

DONALD HARVEY MARKS, M.D., Ph.D. CURRICULUM VITAE

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BIRTHDATE: 27 June 1949
BIRTHPLACE: Buffalo, New York
CITIZENSHIP: United States of America

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Clinical Practice of Medicine

Cooper Green Hospital, Birmingham, AL, 2004 to present. Director, Hepatitis Clinic.
Trace Crossings Medical Clinic, Hoover, AL, 2002 to 2006. General medicine, coverage.
Dover Community Clinic, NJ, 1992-1999. General medicine.
Dotoli Medical Group, Nutley, NJ 1989-1991. General medicine and hospital coverage.
Private Practice, Internal Medicine 7-87 to 12-88.
Medical Staff, Letterman Army Hospital, 1984-1987.
Internship and Residency 1980 to 1983. USF Medical Center Keesler.

PHARMACEUTICAL INDUSTRY EXPERIENCE

- 1) Southern Clinical & Regulatory, LLC, President, 1997 to 2006.
- 2) [Vaxin, Inc.](#) Clinical Research Consultant. 2000 to present.
- 3) Emerging Technology Partners, Nov 1997 to Jan 2000, the biotech division of Economic Development Partnership of Alabama, Senior Vice President, Clinical Research and Regulatory Affairs.
- 4) Immunomedics, Inc., Morris Plains, NJ 7-96 to 1-97; Vice President, Clinical Research.
- 5) PerImmune, Inc., Rockville, MD 7-95 to 7-96; Director, Departments of Medical Research, Regulatory Affairs and Clinical Data Management.
- 6) [Connaught Pasteur Merieux](#), Director of Clinical Research, Swiftwater, PA, 3-91 to 7-95
- 7) [Hoffmann-La Roche](#), Associate Director of Clinical Research, Antibacterials 1-89 to 3-91

Clinical Research Experience

- 1) [Cooper Green Mercy Hospital](#), Birmingham, AL. Director of Hepatitis Clinic, Written and currently conducting three IRB-approved investigator-initiated clinical protocols.
- 2) Southern Clinical & Regulatory.
- 3) Emerging Technology Partners, Vaxin, and Tranzyme, as outlined above.
- 4) Letterman Army Institute of Research, Division of Blood Research, Staff Research Physician 6-83 to 6-87.
- 5) Hoffman La Roche, Connaught, Immunomedics, PerImmune, as outlined above.
- 6) USAF Medical Center Keesler, Clinical Research Laboratory, Research Associate 6-80 to 6-83

Academic and Institution Affiliations:

- 1) [Wallace Kettering Neuroscience Institute](#), Kettering, OH, visiting Research Associate, 2005-current.
- 2) University of Alabama, Birmingham.
Biomedical Engineering, 2002.

General Medicine, 2007-present

FDA Experience:

Annual reports, and protocol presentations to CBER, CDER, NIH and NCI
Outside inspections of IND's and NDA's for corporate partners
Preparation of PMAs and 510K for in-vitro diagnostic devices
Preparation of MAA and PLAs for radioimmunodiagnostic agents and ASI
Preparation of INDs.

UNDERGRADUATE EDUCATION

1968-1971 - Santa Monica College
1970-1972 - California State University, San Bernardino, (B.A., December, 1972)

GRADUATE EDUCATION

1972-1973 - University of California, Riverside, [Department of Plant Physiology](#)
1973-1977 - [University of California, Los Angeles, Department of Bacteriology](#), Ph.D.
Microbiology, December 1977. Thesis Area: Comparative Immunology of Graft Rejection

MEDICAL EDUCATION

1976-1980 - [University of California, Los Angeles, School of Medicine](#), (M.D., June 1980)
June 1980-June 1983 - Residency in Internal Medicine, USAF Medical Center, Keesler AFB, MS

MILITARY EDUCATION

Officers Candidate School, June 1976
Medical Indoctrination for Medical Service Officers, June 1980
[Air Command and Staff College](#), graduate, June 1984
Biological Warfare Course, [Ft. Detrick, MD](#)
Biological Warfare refresher course, 1-05

LICENSURES AND CERTIFICATION

[National Board of Medical Examiners](#) #234173, July 1, 1981
Diplomat, [American Board of Internal Medicine](#) 9-13-1989
State: Alabama 23209, exp 31 Dec 08 UPIN: A50384 NPI 1841272309
DEA: BM5726661, exp. 1-31-2010
Mississippi # 9518; exp. 6-30-08
New York 180133-1; exp. 5-31-09
BLS and ACLS recertification 5-05.

PROFESSIONAL ORGANIZATIONS

[American College of Physicians](#), FELLOW, member since 1991
[Academy of Pharmaceutical Physicians and Investigators](#)
[Regulatory Affairs Professional Society](#), member since 2002
[Medical Association of the State of Alabama](#), member since 2000
[American Society of Microbiology](#)

Hospital Affiliations:

[Cooper Green Mercy Hospital](#), Birmingham, AL, Active Staff with admitting privileges. 2004 – present. Committees: Pharmacy and Therapeutics, Hospital Infection Control.

[Brookwood Medical Center](#), Birmingham, Alabama; Active Non-Admit Staff, Department of Medicine, 2004 - present

Patents:

- 1) [US 6348450](#), February 19, 2002. De-Chu Tang, Donald H. Marks, et al. Noninvasive genetic immunization, expression products therefrom and uses thereof.
- 2) US [06706693](#), March 16, 2004. De-Chu Tang, Donald H. Marks, et al. Vaccination by Topical Application of Genetic Vectors.
- 3) US [06716823](#), April 6, 2004: Tang, De-chu C.; Marks, Donald H.; Curiel, David T.; Shi, Zhongkai Noninvasive genetic immunization, expression products therefrom, and uses thereof.

PUBLICATIONS

1. TenEyck R, Schaerdel AD, Lynett JE, Marks DH, et al: Stroma-free methemoglobin solution as an antidote for cyanide poisoning. A preliminary study. *Clinical Toxicology* 21(3):343-358, 1984.
2. Marks DH, et al: Pelvic hematoma after intercourse while on chronic anticoagulation. *Annals of Emergency Medicine* 13:554-556, 1984.
3. Marks DH, Patressi J, Chaudry IH: Effect of pyridoxalated stabilized stroma-free hemoglobin solution on the clearance of intravascular lipid by the reticuloendothelial system. *Circulatory Shock* 16:165-172, 1985.
4. Marks DH, et al: Pyridoxalated polymerized stroma-free hemoglobin solution for hemorrhagic shock in dogs. *Military Med.* 152(5):265-271, 1987.
5. Marks DH, et al: Antibody Response to Transfusion With Pyridoxalated glutaraldehyde-treated Hemoglobin Solution. *Mil Med* 152(9):473-477, 1987.
6. Marks DH, Hou KC: Removal of bacteria from blood. *Military Med.* 152:156-160, 1987.
7. Marks DH, et al.: Optimization of synthesis of pyridoxalated polymerized stroma-free hemoglobin solution. *Mil Med* 153:44-49, 1988.
8. Marks DH et al: Efficiency of Antibacterial Membrane and effect on Blood Components. *Mil Med* 153(7):337-340, 1988.
9. Davidson IJA, Drukkerr S, Hedlund B, Marks DH et al: Deleterious Effects of Stroma-free Hemoglobin Used As Resuscitative Fluid For Rats With Ischemic Intestinal Shock. *Crit Care Med* 16(6):606-609, 1988.

10. Marks DH et al: Removal of Bacteria From Blood By Charcoal Hemoperfusion. J. Biomaterials, Artificial Cells and Artificial Organs. 16(1-3):135-140, 1988.
11. Moore GL, Marks DH, et al: [Ascorbate-2-phosphate in Red Cell Preservation: Clinical Trials and Active Components](#). Transfusion 26(3):221-225, 1988.
12. Marks DH, et al.:Effect of Polymyxin B on *in vivo* hepatotoxicity of hemoglobin. Mil Med 154(4):180-184, 1989.
13. Keller, D, Koster, FT, Marks, DH et al. [Safety and Immunogenicity of a Recombinant Outer Surface Protein A Lyme Vaccine](#). JAMA, June 8, 94, p 1764-1768.
14. Sigal LH, Zahradnik JM, Lavin P, Patella SJ, Bryant G, Haselby R, Hilton E, Kunkel M, Adler-Klein D, Doherty T, Evans J, Molloy PJ, Seidner AL, Sabetta JR, Simon HJ, Klempner MS, Mays J, Marks D, Malawista SE [A vaccine consisting of recombinant Borrelia burgdorferi outer surface protein A to prevent Lyme disease. Recombinant Outer-Surface Protein A. Lyme Disease Vaccine Study Consortium](#). N Engl J Med (1998 Jul 23) 339(4):216-22
15. Kanesa-thasan N, Smucny JJ, Hoke CH, Marks DH, Konishi E, Kurane I, Tang DB Vaughn DW, Mason PW, Shope RE. [Safety and immunogenicity of NYVAC-JEV and ALVAC-JEV attenuated recombinant Japanese encephalitis virus--poxvirus vaccines in vaccinia-nonimmune and vaccinia-immune humans](#). Vaccine (2000 Oct 15) 19(4-5):483-91
16. VanKampen KR, Shi Z, Gao P, Zhang J, Foster KW, Chen DT, Marks D, Elmets CA, and Tang DC. 2004. [Safety and immunogenicity of adenovirus-vectored nasal and epicutaneous influenza vaccines in humans](#). Vaccine. 2005 Jan 11;23(8):1029-36.
17. Marks, DH. [Evaluation of Medical Causation](#), in Drug Injury: Liability, Analysis and Prevention, Second Edition, Chapter 10. O'Donnell JT editor. L&J Publications, 2005
18. Marks DH, Adineh M, Gupta S: [Determination of Truth from Deception Using Functional MRI and Cognitive Engrams](#). The Internet Journal of Radiology [peer-reviewed serial on the Internet]. 2006. Volume 5, Number 1.
19. Marks DH, Adineh M, Wang B, Gupta S, Udupa JK. [Multidimensional Representation of Concepts as Cognitive Engrams in the Human Brain](#). The Internet Journal of Neurology [peer-reviewed serial on the Internet]. 2007. Volume 6, Number 1.
20. Marks DH, Adineh M, Wang B, Gupta S. [Use of fMRI to Predict Psychiatric Adverse Effects of Interferon Treatment for Hepatitis C](#). Neuropsychiatric Disease and Treatment. 2007;3(5) 655-667.
21. Marks DH. Cardiomyopathy Due to Ingestion of Adderall. 2007. Accepted, [American Journal of Therapeutics](#).

22. Marks DH. [Depression Leading to Suicide As An Adverse Effect of Metoclopramide](#). Internet Journal of Gastroenterology [peer-reviewed serial on the Internet]. 2007. Volume 5 Number 2.

23. Marks DH. [Dangers of OTC Herbal Supplements: Dilated Cardiomyopathy](#) after Ingestion of TRIAC (triiodothyroacetic acid, Tiratricol). Internet Journal of Endocrinology [peer-reviewed serial on the Internet]. 2007. Volume 3 Number 2.

Presentations:

6/2/01	ATLA Conference: The Pharmacology and Regulatory Process of Ephedra
1/22/02	Presentation to FDA Office of Vaccine Research and Review, Lymerix Adverse Effects, Bethesda, MD.
2/18/02	Mealey's Vaccine Litigation Conference: March 18-19, 2002, Philadelphia. Thimerosal, and Adverse Event Reporting Handled by Vaccine Manufacturers.
3/12/02	Mealey's PPA & Ephedra Litigation Conference, March 12-13, 2001. Philadelphia. The FDA Regulations Relating to OTC. Herbal Remedies and Prescription Drugs. Part II.
5/10/02	Neuropsychiatric Effects of Accutane, Depression, Seizures, Psychosis & Suicide, Conference, May 10-11, 2002, Birmingham, AL.
7/10/02	Medication Errors and Drug Adverse Effects, Medical Staff Meeting, Brookwood Medical Center, Birmingham, AL. July 10, 2003.
10/4/02	Neuropsychiatric Effects of SSRI Drugs. Seizures, Psychosis & Suicide, October 4-5, 2002, Philadelphia, PA
2/2/04	Adverse Effects of SSRI Drugs, FDA Psychopharmacologic Drugs Advisory Committee, Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee
3/2/04	Medication Adverse Effects. Scientific Session, Medical Association of the State of Alabama, 3-02.
5/25/04	Considerations for Development of Vaccines, Invited Presentation, American College of Physicians meeting, New Orleans, LA.
6/17/04	Chronic Fatigue Syndrome and Fibromyalgia, Brookwood Medical Center, Birmingham, AL.
9/4/04	Hepatitis C Virus Infection: Diagnosis and Treatment, Cooper Green Hospital, Birmingham, AL.
11/9/04	VIOXX Toxicity, Mealeys Conference, Pasadena, CA.
1/5/05	Chronic Fatigue Syndrome, presentation to Dept of Pharmacology, Rush Univ Med Ctr, Chicago, IL.
1/14/05	VIOXX Toxicity, ATLA Conference, Philadelphia, PA
3/22/06	Application of fMRI to Understand Neuropsychopharmacologic Effects of Peg-Interferon alpha-2 & Their Treatment, presentation to Dept Pharmacology, Rush Univ Med Ctr, Chicago
5/10/06	Hepatitis C Virus Infection: Diagnosis and Treatment, Jefferson County Health Department, Birmingham, AL.

6/21/07	Hepatitis C Virus Infection: Diagnosis and Treatment, Brookwood Medical Center, Birmingham, AL
10/14/07	Use of Functional MR Imaging to Predict Psychiatric Adverse Effects of Therapeutic Medications, American College of Legal Medicine, Chicago.
4/18/08	MR Imaging of Drug-Induced Suicidal Ideation; poster presentation at the 2008 annual meeting of the American Association of Suicidology, Boston.