# Curriculum Vitae

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#### **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)

#### PRINCIPAL POSITIONS HELD:

1979-80	University of California,	Chief Resident, Medicine
1980-82	Davis	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	Director, Division of Anti-Viral Drug Products
1996-97	Research	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	Medical Deputy Director
1999-2004	Food and Drug Administration, Center for Devices and Radiological Health	Director
2004 -06	NDA Partners, L.L.P  (a medical product development consulting group)	Principal



2006 - 08	Élan Pharmaceuticals, Inc.	Senior Vice President of Global Regulatory Affairs and Global Safety Surveillance
2008 - 10	Amgen, Inc.	Vice President of Global Regulatory Affairs
2010 -	NDA Partners, L.L.P	Principal

#### 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 Quality Assurance Department
2004 – 07	Arizona State University	Research Professor, Arizona Biodesign Institute
2005 -		Associate Faulty, School of Law
2005 - 07	University of California, San Diego	Von Liebing Fellow in Entrepreneurship, School of Engineering

#### 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".



FDA Commissioner's Special Citation: "For design and implementation of the Blood Action Plan to strengthen the safety of the nation's blood supply."

#### HONORS AND AWARDS (Continued):

1998

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

#### **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

### **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



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