

MICHAEL B. WAITZKIN
Duke Science & Society • 304 Research Drive • Durham, NC 27708
michael.waitzkin@duke.edu • (202) 528-1684

PROFESSIONAL EXPERIENCE

Duke University, Durham NC

Deputy Director/Senior Lecturing Fellow, Science & Society

Dec 2014—present

Oversee and manage Science & Society programs; design and teach graduate level classes in science policy, law, and ethics; establish, implement and oversee science-related legislative briefing and tracking program, and amicus briefing program; outreach to corporate, non-profit, government and academic science-policy community; recruit and mentor students in MA in Bioethics and Science Policy program; assist in building strategic collaborations internally at Duke University and with external stakeholders; assist in fundraising, Science & Society's participation in university strategic planning effort, and representation of Science & Society at university and external committees and events.

Genomeon LLC, Floyd, VA

Co-founder, Chief Strategy Officer

2011—present

A startup genomic diagnostic and drug target discovery company, which has developed an analytic platform technology utilizing microsatellites in the genome, which others have discarded as "junk DNA". Responsible for negotiating and implementing licenses and contracts, developing and implementing IP, regulatory and reimbursement strategies, and fundraising.

Catawba Consulting LLC, Floyd, VA

Founder; Principal

2009—present

Strategic counsel to the biomedical research community. *Representative projects:* position mid-sized pharmaceutical company for acquisition; evaluate potential acquisition targets for mid-sized pharmaceutical companies, including analysis of non-patent exclusivity of product portfolio, competitive threats, approval prospects of pipeline products and expanding product lines and strength of IP portfolio; develop strategy for orphan products; analysis of requirements and opportunities for pediatric studies and exclusivity; strategy for developing abuse-resistant opioid and pseudoephedrine products; evaluate conflicts of interest issues; develop strategy for approval of microbial-resistant textiles for medical use.

James & Hoffman PC, Washington, DC

Of Counsel

2009—present

FoxKiser Law Firm, Washington, DC

Partner

1998—2009

Partner in law firm that specialized in the representation of the biomedical research community, including legal, regulatory and strategic advice regarding biomedical research, including product development, approval and acquisition, patent and non-patent exclusivity, conduct of clinical trials, conflicts of interest and licensing.

Representative clients and projects: Director of University of Pennsylvania Institute for Human Gene Therapy in aftermath of death of a subject in gene therapy clinical trial, including managing internal university, grand jury, FDA, NIH, congressional and media investigations, and representation in and oversight of resulting tort and corporate litigation; Director of NIH institute in conflicts of interest investigation by congressional committee and media regarding extramural consulting; advised mid-sized pharmaceutical company in development of abuse-resistant opioid platform, including immediate release and extended release products; development of strategy regarding injectable products for mid-sized pharmaceutical company; representation of pharmaceutical companies before FDA Advisory Committees; representation of major pharmaceutical companies in litigation over Orphan Drug Act and product exclusivity; development and management of product exclusivity strategies for major pharmaceutical companies; evaluation and advice regarding strategic alliances with ex-US pharmaceutical companies for US-based company; ethics and conflicts of interest issues.

White House Counsel's Office, Washington, DC

Special Counsel to the President

1997—1998

Represented Office of the President (Clinton) and Office of the Vice President (Gore) in multiple congressional, special prosecutor and media inquiries; management of congressional confirmation hearings for presidential appointees; special projects for Deputy Chief of Staff John Podesta; carried Special Compartmentalized Intelligence [“SCI”] (above Top Secret) security clearance.

Private law practice, Washington DC

Partner

1984—1997

Associate

1980—1983

Complex litigation before trial and appellate courts, regulatory agencies and Congressional committees.

Representative matters: Managed high profile investigations of White House and other government officials, corporations and private individuals; multiple jury and non-jury trials including the (then) highest recovery in a medical malpractice and products liability case in the District of Columbia, the dissolution of a family real estate and commercial empire, both plaintiffs and defendants medical malpractice, products liability cases, shareholder and derivative suits and multiple other commercial and white collar criminal cases; represented multiple law and other professional firms and individuals in partnership withdrawal and dissolution cases; represented Lloyds of London in environmental coverage cases; represented companies and individuals in Foreign Corrupt Practice Act cases; represented company before Iran Claims Tribunal; established liability in the District of Columbia for commercial landlords for injuries caused by third party criminal conduct; briefed and argued numerous appeals in District of Columbia, Federal, 1st, 4th and 8th Circuit Courts and state appellate court; appeared in numerous federal and state trial courts throughout the country in criminal and civil matters; sat on D.C. Bar disciplinary hearing committee; law firm managing partner.

Kennedy For President Campaign, Washington, DC

State and Regional Director of Advance and Scheduling

1979—1980

Ran state and regional advance and schedule operations in Sen. Edward Kennedy's Campaign for President. (Also worked part-time on numerous other presidential, gubernatorial, senatorial and congressional campaigns before and after.)

Public Defender Service, Washington, DC

Trial and Appellate Lawyer
Chief, Trial Division

1975—1979
1979

Represented over 400 indigent criminal defendants and juveniles in trial and appellate courts; numerous jury and non-jury trials, bail hearings, motions arguments, sentencing, and appellate arguments; regularly conducted internal and outside training on trial strategy and techniques

ACADEMIC EXPERIENCE

Duke University, Durham, NC

Science & Society, Masters in Bioethics and Science Policy
Senior Lecturing Fellow

2014—present

Co-taught Science, Law and Policy core course with Prof. Nita Farahany (Fall 2014);
Amicus Lab (Fall 2015); Science Law and Policy (Spring 2016)

Masters of Management in Clinical Informatics

Adjunct Professor, Duke Medical School
Adjunct Professor, Fuqua School of Business

2014—present
2009—2013

Develop curriculum and teach Ethics Seminar in MMCI Program

Develop curriculum and run introductory “Boot Camp” Program
for incoming students.

2014—present

Fuqua School of Business, Health Sector Management Program

Adjunct Professor
Senior Scholar
Visiting Lecturer

2009—2013
2002—2013
1998—2002

Regular lecturer on ethics and politics of developing biotechnologies and conflicts of interest

Director and Moderator, Symposium Series on Current Issues in Health Care

2011—2013

Representative topics: Affordable Care Act; Drug Shortages; Impact of Inconsistent State
Laws on National Health Care Companies; IP and Diagnostics; Data Mining Patient
Records for Clinical Trial Participants

Expert Advisor, COINS (Conflicts of Interest National Study)

2000—2002

Guest Lecturer

Harvard Medical School; Stanford Law School; Stanford Center for Law & the Biosciences;
Duke Law School; Duke Clinical Research Institute; Duke Center for Genome Ethics, Law and
Policy; Wake Forest University Bioethics Program; National Institute for Trial Advocacy

EDUCATION

Yale University, New Haven, CT

L.L.M., School of Law

1975

Commonwealth Fellow in Law, Science & Medicine – worked with Prof. Joseph Goldstein on issues related to the regulation of science and “Beyond the Best Interests of the Child”; worked with Dr. Jay Katz on issues related to human experimentation; worked with Profs. Burke Marshall and (Judge) Guido Calabresi on issues related to society’s response to disasters; drafted and filed lawsuit with Prof. Dennis Curtis against Connecticut State Hospital to bar the housing of juveniles on adult locked psychiatric wards;

Visiting Lecturer, Yale College (Jonathan Edwards College), “Civil Rights of Mental Patients”

Stanford University, Palo Alto, CA

J.D., School of Law

1974

Research assistant to Prof. Michael Wald on field research projects related to the transfer of juveniles to adult court and the differential application of states laws regarding juvenile courts on county-by-county basis; externship at Center for Law and Social Policy, worked with Ben Heineman and (Judge) Patricia Wald on projects relating to the deinstitutionalizing of mental patients and conditions in state juvenile and mental health facilities; Juvenile courts clinic.

University of Virginia, Charlottesville, VA

B.A., College of Arts and Sciences

1971

Government and Political Philosophy: Echols Scholar; Phi Beta Kappa; Omicron Delta Kappa; Raven Society; TILKA

RECENT PUBLICATIONS

Garner, H, McIver, L, Waitzkin, M, *Same Work, Twice the Money?*, NATURE, Vol. 493, Jan. 31, 2013.

Garner, H, Waitzkin, M, Bavarva, J, *What do the changes in the aging genome mean for pharmacogenomics?*, PHARMACOGENOMICS, December, 2014.

Payne R, Sevier D, Sevier C, Moe J, and Waitzkin M, *Medication Monitoring and Drug Testing Ethics Project*, Journal of Opioid Management, Vol. 11, no. 1, Jan/Feb 2015 (findings presented at the International Conference on Opioids, Harvard Medical School, June 2013)

RECENT PRESENTATIONS AND SYMPOSIA

Moderator, “Death with Dignity: the Brittany Maynard Story”, Duke Science & Society Roundtable, Dec. 14, 2014.

Presenter, “Thank You Very Much: Quarantining Ebola Health Workers”, Duke Science & Society Roundtable, March 5, 2015

BAR MEMBERSHIP

District of Columbia; United States Supreme Court

BOARD SERVICE

| | |
|--|-----------|
| Blue Ridge Center for Chinese Medicine , Floyd, VA <i>Board of Directors</i> | 2011—2014 |
| Tri-Area Community Health Center , Laurel Fork, VA <i>Board of Directors</i> | 2011—2013 |
| Conservation Land Trust , Blacksburg, VA <i>Board of Directors</i> | 2010—2012 |
| Stanford University , School of Law <i>Board of Visitors; Law, Science and Technology Advisory Committee; Law and Biosciences Advisory Committee</i> | 2007—2011 |
| Duke University , Sanford Institute (now School) of Public Policy <i>Board of Visitors</i> | 1998—2003 |

PERSONAL

Grew up in South Florida; attended Miami Beach Senior High School

Married to Gibby Waitzkin, artist

rev. May 2015