SARA FAY GOLDKIND, M.D., M.A.
Goldkind Consulting, L.L.C.
Research & Clinical Bioethics Consultant
5630 Wisconsin Avenue, Unit # 807
Chevy Chase, MD. 20815-4456
Cell: 240-353-0866
sfgoldkind@gmail.com
http://www.goldkindconsulting.com

Profile

- Nationally recognized authority in clinical research ethics
- Over 10-year experience at the Food and Drug Administration as the first FDA bioethicist, departing as Senior Bioethicist
- Expert in innovative product development for challenging settings and cutting-edge bioethical concerns
- Expert in human "subjects" protections (informed consent and IRB-related matters), Good Clinical Practice, research integrity and research compliance
- Expert in designing ethics programs (FDA ethics consultative services, and hospital-based ethics consultative services)
- Fellowship training in clinical medical ethics
- Board-certified Internist

Research & Clinical Bioethics Consultant, June 2014- Present:

- Consults on innovative clinical trial design and product development
- Specializes in product-specific consultations (e.g., novel therapies, rare diseases, research involving vulnerable populations, exception from informed consent, and international research)
- Advises on and develops human research protections programs and institutional review boards
- Designs educational programs on research ethics including FDA and HHS regulation-based modules, Good Clinical Practice, human "subjects" protections, scientific integrity, and research compliance
- Consults on clinical medical ethics matters (e.g., hospital-based ethics consultative services, and ethics committee activities and/or functions)
- Develops institutional clinical and research ethics policies

FDA Senior Bioethicist, 2003-May 2014:

- Served as the FDA expert for biomedical research ethics that are highly complex and/or precedent-setting
    - Advised
        - The Commissioner of the FDA
        - Senior management of the Centers within the FDA including the Center for Drug Evaluation & Research, the Center for Biologics Evaluation & Research Center for Devices & Radiological Health, the Center for Tobacco Products
    - Participated in the planning, management and implementation of bioethics activities and policies across the Agency
    - Developed scientific, ethical, and regulatory consensus for optimal solution to specific and general matters
- Provided issue-specific ethics consultations to the various Centers within the Agency
    - In the design, review and monitoring of research protocols (specific applications)
    - On general ethics concerns, including human subject protection and clinical trial oversight
- Developed policies and procedures relevant to bioethics for FDA programs and initiatives
- Developed guidelines (FDA guidances) for FDA stakeholders (including, but not limited to industry, academic communities, advocacy groups, institutional review boards and institutional officials)
- Liaised with other agencies within the Department of Health and Human Services and the federal system as well as external groups (including, but not limited to Congressional staff and members of the press) to develop innovative solutions to complex scientific, regulatory and ethical issues
- Developed educational programs
    - For FDA staff on bioethical issues central to FDA's mission
    - For outside groups on contemporary issues in bioethics arising in clinical research
    - For FDA's institutional review board on human "subjects" protections and research ethics
    - For FDA's field investigators in HHS an FDA human "subjects" protections regulations, federal guidance documents and compliance activities

PROFESSIONAL EXPERIENCE AND POSTDOCTORAL TRAINING

--Bioethicist, Department of Defense, Data Monitoring Committee, September 2018-present

-- Bioethicist, National Center for Complementary and Integrative Health, Data Monitoring Committee, March 2016-present

--Bioethicist, National Center for Complementary and Integrative Health, Protocol Review Committee and Data Monitoring Committee, December 2015-present

--Member, National Academies of Science, Engineering, and Medicine (previously Institute of Medicine) Committee on Military Trauma Care's Learning Health System and its Translation to the Civilian Sector, March 2015-June 2016

--Special Government Expert, The Food and Drug Administration, November 2014-November 2017

--Bioethicist, National, Heart, Lung and Blood Institute trial-specific data safety monitoring board, August 2014-present

--Adjunct Assistant Professor, George Washington University, School of Medicine and Health Sciences, Department of Clinical Research and Leadership, July 2014-August 2016

--Medical Faculty, Fellowship at Auschwitz for the Study of Professional Ethics (FASPE), June 2014- present

- A set of innovative programs for students in professional schools designed to address contemporary ethical issues through a unique historical context
- An intensive two-week fellowship program providing medical, seminary, law, and journalism students a structured examination of the role of their chosen professions in Nazi Germany and the Holocaust in an effort to positively affect current professional ethics

--Member, Walter Reed National Military Medical Center Ethics Committee, January 2013-present

--Member, Research Involving Human Subject Committee (RIHSC, FDA's institutional review board), Fall 2003-Summer 2009

--Member, Institutional Review Board, JAEB Center for Health Research (coordinating center for multi-center clinical trials and epidemiologic research) Tampa, FL, 1993-1999

--Clinical Assistant Professor, Department of Internal Medicine, Division of Medical Ethics and Humanities, University of South Florida, College of Medicine Tampa, FL, 1996-1998

--Ethics Consultant, Transitional Care Hospital
Tampa, FL, 1995-1996

--Ethics Fellow, University of South Florida, School of Medicine, Department of Internal Medicine, Division of Medical Ethics & Humanities

Tampa, FL, 1993-4

-- Fellow, University of Chicago, School of Medicine, Center for Clinical Ethics
Chicago, IL, July 1993

--Intern, Junior Assistant Resident, Senior Assistant Resident, Internal Medicine
Boston City Hospital, Boston, MA, 1983-1986

--Environmental Chemist, Biospherics Inc.
Rockville, MD, 1978-1979

EDUCATION

University of South Florida, M.A., Religious Studies, 1998

- Concentration in Comparative Religious Ethics
- Concentration in Religion and Public Policy

Georgetown University, Kennedy Institute of Ethics, Intensive Bioethics Course XVII, 1991 (Certificate Program)

University of Maryland School of Medicine, M.D., 1983

George Washington University, B.S. Chemistry, with minor concentration in Art History, 1978

- #1 Chemistry student in the graduating class
- Phi Beta Kappa

LICENSURE AND CERTIFICATION

1999 Maryland Medical License (current)

1999 District of Columbia Medical License (non-active status)

1986 Florida Medical License

1984 Diplomat, National Board of Medical Examiners

1983 Massachusetts Medical License

HONORS AND AWARDS

2014 FDA Special Recognition Award for outstanding leadership in revising The CDER MAPP 6030.2, Review of Informed Consent Documents

2014 FDA Distinguished Career Service Award for outstanding performance and expertise in designing FDA's ethics programs

2013 FDA Group Recognition Award for the Final Rule, 21 CFR 50 Subpart D, Additional Safeguards for Children in Clinical Investigations

2011 FDA Group Recognition Award for drafting and publication of the Guidance for Industry and Researchers by the Radioactive Drug Research Committee: Human Research without an Investigational New Drug Application

2011 FDA Office of the Commissioner Award for outstanding organization of the public workshop, Severe Bleeding due to Trauma and Other Causes

2010 FDA Office of Regulatory Affairs Certificate of Appreciation for outstanding contribution to Basic Clinical Bioresearch Monitoring

2009 FDA Office of Regulatory Affairs Certificate of Appreciation for outstanding contribution to Basic Clinical Bioresearch Monitoring

2009 FDA Group Recognition Award for Hemoglobin-Based Oxygen Carriers: Current Status and Future Directions

2007 FDA Group Recognition Award for Emergency Use Authorization Final Guidance

2006 HHS Secretary's Award for Distinguished Service for Pediatric Ethics Subpart D Team

2006 Certificate of Appreciation, Center for Drug Evaluation and Research, Division of Training and Development, "Pediatric Medicine Update"

2006 FDA Office of the Commissioner Group Recognition Award for Emergency Use Authorization Guidance Team

2006 FDA Office of the Commissioner Group Recognition Award for collaborative effort to advance the understanding of Pediatric Obesity Devices

2005 FDA Award of Excellence, Work on Hyperbilirubinemia Product Development

2005 FDA Award of Excellence, Radioactive Drug Research Committee

2004 FDA Award of Excellence, Pediatric Emergency Research

1978 Phi Beta Kappa

1978 American Institute of Chemist's Award-Award for the outstanding Chemistry student at George Washington University

1974-1978 Alpha Epsilon Delta, Pre-Medical Honor Society

1974-1978 Dean's List

MAJOR FEDERAL COMMITTEE APPOINTMENTS

--Member, Informed Consent Working Group, Clinical Trials Transformation Initiative, 2013-2014

> Deliverables: Publication(s) describing current landscape of informed consent processes, recommendations for best practices, proposal for pilot testing recommendations and expert meeting summary, and: recruitment and consent procedures in intensive care unit research

--Member, Center for Drug Development and Research (CDER) Working Group on Informed Consent, 2011-2014

> Deliverables: Seven individual electronic learning modules on informed consent for use by all clinical reviewers in CDER to guide them in their responsibilities in reviewing informed consent documents, how to review them, and when to seek additional input, and; Revision of CDER's internal policies and procedures on informed consent

--FDA representative to the Office of the Secretary of the Department of Health and Human Services in coordination with the Office of Science and Technology Policy Working Group on revisions to human "subjects" research protections, 2009-August 2011.

> Deliverable: Advanced Notice of Proposed Rulemaking, "Enhancing Protections for Research Subjects and Reducing Burden, Delay and Ambiguity for Investigators," Issued July 2011

--Veterans Health Administration Working Group on Post Traumatic Stress disorder and Vulnerable Populations in Research, August-November, 2008

Deliverable: Working Group Report's assessment of ethical dimensions of research in veterans with Post-Traumatic Stress-Applying Guidelines for the Protection of Human Subjects in Research

-- Department of Health and Human Services Representative to World Medical Association on revisions to the Declaration of Helsinki, March 2008

--FDA ex officio to Secretary's Advisory Committee on Human Research Protection (SACHRP), Fall 2006-2014

--FDA ex officio, Subcommittee on Research Involving Children

--FDA ex officio, Subcommittee on Inclusion of Individuals with Impaired Decision-Making in Research

--FDA ex officio, Subcommittee on Harmonization

--FDA ex officio, Subpart A Subcommittee

Deliverables: Ongoing advice and recommendations to SACHRP on issues and topics pertaining to the protection of human research subjects, for parent committee consideration and transmission to the Secretary of the Department of Health and Human Services for implementation. Topics included, research involving children and individuals with impaired decision-making capacity; informed consent and the use of biospecimens; harmonization of human "subjects" regulations and guidance, and; the reduction of regulatory burden with the preservation of appropriate protections for human research subjects

--Co-chair, IRB Working Group, April 2006-2012

Deliverables: Guidance publication, IRB Continuing Review after Clinical Investigation Approval, December 2012

--Chair, 50.24 Consultative Board on the conduct of emergency research with an exception from informed consent (under 21 CFR 50.24), June 2005-present

Deliverables: Formation of a consultative review board comprised of cross-agency experts to conduct prospective consultations and periodic retrospective reviews to assist senior management in evaluating the implementation of the regulation and any needed modifications; Revision of CDER's internal policies and procedures on submissions involving exception from informed consent for emergency research, and; Guidance publication, Exception from Informed Consent Requirements for Emergency Research, March 2011

--Member, Human subject Protection and Bioresearch Monitoring (HSP/BIMO) Council, January 2005-present

> Deliverables: Ongoing coordination and development of cross-cutting policies on modernizing and strengthening FDA's oversight and protection of subjects in clinical trials and integrity of resulting data

--Chair, Subpart D Ethics Working Group, May 2004-October 2006 and Chair, Pediatric Ethics Working Group, April 2004-April 2006

> Deliverables: Establishment of pediatric ethics consultative service, and; guidance publication, Process for Handling Referrals to FDA under 21 CFR 50.54, December 2006

PUBLICATIONS (oldest to most recent)

1) Rogers, E.L., Goldkind, L., **Goldkind, S.F**., *Increasing Frequency of Esophageal Cancer among Black Male Veterans*, CANCER, 1982;49:610-7.

2) Rogers, E.L., **Goldkind, S.F**., Goldkind, L., et. al., *Adenocarcinoma of the Lower Esophagus*, Journal of Clinical Gastroenterology, 1986;8:613-8.

3) Rogers, E.L., Iseri, O., Bustin, M., **Goldkind, S.F**., Goldkind, L., *Adenocarcinoma of the Esophago-gastric Junction: A Distinct Entity*, Abstract, American Association for the Study of Liver Disease, Gastroenterology Research Group, May, 1981.

4) M. Dianne Murphy and **Sara F. Goldkind**, "Regulatory and Ethical Challenges of Pediatric Research," The Grand Bargain: Ethics and the Pharmaceutical Industry in the 21st Century. Cambridge: Cambridge University Press, 2005.

5) **Sara F. Goldkind**. *A Review of: Book Reviews Eric Kodish, Ethics and Research with Children,* American Journal of Bioethics, 2006;6(6):71-2.

6) Robert Temple and **Sara F. Goldkind**, "FDA and Drug Development," The Oxford Textbook of Clinical Research Ethics, Oxford: Oxford University Press, 2008.

7) Katherine L. Wisner, Paul S. Applebaum, Kathleen Uhl, **Sara F. Goldkind**, *Pharmacotherapy for depressed pregnant women: Overcoming obstacles to gathering essential data*, Clinical Pharmacology and Therapeutics, October 2009;86(4):362-5.

8) **Sara F. Goldkind**, Leyla Sahin, Beverly Gallauresi, *Enrolling Pregnant Women in Research-Lessons from the H1N1 Influenza Pandemic*, New England Journal of Medicine, June 17, 2010;362(24):2241-3.

9) P.I. Dickson, A.R. Pariser, S.C. Groft, R.W. Ishihara, D.E. McNeil, D. Tagle, D.J. Griebel, S.G. Kaler, J.W. Mink, E.G. Shapiro, K.J. Bjoraker, L. Krivitzky, J.M. Provenzale, A. Gropman, P. Orchard, G. Raymond, B.H. Cohen, R.D. Steiner, **S.F. Goldkind,** R.M. Nelson, E. Kakkis, and M.C. Patterson, *Research challenges in Central Nervous System Manifestations of Inborn Errors of Metabolism*, Molecular Genetics and Metabolism, 2011;102(3):326-38.

10) Mary C. Blehar, Catherine Spong, Christine Grady, **Sara F. Goldkind**, Leyla Sahin, Janine A. Clayton, *Enrolling Pregnant Women: Issues in Clinical Research*, Women's Health Issues, January 2013;23(1):39-45.

11) Richard H. Beigi, **Sara F. Goldkind**, Indira Jevaji*, Research on Vaccines and Antimicrobials during Pregnancy: Challenges and Opportunities*, Vaccine (2013);31: 4261-3.

12) **Sara F. Goldkind**, Laura Ruse Brosch, Michelle Biros, Robert Silbergleit, George Sopko, *Centralized IRB Models for Emergency Care Research*, IRB: Ethics & Human Research*,* 2014;36(2):1-9.

13) Monique L. Anderson, Joseph Griffin, **Sara F. Goldkind**, Emily P. Zeitler, Liz Wing, Sana Al-Khatib, Rachel E. Sherman, *The Food and Drug Administration and Pragmatic Clinical Trials of Marketed Medical Products,* Clinical Trials, 2015:12(5):511-19.

14) Neal W. Dickert, Jeremy Brown, Charles B. Cairns, Aaliyah Eaves-Leanos, **Sara F. Goldkind**, Scott H.Y. Kim, Graham Nichol, Katie J. O'Conor, Jane Scott, Richard Sinert, David Wendler, David W. Wright, Robert Silbergleit, *Ethical and Regulatory Challenges of Emergency Care Research with Conscious Patients,* Annals of Emergency Medicine Online publication December 18, 2015.

15) Neal W. Dickert, Nir Eyal, **Sara F. Goldkind**, Christine Grady, Steven Joffe, Bernard Lo, Franklin G. Miller, Rebecca Pentz, Robert Silbergleit, Kevin P. Weinfurt, David Wendler, Scott Y.H. Kim, *Re-framing Consent for Clinical Research: A Function-Based Approach,* American Journal of Bioethics Online publication November 17, 2017, Issue 12, pages 3-11.

16) Neal W. Dickert, Michael Frankel, **Sara F. Goldkind**, Andrea R. Mitchell, Raul G. Nogueira, Rebecca Pentz, Robert Silbergleit, Candace D. Speight, Kevin P. Weinfurt, *Abstract WP307: Patients' and Surrogates' Experiences and Views of Consent in Acute Stroke Trials,* Stroke January 2018;49(Suppl1):AWP307.

17) Aleksandra E. Olszewski and **Sara F. Goldkind**, *The Default Position: Optimizing Pediatric Participation in Medical Decision-making,* American Journal of Bioethics (2018):18(3):4-9.

18) Neal W. Dickert, David Wendler, Chandan M. Devireddy, **Sara F. Goldkind**, Y-An Ko, Candace D. Speight, Scott Y. H. Kim, *Consent for Pragmatic Trials in Acute Myocardial Infarctions,* Journal of American College of Cardiology (March 6, 2018): 71(9): 1048-57.

19) Aleksandra E. Olszewski and **Sara F. Goldkind**, *The Default Position: Optimizing Pediatric Participation in Medical Decision-making,* American Journal of Bioethics, Author's Response, American Journal of Bioethics (2018);18(4):W4-W7.

20) Neal W. Dickert, David Wendler, Chandan M. Devireddy, **Sara F. Goldkind**, Yi-An Ko, Candace D. Sreight, Scott Y. H. Kim, *Understanding preferences regarding consent for pragmatic trials in acute care,* Clinical Trials (2018);15(6):567-578.

21) Neal W. Dickert, Victoria M. Scicluna, Opeolu Adeoye, Dominick J. Angiolillo, James C. Blankenship, Chandan M. Devirreddy, Michael R. Frankel, **Sara F. Goldkind**, Gautam Kumar, Yi-An Ke, Andrea R. Mitchell, Raul G. Nogueria, Ruth M. Parker, Manesh R, Patel, Michele Riendford, Robert Silbergleit, Candace D. Speight, Ilana Spokoyny, Kevin P. Weinfurt, Rebecca D. Pentz, *Emergency Consent: Patients' and Surrogates' Perspectives on Consent for Clinical Trials in Acute Stroke and Myocardial Infarction,* Journal of the American Heart Association (2019);8(2):1-12.

22) Jinkuk Kim, Chunglung Hu, Abrie Soucy, Jai Vaze, Christelle Achkar, Ashley Kuniholm, Austin Larson, Lauren Black, Julie Douville, Mary Pendergast, **Sara F. Goldkind**, et.al., *Patient-customized Oligonucleotide Therapy for an Ultra-rare Genetic Disease*, New England Journal of Medicine (2019);381(17):1644-1652.

23) Victoria M. Scicluna, **Sara F. Goldkind**, Andrea Mitchell, Rebecca Pentz, Candace D. Speight, Robert Silbergleit, Neal W. Dickert, *Determinants of Patient and Surrogate Experiences with Acute Care Research Consent: A Key Informant Interview Study,* Journal of American Heart Association (2019);8(22):1-9.

GUIDANCE DEVELOPMENT

- Natural History Studies for Rare Disease Drug Development-Draft Guidance pending publication
- Use of Electronic Informed Consent in Investigational Studies-Draft Guidance pending publication
- A Guide to Informed Consent-Draft Guidance

- Product Development under Animal Rule-Final Guidance pending publication
- Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials-Draft Guidance pending
- Pharmacokinetics During Pregnancy and the Postpartum Period: Study Design, Data Analysis, and Impact on Dosing and Labeling-Final Guidance pending
- Clinical Lactation Studies: Study Design, Data Analysis, and Recommendations for Labeling-Final Guidance pending publication
- Exculpatory Language in Informed Consent, Draft Guidance, August 2011
- IRB Continuing Review after Clinical Investigation Approval, December 2012
- Exception from Informed Consent for Emergency Research, March 2011
- Adverse Event Reporting to IRBs-Improving Human Subject Protections, January 2009
- Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials, October 2008
- Process for Handling Referrals to FDA under 21 CFR 50.54, December 2006

PRESENTATIONS/INSTRUCTION (oldest to most recent)

- Guest Lecturer, *Religion, Ethics and Society*-Undergraduate Course, University of South Florida, Fall 1991
- Speaker*, An Overview of Cross Cultural Spiritual Practices,* Tampa General Hospital, November 1993
- Speaker, *The Ethics of Fetal-Newborn Rights,* Tampa General Hospital, December 1993
- Instructor, *Ethical Policies and Ethical Issues*, Nursing Units and Management Forum, Tampa General Hospital, Fall 1993-Summer 1994
- Instructor, *Medical Ethics and Humanities*, University of South Florida-School of Medicine, 1994-1998
- Speaker, *Truth-telling in Medicine,* Bone Marrow Transplant Program-Didactic Conference, Moffitt Cancer Center, February 1994
- Speaker, *Ethical Issues in Nursing,* Tampa General Hospital Nurse In-Transition Workshop, February 1994
- Speaker, *Hot Topics in Ethics*, Tampa General Healthcare Senior Health Care Series, Sun City Center, February 1994
- Speaker, *Medical Futility: An Ethical Dilemma*, Controversies in Medicine, Boston University School of Medicine, March 1994
- Speaker, *Advance Directives*, Critical Care Transition Course, Tampa General Hospital, April 1994
- Develop and facilitate, *Fiction and Medical Ethics-Reading Group*, Tampa General Hospital, Spring 1994
- Develop and instruct, *Law and Medicine-Intensive Course*, Tampa General Hospital, Spring 1994

- Speaker, *Ethical Considerations in the NICU,* Tampa General Hospital, May 1994
- Speaker, *Ethical Issues in Critical Care*, Tampa General Hospital-Didactic Conference, July 1994
- Panelist, *Medical Futility: When is Enough, Enough?* Inter-hospital Ethics Consortium, "Ethical Dilemmas in Healthcare: Shared Concerns," March 1995
- Speaker, *Medical Futility: What It Is and Is Not,* sponsored by The Tampa Bay Ethics Consortium, February 1995
- Panelist, *Does Medical Futility Exist, Medical Management of Futile Inappropriate Care Requests,* and *The Courts Approach to Medical Futility Issues,* sponsored by The Tampa Bay Ethics Consortium, February 1995
- Speaker, *Truth-telling and Confidentiality Issues in Medicine,* Tampa General Hospital, May 1995
- Guest Lecturer, *Comparative Religious Medical Ethics: Catholic and Jewish Views on Beginning of Life and End of Life Issues*, Berger High School, Spring 1996
- Panelist, *Hospital Policies on Futility: Should We Have Them?* Florida Bioethics Network Fifth Annual Conference, September 1995

  Guest Lecturer, Med IV Elective in Medical Ethics and Humanities, Spring 1996
- Develop and instruct, *Religion, Law, and Medical Ethics* Graduate Level Course #6938, University of South Florida, Department of Religion, Fall 1996
- Speaker and Panelist, *Assisted Suicide-What Are the Issues?* Public Forum, St. Petersburg, FL, sponsored by Menorah Manor, March 6, 1997
- Guest Lecturer, *Jewish Medical Ethics: Jewish Views on Beginning of Life, and End of life Issues* (including Physician-Assisted Suicide), Berger High School, Spring 1997
- Guest Speaker, "Advance Directives," annual Medical Staff meeting, Columbia Newport Richey Hospital, November 24, 1997
- Speaker and Panelist, *Patient Autonomy in Hospitals and Hospices: The Religious Response,* National Conference on Catholic & Jewish Perspectives on Bio-Ethics, Co-sponsored by Saint Leo College and The American Jewish Committee, February 9-10, 1998
- Lecturer, *Ethical Issues in Randomized Control Trials*, Division of Anti-Viral Drug Products, CDER, FDA, January 2004
- Lecturer, *Ethical Issues in Randomized Control Trials*, Division of Pediatric Drug Development, CDER, FDA, February 2004
- Instructor, *IRB Referrals and Human Subjects Protection*, Division of Counter Terrorism, CDER, FDA, February 2004
- Speaker, *Special Ethical Considerations for Protection of Pediatric Research Subjects,* Conference: Quality Improvement for Patient Protection, jointly supported by University of Pennsylvania, Temple University & OHRP, May 6-7, 2004

- Panelist, “Central Versus Local IRBs,” Conference: Quality Improvement for Patient Protection, jointly supported by University of Pennsylvania, Temple University & OHRP, May 6-7, 2004
- Instructor, *IRB Referrals and Human Subjects Protection,* Division of Pediatric Drug Development, CDER, FDA, June 2004
- Instructor, *Research Misconduct and the Ethics of Data Use and Publication*, Research in Human Subjects Committee, FDA, June 2004
- Lecturer, *Assent and Subpart D Regulatory Issues in Pediatric Research*, Pediatric Advisory Board (Pedicomm), FDA, June 2004
- Speaker, *Special Ethical Considerations for Protection of Pediatric Research Subjects,* Conference: Pediatric Drug Development-Evolving Clinical & Regulatory Framework in US and Europe, Drug Information Association Annual Meeting, June 16, 2004
- Speaker, *Special Ethical and Regulatory Protections for Pediatric Research Subjects: Subpart D and Assent,* Joint Grand Rounds with Children’s National Medical Center and George Washington University, June 30, 2004
- Lecturer, *Assent and Subpart D Regulatory Issues in Pediatric Research*, Pediatric Implementation Committee (PdIT), FDA, August 2004
- Speaker, *Introduction to Bioethics and Ethical Principles,* CDRH, FDA, September 21, 2004
- Panelist and Presenter, *Radioactive Drugs for Certain Research Uses,* Open Public Hearing, FDA, November 16, 2004
- Lecturer, *Ethical Issues in Randomized Clinical Trials with a Focus on International Research*, Division of Pulmonary Drug Products, CDER, FDA, December 21, 2004
- Lecturer, *Subpart D and Assent: What does an IRB Need to Know?* RIHSC (FDA-IRB), June 8, 2005
- Panelist, *Adverse Event Reporting to Institutional Review Boards*, Part 15 Hearing, FDA Cross Agency Initiative Task Force, March 21, 2005
- Presenter, *Update on Subpart D Process*, SACHRP, November 2, 2005
- Panelist, *Medical Ethics in the Regulatory Process,* CDER Clinical Reviewers’ Retreat, FDA, November 3, 2005
- Presenter, *Ethical Issues at the FDA,* International Exchange between Japanese and US Representatives: Pediatric Research, FDA, November 10, 2005
- Presenter, *Bioethics Seminar: Informed Consent and Case Analyses*, CDRH, FDA, November 28, 2005
- Presenter, *Ethical Issues in Pediatric Research,* President’s Council on Bioethics, December 8, 2005
- Panelist, *Consortium to Examine Clinical Research Ethics: Policy Forum, December* 14, 2005
- Presenter, *FDA Perspective Regarding Ethics, Regulation, and Research Involving Children,* Children’s Oncology Group, March 24, 2006
- Presenter, *Ethics in Counter-terrorism Trials*, CDER Pediatric Medicine Update, June 1, 2006

- Presenter, *FDA's Role in Human Subjects Protection,* "Human Subjects Protection, Bioresearch Monitoring, Critical Path Update," DIA, June 21, 2006
- Presenter, *Pediatric Subjects in clinical Investigation: Subpart D, Assent, and Inspections,"* Advanced BIMO Course, June 30, 2006
- Instructor, Division Directors for CDER, Pediatric Trial Review and Inspection: Review Pediatric Protocol Review Guide, July 7, 2006
- Speaker and Panelist, *Emergency Research Update,* "Strategies for Research in HIPAA Environment and other Regulatory Issue," NINDS sponsored, July 26, 2006
- Speaker and Panelist, *Emergency Research and Human Subject Protections: Challenges and Solutions*, Part 15 Hearing, FDA Bioresearch Monitoring Initiative, October 11, 2006
- Speaker and Panelist, *When and How to Seek an Emergency Exception to Informed Consent,* PRIM&R, 2005 Annual HRPP Conference: A Commitment to Ethical Research, December 16, 2006
- Speaker and Panelist, *IRB's Experience with FDA's Emergency Research Waiver of Informed Consent Rule,* PRIM&R, 2005 Annual HRPP Conference: A Commitment to Ethical Research, December 17, 2006
- Panelist, *Development of Guidance for the Application of The Exception from Informed consent for Emergency Research,* National Association of EMS Physicians, February 7-8, 2007
- Develop and Moderate, *Defining and Implementing Quality in Clinical Investigations: From Design to Completion,* DIA Workshop, May 10-11, 2007
- Speaker, *Ethics in Clinical Investigations with a Focus on Emergency Research,* Medical Policy Coordination Committee, CBER, April 24, 2007
- Instructor, Trans NIH Bioethics Committee, *Supervisory Responsibilities of Investigators,* June 19, 2007
- Speaker and Panelist, *Can the Prospect of Direct Benefit Be Based on Animal Studies Alone?* American Society for Bioethics & Humanities, October 19, 2007
- Speaker, *FDA Perspectives on "Adverse Events,"* Data and Safety Monitoring: An Educational Program for the NIMH DSMBs, November 19, 2007
- Speaker and Panelist, *Can the Prospect of Direct Benefit Be Based on Animal Studies Alone?* PRIM&R Annual HRPP Conference: Human Research Protection Programs in Evolving Research Landscape, December 1-4, 2007
- Speaker and Panelist: *A Guide to the Perplexed: Navigating OHRPs and FDAs and NIH's Expectations for Reporting Adverse Events and Unanticipated Problems,* PRIM&R Annual HRPP Conference: Human Research Protection Programs in Evolving Research Landscape, December 1-4, 2007
- Speaker and Panelist, *Emergency Exception to Informed consent: When and How?* PRIM&R Annual HRPP Conference: Human Research

Protection Programs in Evolving Research Landscape, December 1-4, 2007

- Speaker & Moderator, *Ethical Issues in International Research*, CDER (& CBER) Scientific Rounds, January 15, 2008
- Speaker, *Genotoxicity: Should we be checking for it?* CDER Pharmacology-Toxicology Scientific Rounds, January 30, 2008
- Speaker, *FDA Perspectives on "Adverse Events,"* Addressing the Challenges of Human Subject Research in 2008, Sacramento Regional Conference Forum for OHRP, February 8, 2008
- Speaker and Panelist, *Conduct of Emergency Research Trials*, Clinical Hold/RTF Committee Meeting, CDER, March 14, 2008
- Develop and Moderate, C*linical Investigations as a Quality System: From Design to Completion,* CDER Workshop, Office of Critical Path Programs, March 18, 2008
- Speaker, *Ethical Perspective on Drug-Induced Liver Injury: Premarketing Clinical Evaluation,* Drug-Induced Liver Injury Workshop, FDA, March 26, 2008
- Speaker, *Ethical Considerations for Trials in Community Acquired Pneumonia,* Anti-infective Drugs Advisory Committee, FDA, April 1, 2008
- Speaker, *Risk-Benefit Considerations in the Context of §50.24 and §312,* Hemoglobin Oxygen Carrier Workshop, FDA-NIH, April 29, 2008
- Panelist, *Developing Guidance on Conducting Scientifically Sound Pharmacoepidemiologic Safety Studies Using Large Electronic Healthcare Data Sets*, FDA Public Workshop, May 7, 2008
- Lecturer, *IRB Considerations Regarding Protection of Vulnerable Subjects with a Focus on Decisionally Impaired Subjects*, RIHSC (FDA-IRB), April 12, 2008
- Lecturer, *Historical and Current Perspectives on the Declaration of Helsinki,* RIHSC (FDA-IRB), May 7, 2008
- Lecturer, *FDA Institutional Review Board and Informed Consent Regulations*, Basic Bioresearch Monitoring 2008 Course, August 12, 2008
- Lecturer, *Ethical Dilemma Associated with Sham Procedures/Treatments*, CDRH, October 17, 2008
- Panelist, *Real Cases, Hard Choices when Balancing Ethics and Regulations,* PRIM&R Annual HRPP Conference: Balancing the Needs of Human Subjects and Science, November 17-19, 2008
- Co-presenter, *Tools for Talking to Parents and Children about Research*, PRIM&R Annual HRPP Conference: Balancing the Needs of Human Subjects and Science, November 17-19, 2008
- Speaker and co-developer, *The Ethics of Studying Drugs and Biologics in Pregnant Women*, CDER Scientific Rounds, April 20, 2009
- Participant, *The Second Wave: Toward Responsible Inclusion of Pregnant Women in Clinical Research*, Georgetown University Medical Center, May 2009
- Lecturer, *FDA Institutional Review Board and Informed Consent Regulations*, Basic Bioresearch Monitoring 2008 Course, March 11, 2009

- Speaker, *Ethical Issues in International Clinical Trials*, Fogarty International Training Program Seminar, June 22, 2009
- Speaker, *Federal Update: What's New from the Feds?* OHRP Research Community Forum "On the Legal and Ethical Frontline", September 11, 2009
- Panelist, *Ask the Feds,* OHRP Research Community Forum "On the Legal and Ethical Frontline", September 11, 2009
- Break Out Session Moderator, Workshop on Ethical and Regulatory issues in Global Pediatric Trials, September 21-22, 2009
- Panelist, *Regulatory issues Associated with Multi-Regional Trials*, The Fourth National FDA Regulatory Symposium, September 30-October 2, 2009
- Lecturer, *FDA Institutional Review Board and Informed Consent Regulations*, Basic Bioresearch Monitoring 2008 Course, October 15, 2009
- Speaker, *Are the FDA regulations and guidance that different from the WMA Declaration of Helsinki?* American Society for Bioethics & Humanities, October 18, 2009
- Lecturer, *Informed Consent and Elements to Assure Safe Use in REMS*, Division of Risk Management Roundtable, CDER, October 20, 2009
- Speaker, *Ethical Issues in Studying Rare Disease*, Inborn Errors of Metabolism/CNS Workshop, Division of Gastroenterology Products, CDER, December 7-8, 2009
- Speaker, *Issues to Consider for Trials Conducted Under 21 CFR 50.24 (Exception from informed consent for emergency research)*, CBER, January 4, 2010
- Lecturer, *FDA Institutional Review Board and Informed Consent Regulations*, Basic Bioresearch Monitoring 2010 Course, March 3, 2010
- Prepared presentation, *Part 50-Informed Consent Process,* Center's Bioresearch Monitoring Course, April 9, 2010
- Speaker, "What's New and Important from the Feds?", OHRP-FDA Educational Conference, May 21, 2010
- Speaker, *Ethical Issues in International Clinical Trials*, Fogarty International Training Program Seminar, June 29, 2010
- Lecturer, *FDA Institutional Review Board and Informed Consent Regulations*, Basic Bioresearch Monitoring 2010 Course, August 25, 2010
- Speaker, *Inside FDA (and emergency research with the exception from informed consent),* PECARN, September 15, 2010
- Speaker, *REMS, Pregnancy, and Ethics,* DIA Maternal and Pediatric Drug Safety Symposium, October 13, 2010
- Speaker, *Pregnancy Women and Clinical Trials: Scientific, Regulatory, and Ethical Consideration,* Research Forum on Issues in Clinical Research: Enrolling Pregnant Women, October 18, 2010
- Panelist, *Pregnancy Women and clinical Trials: Scientific, Regulatory, and Ethical Consideration,* PRIM&R Plenary XIII-Research on Pregnancy: A Necessary Risk? December 8, 2010

- Speaker, *Ethical Consideration in Trauma,* Public Workshop on Product Development Program for Interventions in Severe Bleeding due to Trauma and Other Causes, December 9-10, 2010
- Lecturer, *FDA Institutional Review Board and Informed Consent Regulations*, Basic Bioresearch Monitoring 2011 Course, January 20, 2011
- Lecturer, *Ethics and Device Clinical Trials*, CDRH, January 24, 2011
- Speaker, *Ethical Challenges and FDA's Experience with EFIC Applications*, HRSA sponsored WEBCAST, 2/28/11
- Presenter, *Ethical Issues Associated with a Drug Study in a Foreign Country,* CDER's Regulatory Briefing Meeting, February 25, 2011
- Speaker, *Ethical and Scientific Considerations in Including Pregnant Women in Clinical Trials,* FDA Office of Women's Health Symposium on "Pregnancy and Prescription Medication Use", May 17, 2011
- Speaker, *Ethical and Scientific Considerations in Research (particular focus on vaccines for pregnant women,* CBER, May 24, 2011
- Speaker, *Ethical Issues in International Clinical Trials*, Fogarty International Training Program Seminar, June 20, 2011
- Speaker, *FDA Guidance on Emergency Care Research and IRB Review Processes,* Assistant Secretary for Preparedness and Response, Workshop on IRB Options for Emergency Care Research, 9/19-9/20/11
- Speaker, *Exception from Informed Consent for Emergency Research,* PRIM&R Didactic Session, B11, December 2, 2011
- Lecturer, *FDA Institutional Review Board and Informed Consent Regulations*, Basic Bioresearch Monitoring 2011 Course, February 8, 2012
- Panelist, *Innovative models for clinical trials-how do we ensure data quality and appropriate protections while facilitating innovation,* CDER Scientific Rounds, February 8, 2012
- Speaker, *Ethical Considerations in the Clinical Development of Therapeutics for Rare Diseases,* FDA Meeting the Challenges of Rare Disease Drug Review, February 28, 2012
- Speaker, *Current FDA Activities,* Society of Clinical Research Associates FDA Clinical Trials Requirements Conference, March 7-8, 2012
- Speaker, *Ethical Considerations in the Clinical Development of Therapeutics for Rare Diseases,* Office of Orphan Drug Products, May 14, 2012
- Speaker, *Defining the Status of the Research Subject in Resuscitation Research*, PRIM&R Didactic Session, D14, December 5, 2012
- Lecturer, *FDA Institutional Review Board and Informed Consent Regulations*, Basic Bioresearch Monitoring 2012 Course, December 11, 2012
- Develop content for interactive educational modules on informed consent, 2013
- Panelist and moderator, *The Ethics of Self-care: Avoiding Provider Fatigue and Maintaining Medicine as a Calling,* Embracing the Principle of

Justice in Healthcare, 2013 Annual Healthcare Ethics Symposium, Walter Reed National Military Medical Center, May 15, 2013

- Speaker, *Background on Informed Consent Issues and HIV "Cure" Research,* FDA Meeting on HIV Patient-focused Drug Development and HIV "Cure" Research, June 14, 2013
- Lecturer, *Regulatory Science and Bioethics,* Georgetown University, Introduction to Regulatory Science Graduate Course, September 11, 2013
- Speaker, *Everything statisticians want to know about 50.24 studies but are afraid to ask,* ASA Pharmaceutical Section, FDA-Industry Statistics Workshop, September 17, 2013
- Speaker, *Hot Topics in Bioethics and Human Subject Protections*, Human Subject Protection Multi-Institution Sponsored Regional Meeting, September 20, 2013
- Co-moderator, *Emergency Research and Community Consultation,* PRIM&R, November 8, 2013
- Speaker and panelist, *Tobacco Cessation Studies and Studies Involving Potential Reduced Risk Products in Pregnant Women: Ethical & Scientific Considerations,* Tobacco and Reproductive Health Workshop Sponsored by FDA-NIH-CDC, January 21-22, 2014
- Lecturer, *FDA Institutional Review Board and Informed Consent Regulations*, Basic Bioresearch Monitoring 2014 Course, March 4, 2014
- Speaker, *Overview of Federal Regulations on Emergency Care Research*, Ethical and Regulatory Challenges to Emergency Care Research, NIH-sponsored conference, March 5-6, 2014
- Speaker, *Centralized IRB Review and Emergency Care Research*, Ethical and Regulatory Challenges to Emergency Care Research, NIH-sponsored conference, March 5-6, 2014
- Speaker and panelist, *Comparative Effectiveness Research,* Challenges in Military Medical Ethics, 2014 Annual Healthcare Ethics Symposium, Walter Reed National Military Medical Center, June 5, 2014
- Speaker, *Impact of poor informed consent processes on clinical trials (including information sharing),* National Academy of Sciences, Institute of Medicine, Roundtable on Health Literacy, July 28, 2014
- Speaker, *FDA's perspective on investigator-initiated research and navigating the need for an IND or IDE,* Achieving Excellence in Clinical Research Conference, Advocate Center for Pediatric Research, September 19, 2014
- Speaker, *Ethics of Research with Children*, NIH Course: Ethical and Regulatory Aspects of Clinical Research, October 8, 2014
- Keynote Address, *Physician Aid-in-Dying: A Survey of the National Landscape*, Walter Reed National Military Medical Center, Annual Ethics Symposium, May 13, 2015
- Panelist, *Engaged in the conduct of research? How to keep the government from finding violations and what to do when they do,* American Society for Bioethics and Humanities, October 24, 2015

- Speaker and panelist, *Informed consent, parental permission, and assent,* Leading the Fight to End Duchenne: Unique Burdens of Pediatric Clinical Trials, Parent Project Muscular Dystrophy, April 20-21, 2017
- Moderator, *Delivery Room Research & The Challenges of Informed Consent*, OHRP Workshop, Meeting New Challenges in Informed Consent in Clinical Research, September 7, 2018