

**MICHAEL B. WAITZKIN**

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**PROFESSIONAL EXPERIENCE**

**Duke University, Durham NC**

*Deputy Director/Senior Lecturing Fellow/Director of Graduate Studies* – Duke Initiative for  
Science & Society Dec 2014—present

Oversee and manage Science & Society programs; design and teach graduate and undergraduate level classes in science policy, law, and ethics; design and oversee graduate and undergraduate programs in science policy; chair and manage the admissions process for graduate and undergraduate programs;; designed and established Amicus Lab and Science Regulation Lab; outreach to corporate, non-profit, government and academic science-policy community; recruit and mentor students in MA in Bioethics and Science Policy program; mentor undergraduate students; assist in building strategic collaborations internally at Duke University and with external stakeholders; representation of Science & Society at university and external committees and events.

**Catawba Consulting LLC, Floyd, VA**

*Founder; Principal* 2009—present

Strategic counsel to the biomedical research community. *Representative projects:* evaluation of pharmaceutical investment opportunity for hedge fund; representation of patient in obtaining compassionate use of drug for rare disease; evaluation of regulatory profile of pharmacy compounding; analysis of political and legal risk profile of non-profit voter registration group; evaluation of impact of war on opioid abuse on needs of chronic pain patients; representation of university faculty member in scientific misconduct investigation; ethics advisor to world's largest contract research organization; 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 psuedoephedrine products; evaluate conflicts of interest issues; develop strategy for approval of microbial-resistant textiles for medical use.

**New School for Executive Leadership in Healthcare, Taipei, Taiwan**

International Faculty Member February 2019 -- present

**Orbit Genomics, Boulder, Colorado**

*Co-founder; Board Member* June 2016—present

A startup genomic diagnostic and drug target discovery company; successor to Genomeon's microsatellite technology

**Genomeon LLC**, Floyd, VA

*Co-founder, Chief Executive Officer, Chief Strategy Officer*

2011—2016

A startup genomic diagnostic and drug target discovery company, which 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.

**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, 1<sup>st</sup>, 4<sup>th</sup> and 8<sup>th</sup> 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* 1975—1979  
*Chief, Trial Division* 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  
*Director of Graduate Studies*  
*Chair of Admissions*  
*Senior Lecturing Fellow* in Science & Society and Law School 2014—present

Science, Law and Policy; Amicus Lab; SciReg Lab (“Science Regulation Lab”); Director’s Workshop; Foundations of Bioethics

Huang Fellows - highly selective program for rising sophomore science students to understand science in the context of and in service to society; designed curriculum; oversee and manage all aspects of the program

*Assistant Director; Chair of Admissions* 2016 - present

Duke- Margolis Center for Health Policy

Core Faculty member Educational Faculty Advisory Committee	2017- present
Reimagine Medicine Co-designer and co-founder	2018
Duke Population Health – Education Programs Advisory Committee	2019 - present
Masters of Management in Clinical Informatics (“MMCI”) <i>Adjunct Professor</i> , Duke Medical School <i>Adjunct Professor</i> , 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 <i>Adjunct Professor</i> <i>Senior Scholar</i> <i>Visiting Lecturer</i>	2009—2013 2002—2013 1998—2002
Regular lecturer on ethics and politics of developing biotechnologies and conflicts of interest	
<i>Director and Moderator</i> , 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	
<i>Expert Advisor</i> , 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; North Carolina State University; National Institute for Trial Advocacy

### INVITED GUEST LECTURES, TALKS, SYMPOSIA AND GRANTS

“Facial Recognition: Case Study in the Implementation of AI Technologies”, Duke Plus Data Science In-Person Learning Experiences series, Nov. 11, 2019 (scheduled).

“Federalism: Shared responsibility between Federal and State Governments for Health Policy”, Presentation to Chinese National Healthcare Security Administration, sponsored by Duke Margolis Health Policy Center, August 19, 2019.

“Case Study on Incidental Findings in Genetic Testing”, Duke Masters of Management in Clinical Informatics (MMCi) Bootcamp, August 10, 2019.

“Case studies on Informed Consent and Use of Medical and Genetic Data in Criminal Investigations”, Summer Training Academy in Academic Research (STAR) and Bridging the Gap to Enhance Clinical Research Program (BIGGER), sponsored by Duke Clinical Research Institute, July 11 and 13, 2019.

“Sources of Science Policy”, Huang Fellows Summer Seminar Series, June 27, 2019.

“Where Did All the Abortion Comments Come From? – An Analysis of Notice and Comment Rulemaking”, Duke Data +, June 5, 2019.

Lecturer, Provost’s Duke Summer Doctoral Academy, “Science Policy” and “Health Policy”, May 20-24, 2019.

“Policy Engagement by Scientists”, Duke Department of Cell Biology, Annual Retreat, Asheville, NC, May 4, 2019.

Science Policy Workshop, Duke Departments of Cell and Molecular Biology, April 4, 2019.

Commenter to Talk on “Trade Secret Prosecutions: Protecting Technology Secrets in the US Adversarial System” Duke Law Conference on Data, Technology & Criminal Law, April 6, 2019.

Guest lecturer on “Communicating Science in the Courtroom” in Science & Society Colloquium, Duke Graduate School, March 21 and 23, 2019.

Moderator, “Faculty Roundtable Discussion: What Will Health Care Look Like in 10/20 years?” in Introduction to Healthcare Law & Policy, Duke Law School, November 27, 2018.

“Case studies on Informed Consent and Use of Medical and Genetic Data in Criminal Investigations”, Summer Training Academy in Academic Research (STAR) and Bridging the Gap to Enhance Clinical Research Program (BIGGER), sponsored by Duke Clinical Research Institute, July 16 and 18, 2018.

“Sources of Science Policy”, Huang Fellows Summer Seminar Series, July 12, 2018.

Lecturer, Provost’s Duke Summer Doctoral Academy, “Science Policy”, May 21-25, 2018.

“Duke MA in Bioethics & Science Policy Program”, Association of Bioethics Program Directors, Houston, TX, April 16, 2018.

Project Director (Legal, Ethical and Social issues), “A Roadmap for Affordable Care in the 21<sup>st</sup> Century”, Duke Provost Collaboratories Grant, 2018-2019.

Core Faculty Sponsor, “Risk and Resilience”, Duke Intellectual Community Planning Grant, 2018.

Moderator, “Faculty Roundtable Discussion: Future of Healthcare” in Introduction to Healthcare Law & Policy, Duke Law School, November 28, 2017.

Panelist, “Big Data and Drug Development”, Triangle Privacy Research Hub (“TPRH”) symposium on “Refining Privacy to Improve Health Outcomes”, Durham, N.C., October 27, 2017.

Moderator, “Communicating Science Meets the Science of Communicating”, panel discussion, Duke Alumni Association, Washington, D.C., October 2, 2017.

Reporter and panelist, “No Longer Silent”, conference on providing adequate analgesia to chronic pain patients, Center for Practical Bioethics, Washington, D.C., October 13, 2017.

Guest lecturer on “Communicating Science in the Courtroom” in Communicating Science and Bioethics, Duke Graduate School, September 2017, September 2016 and September 2015.

Seminar on “Who Makes Science Policy?”, Huang Fellows Program, Duke University, August 3, 2017.

Guest lecturer, “Research Ethics & Data Privacy”, Summer Training in Academic Research (“STAR”) and Bridging the Gap to Enhance Clinical Research (“BIGGER”) programs, Duke Clinical Research Institute, July 11-12, 2017.

Panelist on “Comparing Meanings of Responsible Innovation Across Bioengineering Communities”, Dr. Jennifer Kuzma, PI, Genetic Engineering & Society study, North Carolina State University, June 6, 2017.

Panelist on “Emerging Technology and Policy Learning”, Conference on Ethics, Codes and Learning: Building an Adaptive Policy Framework for Emerging Technology, Rethinking Regulation Program of Keenan Institute of Ethics, Duke University, May 5, 2017.

Interviewee for Dr. Dan Ariely’s video series, “Duke Medical Professionalism Project”. 2017

Moderator, “The Internet of Things – An Unprecedented Window into Your Life and Behavior”, Science & Society Dialogs, Duke University, January 19, 2017.

Participant in Blue Devil Teach-X Program, “Science Law & Policy”, March 23, 2016.

Panelist/Reporter, “Public-Private Partnerships”, Center for Practical Bioethics, Kansas City, Mo., March 10-11, 2016.

Guest Lecturer, “The Process of Drug Approval”, Emerging Leaders in Science & Society (“ELISS”), AAAS Fellowship, November 2, 2015.

Selection Committee, Emerging Leaders in Science & Society (“ELISS”), AAAS Fellowship, August 2015.

Moderator, “Death with Dignity: the Brittany Maynard Story”, Science & Society Roundtable, Duke University, December 4, 2014.

#### INVITED PEER REVIEWER

American Journal of Bioethics: Empirical Bioethics

Health Services Research

#### 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

#### 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)

#### BAR MEMBERSHIP

District of Columbia; United States Supreme Court

#### BOARD SERVICE

<b>Quintiles</b> , Durham, NC <i>International Ethics Advisory Board</i>	2015
<b>Stanford University</b> , School of Law <i>Board of Visitors; Law, Science and Technology Advisory Committee; Law and Biosciences Advisory Committee</i>	2007—2011
<b>Duke University</b> , 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. September 2019