 by in situ hybridization. *Cytogenetics and Cell Genetics* 53:112-114
- 68. Sertic, J., Vincek, V., **Ledley, F.D.**, Figueroa, F., Klein, J. (1990) Mapping of the L-methylmalonyl CoA mutase gene to mouse chromosome 17. *Genomics* 6:560-564.
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<sup>&</sup>lt;sup>3</sup> Dr. Ledley led a team that proposed creation of a registry for patients enrolled in gene therapy trials to facilitate adverse event reporting. This proposal was reviewed favorably by the RAC, but not funded. This article, derived from the RAC proposal, describes the foundation for such a registry.

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- 14. **Ledley, F.D.** (1993) review of: Ahrens A.H. "The Crisis in Clinical Research" *The American Journal of Human Genetics*. 52:632-633. www.ncbi.nlm.nih.gov/pmc/articles/PMC1682170/pdf/ajhg00061-0187.pdf
- 15. **Ledley, F.D.** (1993) review of: Kevles and Hood "The Code of Codes: Scientific and Social Issues in the Human Genome Projec" *The New England Journal of Medicine*. 329:584-585, 3. www.nejm.org/doi/full/10.1056/NEJM199308193290821

#### **US PATENTS**<sup>4</sup>

#### Issued patents

- 1. Singer, D.S., Kohn, L.D., Mozes, E., Saji, M., Weisman, J., Napolitano, G., and **Ledley**, **F.D.** Methods for Assessing the Ability of a Candidate Drug to Suppress MHC Class Expression. #5,556,754. Method for treating inflammatory diseases and transplantation.
- 2. Singer, D.S., Kohn, L.D., Mozes, E., Saji, M., Weissman, J., Napolitano, G., and Ledley, F.D. Methods of treating autoimmune diseases and transplantation rejection. #5,871,950. Method for treating inflammatory diseases and transplantation.
- 3. **Ledley, F.D.** and O'Malley, B.O. Jr., Somatic Gene Therapy to Cells Associated With Fluid Spaces. # 5,770,580. Methods for somatic gene therapy targeted to joints, thyroid, eye, and ear.
- 4. **Ledley, F.D.** and O'Malley, B.O. Jr., Transformation of cells association with fluid spaces. #5,792,751. Methods for somatic gene therapy targeted to joints, thyroid, eye, and ear.
- 5. **Ledley, F.D.** and Henning, S.J. Gene Therapy Using the Intestines. #5,821,235 Methods for orally administered gene therapy
- 6. **Ledley, F.D.** and Henning, S.J. Gene Transfer to Intestines. #5,786,340 Methods for orally administered gene therapy.
- 7. Housman, D.E., **Ledley, F.D.**, Stanton, V.P. Inhibitors of Alternative Alleles of Genes Encoding Products that Mediate Cell Response to Environmental Changes. #6,200,754. Methods for developing drugs targeted to normal genetic variations.
- 8. **Ledley, F.D.** and Stankovics, J. Natural or Recombinant DNA Binding Proteins as Carriers for Gene Transfer or Gene Therapy. #6,191,257. Bifunctional proteins for gene therapy with DNA binding activity and trophism for membrane receptors.
- 9. **Ledley, F.D.** Method for increasing utilization of genetic testing. #8,483,966. Information systems that provide consumers with direct access to genetic tests and services. (Continuation pending)
- 10. **Ledley, F.D.** Instruments and methods for obtaining informed consent to genetic tests. 8,438,042. Information systems that provide patient education and obtain informed consent for genetic testing. (Continuation pending)

#### Patents pending and published

11. **Ledley, F.D.** Methods for providing current assessments of genetic risk. US 2003/0040002. Information systems that provide updated assessment of genetic risk based on genetic test results and emerging clinical data.

<sup>&</sup>lt;sup>4</sup> Dr. Ledley is also inventor on international patent filings and patent linked to US patents listed above.

#### **BLOGS**

- 1. **Ledley, F.D.** (2013) Biotech: Not just for geeks. www.bentley.edu/impact/articles/biotech-not-just-geeks
- 2. **Ledley, F.D.** (2013) What courses matter most in college? Learning in unexpected places. www.bentley.edu/impact/articles/what-courses-matter-most-college
- 3. **Ledley, F.D.** (2013) Why innovation is stuck in slow motion. Creating economic growth from the third industrial revolution. www.bentley.edu/impact/articles/why-innovation-stuck-slow-motion
- 4. **Ledley, F.D.** (2013) An entrepreneur's view on the effects of GDP revisions on R&D investment and the economy. www.bentley.edu/impact/articles/rd-stimulus
- 5. **Ledley, F.D.** (2014) Defining College Value in Preparing for Change Reassessing the value of college graduation for millennials after the Great Recession http://www.bentley.edu/impact/articles/defining-college-value-preparing-changeh
- 6. **Ledley, F.D.** (2013) Could Human Genome Sciences have become Standard Oil? www.scienceandindustry.org
- 7. **Ledley, F.D.** (2014) Why does society support science, and how to repay this support. www.scienceandindustry.org
- 8. **Ledley, F.D.** (pending) Sophisticated Management Driving the Rapidly Increasing Pace of Change.

#### **CREATIVE WORKS**

Sputnik's Child by Fred Ledley, (a novel) CreateSpace:November 2011, 334 pages. ISBN (paperback): 978-1453653869, ISBN (Kindle) 1453653864, ISBN (e-book) 9781466061583.
www.sputnikschild.com From the back cover: "This engaging novel recalls the events that shaped the ideas and lives of the baby boom generation and laid the groundwork for an age of technology and its challenges."

# Recognition of Sputnik's Child:

"Outstanding Scholarly Contribution; in recognition of contributions to academic excellence at Bentley University," 2012.

"Certified Space Imagination Product," National Space Foundation, 2012.

# **Committee on Energy and Commerce** U.S. House of Representatives Witness Disclosure Requirement - "Truth in Testimony"

Required by House Rule XI, Clause 2(g)

1.	Your Name: Fred David Ledley				
2.	Are you testifying on behalf of the Federal, or a State or local government entity?	Yes	No X		
3.		Yes	No X		
4.	Other than yourself, please list which entity or entities you are represent				
	Not applicable.				
5.	Please list any Federal grants or contracts (including subgrants or subcontracts) that you or the entity you represent have received on or after October 1, 2011:				
	Not applicable				
6.	If your answer to the question in item 3 in this form is "yes," please describe your position or representational capacity with the entity or entities you are representing:				
	Not applicable				
7.	If your answer to the question in item 3 is "yes," do any of the entities disclosed in item 4 have parent organizations, subsidiaries, or partnerships that you are not representing in your testimony?	Yes	No		
8. If the answer to the question in item 3 is "yes," please list any Federal grants or contracts (including subgrants or subcontracts) that were received by the entities listed under the question in item 4 on or after October 1, 2011, that exceed 10 percent of the revenue of the entities in the year received, including the source and amount of each grant or contract to be listed:					
9.	9. Please attach your curriculum vitae to your completed disclosure form.				
Attached					
Signature:					