

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

CHARLES SEIFE,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION and
DEPARTMENT OF HEALTH AND HUMAN
SERVICES,

Defendants,

and

SAREPTA THERAPEUTICS,

Intervenor-Defendant.

Case No. 1:17-cv-3960

May 29, 2018

DECLARATION OF PETER LURIE

I, PETER LURIE, MD, MPH, declare as follows:

1. I, Peter Lurie, am President of the Center for Science in the Public Interest, former Associate Commissioner for Public Health Strategy and Analysis at the Food and Drug Administration (FDA) and the agency lead on transparency activities, former medical school professor, and a physician and epidemiologist. I submit this expert declaration in support of plaintiff Charles Seife's opposition to the government's and intervenor-defendant Sarepta Therapeutics' (Sarepta) motions for summary judgment and in support of Seife's cross-motion for summary judgment. I was not myself involved in the decision-making process surrounding the approval of Exondys 51; this declaration is based solely on facts in the public record. The opinions and conclusions derive from my more than thirty years of experience in public health, applied the public record cited below. I was not compensated for this declaration.

I. QUALIFICATIONS

2. I am currently President of the Center for Science in the Public Interest, a non-profit watchdog organization in the public health and nutrition space. Prior to assuming this position, I served for eight years at the FDA in various capacities, including as the Associate Commissioner for Public Health and Strategy and Analysis, and the Associate Commissioner for Policy and Planning, where I oversaw a 101-person, \$16.3 million unit responsible for policy formation, regulation, guidance development, quantitative analysis, and strategic planning. During my tenure at the FDA, I was the agency lead on transparency activities as well as on streamlining expanded access procedures for patients seeking access to experimental, typically unapproved, medications. I was also the agency representative to the Department of Health and Human Services (HHS) on Data Management and Verification, Evaluation and Evidence, and Social Determinants of Health. I coordinated agency responses to reports by the Government Accountability Office and HHS Office of the Inspector General. While at the FDA, I received over thirteen awards for my work, including the HHS Secretary's Award for Distinguished Service to the Opioid Initiative Team and the FDA Commissioner's Special Citation "for promoting public health through increasing the transparency of animal drug sales to support the public's interest in antimicrobial resistance." I also authored over eight reports for the US government on divergent results between Phase 2 and Phase 3 clinical trials, prescription drug abuse and addiction, the public health evidence for oversight of laboratory developed tests, the silent epidemic of viral hepatitis, and a review of the FDA's approach to medical product shortages, as well as numerous reports in the peer-reviewed medical literature, including several on transparency.

3. Before my work at the FDA, I was Deputy Director at Public Citizen's Health Research Group, a consumer advocacy organization, where I developed and promoted advocacy positions on a wide variety of public health issues, including researching pharmaceutical safety and efficacy, and

testified before Congress on eleven occasions, including on pediatric drug and device policy. I appeared approximately fifty times before various federal and public health committees and also testified before the FDA's Transparency Task Force.

4. I have also been a Visiting Assistant Research Scientist at the University of Michigan Institute for Social Research, where I was the principal investigator of a National Institutes of Health (NIH) funded multi-site case control study of needle exchange program effectiveness; an Assistant Professor at the University of California, San Francisco in the Departments of Epidemiology and Biostatistics and of Family and Community Medicine; and have held adjunct faculty positions at Johns Hopkins Bloomberg School of Public Health and George Washington University School of Public Health.

5. I completed multiple post-doctoral fellowships at the University of California, San Francisco where I also did a medical residency in the Family Practice program. I did a second residency at the University of California, Berkeley in Preventive Medicine and also received my Masters in Public Health there in Epidemiology. I obtained my medical degree from Albert Einstein College of Medicine and my undergraduate degree from Cornell University, where I graduated with distinction.

6. I maintain an active medical license in the District of Columbia.

7. I have published over a hundred articles in medical journals, including about access to experimental medications, clinical trial design, researcher conflict of interest, research ethics, drug efficacy and safety, cost-effectiveness, HIV prevention, international health, and drug promotion and labeling. These include an article on FOIA and clinical data.¹

¹ Peter Lurie & Allison Zieve, *Sometimes the Silence Can Be Like the Thunder: Access to Pharmaceutical Data at the FDA*, 69 *Law and Contemporary Problems* 85 (2006) (Kenney Decl., Ex. BB, 52-64).

II. PUBLIC HEALTH INTEREST IN RELEASE OF THE WITHHELD INFORMATION

A. EFFICACY

8. When researchers design trials, they pre-specify the study measures of efficacy, also known as “endpoints.” Primary endpoints are typically measures of clinical effectiveness, by which the efficacy of the drug is gauged. Primary endpoints are designed to measure the most important (or primary) question asked by the clinical trial. Many trials, including Studies 201 and 202, have “secondary” outcome measures too; these are also designed to measure efficacy but are considered less critical to the overall assessment of the drug’s effectiveness. It would be virtually impossible for a drug to be approved without revealing the “primary endpoints” to the FDA and the public, generally through the approval package, the drug label, advisory committee testimony, journal publications, www.clinicaltrials.gov, or Securities and Exchange Commission filings. This is particularly true, where, as here, there are certain standardized endpoints, such as the 6-minute walk test, which are routinely used by researchers to test the effectiveness of drugs used to treat muscular dystrophy.

9. In assessing the effectiveness of a drug, it is essential to understand the outcomes for all secondary measures. There are circumstances where the primary outcome measures suggest a drug is ineffective whereas the secondary outcome measures indicate the drug is actually effective. In such a case, as is true here given the weak evidence of efficacy demonstrated on Sarepta’s primary endpoint, it would be important for all secondary outcome measures to be made public. On the other hand, if the primary outcome did not provide clear evidence of effectiveness, and only one secondary endpoint of several were positive, that would open the FDA’s approval decision to legitimate question. It is therefore important to be transparent about all secondary outcomes, so that positive ones can be assessed in context.

10. Access to Clinical Study Reports (CSRs) data could also show whether a researcher has engaged in retrospectively highlighting positive outcomes to make a drug appear more effective than it actually is. This is a potential concern in this case, as the sponsor converted the 6-minute walk test from an “exploratory” to a secondary endpoint. In the world of medical research, researchers all too often skew clinical trial reports to make drugs seem more effective than they are. For example, I wrote a journal article about a paper about a medical device that reported certain, but not all, secondary endpoints as evidence of the efficacy of its device.² I obtained information the company had presented to an FDA Advisory Committee that enabled me to show that endpoints were disproportionately published if they achieved statistical significance—indeed, at a rate three times more than secondary endpoints that did not achieve statistical significance. Given the controversy surrounding Exondys 51’s approval, it is in the public interest to release the secondary endpoint data withheld in the CSR to ensure that the data were fairly reported by Sarepta. Release of the withheld data would also allow researchers to validate the trials by seeing if Sarepta made any obvious analytical errors with respect to setting and testing the secondary endpoints. and if the endpoints support efficacy.

11. When a researcher tests numerous hypotheses instead of just one or two, there is a higher likelihood that one of those many endpoints will reach statistical significance by chance, rather than reflecting a true phenomenon. Releasing the results data for all secondary endpoints would allow doctors and patients, and the public at large, to understand positive secondary outcomes in their proper statistical context, and to prevent Sarepta from “cherry picking” data.

B. SAFETY

12. Adverse Events (AEs) are negative reactions experienced by patients that may or may not be caused by the drug they are taking. There is a substantial public health interest in release of the

² Eunice Yu & Peter Lurie, *Transcranial Magnetic Stimulation Not Proven Effective*, *Biological Psychiatry* 2010;67:e13.

requested Adverse Event (AE) and other safety information for Exondys 51 because such transparency would promote informed doctor-patient decision-making about the drug. This is particularly the case where, as here, there is considerable doubt regarding whether the drug's risks outweigh its benefits.

13. Safety data from CSRs are particularly valuable to patients and researchers. CSRs, which form the primary basis of FDA approval, contain the results of randomized, controlled clinical studies. Clinical studies generally contain data on AEs for patients in two separate, randomized groups: those in the treatment arm of the study who received the drug and those in the control (or comparison) group who received a placebo or an alternative therapy. Because of this randomization, researchers can draw inferences about whether taking a drug *caused* an AE or not. By contrast, the other source of pre-market safety data available to researchers, the so-called safety database, contains a large amount of non-randomized data, so it does not provide the same reliable information about causation. Here, providing access to the CSRs for Study 201 and 202 would let doctors and patients better assess whether particular AEs were likely caused by Exondys 51.

14. Although post-market AE data are publicly available for all approved drugs, the pre-market AE data that are being withheld for Studies 201 and 202 have unique value because, in addition to being randomized, they contain more reliable estimates for both the numerator (the number of patients who experienced each AE) and the denominator (the number of patients in each arm of the trials).

15. The number of AEs (the numerator) is known to be significantly underreported in post-market data, since the reporting is generally done on a voluntary basis and without substantial detail. In contrast, for AEs in pre-market clinical trials, there will be considerable detail about the number of AEs through patient diaries. The number of patients taking the drug (the denominator) is also more accurate in pre-trial clinical study data. Researchers are often forced to resort to proprietary

prescription data, which are difficult to obtain and lacking in detail. In contrast, for AEs in pre-market clinical trials, there will be considerable detail about the number of patients taking the drug through pill counts and/or patient diaries, as well as for how long they took it.

16. By corollary, any estimate of the fraction of patients experiencing the AE over time drawn from post-market data will be less reliable than that drawn from the clinical trial.

17. Moreover, there is generally no control group in the postmarket data, so it is not possible to draw conclusions about whether the frequency of AEs is elevated for those taking the drug. While the FDA released the denominator from the clinical trials (12 patients), it has withheld the numerator (the number of patients who experienced particular AEs). Without both numbers, the frequency of AEs cannot be estimated, nor can doctors, researchers, and patients independently assess whether the drug caused those AEs. Given the FDA's approval of Exondys 51, it is likely that, for ethical reasons, Study 201 may remain the only source of randomized, placebo-controlled data on AEs for patients taking exon 51-skipping drugs.

18. Although some safety data are on a drug's label, CSRs contain additional information about those AEs, such as duration and narrative descriptions. CSRs can also reveal other AEs not listed on the label. Release of this information may allow clinicians to monitor their patients for the AEs observed in the trial, diagnose the AE sooner, and discontinue the drug or treat the AE more effectively. When doctors and patients decide whether to use a drug, they weigh the potential benefit against the potential harm. Disclosure of AEs not on the label is especially important where, as here, there are material concerns about a drug's efficacy, and the benefits of taking a drug are in question.

C. OTHER CONSIDERATIONS

19. Patients join clinical trials not merely for personal reasons, but for altruistic ones as well: to make data about a drug available to other prospective patients with the same condition in order to improve their health outcomes. To the extent that CSR data are not fully exploited, this is a violation

of participants' desires to maximize the benefits and minimize risks posed by the drug to subsequent patients who may be unknowingly exposed to risk. Indeed, for drugs where the efficacy is in doubt, reporting CSR results fully informs both the conduct of ongoing clinical trials, as well as prescribing decisions should the product be approved.

20. Finally, the more information about a drug is made public, the more likely it is to improve public health and save patient lives. The more pairs of responsible eyes there are on the data, the more likely it is that researchers will have unique insights into a drug's profile. All of this is especially true where, as here, there is controversy or competing interpretation of contested data. In looking at the data for Studies 201 and 202, researchers may have new interpretations or questions that tilt the balance in terms of the advisability or content of warning labels, or even pulling a drug from the market, thereby preventing large numbers of patients from being exposed to a potentially ineffective or dangerous drug.

III. RELEASE OF THE WITHHELD INFORMATION WOULD BE UNLIKELY TO BE OF AFFIRMATIVE USE TO SAREPTA'S COMPETITORS

21. Sarepta claims that disclosure would allow other companies to use its analytic methods, but this has no merit as the relevant disclosures have already been divulged through the label, the Action Package, and the Advisory Committee materials and hearing. It is very difficult to believe that the statistical methods are not generally known, especially in light of the FDA's release of additional information about the drug when it was approved. Indeed, the FDA has already released a Statistical Review of Sarepta's analysis,³ and there is no evidence that releasing the additional withheld details relating to Sarepta's analysis will be of affirmative use to Sarepta's competitors.

³ See Xiang Ling, Office of Biometrics, US Food and Drug Administration, *Statistical Review and Evaluation [of Exondys 51]* (2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488Orig1s000StatR.pdf (Kenney Decl., Ex. R, 2-35).

22. Sarepta argues that they are studying “dosing” and that this information is valuable to competitors, but information about dosing is already part of the label and thus known to competitors. The label specifies how frequently to administer a dose, in what amount, and how to administer the dose, including how to prepare it, if necessary.⁴ It strains credulity that releasing the additional withheld details relating to Sarepta’s dosing will be of affirmative use to competitors.

23. Sarepta argues that data about its clinical endpoints would be valuable to competitors, but the efficacy endpoints that are most commercially valuable are already known in the research community, among university researchers and academics. Moreover, as noted, they have already been disclosed through the approval package, the drug label, advisory committee testimony, journal publications, and www.clinicaltrials.gov. Their main clinical endpoint, the 6-minute walk test, which measures how far (in meters) a patient can walk in 6 minutes, is widely used in the field, and its methods are generally understood. Thus, it is extremely improbable that the data for the 6-minute walk test would be of great commercial value, as the company is one of many in the field using this measure. To the extent Sarepta did, somehow, modify the generally accepted methods of the 6-minute walk test, that is still important on balance for patients, doctors, and researchers to know, so that the data can be understood and compared to other studies on an apples-to-apples basis.

24. Sarepta argues that the Appendices from Studies 201 and 202 could be used as a “historical control” by competitors. Historical controls are “control groups” that are not from the same study but contain detailed information about patients in other studies that are close in demographic information and disease status to the treatment group of the study in question. It is my understanding that Seife is seeking de-identified data from Studies 201 and 202, where information related to patient

⁴ See *Exondys 51 (eterplirsen) Injection Label*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/206488lbl.pdf (last accessed May 21 2018) (Kenney Decl., Ex R, 38-40).

age, height, weight, and demographic information is redacted to preserve patient privacy. But such redacted data would not be reliable enough to support FDA approval based on the FDA's extensive requirements for historical controls in studies of Duchenne Muscular Dystrophy that Sarepta itself cites, which mandate patients be compared to an extremely similar population demographically.⁵ The Guidance states that "it would be critical to establish that the control group was prospectively well matched to the treatment group across important baseline and prognostic variables, including age, baseline value of the primary efficacy measure and other measures of disease stage, type and intensity of supportive care, dose and duration of concomitant pharmacotherapies, and genotype, among others."⁶ Thus, Sarepta cannot demonstrate that release of the de-identified information could be used as a historical control in any meaningful way.

25. For the same reasons, it is unlikely that release of the de-identified information could be used to create a "head to head" trial with Exondys 51. Sarepta implies two possibilities: (1) A competitor could (according to Sarepta) take information related to Sarepta's treatment groups in Studies 201 and 202 and compare that information to its own drug to draw a conclusion about which drug is better; or (2) A competitor could (again according to Sarepta) take information related to the placebo group and use that as a control group for their trial. But, like Sarepta's historical control theory, in order to do this to the level of detail required for FDA approval, a competitor would need to have information about the patient's demographics, age, weight, etc., which Seife is not seeking. This is because the FDA in its guidance specifies the groups must be provably similar with regard to patient population being treated.⁷

⁵ US Food & Drug Administration, *Duchenne Muscular Dystrophy and Related Dystrophinopathies: Developing Drugs for Treatment Guidance for Industry* (2018), <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM450229.pdf> (Kenney Decl., Ex. U, 9).

⁶ *Id.*

⁷ *Id.*

26. Finally, while Sarepta does not state this clearly in its briefing, its arguments at bottom consist of advocating that competitors conduct trials that are “dead ends” so Sarepta can preserve its competitive advantages, and thereby expose pediatric patients—children—to trials that are expected to be useless and that carry risk because they could be accompanied by AEs. Knowingly performing unnecessary experiments on patients is unethical and is a violation of the Declaration of Helsinki, an international accord that governs ethics in medical trials, which requires that “Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.”⁸

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed this 29st day of May 2018, in Washington, DC.



Peter Lurie, MD, MPH

⁸ World Medical Association, Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects, 18th WMA General Assembly, Helsinki, Finland, (June 1964), <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/> (Kenney Decl., Ex. HH, 4).

CURRICULUM VITAE
PETER GRANT LURIE, MD, MPH

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Washington, DC 20009
Telephone: [REDACTED] (work)
Cell: [REDACTED]
Fax: [REDACTED]
Email: [REDACTED]
[REDACTED] (personal)

Birthdate: [REDACTED], 1959
Birthplace: Cape Town, South Africa
Citizenship: United States

PROFILE

- Highly trained physician and epidemiologist with distinguished academic career
- Long experience promoting the public health from within and outside government
- Proven leader with strong ability to work with a wide array of people

WORK EXPERIENCE

President and Executive Director September 2017-present

Center for Science in the Public Interest

Led 45-person, \$15 million public interest group advocating for nutrition and other public health issues

Accomplishments

- Food-related advocacy
 - Pressured FDA to finalize proposals on menu labeling, nutrition facts labels
 - Submitted comments to USDA on several food safety proposals
 - Facilitated litigation against leading food corporations for misleading advertising or promotion
 - Produced report on sesame allergy
- Other advocacy
 - Defended FDA against potential outsourcing of certain drug and device approval functions
 - Produced report on dietary supplement companies making opioid withdrawal treatment claims, leading to FDA enforcement action
 - Led or participated in campaigns to prevent three administration health nominees
- Administrative
 - Reorganized the entire office along functional lines
 - Initiated hiring of new Chief Operating Officer
 - Clarified organization's gift-giving policy

Associate Commissioner for Public Health Strategy and Analysis September 2014-August 2018

U.S. Food and Drug Administration, Silver Spring, MD

Directed staff responsible for quantitative and qualitative analyses of proposed and existing agency policies

Accomplishments

- Provided rapid policy assessment on developing policy issues
 - Agency lead on antimicrobial resistance
 - Hydrocodone upscheduling
 - Led HHS subcommittees on opioids and marijuana
 - Led HHS working group on naloxone, including leading Naloxone App Prize Competition
 - Pediatric oxycodone prescribing
 - Publication rates for post-marketing studies
 - Agency lead on liaison with GAO and HHS OIG
 - Appearance conflicts on FDA advisory committees
 - State requirements for opioid-related CME
 - Laboratory-developed tests
 - Use of decision analysis to aid Agency decision-making
 - Morcellation and risk of uterine sarcoma
 - Agency lead on transparency activities
 - Agency lead on streamlining expanded access procedures, including Congressional testimony
 - Acquired poison control center data for FDA
 - President's Emergency Plan for AIDS Relief (PEPFAR) evaluation
 - Investigation of events surrounding NIH Pharmaceutical Development Section
 - Agency representative to HHS committees on Data Management and Verification, Evaluation and Evidence, and Social Determinants of Health
- Reviewed and cleared Agency documents
 - Regulations and guidances
 - Annual Agency reports to Congress
 - Agency correspondence with outside parties and other Federal agencies
 - Agency policy on Federal legislative proposals
- Coordinated Agency responses to reports by Government Accountability Office and Health and Human Services Office of the Inspector General

Associate Commissioner for Policy and Planning January 2014-September 2014

Acting Associate Commissioner for Policy and Planning September 2012-January 2014

U.S. Food and Drug Administration, Silver Spring, MD

Directed 101-person, \$16.3 million unit responsible for leading policy formulation, regulation and guidance development and strategic planning

Accomplishments

- Directed Immediate Office and oversaw budget, personnel policies and overall performance of Office of Planning and Office of Policy, in collaboration with Assistant Commissioners

- Co-lead quarterly FDA-Track meetings
- Provided rapid policy assessment on developing policy issues
 - Caffeinated beverages
 - Pharmacy compounding
 - Sodium content of food
 - Arsenic in animal feed, apple juice and rice
 - Fish consumption by pregnant and breastfeeding women
- Reviewed and cleared Agency documents
 - Regulations and guidances
 - Annual Agency reports to Congress
 - Agency correspondence with outside parties and other Federal agencies
 - Agency policy on Federal legislative proposals
- Coordinated Agency responses to reports by Government Accountability Office and Health and Human Services Office of the Inspector General

Senior Advisor, Office of Policy and Planning

December 2009-September 2012

U.S. Food and Drug Administration, Silver Spring, MD

Provided technical and policy assistance to the Associate Commissioner for Policy and Planning at a large Federal agency, including leading specific agency studies and initiatives

Accomplishments

- Researched and contributed to the development of multiple Agency policies
 - Antibiotic resistance
 - Drug shortage programs
 - Access to Poison Control Center data
 - Blood banking metrics
 - Infant formula claims
 - Human breastmilk banking
 - Regulation of nicotine-containing products
 - Mentholated tobacco products
 - Device issues in Agency user fee reauthorization legislation
 - Rotavirus vaccine contamination
- Detailee to Center for Tobacco Products
 - Represented Agency in discussions with U.S. Trade Representative on TransPacific Partnership trade agreement
 - Organized first International Tobacco Regulators' Conference
 - Developed confidentiality commitments with foreign countries
 - Formulated government response to clove tobacco litigation
- Represented Agency on Health and Human Services and international committees
 - Behavioral Health Coordinating Committee (co-chaired Prescription Drug Abuse Subcommittee and Naloxone Working Group)
 - Hemoglobinopathies
 - Interagency Work Group on Healthcare Quality
 - Prevention policy
 - Healthcare-associated infections
 - Epilepsy
 - Viral hepatitis

- Measurement Policy Council
- World Economic Forum's Healthy Living Charter
- Co-chaired Research Involving Human Subjects Committee

Deputy Director

August 2000-November 2009

Medical Researcher

July 1998-August 2000

Public Citizen's Health Research Group, Washington, DC

Developed and promoted advocacy positions on a wide variety of public health issues for a leading national consumer advocacy organization.

Accomplishments

- Researched, developed and promoted the organization's public health advocacy positions
 - Pharmaceutical safety and efficacy
 - Medical devices
 - Healthcare delivery policy
 - Food safety
 - Occupational safety and health
- Testified before Congress on 11 occasions
 - HIV prevention policy
 - Clinical trial ethics
 - Mad Cow Disease policy
 - Pharmaceutical company payments to physicians
 - Direct-to-consumer advertising
 - Access to medicines in the developing world
 - Pediatric drug and device policy
- Approximately 50 appearances before various Federal and other public committees
- Led development of and co-authored Worst Pills, Best Pills, a 1000-page consumer guide to medications
- Over six dozen articles and opinion pieces in Public Citizen and other lay publications
- Over two dozen letters to the editor in major newspapers
- Lead role in personnel management, budget development and website promotion
- Wrote and was awarded grants to support program activities from the Greenwall Foundation, Open Society Institute, Irene Diamond Foundation, Park Foundation and Public Welfare Foundation
- Numerous national media appearances

Visiting Assistant Research Scientist

July 1997-December 1999

University of Michigan Institute for Social Research, Residential College and Inteflex Combined Undergraduate-Medical School Program, Ann Arbor, MI

Conducted cutting-edge research in HIV epidemiology and prevention policy in the U.S. and abroad and developed research-based public health activism course for undergraduates.

Accomplishments

- Principal investigator for National Institutes of Health-funded multi-site case-control study of needle exchange program effectiveness
- Designed, conducted and published studies of HIV prevention programs
 - HIV prevention among injection drug users
 - Non-occupational post-exposure prophylaxis
- Peer-reviewed publications with activist course students
 - International tobacco labeling
 - Sex education information on the Internet
 - Hepatitis B vaccination attitudes and practices among college students

Assistant Professor

July 1993-December 1998:

University of California, San Francisco Department of Epidemiology and Biostatistics, Department of Family and Community Medicine and Institute for Health Policy Studies, San Francisco, CA

Conducted cutting-edge research in HIV epidemiology and prevention policy in the U.S. and abroad and provided clinical services and instruction at major urban hospital.

Accomplishments

- Principal investigator on first comprehensive Federally funded study of needle exchange programs
- Designed, conducted and published numerous studies of HIV prevention programs
 - HIV prevention among injection drug users
 - Cost-effectiveness of HIV counseling and testing policies
 - Ethics of HIV vaccine trials in developing countries
 - Impact of macro-economic policies on HIV dissemination
- Acted as mentor for visiting HIV prevention scholars from developing countries and designed, conducted and authored studies based on research conducted in Africa, Asia and Latin America
- Elected to Center for AIDS Prevention Studies Executive Committee
- Co-directed Clinical Research Training Program for medical fellows

ADJUNCT FACULTY POSITIONS

- 2008-present: Associate, Johns Hopkins Bloomberg School of Public Health
- July 2006-2013: Associate Professorial Lecturer, George Washington University School of Public Health and Health Sciences Environmental and Occupational Health
- April 2005-June 2006: Adjunct Associate Professor, George Washington University School of Public Health and Health Sciences Environmental and Occupational Health

EDUCATION

Post-doctoral

- Pew Health Policy Research Fellow, University of California, San Francisco, 1990-1993
- Traineeships in AIDS Prevention Studies Fellow, Center for AIDS Prevention Studies, University of California, San Francisco, 1990-1993
- Clinical Fellow, Department of Family and Community Medicine, University of California, San Francisco, 1990-1993
- Masters in Public Health, University of California, Berkeley, Epidemiology, May 1991

Residencies

- University of California, Berkeley, Preventive Medicine Residency Program, 1990-1992
- University of California, San Francisco, Family Practice Residency Program, 1987-90

Medical School

- Albert Einstein College of Medicine, Bronx, NY, M.D., May 1987

Undergraduate

- Cornell University, Ithaca, NY, A.B. Chemistry, June 1982
Graduated with Distinction; Dean's List five times

Secondary

- Brighton High School, Rochester, NY, High School Diploma, June 1978
- Herzlia School, Cape Town, South Africa, 1966-1976

LICENSURE

- Active District of Columbia Medical License, 2000-present (License number: MD33864)

AWARDS

- Food and Drug Administration Commissioner's FDA Leveraging/Collaboration Award "For outstanding teamwork and collaboration in acquiring FDA Agency-wide real-time access to the National Poison Data System which will strengthen FDA's product safety surveillance to protect public health," 2017
- Food and Drug Administration Commissioner's Group Recognition Award "For conceiving and conducting the 2016 FDA Naloxone App Competition innovatively addressing the opioid epidemic by connecting individuals carrying naloxone with those suffering an opioid overdose," 2017

- Food and Drug Administration Commissioner's Group Recognition Award "For outstanding communications surrounding the FDA's Opioid Action Plan," 2016
- Food and Drug Administration Commissioner's Group Recognition (Crosscutting) Award "For superior teamwork in streamlining the application process for FDA's single patient expanded access program," 2016
- Food and Drug Administration Commissioner's Group Recognition (Crosscutting) Award "For their vision and collaboration in developing and launching a new website section to serve as FDA's Expanded Access Web Portal," 2016
- Health and Human Services Secretary's Award for Distinguished Service to the Opioid Initiative Team, 2015
- Food and Drug Administration Commissioner's Group Recognition Award (Crosscutting) "For superior teamwork in proactively and collaboratively expediting development and availability of medical products in support of FDA's response to the West Africa Ebola epidemic," 2015
- Center for Devices and Radiological Health Director's Excellence in Postmarket Safety Award "For rapid response to a postmarket safety signal [morcellation] of public health significance," 2015
- Food and Drug Administration Commissioner's Group Recognition (Crosscutting) Award "For rapid and comprehensive action to protect the public and FDA employees from potential exposure to infectious and toxic agents [the discovery of smallpox on the National Institutes of Health campus], and prevent future incidents," 2015
- Food and Drug Administration Commissioner's Special Citation "For promoting public health through increasing the transparency of animal drug sales to support the public's interest in antimicrobial resistance," 2015
- Food and Drug Administration Commissioner's Special Recognition Award "For organizing and executing the Third Annual FDA Health Professional Organization Conference fostering dialogue and encouraging collaboration to promote public health." 2015
- Food and Drug Administration Commissioner's Group Recognition Award to the CT Colonography Advisory Committee Meeting Team, 2014
- Center for Drug Evaluation and Research Director's Award for Team Excellence "For outstanding team performance in evaluating complex scientific, public health, and regulatory issues related to the safety of extended-release and long-acting opioid analgesics," 2014
- Food and Drug Administration Commissioner's Special Citation "For outstanding performance, tireless dedication to duty and steadfast commitment to protecting the nation's public health responding to the 2012 multi-state meningitis outbreak," 2013
- Food and Drug Administration Commissioner's Special Citation "For outstanding leadership, innovation, organizational skills and collaboration in creating the inaugural World Health Organization/FDA International Tobacco Regulators' Conference," 2012

- Center for Tobacco Products Director's Special Citation "For leadership and expertise in assisting CTP to develop and implement an international policy agenda to support the Family Prevention and Tobacco Control Act," 2011
- Appointed member of Centers for Disease Control Blue Ribbon Panel on Vaccine Safety, 2004
- Appointed member of advisory group on Mad Cow Disease to Health and Human Services Secretary Tommy Thompson, 2001
- Appointed member U.S. Food and Drug Administration Advisory Committee on Transmissible Spongiform Encephalopathies, 1998-2001
- Winner, Alfred R. Lindesmith Award for excellence in scholarship, Drug Policy Foundation, 1997
- Winner, "Activist of the Year," ACTUP Golden Gate, 1996
- Named one of the "50 Most Innovative U.S. AIDS Researchers," Poz Magazine, 1996
- Plaque of Appreciation, Colorado Governor's AIDS Council, 1996
- Nominated for Heinz Award, 1995, 1996, 1997
- Winner, Project Censored's "Best Censored Story of 1994"
- Nominated for UCSF Chancellor's Award for Community Service, 1992
- Member, San Francisco Mayor's Budget Task Force, 1991
- International Health Fellowship Award, 1985
- Phi Beta Kappa, 1982

HEALTH-RELATED FOREIGN TRAVEL

- 2016: India – U.S. government representative to Government of India/WHO meeting on antimicrobial resistance, Delhi
- 2008: Germany – Invited plenary speaker at Health Action International Europe Annual Meeting, Berlin
- 2008: Japan – Invited speaker at 10th Annual Medwatcher Symposium, Tokyo
- 2003: Canada – Society for General Internal Medicine Annual Meeting, Vancouver
- 2002: Brazil – Invited speaker at International Association of Bioethics meeting, Brasilia
Switzerland – Delegate to Council for International Organizations of Medical Sciences meeting, Geneva
- 1999: Nigeria – Site visit to team conducting peer intervention for young adults
- 1998: Brazil – Invited speaker at International Harm Reduction Conference, Sao Paulo
- 1997: Kenya – Site visit to team researching risk behaviors among adolescents at truck stops on Trans-Africa Highway
- 1997: Cote d'Ivoire – Invited speaker at International Conference "Information Research and Action Programme on HIV/AIDS, STDs and TB," Abidjan.
- 1996: Brazil – Invited speaker at International Conference "Drugs: Multidisciplinary Debate," Sao Paulo
- 1995: Belgium – Invited speaker at World AIDS Day Forum, Instituut voor Tropische Geneeskunde, Antwerp

- 1995: Brazil – Site visit to two teams implementing interventions to prevent HIV among injection drug users -- Invited speaker at “Conference on the Use and Abuse of Drugs,” Salvador, Bahia
- 1994: Zambia – Site visit to team investigating relationship between “dry sex” and HIV transmission
- 1993: Switzerland – Consultant to World Health Organization on ethical, social and behavioral aspects of HIV vaccine trials in developing countries
- 1992: England, Netherlands – Visited needle exchange programs
- 1992: Zambia – Site visit to team investigating relationship between “dry sex” and HIV transmission
- 1992: Kenya – Investigated conduct of local pharmaceutical companies
- 1989: Bolivia – Trained primary health care workers; provided clinical care
- 1987: South Africa – Occupational health research on AIDS, lead exposure and the Machinery and Occupational Safety Act; trained primary health care workers; clinical practice in urban and rural settings
- 1986: Netherlands – Researched pharmacology and third world marketing of anabolic steroids
- 1984: Cuba – Attended Colloquium on Occupational Respiratory Disease

FOREIGN LANGUAGES

- Hebrew (written and spoken)
- Afrikaans (written and spoken)
- Spanish (intermediate)
- Dutch (beginner)
- Portuguese (beginner)
- French (beginner)
- Russian (beginner)

REFERENCES (Contact information available upon request)

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FDA Office of the Commissioner Joint Meeting of the Gastroenterology Urology Devices Panel and the Radiological Devices Panel of the Medical Devices Advisory Committee on Computed Tomography Colonography (CTC), Silver Spring, MD, September 9, 2013.

Role of Naloxone in Opioid Overdose Fatality Prevention, Public Meeting, Silver Spring, MD, April 12, 2012.

International Tobacco Regulators Conference, Leesburg, VA, November 14-16, 2011.

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