

# Curriculum Vitae

David W. Feigal, Jr., M.D., M.P.H.

11806 Barranca Road  
Santa Rosa Valley, CA 93012  
+1 (301) 613 2779 (Mobile)  
[Feigal\\_david@msn.com](mailto:Feigal_david@msn.com)

## EDUCATION

Attended	Institution & Location	Degree Granted	Degree Conferred, Title or Status	Subject
1967-71	University of Minnesota Minneapolis, MN	1971	B.A. summa cum laude	Psychology
1971-1976	Stanford University Palo Alto, CA	1976	M.D.	Medicine
1976-1979	University of California, Davis Sacramento, CA		Intern and Resident	Internal Medicine
1982-1983	University of California, Berkeley, CA	1983	M.P.H.	Epidemiology & Biostatistics
1982-1984	University of California, San Francisco, CA		A.W. Mellon Scholar in Clinical Epidemiology	Epidemiology

## LICENSES, CERTIFICATIONS:

1977 -	Medical License: California (# G34473)
1979	Certified, American Board of Internal Medicine (# 71092)

## EMPLOYMENT: PRINCIPAL POSITIONS HELD

1979-80	University of California, Davis	Chief Resident, Medicine
1980-82		Assistant Professor, in Residence of Medicine
1984-85	University of California, San Francisco	Adjunct Assistant Professor of Epidemiology and International Health with joint appointment in Medicine

1986-89		Assistant Professor, in Residence of Medicine with joint appointment in Epidemiology and Biostatistics
1989-91	University of California, San Diego	Associate Clinical Professor of Medicine
1992-96	Food and Drug Administration, Center for Drug Evaluation and Research (CDER)	Director, Division of Anti-Viral Drug Products
1996-97		Acting-Director, Division of Anti-Infective Drug Products
1995-97		Director, Office of Drug Evaluation-IV
1997-99	Food and Drug Administration, Center for Biologics Evaluation and Research (CBER)	Medical Deputy Center Director
1999-2004	Food and Drug Administration, Center for Devices and Radiological Health (CDRH)	Center Director
2004 -06	NDA Partners L.L.C	Partner
2006 - 08	Élan Pharmaceuticals, Inc.	Senior Vice President of Global Regulatory Affairs, Global Safety Surveillance and Biostatistics
2008 - 10	Amgen, Inc.	Vice President of Global Regulatory Affairs
2010 -	NDA Partners L.L.C	Partner

## ANCILLARY POSITIONS HELD CONCURRENTLY:

1980-82	Univ. of California, Davis Department of Medicine	Residency Training Program Coordinator
1984-88	Univ. of California, San Francisco	Associate Director: AW Mellon Program in Clinical Epidemiology
1984-89		Faculty, Institute for Health Policy
1984-89		Adjunct Faculty, Clinical Pharmacology
1986-89		Director, Data Center, AIDS Clinical Research Center
1986-89		Joint Appointment in School of Dentistry
1985-89	San Francisco General Hospital	Chair of Department of Quality Assurance and Risk Management
2004 – 07	Arizona State University	Research Professor, Arizona Biodesign Institute

2005 -		Adjunct Professor, Sandra Day O'Connor School of Law
2005 - 07	University of California, San Diego	Von Liebing Fellow in Entrepreneurship, School of Engineering
2011 - 12	Topica Pharmaceuticals	Chief Medical Officer
2012 -	ExsoMed	Chief Medical Officer
2013 -14	CytoDyn Inc.	Chief Medical Officer

## HONORS AND AWARDS:

1969	Phi Beta Kappa
1981	Junior Faculty Teaching Award (selected by the medical school senior class, UC Davis)
1986	'Outstanding Graduate Student Instructor' (selected by School of Public Health, UC Berkeley)
1997	FDA Award of Merit: "For providing outstanding leadership and management of Office of Review Management resources resulting in rapid delivery of safe, effective new drug products to the public."
1997	CDER Excellence in Communication Award: "For exceptional team efforts in improving communications with Industry and within FDA to facilitate the review and development of safe and effective drugs in the Office of Drug Evaluation IV".
1998	FDA Commissioner's Special Citation: "For design and implementation of the Blood Action Plan to strengthen the safety of the nation's blood supply."
1998	FDA Award of Merit: "For advancing the field of AIDS by leading the collaborative evaluation of HIV-RNA as an endpoint in clinical trials for anti-HIV drugs."
1998	FDA Commendable Service Award: " For exceptional efforts by the Guidance for Industry – Evaluating Clinical Studies of Antimicrobial Drug Products Team leading to consistency in the evaluation of anti-infective drugs.
1999	FDA Group Recognition Award: "For developing guidance for the Fast Track provision of FDAMA to speed availability of products to consumers suffering from serious and life-threatening conditions."
2002	Presidential Executive Rank Award : "For Sustained Outstanding Performance."
2005	Health and Human Service Secretary's Award for Distinguished Service for the Tissue Action Plan
2011	Regulatory Affairs Professional Society: Honorary Fellow (the first such award)

## UNIVERSITY SERVICE:

### UC DAVIS CAMPUS WIDE:

1980-82          Human Subjects Committee

### UC DAVIS SCHOOL OF MEDICINE:

1980-82          Educational Advisory Committee

1982             Physicians Advisory Committee to the Hospital Information System

### UC DAVIS DEPARTMENT OF MEDICINE:

1979-82          Third year Medicine Clerkship Committee

1979-82          Intern and Resident Selection Committee: (Chair 1980-1982)

1981-82          Residency Review Committee: (Chair)

### UC SAN FRANCISCO SYSTEM-WIDE:

1985             University-wide Task Force on AIDS: Study Section

### UC SAN FRANCISCO SAN FRANCISCO GENERAL HOSPITAL CAMPUS-WIDE:

1985-89          Quality Assurance Committee, (Chair)

1985-89          Utilization Review Committee

1985-89          Self-Accreditation Committee, (Co-Chair)

1985             Product Evaluation Committee

1985-89          Joint Conference Committee

1985-86          Medical Information Steering Committee

1985-86          Ad Hoc Committee on Open Heart Surgery at SFGH

1987             Ad Hoc Committee on Interdepartmental Relationships and Privileges

1988             Ad Hoc Committee on HIV Testing

1989             HIV Policy Committee

### UC SAN FRANCISCO INSTITUTE FOR HEALTH POLICY

1985-9          Publications Advisory Committee

### UC SAN FRANCISCO, DEPARTMENT OF MEDICINE

1985-6          SFGH Primary Care Internship Selection Committee

### Arizona State University, Sandra Day O'Connor School of Law

2008 -          Advisory Board member, Center for Law, Science & Innovation

## **TEACHING ACTIVITIES: UC Davis**

Academic Years	Course	Nature of Contribution
1978-82	Physical Diagnosis	Lecture: The Problem Oriented Record; Preceptor
1979-82	Gastroenterology: Year II Medical student Core Curriculum	Lecture and Videotape (patient interview) Stress and the GI Tract
1979-82	Medicine Wards	Ward Attending
1979-82	Third Year Medicine Clerkship	Prepared and graded all written examinations
1979-82	General Medicine Clinic	Clinic Attending
1980-82	General Medicine Consult	Consult Attending
1980-82	Acting Internship in Medicine	Course Chair
1980-82	Behavioral Medicine Clinic	Clinic Attending

### **Lectures at UC Davis**

1980	Medical Grand Rounds, "Stress and the GI Tract" Family Practice Grand Rounds, "Dementia and Delirium" Medical M&M Conference, "Fever and Abdominal Pain in an Elderly Woman" Continuing Medical Education Conference on Preoperative Evaluation, "Anesthetic Risk"
1981	Second Annual Conference on Preoperative Evaluation, "Use of Blood Products" Internal Medicine Noon Conferences, "Dementia and Delirium" Medical M&M Conference, "Sudden Death in 27 Year Old Black Female with a Valve Replacement" Biostatistics Review Course for faculty and fellows (12 workshop style lectures),
1982	Ambulatory Case Conference, "Stress & the GI Tract" Medical M&M Conference, "Dementia in a 54 year old Woman"
1983	Third Annual Conference on Preoperative Evaluation, "Preoperative Assessment of the Elderly Patient"

## **TEACHING ACTIVITIES: UC San Francisco / UC Berkeley**

Academic Years	Course	Nature of Contribution
1982-89	Ambulatory Care Clerkship	Preceptor
1982-85	A.W. Mellon Summer Student Research Design Workshop	Lecturer; Preceptor
1982-89	Research design Workshop and Advanced Epidemiology	Lecturer; Faculty Preceptor

	Seminar	
1982-89	General Medicine Clinic	Clinic Attending
1983-86	Computer Workshop: Data skills for new faculty and fellows	Course Director (5 week course)
1984-89	Medicine Wards	Ward Attending
1984-89	General Medicine Consult	Consult Attending
1984-89	Epidemiology: 1 <sup>st</sup> year medical student core curriculum	Section Leader
1985-86	UC Berkeley BEHS 160: Introduction to Public health	Faculty in charge of two 10 lecture modular sections on epidemiological methods
1985-1987	UC SF IDS 140.22: Responsibilities of Medical Practice	Lectures on Hospital Quality Assurance Programs
1987-89	Clinical Pharmacology and Therapeutics Elective	Lectures on Pharmacoepidemiology
1987	UC Berkeley: Introduction to Epidemiology	Lectures on Clinical Epidemiology
1987-89	AIDS Epidemiology Seminar	Weekly Seminar organizer

## Lectures at UCSF

1984	Primary Care Grand Rounds, "Isolated Systolic Hypertension"
	Family Practice Grand Rounds, "Elevated Cholesterol and your Heart: What have we learned from recent clinical trials?"
1985	Epidemiology Grand Rounds, "Pharmacoepidemiology: How we find adverse drug reactions"
	Conference on Practical Advances in Medicine, "Computers: How to retrieve medical information in a practical way"
	Clinical Pharmacology Research Seminar, "Pharmacoepidemiology", San Francisco, CA
	Occupational Medicine Grand Rounds, "Methodology to Detect Rare Events", San Francisco, CA
	Primary Care Grand Rounds, "How are adverse drug reactions detected?"
	Primary Care Grand Rounds, "Mild Hypertension: the case for nonpharmacologic treatment"
	Clinical Pharmacology: Topics in Therapeutics, "Pharmacoepidemiology: Postmarketing drug surveillance"
	Family Practice Grand Rounds, "Mild Hypertension: the case for nonpharmacologic treatment"
1986	Medicine Noon Conference, "How to read the medical literature; Part I: observational studies; Part II: experimental studies"
	Departments of Medicine and Anesthesia Conference: Preoperative Evaluation of the Surgical Patient, "Surgery and the Elderly Patient"
	SFGH Medical Grand Rounds, "Legal Aspects of Quality Medical Care"

- Comprehensive Care of the AIDS Patient: A Workshop, "Integrating Research into the Clinical Setting"
- 1987 Conference: Legal Aspects of Medical Practice, "The Epidemiology of Malpractice"
- Departments of Medicine and Anesthesia Conference: Preoperative Evaluation of the Surgical Patient, "Surgery and the Elderly Patient"
- Occupation Health Grand Rounds, "Application of Statistical Methods to Problems in Occupational Health"
- Comprehensive Care of the AIDS Patient: A Workshop, "Integrating Research into the Clinical Setting"
- San Francisco Department of Public Health: National AIDS Conference, "Care: Acute Inpatient Hospital Quality Assurance Programs"
- APEX Program for AIDS Education, "AIDS Drug Protocols"
- Conference, "Hospital Quality Assurance Programs"
- Veteran's Administration Conference on Geriatric Care: Controversies in Geriatric Care, "Debate: Problems in the Treatment of Isolated Systolic Hypertension"
- 1988 National AIDS Conference: San Francisco Department of Public Health, "AIDS Drug Protocols and The Testing and Approval of New Drugs"
- Conference, "Hospital Quality Assurance, Utilization Review, and Risk Management Programs"
- CME Course: Comprehensive Care of the AIDS Patient, "AIDS: Cost of Care"

### **TEACHING ACTIVITIES: UC San Diego**

Academic Years	Course	Nature of Contribution
1990-91	Logistic Regression Workshop	Course lecturer (10 week workshop)
1990-91	General Internal Medicine / Geriatrics Journal Club	Coordinator
1990-91	General Medicine Clinic	Clinic Attending
1990-91	Medicine Wards	Ward Attending
1990-91	General Medicine Consult	Consult Attending

### **Lectures at UC San Diego**

- 1989 Physicians for AIDS Care: Update on the prevention and management of PCP, "PCP Prophylaxis", San Diego, CA
- University of California, San Diego Infectious Disease Conference, "Oral Manifestations of HIV Infection", San Diego, CA
- 1990 Medical Grand Rounds, "Prophylaxis and treatment of Pneumocystis carinii with aerosolized pentamidine", San Diego, CA
- Annual Conference on the Evaluation of the Preoperative Patient, "The Political Economy of Surgery"

## **TEACHING ACTIVITIES: Arizona State University**

Academic Years	Course	Nature of Contribution
2005 -	Food and Drug Law	Course Director (15 week, 2 or 3 Credit, Fall Semester open to Law School students and graduate level students in the School of Engineering and Life Sciences).
2011 -2012	U.S. Consumer Protection Agencies	Instructor (15 week 3 Credit, Undergraduate course)

## **PREDOCTORAL STUDENTS SUPERVISED:**

1983	Chris Cox	(Medical Student, UCSF)
1985	Tamara Barr, R.N.	(MPH Candidate, UC Berkeley)
1986	Constance Rainer	(Medical Student, University of Minnesota)
1986	David Kirn	(Medical Student, UCSF)
1987	Tom Tieri	(Medical Student, UCSF)
1988	Deborah Kato	(Medical Student, Cornell)
1988	Paul Cusick	(Medical Student, University of Massachusetts)
1989	Eckart V. Hirschhausen	(Medical Student, University of Heidelberg, Germany)

## **POSTDOCTORAL FELLOWS PRECEPTED:**

1983-85	Susan Cummins, M.D.	(Epidemiology Fellow)
1984-85	Richard Glaser, M.D.	(Epidemiology Fellow)
1987-89	Robin Edison, M.D.	(Preventive Medicine Resident)
1989	David Glidden	(University of Washington, Biostatistics Ph.D. Student)
1991	Fernando Rubenstein	(Primary Care Fellow)
2005-6	Christine Meis McAuliffe	(Law School Doctoral Dissertation Committee)



## **GOVERNMENT SERVICE:**

### **WORLD HEALTH ORGANIZATION:**

#### **Global Program on AIDS:**

- |         |  |
|---------|--|
| 1993-96 | Steering Committee on Drug Clinical Trials: Member   |
| 1993    | Second Meeting on the Development of Drugs and Vaccines for AIDS:<br>Speaker and FDA representative: Harmonization of Regulatory<br>Requirements for AIDS Drugs, "Accelerated Approval", Geneva,<br>Switzerland  |
| 1993    | Workshop on the Development of Agents to Prevent Heterosexual transmission<br>of HIV: "Topical Microbicides, "Regulatory Requirements for Vaginal<br>Microbicides to Prevent HIV Infection", Geneva, Switzerland |
| 1993-97 | International Working Group on Vaginal Microbicides: chair and founding<br>member  |
| 1994    | Global program on AIDS Consensus Panel on Prevention of perinatal<br>transmission of HIV: Speaker and panelist   |
| 1994    | Workshop on Harmonization of Regulatory Requirements for AIDS Drug<br>Development: Invited participant   |

### **INTERNATIONAL CONFERENCE ON HARMONIZATION**

- |          |   |
|----------|---|
| 1995-96  | Efficacy Lead: Center for Drug Evaluation and research, FDA   |
| 1995     | 3 <sup>rd</sup> ICH Delegate  |
|          | 3 <sup>rd</sup> International Conference on Harmonization, "General Considerations for<br>Clinical Trials", Yokohama, Japan, 1995 |
| 1995-96  | CDER Topic Lead E8: "General Considerations"  |
| 1997- 99 | CDER Topic Lead: M4 "Common Technical Document, Efficacy"   |
| 1998     | ICH Update, "The ICH Common Technical Document", Bethesda, MD   |

### **GLOBAL HARMONIZATION TASK FORCE**

- |           |   |
|-----------|---|
| 2000 – 04 | GHTF Steering Committee Member: Lead US Regulatory Delegation   |
| 2000      | 8 <sup>th</sup> Global Harmonization Task Force Meeting, "DEHP Plasticizers in Medical<br>Devices", Quebec, Canada, 2000  |
| 2002      | 9 <sup>th</sup> Global Harmonization Task Force Meeting, "Total Product Life Cycle:<br>Postmarket Surveillance and Vigilance", and "New and Emerging<br>Technologies: Consumer Protection that Fosters Innovation", Singapore, 2002 |

## **EUROPEAN MEDICINES EVALUATION AGENCY (EMA)**

1996                      Invited Presentation: Surrogate markers, combination nucleosides and protease inhibitors

## **NATIONAL ACADEMIES OF SCIENCE**

### **Institute of Medicine**

Combination HIV Therapies: Considerations for Policy and Research, “Preclinical Data Requirements”, Washington, DC, 1992  
Changing Demographics of the AIDS Epidemic: Implications for Clinical Research, “Enhancing Diversity in Drug Development, An FDA Perspective”, Washington, DC, 1993  
IOM Panel to Review FIAU, “The FIAU Experience”, Washington, DC, 1994  
Roundtable for the Development of Drugs and Vaccines Against AIDS: Collaboration between Government and Industry, “Challenges and Opportunities for HIV Drug and Vaccine Development”, Washington, DC, 1994  
IOM Conference on Therapeutics of Children, “Special Considerations for Evaluating Medical Devices in Infants and Children”, Washington, DC, 1999  
IOM Workshop: Innovation and Invention in Medical Devices, “Innovation and Invention in Medical Devices”, Washington, DC, 2000  
New Approaches to Early Detection and Diagnosis of Breast Cancer: Accelerating the Flow from Concept to Clinic, “Challenges in assessing the safety and efficacy of cancer detection devices”, Washington, DC, 2003  
IOM Committee on Post-marketing Surveillance of Pediatric Medical Devices.” Device Post-Market Surveillance in Children.” Consultant to the Committee 2004 -2005  
IOM Workshop on Modifications to the 510(k) Clearance Process. Invited Paper. 2010

### **National Academy of Engineering**

Bioengineering, Materials (BEMA) Roundtable, “FDA Perspective on Medical Device Development”, Washington, DC, 2000  
National Academy’s Biomedical Materials Roundtable Meeting, “Developing Biomaterials: An FDA Perspective”, Washington, DC, 2002  
BEMA – “Science-Based Assessment: Accelerating Product Development of Combination Medical Devices”, Washington, DC, 2003  
AIMBE Symposium: Imaging and Bioengineering, Partners for the Future, “Public Policy Issues Related to Imaging”, Washington, D.C. 2004  
BEMA – “Examining the Regulatory Path for Emerging Biomaterials Technologies” , Woods Hole, MA, 2004

### **National Research Council, Board on Mathematical Sciences**

National Research Council, Board on Mathematical Sciences: Science and Technology Symposium, “Surrogate Markers”, Washington, DC, 1992

## **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Secretary's Advisory Committees**

- 1996 – 98      HHS Panel on Clinical Practices for Treatment of HIV Infection
- 2000 – 02      Secretary's Advisory Committee on Genetic Testing,  
Presentation: "FDA's Role in the Transition of In Vitro Diagnostic Devices  
from Research to Routine Testing", Washington, DC, 2000
- 2001            Women's Health Dialogue, Washington, DC, 2001
- 2002            Secretary's Advisory Committee on Regulatory Reform, "FDA and CMS  
Collaboration", Minneapolis, MN
- 2003 – 04      Secretary's Advisory Committee on Genetics Health and Society, FDA Liaison  
Representative  
Presentation: "FDA's Regulation of Genetic Tests, Washington, DC, 2003

### **HHS Workshops**

- National AIDS Task Force on Drug Development, "Surrogate Markers: FDA proposal for  
and integrated approach", Washington, DC, 1994
- Public Health Service Disability Awareness Conference, "Opening Remarks ", Rockville,  
MD, 1996
- Office of AIDS Policy Workshop, "Clinical Practice of HIV Treatment", Washington, DC,  
1997
- HHS Consumer Roundtable, "Medical Devices and Radiological Health", Washington, DC,  
2000
- White House Conference on Alternative Medicine, "Medical Devices and Alternative  
Medicine", Washington, DC, 2000
- CMS – Medicare Medical Directors Workgroup, "New Technology in Medicine",  
Baltimore, MD, 2001

## **NATIONAL INSTITUTES OF HEALTH**

- 1992 – 96      AIDS Clinical Drug Development Committee
- 1992 – 97      Faculty: IDSA AIDS Fellowship Program
- 1992 – 96      Executive Committee: AIDS Clinical Trials Group

### **PHS Consensus Conferences**

- US Public Health Service Consensus Panel on Prophylaxis against PC in HIV infected  
Patients, "Evaluation of the trimethoprim-sulfamethoxazole", Bethesda, MD, 1987
- Steroid Use in *Pneumocystis carinii* pneumonia, "Acute mortality of PCP pneumonia: A  
case series of the first 500 cases at San Francisco General Hospital 1981 – 1986", San  
Diego, CA, 1990
- Consensus Conference on Steroids and PCP, "Predictors of early mortality upon hospital  
admission for PCP", San Diego, CA, 1990
- NIH Workshop on the Placebo, "Use of placebos in clinical trials to test procedural  
interventions", Bethesda, MD, 2000

## NIH Workshops and Conferences

- NCI** National Cancer Institute: Third National Forum on Biomedical Imaging in Oncology, "Cancer Imaging Products: Drug, Biologicals, and Devices", Arlington, VA, 2002  
Fourth National Forum on Biomedical Imaging in Oncology, "Regulatory Update", Bethesda, MD, 2003  
Fifth National Forum on Biomedical Imaging in Oncology, "Current Issues in Imaging Device Regulation", Bethesda, MD, 2004  
BIROW II: Biomedical Imaging Research Opportunities II, "Developing New Imaging Technology: An FDA Perspective", Bethesda, 2004
- NIAID** ACTG Annual Meeting, "Women and special populations in HIV Drug Trials", Washington, DC, 1993  
12<sup>th</sup> meeting of the acquired Immunodeficiency Syndrome Program Advisory Committee (APAC), "Accelerated Approval", Bethesda, MD, 1993  
CPCRA: Annual Meeting, "Data collection requirements and monitoring clinical trials", Alexandria, VA, 1993  
NIAID-UNAIDS Satellite Symposium on Topical Microbicides, "Topical Microbicides", Vancouver, BC, 1996
- NIDCR** National Institutes of Health: NIDCR – Dental, Oral & Craniofacial Forum, "FDA and Medical product Consumer Protection", Washington, DC, 2001
- NIHCHD** Contraceptive Technology Workshop, "Development of Vaginal Microbicides to Prevent HIV transmission", Bethesda, MD, 1994
- Clinical Center Rounds Other NIH Workshops** NIH Clinical Center: Critical Care Medicine Department Conference, "Evidence based Medicine and Device Regulation: How to Foster Innovation", Bethesda, MD, 2002  
Cost Effective Strategies for the Diagnosis of Pulmonary Complications: Calculations of 'Cost Effectiveness', "NIH Workshop on the Pulmonary Complications of AIDS", San Francisco, CA, 1987  
NIH – FDA Symposium on AIDS Clinical Trials, "AIDS Clinical Trials: Non traditional study designs", Rockville, MD, 1990  
Fogarty Center, NIH: US-Japan Cooperative Medical Science Program: Sixth Joint Scientific Meeting of the AIDS Panels, "Scientific Research Opportunities in the Pacific: FDA Perspectives", Palm Springs, CA, 1994  
Gene Therapy Conference, "Surrogate Markers NIH," Bethesda, MD, 1997  
Research Needs for the Design and Analysis of Surrogate Endpoints in Clinical Trials, "Clinical Perspectives on Surrogate Markers", Potomac, MD, 1998  
Prenatal Gene Therapy Workshop, "Clinical Endpoints and Measurement Outcome", Bethesda, MD, 1999  
FDA/NIH Workshop on Non-Clinical Toxicological Study Design Issues for Development of AAV-Based Gene Therapies: A Platform Studies Approach, "Role of Platform Studies in Drug Evaluation", Bethesda, MD, 1999  
NIH Technology Assessment Conference on Improving Medical Implant Performance Through Retrieval Information: Opportunities and Challenges, "National Implant Data Retrieval and Analysis", Bethesda, MD, 2000  
Foundation for NIH: Imaging Database Resources Initiative, "Importance of FDA-NIH-Industry Collaboration", Bethesda, MD 2004

## INVITED PAPERS, LECTURES AND PRESENTATIONS

### Academic Institutions

Applied Sciences University, Lubeck Germany	International Seminar on Harmonization of Standards (Honoring the Retirement of Professor Horst Frankenberger), "Global Harmonization of Medical Devices", Lubeck, Germany, 2003
Arizona State University	Personalized Medicine and Molecular Diagnostics, Legal Regulatory and Ethical Perspectives, "Regulatory Issues for Personalized Medicine", 2007
Carnegie Mellon University	Materials Science Seminar Series, "Medical Devices", Pittsburgh, PA, 2001
Columbia University	FDA Workshop: Community based clinical trials, "The San Francisco Community based trials of PCP prophylaxis", New York, NY, 1989 Symposium on Quality of Life, "Drugs, Drug Companies and Quality of Life Issues: Quality of Life Measures: An FDA Perspective", New York, NY, 1993 The American Institute of Life-Threatening Illness and Loss: Regulatory Issues, Pharmacoeconomics and Quality of life Issues in the Evaluation of Therapeutic Agents: Oncologic, Cardiovascular, and other Drugs as Models, "Assessment of Drug Therapies Using Quality of Life Measures", New York, NY, 1997
Dartmouth Medical School	Device and Drug 3D1 Symposium, "Clinical Development and Commercialization: Differences: United States and Europe/United Kingdom", Woodstock, VT, 2003 Seminar:, "Role of Clinician Inventor/Entrepreneur in Pre-Clinical and Clinical Development of a new Medical Device", Lebanon, NH, 2003 Medical Grand Rounds, "Innovation and Consumer Protection – FDA and New Technology", Lebanon, NH, 2004 Device and Drug 3D3 Symposium, "Conflict of Interest: Medical Device Development", Woodstock, VT, 2005 Device and Drug 3D4 Symposium, "International Harmonization of Regulatory Standards, Is it worth the trouble?", Woodstock, VT, 2006
Duke University	Device Drug Eluting Stents Conference, "The Shrinking Total Product Life Cycle: Regulatory Processes and Innovation", Washington, DC, 2002 Clinical Research Institute Roundtable, "New Technology Review", Tyson's Corner, VA, 2002 Clinical Research Institute: Genetics and Cardiovascular Disease II, "", Pentagon City, VA, 2003 Clinical Research Institute: Device Evaluation Think Tank, "", Rockville, MD, 2003
Georgetown University	Georgetown Clinical Pharmacology Conference, "Rapid Drug Development: The Protease Inhibitors", Washington, DC, 1997 Center for Drug Development Science Course: Modeling and Simulation of Clinical Trials in Drug Development and Regulation, "PK/PD Modeling in Regulatory Decisions for Effectiveness", Herndon, VA, 1997 Center for Drug Development Study Conference, "Pharmacogenomics", Washington, DC, 1999

	Center for Drug Development Study Conference: Protein Pharmacology, "Protein PK/PD: A Regulatory Perspective", Annapolis, MD, 1999
	Center for Drug Development Studies, Georgetown University: Confirmatory Evidence (to Support a Single Clinical Trail (SCT): An Exploratory Workshop, "The Nature and Source of Evidence for Effectiveness", Washington, DC, 2002
	Center for Drug Development Study Conference: Clinical Development of Oncologic Agents: Challenging the Tradition, "Predictive diagnostics, biomarkers/surrogate endpoints and how they can be used in drug development", Washington, DC, 2003
	The International Life Science Summit East, "Drug and Device Development: The Challenge of Turning Research into Reality", Washington, DC, 2003
Georgia Tech	Biomedical Engineering Seminar, "One Hundred Years of Consumer Protection", Atlanta, GA, 2001
	Medical Technology Leadership Forum Summit – Defining a Regulatory Process for Combination Product: The emergence of Tissue Engineering, "Regulatory Approaches to Tissue Engineering", Atlanta, GA, 2002
Golden Gate University	Conference, "Hospital Quality Assurance Programs", San Francisco, CA, 1987
	Conference, "Hospital Quality Assurance, Utilization Review, and Risk Management Programs", San Francisco, CA, 1988
Harvard University	Contemporary Issues in Clinical Trials Harvard School of Public Health, Department of Biostatistics, "Current and Future FDA Criteria for the Evaluation of Anti-HIV Drugs by the FDA, Boston, MA", Boston, MA, 1997
	Medical School Seminar-The Clinical Investigator Training Program, "Endpoints in Clinical Trials", Boston, MA, 1999
	Center for Innovation in Medical Technology – Harvard Medical School – Stanford Conflict of Interest Forum, "", Boston, MA, 2002
Howard University	Deadly Diseases & People of Color: Are Clinical Trials an Option?, "New Therapies for Diseases Affecting People of Color: AIDS", Washington, DC, 1996
Johns Hopkins University	Medical School Symposium, "Prophylaxis with Aerosolized Pentamidine for PCP", Baltimore, MD, 1989
Memorial Sloan Kettering	Pulmonary Grand Rounds, "Prophylaxis against P carinii pneumonia", New York, NY, 1990
New Jersey University of Medicine and Dentistry	Infectious Disease Rounds, "New agents in the treatment and prevention of PCP", Newark, NJ, 1990
San Diego State University	Regulatory Affairs Student Seminar, "Consumer Protection and Medical Devices", Rockville, MD, 2001
	Student FDA Field Visit, "Consumer Protection: Devices and Radiological Products", Rockville, MD, 2002
Scripps Clinic	Scripps Clinic Symposium: The Changing World of International Product Development, "Pharmacogenomics: A Regulatory Perspective", La Jolla, CA, 1999



	Symposium, "Drug Delivery: Problems and Possibilities", La Jolla, CA, 2001
	5th Bio Symposium, "Perspectives on the Future FDA", La Jolla, CA, 2003
Shanghai Institute of Mental Health	"Quality Assurance in Acute Care Hospitals, Peer Review of Medical Staff, Accreditation and Licensing American Hospitals, Use of Small Computers in Medical Departments (A day long seminar for Hospital Administrators)", Shanghai, China, 1988
Stanford University Law School	Program in Law Science and Technology Conference, "Genetic in vitro Diagnostics", Stanford, CA, 2000
Stanford University School of Engineering	Bioengineering Class: Innovation and Technology, "Innovation and the FDA – 100 years of Consumer Protection" 2005
Suffolk University School of Law	FDA Regulation of Medical Technologies, "Defining a Medical Device", "Device Classification", "An Inside Look at the FDA Approval Process"; Boston, MA 2004
Tufts University	PRIM&R (Public Responsibility in Medicine and Research): AIDS Clinical Research and Care: Meeting the Challenges of an Epidemic in Flux, "An Overview of the Status of AIDS Research in the '90s", Boston, MA, 1992
	Accelerated Approval of New Drugs, "Constructing a Framework for Surrogate Endpoint Selection", Boston, MA, 1994
	New Technologies, Challenges and Opportunities for the Medical Device Industry: A Collaborative Workshop Sponsored by the Tufts University Schools of Engineering & Medicine. "Innovation and Regulation.", Boston 2004
Uniformed Services University of Health Sciences	Clinical Pharmacology Seminar, "Surrogate Markers in Drug Development", Bethesda, MD, 1994
University of Arizona	The Promise of Stem Cells: Tissue Engineering And Regenerative Medicine, "Regulation of Stem Cells: Role of FDA, States and Others", Tucson, AZ 2006
University of California, Berkeley	Haas School of Business: New Economic Forum, "Biotechnology and Medical Devices", Portola Valley, VA, 2003
University of California, Davis	Conference on Practical Advances in Medicine, "Computers: How to retrieve medical information in a practical way", Sacramento, CA, 1985
	University of California Davis Conference, "The Political Economy of Surgery: Surgical practice in a changing environment", Carmel, CA, 1989
	Annual Conference on the Evaluation of the Preoperative Patient, "The Political Economy of Surgery", Carmel, CA, 1990
	Annual Conference on the Evaluation of the Preoperative Patient, "The Political Economy of Surgery", Carmel, CA, 1990

University of California, San Diego	von Liebig Forum Lecturer, the Jacobs School of Engineering, "Innovation and Consumer Protection – FDA and New Technology", San Diego, CA 2004
University of California, San Francisco	Department of Epidemiology and Biostatistics: Clinical Trials Workshop, "Interacting with the FDA", San Francisco, CA, 1995
	School of Dentistry, "Rapid Development of AIDS Drugs", San Francisco, CA, 1995
	San Francisco County Health Department, "Update on AIDS Drug Development", San Francisco, CA, 1996
	UCSF Department of Epidemiology and Biostatistics: Clinical Trials Workshop, "Interacting with the FDA", San Francisco, CA, 1996
	UCSF Department of Epidemiology and Biostatistics: Clinical Trials Workshop, "Placebo vs. Active Controlled Clinical Trials", San Francisco, CA, 1996
	8th Symposium on Clinical Trials: Design Methods and Controversies, "FDA Perspectives on Drug Development", San Francisco, CA, 2000
University of Indiana	Medical Technology Leadership Forum Technology Conference, "Medical Device Innovations Based on Information Technology", Indianapolis, IN, 2000
University of Iowa	Conference: AIDS '89, "Management and Prevention of Pneumocystis carinii Pneumonia", Ames, IA, 1989
University of Maryland	Institute of Human Virology Conference: Immune Reconstruction and Surrogate Markers in HIV/AIDS: Defining the Obstacles, "Predicting Clinical benefit from Immune Markers", Bethesda, MD, 1999
	Bioscience Research Day: CEO's Breakfast, "Academic Government Partnerships", College Park, MD, 2001
	Policy Development Seminar, "Score Cards and Strategic Planning", College Park, MD, 2003
University of Minnesota	School of Public Health Grand Rounds, "Development of Drugs for HIV Infection", Minneapolis, MN, 1996
	Medical Technology Leadership Forum - Facilitating the Continuum from Experimental to Clinical Use: Designing Alternative Models, "Medical Devices: Overcoming Regulatory Hurdles", Minneapolis, MN, 2003
University of Rhode Island	School of Pharmacy: Changing Paradigm of Blood Regulation, "CBER's Blood Action Plan", New Orleans, LA, 1999
University of Texas, San Antonio	Pulmonary Fellows Conference, "Pulmonary Complications of HIV Infection", San Antonio, TX, 1989
University of Texas, Austin	International Conference for Drug Development, "Current Issues in Biologics", 1998; "Regulatory path for emerging therapeutic technology", Barton Creek, TX 2004
University of Washington	School of Public Health: The Impact of Regulatory Programs on Medicine and Public Health, "Off-label Use of Medical Products", Seattle, WA, 2002
Vanderbilt University	Bioengineering Departmental Seminar: "Emerging Therapeutic Technology", Nashville, TN, 2004
Virginia Tech	Virginia Tech - FDA Seminar, "Center for Devices and Radiological Health", Blacksburg, VA, 2001
Yale University	Yale / Genaissance Genomics Symposium, "Drug Development, Regulation, and Genetically Guided Therapy", New Haven, CT, 2001



## FDA Sponsored Presentations

Advisory Committee	FDA anti-infective advisory panel meetings, "Aerosolized Pentamidine for prophylaxis against PCP in HIV infected adults", Rockville, MD, 1988
	FDA Anti-infective Advisory panel meeting, "Considerations of the Parallel Track proposal for early drug availability", Bethesda, MD, 1989
	CDER Scientific Advisory Committee New Member Orientation, "Role of Members and Perspectives from the Infectious Disease Committees", , 1996
	CDER: Orientation for CDER Advisory Committee Members, "Roles of members and Perspectives of a Former Member", Rockville, MD, 1997
	Anti-infective Drug Advisory Committee, CDER, "Evaluability Criteria for the Evaluation of Antimicrobials", Gaithersburg, MD, 1997
	FDA Workshop for Patient Representatives, "Device Advisory Committees", Rockville, MD, 2001
CBER	CBER / ORA Training Course: Blood Bank Inspection, "Oversight of the Blood Industry", Annapolis, MD, 1997
	Team Biologics Training, "Blood Oversight and Regulation", Potomac, MD, 1998
Consumer Round Table	FDA Consumer's Roundtable, "The Mammography Quality Standards Act", San Juan, PR, 2000
District Meetings	FDA South East District Conference, "Spotlight on Radiological Health", San Juan, PR, 2001
	FDA Dallas District Staff Seminar, "Consumer Protection: Device and Radiological Products - Center and Field", Dallas, TX, 2001, 2004
FDA: Scientific Rounds	Center for Drug Evaluation and Research, FDA: Scientific Rounds, "End-point Methodology in HIV infection", Rockville, MD, 1992
	FDA Scientific Rounds: Office of Clinical Pharmacology and Biopharmaceutics (OCPB), "Pharmacogenomic Data Submissions - The Path from Concept to Reality", Rockville, MD, 2003
Grassroots	Grassroots Meeting, "CDRH Priorities", Denver, CO, 2002, Salt Lake City 2003 Dallas TX, 2003, 2004
Public Affairs Specialists	The Public Affairs Specialist/Public Affairs Liaison National Training Conference "2001 - A Consumer Protection Odyssey", "Spotlight on Radiological Health", Leesburg, VA, 2001
	HHS/FDA National Public Affairs Conference: Communicating Risk, Results and Relevance to American Consumers - A dialogue on safety and security through science", "Medical Devices: Communicating Success and Risk", Nashville, TN, 2003
Science Board	FDA Science Board, "Programmatic Peer Review: Center for Devices & Radiological Health", Rockville, MD, 2000
	FDA Science Board, "Update: CDRH Science Review", Rockville, MD, 2001
	FDA Science Board, "Tissue Engineering and Device Regulation", Washington, DC, 2001
	FDA Science Board, "CDRH Science Review", Rockville, MD, 2001
	FDA Science Board, "Developing Biomaterials", Rockville, MD, 2002
	FDA Science Board, "Quality Teams and Regulatory Review", Rockville, MD, 2003

Science Forum	FDA Science Forum, "Detecting Biological and Security Risks", Washington, DC, 2003
FDA Workshops	<p>FDA Workshop: Geriatric Drug Testing, "Adverse Reactions in the Systolic Hypertension in the Elderly Trial", Washington, DC, 1985</p> <p>CANDA Workshop, "The Computerized Rolling NDA", Rockville, MD, 1994</p> <p>FDA: Clinical Trials Workshop, "Designing Trials with Clinical End-points", Bethesda, MD, 1995</p> <p>Clinical Trials Workshop, "FDA Role and Responsibility in Clinical Trials", San Francisco, CA, 1998</p> <p>Minimizing Medical Product Errors - A Systems Approach, "CBER Perspective on Medication Errors", Bethesda, MD, 1998</p> <p>FDA and the Changing Paradigm for Blood Regulation, "CBER's Action Plan for Improving Blood Safety", New Orleans, LA, 1998</p> <p>FDA Symposium on Drugs and the Liver, "FIAU and Chronic Hepatitis B", Rockville, MD, 1999</p> <p>National Patient Safety Forum: Patient Safety - Emerging Opportunities in the Health Care System, "Building Safety In: The Essential Role of Device Users", Bethesda, MD, 2000</p> <p>FDA Workshop: Human Bone Allograft: Manipulation &amp; Homologous Use in Spine and Other Orthopedic Reconstruction and Repair, "Medical Devices from Human Bone", Bethesda, MD, 2000</p>
FDA Workshops (continued)	<p>FDA Statistician's Meeting, "Statistical Issues in Medical Devices", Rockville, MD, 2000</p> <p>Mutual Recognition Agreement Medical Devices Annex Training, "Mutual Recognition Agreements", Gaithersburg, MD, 2001</p> <p>FDA Workshop - Home Health Care, "Home Health Care and Medical Devices", Bethesda, MD, 2002</p> <p>CDRH Clinical Trials Methodology Course, "Surrogate Markers", Gaithersburg, MD, 2003</p> <p>CDRH Staff College: Total Product Life Cycle 101 Training Course, "Total Product Life Cycle", Gaithersburg, MD, 2003, 2004</p> <p>FDA Workshop on the Development of Novel Drug Delivery Devices, "Opening Remarks", Rockville, MD, 2003</p> <p>CDRH Workshop on the Development of SARS Diagnostics, "Rapid Development of Diagnostic Devices for New Infectious Disease Threats", Rockville, MD, 2003</p> <p>First Annual MDUFMA Stakeholders' Meeting, "Medical Device User Fees: The First Year", Gaithersburg, MD, 2003</p>

## Other Regulatory Body Presentations

MDA / NAPSE	The Medical Devices Agency (UK) 2nd Annual Conference: Protecting Patients - Improving Safety, "Regulatory Issues in the United States", London, England, 2002
MHRA	MHRA (UK) Staff Seminar: Beyond "Pre-market and Post-market" : Regulation and the total product life cycle, 2006
SFDA	State FDA (China) with the Beijing University International MBA Program: 14 Lecture Short Course on US FDA Regulation of Pharmaceutical Medicine, Beijing, 2005

## Professional Organizations and Societies

AAAS	American Association for the Advancement of Science, Annual Meeting, "The Evolving Genome in Clinical Development and policy", Denver, CO, 2003
AAMC	American Association of Medical Colleges Council of Deans, "Institutional Review Boards: Current Challenges", Rio Grande, PR, 2000
AAMI	10th Annual Association for the Advancement of Medical Instrumentation/FDA International Standards Conference, "Global Standards – Global Quality", McLean, VA, 2000 - 2003
AAOS	American Academy of Orthopedic Surgeons/Orthopedic Surgical Manufacturers Association Device Forum, "CDRH External Science Review Recommendations", Gaithersburg, MD, 2002
AAPS	AAPS Western Regional Meeting, "Accelerated Drug Development and Approval", San Francisco, CA, 1997 American Association of Pharmaceutical Scientists Annual Meeting, "The Treatment of AIDS- A Revolutionary Paradigm in Drug Discovery, Development and Approval", Boston, MA, 1997 AAPS Symposium on Clinical Pharmacology: Optimizing the Science of Drug Development, "Role of Clinical Pharmacology in Accelerated Approval of Antivirals", Crystal City, VA, 1998 AAPS Annual Meeting, "FDA Perspectives for Accelerated Approval of AIDS Drugs", San Francisco, CA, 1998 AAPS Annual Meeting, "drug/disease modeling to increase the efficiency of drug development", Baltimore, MD 2004
ABA	Arizona Biotech Association: "FDA and CLIA: Trends in Medical Diagnostic Commercialization", 2006
ABRA	American Blood Resources Association Plasma Forum, "The Blood Action Plan", Washington, DC, 1998
ACC	American College of Cardiology Course, "International Trends in Cardiovascular Disease Mortality: Possible explanations", San Francisco, CA, 1987 American College of Cardiology, "Sharing a Commitment to Improve Cardiovascular Disease", Bethesda, MD, 2001 American College of Cardiology Industry Forum, "Cardiovascular Devices: Regulation and Consumer Protection", Bethesda, MD, 2002
ACCP	American College of Clinical Pharmacology: Annual Meeting, "Keynote Address: Genetically Guided Therapy: The Genome, biomarkers and pharmacology", Tampa Bay, FL, 2003
ACLA	American Clinical Laboratories Association, Annual Meeting, "Regulation of Genetic Tests", Washington, DC, 2002
ACOG	American College of Obstetrics and Gynecology: Preventing perinatal transmission of HIV infection, "ACTG 076 - The FDA Review Process", Washington, DC, 1994
ACP	American College of Physicians: Preparing for Surgery: Medical Evaluation of the Preoperative Patient, "Improving Patient Risks: Assessing new technologies", Carmel, CA., 1992
AFCR	American Federation for Clinical Research/ASCI/AAP: Surrogate End Points, New Drug Development and the Clinical Investigator, "Surrogate Endpoints", Washington, DC, 1993
AmFAR	American Foundation for AIDS Research, NIH: Annual Meeting: Community Based Trials Clinical Trials Network, "AIDS Treatment: What do we know and how did we learn it?", Alexandria, VA, 1993 AmFAR: Off-Label Drug Use in HIV Disease, "Issues and Concerns of the FDA

	Regarding Off-Label Drug Use", Washington, DC, 1994
	AmFAR: Update on HIV Treatment, "New AIDS Drugs: Guide to early access for the primary care physician", New York, NY, 1995
APA	5th Annual American Pharmaceutical Association End-of-Summer Science Symposium: The Yellow Brick Road Gets Longer: Social, Economic and Technological Issues Shaping Clinical Design in the '90s, "Impact of Innovation in the Clinical Study Design on AIDS Drug Approval", Washington, DC, 1992
ASAI0	American Society for Artificial Internal Organs: Annual Meeting - Keynote Address, "The FDA Modernization Act", New York, NY, 2000
	ASAI0 - ISAO Annual Meeting, "How to Become More Involved in the Regulatory Process", Washington, DC, 2003
ASCO	American Society for Clinical Oncology Research Methods on Clinical Trials, "Design of Trials for Rapid Drug Development", Vail, CO, 1997
ASCPT	American Society for Clinical Pharmacology and Therapeutics: Annual Meeting, "Safety Assessment of High Risk Drugs: The FIAU experience", Orlando, FL, 1996
	Annual Meeting: "Clinical Trials and Modeling in Drug Development", 2007, 2009
ASM	American Society of Microbiology: An FDA perspective on the preclinical evaluation of activity for potential HIV therapeutics, "Introduction: The importance of preclinical activity studies in the development of HIV therapeutics", Anaheim, CA, 1992
ASTRA	American Society for Therapeutic Radiology and Oncology Annual Meeting, "CDRH's Role in Radiation Oncology", New Orleans, LA, 2002
ATS	American Thoracic Society Annual Meeting, "Statistics Course for Physicians: Trials with categorical and survival outcomes", Phoenix, AZ, 1989
CFF	Cystic Fibrosis Foundation: Workshop on Surrogate Markers for CF, "Use of Surrogate Markers in Accelerated Approval Process", Bethesda, MD, 1997
	CFF: Williamsburg Conference: Gene Therapy Section, "FDA Expedited Review Process", Williamsburg, VA, 1997
CRT	Cardiovascular Radiation Therapy III, "Vascular Brachytherapy - An FDA Perspective", Washington, DC, 2001
	Cardiovascular Radiation Therapy IV and Testenotic Forum, "Brachytherapy and Drug Eluting Stents: A regulatory perspective", Washington, DC, 2002
CSS	Canadian Statistical Society, Annual Meeting: Plenary Session, "Methodological Problems in AIDS Epidemiology", Victoria, Canada, 1988
ECRI	ECRI Annual Meeting, "Assessment of the Quality of Life Impact of Medical Devices", Plymouth Meeting, PA, 1999
	ECRI Annual Meeting, "Beyond Medical Error - FDA Last Hurdle or only the First?", Plymouth Meeting, PA, 2000
	ECRI Annual Meeting: From Populations to Persons: Putting EBM Research into Practice, "Medicine in the Information Age: From population to people", Plymouth Meeting, PA, 2003
EUFEPS	European Federation for Pharmaceutical Sciences Conference on Optimizing Drug Development, "The impact and use of biomarker-based diagnostic kits in drug development and clinical practice", Basel, Switzerland, 2001
FDLI	The Food and Drug Law Institute: Advanced Drug Law Workshop, "Improving the Drug Approval Process", Washington, DC, 1992
	FDLI Dispute Resolution Workshop, "Tutorial: Resolving disputes with the FDA", Washington, DC, 1998
	FDLI 42nd Annual Educational Conference, "Blood and Tissue Safety", Washington, DC, 1998

	FDLI Medical Technology Symposium 2000, "Device Regulation", Washington, DC, 2000
	FDLI Clinical Trials Workshop, "Evidence Based Medicine", Washington, DC, 2001
	FDLI Annual Educational Conference, "CDRH: Looking ahead", Washington, DC, 2001 - 2003
FHI	Family Health International: Opportunities for Industrial Collaboration in Contraceptive Research, "FDA Regulatory Issues: Anti-infective products", Durham, NC, 1996
IADR	International Association for Dental Research, "The Epidemiology of Oral Manifestations of HIV", Montreal, Canada, 1988
ICAAC	Interscience Conference on Antimicrobial Agents and Chemotherapy: Symposium - Prophylaxis in the HIV-infected patient, "Assessment of New Drugs and Combinations for OI Therapy Prior to Phase 3 Trials", Anaheim, CA, 1992 ICAAC Annual Meeting, "Regulatory Requirements of Clinical Trials", "Acyclovir Forum", and Panel on AIDS Clinical Trials", Anaheim, CA., Anaheim, CA, 1993 ICAAC Annual Meeting, "New Modeling Methodologies: Influence on Clinical Trial Design", New Orleans, LA, 1994
ICP	9th International Conference on Pharmacoepidemiology: Use of Pharmacoepidemiology in Public Health, "Postmarketing surveillance and other uses of epidemiology in the development of anti-viral drugs", Washington, DC, 1993
IDSA	Infectious Disease Society of America Workshop on Clinical Trials in Anti-infective Drug Development, "FDA Regulations, and Guidance", San Francisco, CA, 1997
IICC	Second International Interdisciplinary Conference on Cardiovascular Medicine and Science, "Cardiovascular Devices, Medicine, Science and Society", Bethesda, MD, 2003
IPC	37th International Industrial Pharmacy Conference, "CBER's Vision for the Modernization of FDA", Austin TX, 1998
IRT	Intracoronary Radiation Therapy 2000, "Intracoronary Radiation: AN FDA Perspective", Washington, DC, 2000
ISCE	International Society of Computerized Electrocardiography, "Computers in Medical Product Development", Gaithersburg, MD, 2003; "Current Issues in the Regulation of Electrocardiography", Gaithersburg, MD, 2004.
ISACVB	International Society for Applied Cardiovascular Biology, Biennial Meeting, "Safe and Effective Tissue Engineering", Savannah, GA, 2004
ISNA	3rd International Symposium on Nutrition and HIV, "FDA Guidelines on Nutritional Claims and Products", Philadelphia, PA, 1994
ISTAHC	International Society for Technology Assessment in Health Care 2001, "Evaluating Breakthrough Technology", Philadelphia, PA, 2001
Keystone	UCLA Conference on Acquired Immunodeficiency Syndrome, "Modeling the impact of PCP prophylaxis on survival", Keystone, CO, 1990 Keystone Symposia on Molecular & Cellular Biology: Discovery and Development of Therapeutic Compounds, "CD4 Counts and Clinical Outcomes: Follow-up of ddI and ddC trials", Snowmass, CO, 1993 Keystone Dialog on Pharmacogenomics, "", Washington, DC, 2003
Lab Institute	21st Annual G2 Lab Summit, "Medical Diagnostics: Overcoming Regulatory Hurdles", Arlington, VA, 2003



<b>NAMA</b>	Nucleic Acid Medical Applications: International Conference on Nucleic Acid Medical Applications, "The Interaction among FDA, Industry and Research Institutions on Nucleic Acid Medical Applications", Cancun, Mexico, 1993
<b>NFID</b>	National Foundation for Infectious Diseases and American Society for Microbiology: First National Conference on Human Retroviruses and Related Infections, "Clinical Drug Trials, Surrogate Markers and Disease Progression", Washington, DC, 1993
<b>PAF</b>	Pediatric AIDS Foundation: Identification of Critical Areas for Research in Pediatric AIDS, Santa Barbara, CA, 1994
<b>PCA</b>	Patient Care Assessment Council (Professional Organization of Quality Assurance Coordinators): Annual Meeting:, "Statistics and quantitative methods in quality assurance", Oakland, CA, 1986
<b>Pop Council</b>	Women's Health Action and Mobilization / Population Council Meeting, "Practical and Ethical Dilemmas in Testing of Microbicides", Airle, VA, 1997
<b>PRSA</b>	Public Relations Society of America, "Consumer Protection: Medical Devices and Radiation Emitting Products", Rockville, MD, 2003
<b>SCI</b>	Society for Clinical Immunology: Annual Meeting, "Surrogate Markers for Immune Based Therapies", Williamsburg, VA, 1993
<b>SCT</b>	Society for Clinical Trials and the International Society for Clinical Biostatistics: 2nd Joint Meeting:, "Surrogate Markers", Boston, MA, 1997
<b>STM</b>	Society of Transplant Medicine: Annual Meeting:, "Clinical Trial Design for Transplant Drugs", Houston, TX, 1993 STM Consensus Conference on Therapeutic Drug Monitoring in Transplantation Medicine, "Development of Drugs for Solid Organ Transplantation", Lake Louise, Alberta, Canada, 1995
<b>SWHR</b>	Society for Women's Health Research: Annual Corporate Advisory Council Meeting, "Development of Drugs and Medical Devices", Washington, DC, 2003
<b>TCT</b>	Transcatheter Cardiovascular Therapeutics 2002, "Cardiovascular Devices: What's New at CDRH", Washington, DC, 2002

## Trade and Industry Associations

<b>AdvaMed</b>	Advanced Medical Technology Association (AdvaMed): Annual Device Submission Workshop, "CDRH Directions", Washington, DC, 1999 - 2003 AdvaMed Technical and Regulatory Board, "CDRH: The next 5 years", Washington, DC, 2000 AdvaMed Annual Meeting, "CDRH Looking Ahead", Palm Springs, CA, 2001; Carlsbad, CA, 2002; Aventura, FL, 2003 AdvaMed Annual Meeting, "CDRH Enforcement Priorities", Palm Springs, CA, 2001 Innovation for Preparedness: The Public-Private Partnership, "CDRH's Role in Counterterrorism", Washington, DC, 2003 AdvaMed Board of Directors Meeting, "MUDFMA Progress Report", Washington, DC, 2003 AdvaMed Annual Meeting, "Building CDRH of the Future", Phoenix, AZ, 2004 AdvaMed Audioconference: "Developing a Strategic Relationship with
----------------	---

	FDA”, Washington DC 2004
Biotech	Biotech Meeting, "CDRH Update", Laguna, CA, 2000
	Biotech Meeting, "FDA Policy and Biotech", Laguna, CA, 2002
Blue Cross	Blue Cross of Northern California Technology Assessment Meeting, "Evidence Standards for Medical Device Approvals", San Francisco, CA, 2001
CMDMA	Colorado Medical Device Manufacturers Association Meeting, "Device Regulation - A look to the Future", Denver, CO, 1999, 2002
DDMA	Dallas Device Manufacturers Meeting, "Issues in Medical Device Regulation", Dallas, TX, 2002
DIA	Drug Information Association Annual Meeting, "Accelerated Review: Problems, Opportunities, and Experience to Date: A perspective from the Anti-Viral Division", Chicago, IL, 1993
	Drug Information Association: Clinical Trials in Biotechnology: Planning to Prevent the Pitfalls, "Pivotal Trial Issues in HIV Disease", Newport Beach, CA, 1994
	DIA Annual Meeting, "Effective FDA / Industry Meetings: FDA Perspectives", Washington, DC, 1994
	DIA Annual Meeting, "Subgroup Analyses", Washington, DC, 1994
	Drug Information Association: Regulatory aspects of Quality of Life Measurement in Drug approval, Safety Reporting and promotion, "Quality of Life Measurement and Drug Effects: Issues in AIDS Talks", Washington, DC, 1994
	DIA Annual Meeting, "Expanded Access to Drugs for HIV Infection", Orlando, FL, 1995
	DIA/CDER/CBER: Workshop on Proposed Interim Guidance for Electronic Submission of Case Report Forms and Tabulations, "An Office Level Perspective on Electronic Submissions", Washington, DC, 1996
	DIA Meeting: Clinical Trials - Contemporary Design Solutions, "Clinical Endpoints and Surrogate Markers in High Mortality Diseases, AIDS as the Model Improving for Improving Drug Development", Philadelphia, PA, 1997
	DIA Annual Meeting, "Clinical Research Training of Physicians: An Unmet Need - A Government Perspective", Boston, MA, 1998
	DIA/FDA Project Management Workshop, "Project Management, CBER Perspectives", Bethesda, MD, 1998
	DIA Annual Meeting, "CDRH Update", Chicago, IL, 2002
EUCOMED	European Medical Technology Industry Association Annual Meeting, "CDRH: Current Issues", Berlin, Germany, 2000
	Annual Meeting: Workshop on Clinical Evidence in Medical Device Approvals, Brussels, Belgium 2010
EUROM	European Federation of Precision Mechanical and Optical Industries: EUROM VI Medical Device Technology General Assembly, "Global Markets through International Harmonization - A US Perspective", Brussels, Belgium, 2003
FDMA	Florida Device Manufacturers Meeting, "Current Issues for Medical Device Regulation", Orlando, FL, 1999
Guidant	Post-Approval Registries Summit, 2005
IDM	Irish Devices Manufacturers Delegation Visit, "US Regulation of Medical Devices", Gaithersburg, MD, 2003
IMDMC	Indiana Medical Device Manufacturers Consortium Annual Meeting, "One HHS: FDA/CMS Harmonization", Indianapolis, MN, 2002

InHealth	Institute for Health Technology Studies: Medical Technology: Breaking Barriers between the Bench and the Bedside, "Accelerating Solutions for Patients -- Regulatory Reform", Washington DC, 2006
Institute for Regulatory Science	CMR Conference: Regulating Personalized Medicine, "Utilizing Diagnostics: implications for Personalized Medicine (by videotape)", Surry, UK, 2003
JFMDA	Japanese Federation of Medical Device Associations, "Issues of Medical Device Regulation in the US Market", Tokyo, Japan, 2002
Marwood Group	Marwood Group Washington Investor's Meeting, "Regulation and Innovation: Recent Case Studies", Washington, DC, 2003
MassMedic	Massachusetts Medical Device Industry Council (MassMedic) Annual End-of-the-Year Regulatory Issues Forum, "CDRH Priorities", Boston, MA, 1999, 2001, 2003
MD&M	Medical Design and Manufacturing - West - Conference, "CDRH 2002: Current Objectives and New Initiatives", Anaheim, CA, 2002
MDMA	Medical Device Manufacturing Association - Annual Meeting, "CDRH Update", Alexandria, VA, 2000 - 2003
MDT	Medical Device Technology Annual Conference, "Device Regulation in an International Milieu", Paris, France, 2000 MDT Annual Conference, "Device Regulation: Global Standards - Global Quality", Ireland, 2001 MDT Annual Conference, "The Evolution of the Regulation of Medical Devices", Birmingham, UK, 2003
Medical Alley	Medical Alley Medical Device Meeting, "CDRH: Hot Topics", St. Louis Park, MN, 2000 Minneapolis Regulatory Reform Forum, "Regulation of Medical Devices", Minneapolis, MN, 2002
MTLF	Medical Technology Leadership Forum: Capital Forum, Rayburn House Office, Washington, DC, 2002, 2004 MTLF: Capital Forum, "Tissue Engineering: Where do we go from here?", Rayburn House Office, Washington, DC, 2003 "Innovative Approaches to the Regulation of Combination Products & New Science: Options for Policymakers", San Diego 2004
NCPDG	Northern California Pharmaceutical Discussion Group, "Speeding Up Drug Development - Lessons from the AIDS Drugs," Milbrae, CA, 1997
NEMA	NEMA Diagnostic Imaging and Therapy Systems, 24th Annual Meeting, "CDRH Update", Roslyn, VA, 1999
OCRA	Orange County Regulatory Associations Meeting, "CDRH's Strategic Plans", Irvine, CA, 2000
PhARMA	PhARMA: PMA AIDS Task Force, "Expanded Access, Parallel Track and Treatment IND's - The current status", Washington, DC, 1992 Pharmaceutical Manufacturers Association: PMA Medical Section: Fall Meeting, "Accelerated Approval: An FDA Perspective", Arlington, VA, 1992 PhARMA Spring Science Meeting, "More rapid approvals - lessons learned from the AIDS experience", Parsippany, NJ, 1994 PhARMA Biostatistics Annual Workshop, "The Interactive NDA Review Process", Baltimore, MD, 1997 Improving Clinical Trials: Contemporary Design Solutions, "Accelerated Biologicals Development, Philadelphia, PA", Philadelphia, PA, 1998 Biostatistics and Data Monitoring Conference Workshop, "The Road Ahead for Drug Development", Bethesda, MD, 2001



Piper Jaffrey	US Bancorp Piper Jaffray: Health Care Conference, "Medical Devices", New York, NY, 2001
RAPS	Regulatory Affairs Professional Society Annual Meeting: Changes, Challenges, Choices, "Fundamental Benefits and Failures of Early Patient Access Programs for Investigational Drugs", Washington, DC, 1992 RAPS Annual Meeting, "Drug Approvals 1962-1993: Future Directions for Drug Regulation in the United States", Washington, DC, 1994 RAPS Annual Meeting, "Rapid Drug Development: The HIV paradigm", Washington, DC, 1997 RAPS Annual Meeting, "CBER Executive Update, Washington, DC", Washington, DC, 1998 RAPS Annual Conference and Exhibition, "CDRH Executive Briefing", Washington, DC, 1999 - 2003
SDRAN	San Diego Regulatory Affairs Network Meeting, "CDRH: Current Goals and Objectives", La Jolla, CA, 2002
ULSA	Utah Life Sciences Association Meeting, "Device Regulation and Innovation", Salt Lake City, UT, 2003
WRG	The Washington Research Group's Seventh Annual Health Care Conference, "Device Regulation and New Technology", Washington, DC, 2002 The Washington Research Group's Eighth Annual Health Care Conference, "Medical Devices: Innovation and Regulation", Washington, DC, 2003
WAFDO	Annual Meeting, "The Role of FDA in the Future of Pharmacogenomics", Phoenix AZ 2005

## Other Sponsored Workshops

ACI	4th National Conference on Managing Legal Risks in Conducting & Promoting Clinical Trials: "Compliance with the Regulatory Landscape" New York City, NY 2006
ACT	Applied Clinical Trials, "Designing and Managing Politically Charged Clinical Trials: AIDS and Expedited Drug Development", New Brunswick, NJ, 1994
Biocom Biologics Update Biomedical Focus	BIOCOM Meeting, "Medical Device Development", San Diego, CA, 2002 Biologics Update '98, "Safety issues for biological products: How safe is safe? Blood Safety", Washington, DC, 1998 Biomedical Focus 2000, "Medical Devices: Evidence of Benefit - From Performance Standards to Quality of Life", St. Paul, MN, 2000 50th Annual Minnesota Quality Conference & 17th Annual Biomedical Focus Conference, "Medical Device User Fee Legislation; Third Party Auditing", Minneapolis, MN, 2003
Cannan Partners	Cannan Partners CEO Meeting: Driving Innovation: "FDA Challenged", San Francisco, 2006
CHI	Cambridge Healthtech Institute: AIDS Drug Development, "FDA Perspective on Clinical Development of Treatment for HIV Infection", Alexandria, VA, 1994 CHI Workshop: HIV Surrogate Markers: Virological and Immunological Indicators, "Validation and Use of Viral Load Assays in Clinical Trials", McLean, VA, 1996

CPM	10th International Conference on Pharmaceutical Medicine, "Accelerating Drug Development and the Approval Process", Boston, MA, 1998
FDC Reports	"Trials and Tribulations: Randomized Trials vs. Practical Clinical Studies for Drugs and Devices", Teleconference 2004
GBF	Global Business Forum, "The FDA and the Development of AIDS Drugs", United Nations Building, New York, NY, 1993
IBC	IBC New Antiviral Therapeutics Workshop, "Accelerated Approval", Arlington, VA, 1993 IBC: Surrogate Markers in Drug Development Workshop, "Surrogate Markers", McLean, VA, 1994 IBC Conference on Surrogate Markers, "Standards of Evidence for Drug Approval -- An FDA Perspective", London, 1999
IIR	Institute for International Research: The 2nd Annual CANDIA/CAPLA Technology Conference, "The Rolling NDA: Computer-assisted applications for life-threatening diseases", Alexandria, VA, 1993
MF	Management Forum, "Development of Drugs for HIV Infection", London, England, 1994, 1995 Management Forum, "Drug/Device Combination Products – The US FDA Regulatory Approach, 2005
NeoPharma	Advances in Liposomes, "Regulation of New Medical Products – Innovation and Consumer Protection", Chicago, 2004
PERI	Pharmaceutical Education and Research Institute: Advanced GCP's, "Good Clinical Practice", Arlington, VA, 1998 PERI: Advanced Good Clinical Practices, "World-wide Regulatory Update on Drugs and Biologics", Roslyn, VA, 1999
Pharmillennium	Pharmillennium99: Accelerating the Pipeline: From Drug Discovery to Market, "Accelerated Approval and Fast Track Drug Development,", Washington, DC, 1999
RAND	Rand Corporation Conference, "Assessment of the Quality of Care of Pneumocystis carinii Pneumonia", Los Angeles, CA, 1988
Texas AIDS Update	Texas AIDS Update, "Prevention of PCP Pneumonia", Houston, TX, 1990
US Oncology	US Oncology Annual Meeting, "What does the FDA Look for in Clinical Trials Monitoring", Dallas, 2004; "Post-marketing Surveillance – Recent changes in FDA's Requirements", 2008

## **PUBLISHED WORKS**

### **ORIGINAL ARTICLES**

1. Feigal DW, Blaisdell FW. The estimation of surgical risk. *Medical Clinics of North America* 63:1131-44, 1979.
2. Jakle C, Feigal DW, Robbins D, Shapiro R, Wiesner K. Serum IgG and IgM rheumatoid factors and complement activation in extra-articular rheumatoid disease. *J Rheumatology* 12:227-232, 1985.
3. Pollet S, White RH, Jang H, Yim CW, Feigal DW. Aspirin dosing using 15 grain enteric-coated tablets. *J Rheumatology* 12:337-342, 1985.
4. Feigal DW, Robbins D, Leek JC. Giant cell arteritis associated with mononeuritis multiplex and complement-activating 19S IgM rheumatoid factor. *American Journal of Medicine* 79:495-500, 1985.
5. Robbins D, Feigal DW, Leek JC, Shapiro R, Wiesner K. Complement Activation by 19S IgM Rheumatoid factor in Vitro: Relationship to Disease Activity in Rheumatoid Arthritis. *J Rheumatology* 13:33-38, 1986.
6. Hulley SB, Feigal DW, Ireland C. The systolic hypertension in the elderly program (SHEP): the first three months. *J Amer Geriatrics Society* 34:101-105, 1986.
7. Smith WM, Feigal DW, Furberg CD, Greenlick M, Kuller L, Perry HM, Schnaper HW, Schoenberger JA. Uses of diuretics in treatment of hypertension in the elderly. *Drugs* 31 (Suppl 4): 154-164, 1986.
8. Snyder NA, Feigal DW, Arief AI. Hyponatremia in the elderly: A heterogeneous, morbid and iatrogenic entity. *Annals of Internal Medicine*. 107:309-319, 1987.
9. Siegel D, Kuller L, Lazarus NB, Black D, Feigal DW, Hughes G, Schoenberger JA, Hulley SB. Predictors of cardiovascular events and mortality in the Systolic Hypertension in the Elderly Program pilot project. *Amer J Epidemiol* 1987; 126:385-99.
10. Chaisson RE, Leuther MD, Allain J-P, Nusinoff-Lehrman S, Boone GS, Feigal DW, Volberding PA. Effect of zidovudine on serum HIV core antigen (HIV-Ag) levels: results from a placebo-controlled trial. *Archives of Internal Medicine* 1988; 148:2151-3.
11. Jacobson MA, O'Donnell JJ, Porteous D, Brodie HR, Feigal DW, Mills J. Retinal and gastrointestinal disease due to cytomegalovirus in patients with the acquired immune deficiency syndrome. *Quarterly Journal of Medicine*, 1988; 254:473-486.
12. Golden JA, Chernoff D, Hollander H, Feigal DW, Conte JE. Inhaled pentamidine prophylaxis for *Pneumocystis carinii* pneumonia in patients with acquired immunodeficiency syndrome and AIDS related complex. *Lancet*. 1:654-657, 1989.

13. Masur H., Allegra C., Armstrong D., DeGruttola V., Ellenberg S.S., Feigal D.W., et. al. Guidelines for prophylaxis against *Pneumocystis carinii* pneumonia for persons infected with Human Immunodeficiency virus. *MMWR* 38:S5 1-9, 1989.
14. Jacobson MA, Peiperl L, Volberding PA, Porteus D, Toy PTCY, Feigal DW. Packed red blood cell transfusion therapy for anemia in patients with AIDS and ARC: incidence, associated factors and outcome. *Transfusion*, 1990; 30:133-7.
15. Lemp GF, Payne SF, Rutherford GW, Hessol NA, Winkelstein W, Wiley JA, Moss AR, Chaisson RE, Chen RT, Feigal DW, Thomas PA, Werdegard D. Demographic projections of AIDS morbidity and mortality in San Francisco. *JAMA* 1990; 263:1497-1501.
16. Leoung GS, Montgomery AB, Abrams DI, Adams M, Corkery K, Wardlaw L, Busch D, Gordon S, Jacobson MA, Volberding PA, Feigal DW. Aerosolized pentamidine for prophylaxis against *Pneumocystis carinii* pneumonia: The San Francisco Community Prophylaxis Trial. *NEJM* 1990; 323:769-776.
17. The National-Institutes of Health - University of California Expert Panel for Corticosteroids as Adjunctive Therapy for Pneumocystis pneumonia. *NEJM* 1990; 323:1500-1504.
18. Greenspan D, Greenspan JS, Overby G, Hollander H, Abrams DI, MacPhail L, Borowsky C, Feigal DW Jr. Risk factors for rapid progression from hairy leukoplakia to AIDS: a nested case-control study. *J Acquir Immune Defic Syndr* 1991; 4:652-8.
19. MacPhail LA, Greenspan D, Feigal DW, Lennette ET, Greenspan JS. Recurrent aphthous ulcers in association with HIV infection. Description of ulcer types and analysis of T-lymphocyte subsets. *Oral Surg Oral Med Oral Pathol* 1991; 71:678-83.
20. Feigal DW, Katz MH, Greenspan D, Westenhouse J, Winkelstein W Jr, Lang W, Samuel M, Buchbinder SP, Hessol NA, Lifson AR, et al. The prevalence of oral lesions in HIV-infected homosexual and bisexual men: three San Francisco epidemiological cohorts. *AIDS* 1991; 5:519-25.
21. Jacobson MA, Hopewell PC, Yajko DM, Hadley WK, Lazarus E, Mohanty PK, Modin GW, Feigal DW, Cusick PS, Sande MA. Natural history of disseminated *Mycobacterium avium* complex infection in AIDS. *J Infect Dis* 1991; 164:994-8.
22. Dodd CL; Greenspan D; Katz MH; Westenhouse JL; Feigal DW; Greenspan JS. Oral candidiasis in HIV infection: pseudomembranous and erythematous candidiasis show similar rates of progression to AIDS. *AIDS* 1991; 5:1339-43.
23. Kemper CA, Meng TC, Nussbaum J, Chiu J, Feigal DW, Bartok AE, Leedom JM, Tilles JG, Deresinski SC, McCutchan JA. Treatment of *Mycobacterium avium* complex bacteremia in AIDS with a four-drug oral regimen. Rifampin, ethambutol, clofazimine, and ciprofloxacin. The California Collaborative Treatment Group. *Ann Intern Med* 1992; 116 :466-72.
24. Devor M, Barrett-Connor E, Renvall M, Feigal DW Jr, Ramsdell J. Estrogen replacement therapy and the risk of venous thrombosis. *Am J Med* 1992; 92:275-82.

25. Bozzette SA, Feigal D, Chiu J, Gluckstein D, Kemper C, Sattler F. Length of stay and survival after intensive care for severe *Pneumocystis carinii* pneumonia. A prospective study. California Collaborative Treatment Group. *Chest*. 1992 ; 101: 1404-6
26. Behrman RE, Kammerman LA, Feigal DW. Continued zidovudine or didanosine for human immunodeficiency virus infection. [letter] *N Engl J Med*. 1992; 327: 1598-9.
27. Tamayo SG, Rickman LS, Mathews WC, Fullerton SC, Bartok AE, Warner JT, Feigal DW Jr, Arnstein DG, Callandar NS, Lyche KD, et al. Examiner dependence on physical diagnostic tests for the detection of splenomegaly: a prospective study with multiple observers. *J Gen Intern Med*. 1993; 8: 69-75.
28. Broadus VC, Feigal DW Jr. Starting an academic career. A survey of junior academic pulmonary physicians. *Chest*. 1994; 105: 1858-63.
29. Devor M, Wang A, Renvall M, Feigal D, Ramsdell J. Compliance with social and safety recommendations in an outpatient comprehensive geriatric assessment program. *J Gerontol*. 1994; 49: M168 –73.
30. Montgomery AB, Feigal DW Jr, Sattler F, Mason GR, Catanzaro A, Edison R, Markowitz N, Johnson E, Ogawa S, Rovzar M, *et al*. Pentamidine aerosol versus trimethoprim sulfamethoxazole for *Pneumocystis carinii* in acquired immune deficiency syndrome. *Am J Respir Crit Care Med*. 1995; 151; 1068 -- 74.
31. Perez Stable EJ, Coates TJ, Baron RB, Biro BS, Hauck WW, McHenry KS, Gardiner PS, Feigal D. Comparison of a lifestyle modification program with propranolol use in the management of diastolic hypertension. *J Gen Intern Med*. 1995; 10: 419--28.
32. Panel on Clinical Practices for Treatment of HIV Infection. Guidelines for the Use of Antiretroviral Agents in HIV Infected Adolescents. *Annals of Internal Medicine* 128:12(Part 2) 1079-1100.
33. Feigal D. FDA explores new antiretroviral trial designs: interview with David Feigal, M.D. Interview by John S. James. *AIDS Treat News* 1997:1-5.
34. Feigal DW, Jr. FDA public health advisory: risk of electromagnetic interference with medical telemetry systems. *Int J Trauma Nurs* 2000; 6:113-4.
35. Feigal DW, Jr. Recall of Clinipad sterile products used in prepackaged procedure kits and trays. *Int J Trauma Nurs* 2000; 6:101-2.
36. Feigal DW, Jr., Hughes JM. Public health advisory: infections from endoscopes inadequately reprocessed. *Int J Trauma Nurs* 2000; 6:1-3.
37. Feigal DW, Jr., Woodcock J. FDA public health advisory: potential for injury from medical gas misconnections of cryogenic vessels. *Int J Trauma Nurs* 2001; 7:121-2.
38. Feigal D. Who's on first? what's on second? *Control Clin Trials* 2001; 22:139-41.

39. Galluppi GR, Rogge MC, Roskos LK, Lesko LJ, Green MD, Feigal DW, Jr., Peck CC. Integration of pharmacokinetic and pharmacodynamic studies in the discovery, development, and review of protein therapeutic agents: a conference report. Clin Pharmacol Ther 2001; 69:387-99.
40. Feigal DW, Jr. FDA public health notification: reducing radiation risk from computed tomography for pediatric and small adult patients. Int J Trauma Nurs 2002; 8:1-2.
41. Petricoin EF, 3rd, Hackett JL, Lesko LJ, Puri RK, Gutman SI, Chumakov K, Woodcock J, Feigal DW, Jr., Zoon KC, Sistare FD. Medical applications of microarray technologies: a regulatory science perspective. Nat Genet 2002; 32 Suppl:474-9.
42. Feigal DW, Gardner SN, McClellan M. Ensuring safe and effective medical devices. N Engl J Med 2003; 348:191-2.
43. Feigal DW Jr. Public health notification: diathermy interactions with implanted leads and implanted systems with leads. J Ir Dent Assoc. 2003;49(1):26-7.
44. Gutman S, Feigal D. Decision making in pharmacogenomic diagnosis: is there anything new under the sun? Drug Discov Today. 2003 Sep 1;8(17):765-6.
45. Kaplan AV, Baim DS, Smith JJ, Feigal DA, Simons M, Jefferys D, Fogarty TJ, Kuntz RE, Leon MB. Medical device development: from prototype to regulatory approval. Circulation. 2004 Jun 29;109(25):3068-72.
46. Mehran R, Leon MB, Feigal DA, Jefferys D, Simons M, Chronos N, Fogarty TJ, Kuntz RE, Baim DS, Kaplan AV. Post-market approval surveillance: a call for a more integrated and comprehensive approach. Circulation. 2004 Jun 29;109(25):3073-7.
47. Califf RM, Nissen SE, DeMaria AN, Ohman EM, Pitt B, Willerson JT, Bilheimer DW, Cohn JN, Feigal DW Jr, Hampson L, Lorell BH, Pepine CJ, Popp RL. Task force 2: Investigator participation in clinical research. J Am Coll Cardiol. 2004 Oct 19;44(8):1729-36.
48. Myerburg RJ, Feigal DW, Jr., Lindsay BD. Life-threatening malfunction of implantable cardiac devices. N Engl J Med 2006;354(22):2309-11.
49. Baim, D.S., et al., Medical device development: managing conflicts of interest encountered by physicians. Catheter Cardiovasc Interv, 2007. 69(5): p. 655-64.
50. Jacobson, J.D. and D. Feigal, Red sky in the morning: modifying prescription drug labels as a result of postmarket surveillance. Food Drug Law J, 2007. 62(3): p. 529-46.

## **II. INVITED ARTICLES, BOOK CHAPTERS, BOOKS**

1. Feigal DW, Hulley SB. Mild hypertension: where should treatment begin? (Editorial) *Western J Med* 141:515-7, 1984.
2. Feigal DW, Glasser R. Preoperative risk in the elderly. in Bolt RJ ed., *Medical evaluation of the surgical patient*. Futra Publishing, Mount Kisco, New York. pp 67-96, 1987.
3. Lo B, Feigal DW, Hulley SB. The study subjects: III. Ethical considerations. In: *Health research methods: An epidemiologic approach*, ed. Hulley SB, Cummings S. Williams & Wilkins, 1987.
4. Feigal DW. Data management & Analysis: In: *Health research methods: An epidemiologic approach*, ed. Hulley SB, Cummings S. Williams & Wilkins, 1987.
5. Feigal DW, Gutman S. Drug Development, Regulation and Genetically Guided Therapy 2002
6. Feigal, D.W., Chapter III.2.11 – Postmarket Considerations in Biomaterials and Medical Devices, in Biomaterials science: an introduction to Materials in Medicine, B.D. Ratner, Editor. Elsevier/Academic Press, Boston. 2013



## **Board Service**

### **Renovo Ltd, Manchester, England**

A biotech company developing anti-scarring biologicals and drugs

September 2004 - May 2006	Non-Executive Member, Board of Directors Privately Held Venture Funded Biotech
June 2006 – Feb 2009	Non-Executive Member, Board of Directors Traded on the London Stock RNVO Committees: Audit Committee

### **Aspect Medical Inc., Newton, Massachusetts**

A medical device company developing anesthesia monitoring equipment

January 2005 - Sept - 2009	Non-Executive Member, Board of Directors Traded on the NASDAQ ASMP Committees: Audit Committee
-------------------------------	--

### **Alexza Inc., Palo Alto, California**

A drug delivery company developing inhaled medications for acute care

September 2004 - May 2006	Scientific and Regulatory Advisory Board Member Traded on the NASDAQ ALXA
------------------------------	--

### **Baird Venture Partners, Chicago, Illinois**

A venture fund managing investments in Medical Devices and IT

September 2004 - 2008	Scientific Advisory Board Member
--------------------------	----------------------------------

### **Panorama Capital, Palo Alto, California**

A venture fund managing investments in Medical Innovation

June 2006 - May 2007	Scientific Advisor
-------------------------	--------------------

### **EJ Financial Services, Phoenix, AZ**

A Medical Technology Investment Company

September 2006 - August 2007	Scientific Advisor
---------------------------------	--------------------

### **In Vivo Therapeutics**

A Biotechnology Company

September 2006 - 2013	Scientific Advisory Board
-----------------------	---------------------------



# Prior Testimony

David William Feigal, Jr., MD MPH

---

## Trial or Arbitration Testimony in the Last 4 years (Since October 1, 2012)

12-23-2012 New York, NY	Arbitration Hearing: Eagle Pharmaceuticals, Inc., Claimant, -against- The Medicine Company, Respondent. American Arbitration Association. Case No. 13 122 Y 02642 11
3-20-13 Cleveland, OH	In Re: Gadolinium Based Contrast Agents Products Liability Litigation (mdl No. 1909) Paul Decker and Karen Decker, Plaintiffs, vs. GE Healthcare, Inc., Et al., Defendants. In the United States District Court Northern District of Ohio Eastern Division. Case No. 1:12 GD 50004
4-3-13 Los Angeles, CA	Jack and Nancy Cooper, Plaintiff, v. Takeda Pharmaceuticals, et. al., Defendants, in the Superior Court, State of California, County of Los Angeles, Case No. 12-518535.
5-3-13 Chicago, IL	Dolores and Milton Tietz, Plaintiff v. Abbott Laboratories, Defendant, in Circuit Court of Cook County, Illinois. Case No. 12L-002715
8-21-13 San Diego, CA	Kevin Fleischmann, Plaintiff v. DJO, Inc., Defendant, in Superior Court of the State of California in and for the County of San Diego, Case No. 37-2010-00093122-CU-PL-CTL
9-24-13 Baltimore, MD	Camhong An, et al. Plaintiffs, v. Takeda Pharmaceuticals America Inc., et al. Defendants, in the Circuit Court for Baltimore City, Baltimore, MD. Case No. 24-C-12-003565
12-6-13 Las Vegas, NV	Alsabaugh, Alen, Plaintiff, v. Takeda Pharmaceutical America Inc., et al, Defendant, in the Eight Circuit Court of Nevada, Las Vegas, NV. Eighth District Court, Nevada. case number A-12-655741-C
2-27-14 Atlantic City, NJ	Kamie S. Kendall, Plaintiff, v. Hoffmann-la Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-la Roche Ltd.; and Roche Holding Ltd., Defendants, in Superior Court of New Jersey Law Division: Atlantic County, Docket No.: ATL-L-8213-05 MT
3-27-14 and 3-28-14 Lafayette, LA	in Re: Actos (pioglitazone) Products Liability Litigation, MDL No. 6:11-Md-2299, Terrence and Susan Allen v. Takeda Pharmaceuticals International, Inc., et al, in the United States District Court for the Western District of Louisiana, Lafayette Division, No. 6:12-cv-00064-rfd-pjh

## **Trial Testimony in the Last 4 Years**

4-13-14 and 4-14-14 Chicago, IL	In Re: Actos Litigation, Diane Whitlatch, Individually and as Special Administrator for the Estate of William M. Whitlatch, Plaintiff, vs. Takeda Pharmaceuticals America, Inc.; Takeda Pharmaceuticals U.S.A., Inc., f/k/a Takeda Pharmaceuticals North America, Inc.; and Takeda Pharmaceutical Company Limited, Defendant, in the Circuit Court of Cook County, Illinois County Department Case No.: 201 L-I-010011 Case No.: 2012-I-006087
7-28-14 Boston, MA	Michael Tersigni v. Wyeth Pharmaceuticals, Inc., and Pfizer, Inc. in United States District Court for the District of Massachusetts Civil Action No. 1:11-CV-10466-JLT
10-01-14 Philadelphia, PA	Frances Wisniewski, Plaintiff, v. Takeda Pharmaceuticals North America, Inc., et al., Defendants, in the Court of Common Pleas First Judicial District of Pennsylvania Civil Trial Division, July Term, 2012, No. 02272 Philadelphia, Pennsylvania.
11-5-14 and 11-6-14 Martinsburg, WV	Richard P. Myers and Cynthia Myers v. Takeda Pharmaceuticals North America, Inc., et al., Defendants, in the Circuit Court of Berkeley County, West Virginia, Civil Actin 13-C-315.
11-12-14 and 11-13-14 Burlington, VT	Kevin Drake and Lori Drake, Individually and as Next Friend of J.D, Plaintiffs, v. Allergan, Inc., Defendant, In the United States District Court for the District of Vermont Case No. 2:13-CV-234
2-3-15, 2-4-15, and 2-9-15 Philadelphia, PA	John Kristufek v. Takeda Pharmaceuticals America, Inc., et al., in the Court of Common Pleas of Philadelphia County, First Judicial District of Pennsylvania, Civil Trial Division, July Term, 2012, No. 02275
2-5-15 Reno, NV	Kevin Phillips, Plaintiff, v. C. R. Bard, et al., Defendants, in the U. S. District Court for the District of Nevada, Civil Action Number 3:12-cv-00344-RCJ-WGC
5-12-15 New York, NY	Pericor Therapeutics, Inc., Claimant, v. Merck & Co., Inc., et.al., before the American Arbitration Association, Arb No. 13 122 Y 03052 11
9-29-15 to 10-01- 15, 10-06-15 Las Vegas, NV	George Decou and Mary Iorio v. Takeda Pharmaceuticals, Inc., et al., in District Court, Clark County, Nevada, Case No. A-13-683446-C

## Deposition Testimony in the Last 4 Years

12-6-12 New York, NY	Eagle Pharmaceuticals, Inc., Claimant, -against- The Medicine Company, Respondent. American Arbitration Association. Case No. 13 122 Y 02642 11
12-30-12 San Francisco, CA	In Re: Gadolinium Based Contrast Agents Products Liability Litigation (MDL No. 1909) Paul Decker and Karen Decker, Plaintiffs, vs. GE Healthcare, Inc., Et al., Defendants. In the United States District Court Northern District of Ohio Eastern Division. Case No. 1:12 GD 50004
1-28-13 Washington, DC	Jack and Nancy Cooper, Plaintiff, v. Takeda Pharmaceuticals, et. al., Defendants, in the Superior Court, State of California, County of San Francisco. Case No. 12-518535; Camhong An, et al., Plaintiffs, v. Karl Nieberlein and Takeda Pharmaceuticals, et. al., in the Circuit Court of the City of Baltimore State of Maryland. Case No. 24-C12003565
6-12-13 New York, NY	
1-30-13 San Francisco, CA	Jessica Wells, Individually and as Next Friend of Jackson Wells, v. Allergan Inc., Defendants, in the United States District Court for the Western District of Oklahoma. Case No. 5:12-CV-00973-C.
4-30-13 San Francisco, CA	In Re: C.R. Bard, Inc. Pelvic Repair System Products Liability Litigation (MDL No. 2187), in the United States District Court for the Southern District of West Virginia Charleston Division
6-12-13 New York, NY	Camhong An, et al. Plaintiffs,v. Takeda Pharmaceuticals America, Inc., et al. Defendants, in the Circuit Court for Baltimore City, Baltimore, MD. Case No. 24-C-12-003565
7-25-13 San Francisco, CA	In Re: Diet Drugs (phentermine / fenfluramine / dexfenfluramine) Products Liability Litigation (MDL No. 1203) in United States District Court for the Eastern District of Pennsylvania
8-14-13 San Francisco, CA	Heather Brown, Danny & Shauna Brown v. George W. DeMuth, MD, et al., in the Circuit Court of Montgomery County, Alabama. Case No. Case No. CV-2009-900734.00
10-9-13 San Francisco, CA	In Re: Actos (pioglitazone) Products Liability Litigation (MDL No. 6:11-md-2299), in the United States District Court for the Western District of Louisiana
11-6-13 San Francisco, CA	In Stephen Wendell & Lisa Wendell, Plaintiffs, V. Johnson & Johnson; Centocor, Inc.; Abbott Laboratories; Smithkline Beecham d/b/a Glaxosmithkline; Teva Pharmaceuticals USA; Gate Pharmaceuticals, A Division of Teva Pharmaceuticals USA; Par Pharmaceuticals; Mylan Laboratories, Inc., Defendants, in United States District Court, Northern District of California Oakland Division, Case No. CV09-4124 CW
11-21-13 San Francisco, CA	In Anthony Payne and Johnita Payne, His Wife, Plaintiffs, vs. C. R. Bard, Inc. and Bard Peripheral Vascular, Inc., Defendants, in United States District Court Middle District of Florida Orlando Division, Case No. 6:11-cv-01582-orl-37gjk

## Deposition Testimony in the Last 4 Years

12-24-13 Redondo Beach, CA	Kamie S. Kendall, Plaintiff, vs. Hoffmann-la Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-la Roche Ltd.; and Roche Holding Ltd., Defendants, in Superior Court of New Jersey Law Division: Atlantic County, Docket No.: ATL-L-8213-05 MT
2-19-14 San Francisco, CA	Diane Whitlatch, Individually and as Special Administrator for the Estate of William M. Whitlatch, Plaintiff, vs. Takeda Pharmaceuticals America, Inc.; Takeda Pharmaceuticals U.S.A., Inc., f/k/a Takeda Pharmaceuticals North America, Inc.; and Takeda Pharmaceutical Company Limited, Defendant, in the Circuit Court of Cook County, Illinois County Department Case No.: 201 L-I-010011 Case No.: 2012-I-006087
5-21-14 San Francisco, CA	Kevin Phillips, Plaintiff, v. C. R. Bard, et al., Defendants, in the U. S. District Court for the District of Nevada, Civil Action Number 3:12-cv-00344-RCJ-WGC; Melanie Rackliff, Plaintiff, v. CR Bard, Inc., Bard Peripheral Vascular, Inc., Defendants, Superior Court of Arizona, Maricopa County, Case No. CV2011-021206; and, Tina Barkley and Jeffery Barkley, Plaintiffs, v. CR Bard, Inc., Bard Peripheral Vascular, Inc., Defendants, Superior Court of Arizona, Maricopa County, Case No. CV2011-021250
7-17-14 San Francisco, CA	Donald Gates, Plaintiff, v. Sutter General Hospital, and Intuitive Surgical, in Superior Court, State of California or the County of Sacramento, Case No. 34-2011-00103436.
8-6-14 Cary, NC	Candie L. Willoughby and Jerome Willoughby, Plaintiffs, v. Johnston Memorial Hospital Authority, Defendant and Third-party Plaintiff, v. Steris Corporation and General Electric Company, Third-party Defendants, in the State of North Carolina in the General Court of Justice, Superior Court Division, County of Johnston, File No. 11-CVS-3008
8-19-14 San Francisco, CA	Kevin Drake and Lori Drake Individually and as Next Friend of J.D., Plaintiffs, vs. Allergan, Inc., Defendant, in the United States District Court for the District of Vermont Case No. 2:13-CV-234
9-16-14 San Francisco, CA	Jennifer Campbell, vs. Plaintiff, C.R. Bard, D/b/a Bard Peripheral Vascular, Inc., Bard Peripheral Vascular, Inc.; Georgetown Community Hospital, LLC, A/k/a the Bariatric Center Georgetown Community Hospital; St. Joseph Healthcare, Inc., Central Kentucky Radiology, PLLC; Dale Absher, MD, Individually; and Jason Alexander Harper, MD, Individually, Defendants. In, Commonwealth of Kentucky, Scott Circuit Court, Division I, Civil Action No. 08-CI-541
9-25-14 Baltimore, MD	Kevin Brunston and Roshanda Guy, Plaintiffs, vs. Bayer Healthcare Pharmaceuticals, Inc, et al., Defendants, in the Superior Court of California, for the County of San Bernardino, Case No. CIVDS 1310687

## Deposition Testimony in the Last 4 Years

10-20-14 New York, NY	Mary K. Jones, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. Pfizer Inc., et al., Defendants, in the United States District Court, Southern District of New York, No. 10-CV-03864(AKH)
11-18-14 Phoenix, AZ	In Re: Zimmer Nexgen Knee Implant Products Liability Litigation, In the United States District Court Northern District of Illinois Eastern Division, Master Docket Case MDL No. 2272 All Cases No. 1:11-CV-05468
12-2-14 Phoenix, AZ	Karen Larson, Plaintiff, vs. Abbott Laboratories, et al., Defendants, in the Circuit Court for Baltimore City, Maryland Case No.24-C-13-000002
6-9-15 San Francisco, CA	In Re: AlloDerm Litigation, Superior Court of the State of New Jersey Law Division: Middlesex County, Case Code 295.
6-17-15 Los Angeles, CA	Theresa Enoch, et al., Plaintiffs, vs. Forest Research Institute, Inc., et al, Defendants, In Re: Forest Research Institute, United States District Court District of New Jersey Camden Vicinage, Master Docket No.13-cv-1832-RBK/AMD.
8-11-15 San Diego, CA	Anna A. Good, and Dennis W. Good, Plaintiffs, vs. Pfizer Inc.; Wyeth Pharmaceuticals, Inc.; Wyeth LLC F/K/A, American Home Products Corporation; McKesson Corporation; and Does 1 through 10, in Superior Court for the State of California, County of Los Angeles, JCCP No.: 4032, [San Diego Superior Court Case No.: 37-2012-00084244-CU-PL-CTL]
10-20-15 Los Angeles, CA	In Re: Mirena IUD Products Liability Litigation MDL No. 2434, in the U.S. District Court Southern District of New York, Case No. 7:13-md-02434-cs-lms, and the Superior Court of New Jersey, Law Division, Bergen County, Case No. 297.
11-13-15 Boston, MA	United States of America, States of California, Colorado, et al., ex rel. Alex Booker and Edmund Hebron, Plaintiffs, Vs. Pfizer, Inc., Defendant, in the U.S. District Court, District of Massachusetts, Case No. 110-cv-11166-dpw
11-19-15 San Francisco, CA	Eve Sherrer, Plaintiff, vs. Truman Medical Center, Inc., Boston Scientific Inc., C.R. Bard, et al., Defendants, in the Circuit Court of Jackson County, Missouri at Kansas City, Case No. 1216-cv27879
4-26-16 Chicago, IL	Första Ap-Fonden and Danske Invest Management A/S, Individually and on Behalf of All Others Similarly Situated, Plaintiffs, v. St. Jude Medical, Inc., Daniel J. Starks, John C. Heinmiller, Eric S. Fain, Michael T. Rousseau, and Donald J. Zurbay, Defendants, in United States District Court, District of Minnesota, Class Action, Civil No. 12-3070 (JNE/HB)

## Deposition Testimony in the Last 4 Years

5-3-16 Los Angeles, CA	H.B., a minor, by STACY BARTOLINI, Individually and as parent and next friend of H.B., E.G., a minor, by CHRISTINA RAQUEL, Individually and as parent and next friend of E.G., T.C., a minor, by KAYLA-ROSE MCGUINNESS-COLON, Individually and as parent and next friend of T.C., Plaintiffs, vs. ABBOTT LABORATORIES INC., Defendants, in the United States District Court for the Southern District of Illinois. Case No. 15-cv-702-NJR-SCW
5-4-16 Los Angeles, CA	Katrina Dawn Copley, Plaintiff, V. Bayer Healthcare Pharmaceuticals, Inc., BayerPharma Ag, and Bayer Oy, Defendants, in the United States District Court for the Middle District of Tennessee, Nashville Division Civil Action No. 3:14-cv-00406
7-1-16 San Francisco, CA	Ernestine Jones, Plaintiff, v. Novartis Pharmaceuticals Corporation, Defendant, in the United States District Court for the Northern District of Alabama, Southern Division, Case Number CV-13-00624-UNA-VEH
8-3-16 Los Angeles, CA	Mariah Lopez v. Abbott Pharmaceuticals vs. Abbott Laboratories, Inc. in Missouri Circuit Court Twenty-second Judicial Circuit (City of St. Louis), Cause No. 1222-CC-02479-01
9-1-16 San Francisco, CA	Clare Austin Plaintiff, v. C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., Matthew Robbins, M.D., and the Cleveland Clinic Florida, Defendants.in the Circuit Court of the 17th Judicial Circuit, in and for Broward County, Florida Case No: CACE-15-008373 Div: 07
9-22-16 Los Angeles, CA	N.K., an infant by his mother and natural guardian, Tanja Bruestle-Kumra, vs. Abbott Laboratories, Defendants, in the United States District Court for the Eastern District of New York. Case No. 14-Civ-04875 (BMC) (RER)
9-28-16 Baltimore, MD	Kathy Moughler and Brian Moughler, Individually and as Parents and NaturalGuardians of L.M., A Minor, et al., Plaintiffs, vs. Abbott Laboratories and Abbvie Inc., Defendants, in the United States District Court Eastern District of Kentucky, Northern Division At Covington. Case No.214CV00081WOBCJS