

## **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 2000 to 2008.
- 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 radioimmundiagnostic 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. 6-30-09  
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, 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. <http://www.ispub.com/ostia/index.php?xmlFilePath=journals/ijra/vol5n1/engram.xml>
18. 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. <http://www.ispub.com/ostia/index.php?xmlFilePath=journals/ijn/vol6n1/brain.xml>
19. 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.

20. Marks DH. Cardiomyopathy Due to Ingestion of Adderall. [American Journal of Therapeutics](#). 15(3):287-289, May/June 2008.
21. 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. <http://www.ispub.com/ostia/index.php?xmlFilePath=journals/ijge/vol5n2/depression.xml>
22. 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. <http://www.ispub.com/ostia/index.php?xmlFilePath=journals/ijen/vol3n2/otc.xml>
23. Marks, DH and Milby, J. Interferon and Risk for Drug-Seeking Behavior, Internet Journal of Pain, Symptom Control and Palliative Care [peer-reviewed serial on the Internet]. Accepted 2008.

***Articles Submitted to Peer-Reviewed Journals:***

- *MR Imaging of Drug-Induced Suicidal Ideation*
- *Homicidal Ideation Causally Related To Therapeutic Medications*
- *Treatment of Hepatitis C Virus Infection at an Inner City Hospital*

**Non-Peer Reviewed Articles**

1. 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.
2. Marks DH and Middlekoop T. Accutane: Focus on Psychiatric Toxicity and Suicide, in [Drug Injury: Liability, Analysis and Prevention, Second Edition](#), Chapter 20. O'Donnell JT editor. L&J Publications, 2005.
3. Minimal Length of Exposure to Vioxx Necessary for Toxicity, MEALEY'S LITIGATION REPORT: Arthritis Drugs Vol. 3, #1 June 2006.
4. [Drug-Induced Pancreatitis. CME Activity produced for UAB Department of Medicine. 2008.](#)
5. [Drug-Induced Liver Disease. CME Activity in preparation for UAB Department of Medicine. 2008](#)

6. Marks DH. Interrogation Using Functional MRI and Cognitive Engrams. The Journal of the Institute of Justice and International Studies, Accepted 2008.

**Member of the Editorial Board:**

[The International Journal of Risk & Safety in Medicine](#)

**Presentations:**

6/2/01	The Pharmacology and Regulatory Process of Ephedra; ATLA Conference
1/22/02	Presentation to FDA Office of Vaccine Research and Review, Lymerix Adverse Effects, Bethesda, MD.
2/18/02	Thimerosal, and Adverse Event Reporting Handled by Vaccine Manufacturers, Mealey's Vaccine Litigation Conference: Philadelphia.
3/12/02	FDA Regulations Relating to OTC. Herbal Remedies and Prescription Drugs. Part II. Mealey's PPA & Ephedra Litigation Conference, Philadelphia.
5/10/02	Neuropsychiatric Effects of Accutane, Depression, Seizures, Psychosis & Suicide, Conference, Birmingham, AL.
7/10/02	Medication Errors and Drug Adverse Effects, Medical Staff Meeting, Brookwood Medical Center, Birmingham, AL.
10/4/02	Neuropsychiatric Effects of SSRI Drugs. Seizures, Psychosis & Suicide, 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.
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.
2/19/08	“MR Imaging for Interrogation Of Terror Suspects – Technical and Ethical Aspects,” Conference on <a href="#">TERRORISM &amp; JUSTICE: The Balance for Civil Liberties</a>
4/18/08	<a href="#">MR Imaging of Drug-Induced Suicidal Ideation</a> ; poster presentation at the 2008 annual meeting of the American Association of Suicidology, Boston. MA
5/29/08	Drug-Induced Pancreatitis, presented at Medical Rounds, Brookwood Medical Center, Birmingham, AL
8/14/08	Drug-Induced Liver Disease, presented at Medical Rounds, Brookwood Medical Center, Birmingham, AL
10/8/08	<b>Interferon Treatment for Hepatitis C and Risk for Drug-Seeking Behavior</b> , AMERSA National Conference, Washington, DC <a href="http://www.amersa.org/Conf-at-glance%20225.pdf">http://www.amersa.org/Conf-at-glance%20225.pdf</a>