DECLARATION AND OPINION OF JONATHAN D. MORENO, Ph.D.

I, JONATHAN D. MORENO, Ph.D., pursuant to 28 U.S.C. § 1746, declare as follows:

1. My name is Jonathan David Moreno. I reside at 3079 Ordway Street NW, Washington, DC. I am the David and Lyn Silfen University Professor of Ethics at the University of Pennsylvania, where I am also Professor of Medical Ethics and of the History and Sociology of Science. In order to achieve the status of University Professor at University of Pennsylvania one must have been elected to tenure by the faculty of more than one school of the university, in my case the School of Medicine and the School of Arts and Sciences. I also hold a secondary appointment as Professor of Philosophy. Before coming to the University of Pennsylvania I held an endowed chair at the University of Virginia School of Medicine. I have also held tenured professorships at the State University of New York Health Science Center at Brooklyn and George Washington University in Washington, D.C. I have taught at all levels of medical education for thirty years, from undergraduate pre-medical students to medical students to residents to physicians in continuing education.

2. I am an elected member of the Institute of Medicine of the National Academies, of the New York Academy of Medicine and the Hastings Center. A few months ago the College of William and Mary Law School awarded me the Benjamin Rush Medal for my contributions to the study of medical ethics. I have published hundreds of books, papers and articles on various issues in the field of bioethics, including the ethics of research involving human subjects. I am the co-editor of the textbook *Ethical and Regulatory Aspects of Clinical Research* (Johns Hopkins University Press). Both the Bill Clinton and George W. Bush administrations appointed me to

human research protections advisory committees for the Department of Health and Human Services, and I have served as senior staff for two presidential advisory commissions. I have been a member of the national accrediting board for human research protection programs and have taught hundreds of members of institutional review boards in various settings. I have served as a member of data monitoring committees for the National Heart, Lung and Blood Institute of the National Institutes of Health. In the past year I have given invited talks on the ethical and policy issues associated with expanded access to experimental treatments to the Food and Drug Law Institute and the annual meeting of general counsels of companies that are members of the Biotechnology Industry Organization.

3. My *curriculum vitae* is attached.

4. I have served as an expert consultant on a number of legal cases over the past four years. I have listed the cases to the best of my ability. That list is also attached.

5. My fee for research and writing is $300 per hour. This fee was established following inquiries with colleagues who engage in this sort of work and are believed to be in accord with appropriate professional standards.

6. I have been retained by counsel for PTC Therapeutics, Inc. to address several ethical and public policy questions that are critical to this case. My opinions are based on my three decades of research, teaching and advising on ethical problems and public policy issues in the conduct of research involving human subjects. This declaration is a complete statement of all the opinions I will express if called to testify in this matter and the basis and reasons for them. However, I reserve the right to supplement my opinions if presented with additional materials to consider. My opinions

are also based on my consideration of certain materials provided by counsel that I have reviewed as follows: Cover Letter with Motions; Motion for Entry of a Preliminary Injunction; Brief for Preliminary Injunction Motion; Gunvalson Declaration with Exhibits (July 22, 2008); Proposed Order for Preliminary Injunction Motion; Hatch Declaration with Exhibits (July 16, 2008); Parkin Declaration with Exhibits (July 15, 2008); Halpern Declaration with Exhibits (July 24, 2008); Miller Declaration (August 11, 2008); Peltz Affidavit (August 11, 2008); Furlong Declaration (August 11, 2008); Goetz Affidavi (August 12, 2008); Hirawat Affidavit (August 12, 2008); and the Finkel Declaration (August 12, 2008).

7. I am not an attorney and will express no opinions about legal matters, but only on the ethical and public policy issues raised in this case. Nor will I opine on the assertions or denials about promises made or not made in the course of the events that have led to this litigation.

What is the purpose of the regulatory system for clinical trials?

8. The system of carefully controlled clinical trials for new drugs and devices is remarkably recent in origin, dating back only to the post-World War II era. That system includes rigorous peer review to ensure that the scientific basis of a study is sound and that data collected are as free as practically possible from extraneous influence, so that a specific scientific question can be answered to a high degree of confidence. The double-blinded-randomized controlled clinical trial (RCT) is generally considered the "gold standard" of sound studies. The RCT is intended to wring as much irrelevant and misleading "noise" out of the data as possible. In addition, the ethical standards that have emerged in the past half century are intended to ensure that desperate patients are not

exploited through participation in studies that are both unlikely to benefit them and may even subject them to undue risks.

9. Furthermore, as clinical trials have come to involve increasingly sophisticated potential treatments, more and more recalcitrant and complicated diseases, and more seriously ill patients, they have become more difficult to design and execute. Early data on toxicity and efficacy are notoriously unreliable, accounting for the fact that less than one-third of drugs in Phase 2 trials are ultimately approved by the U.S. Food and Drug Administration, and even then their approval is generally for a narrowly defined indication for a specific patient population. The expenses involved in bringing a potential drug therapy from animal trials to approval can approach a billion dollars. Therefore a clinical trial in which an otherwise well-designed protocol is compromised by inappropriate or premature exceptions may not only mean that many sick patients have volunteered in vain and the loss of what is often a major public investment, it could also result in significant setbacks for the study of the relevant scientific questions.

<u>What are the risks of access to experimental treatments outside the clinical trial system?</u>

10. For all these reasons entrance into a clinical trial and access to experimental treatments are carefully controlled. A single patient's inappropriate participation could not only undermine the validity of a particular study's results but might inadvertently jeopardize an entire area of research into a serious disease. Thus sound public policy demands that potential benefits to countless future patients not be threatened by otherwise good intentions that are not scientifically justified and may in fact cause more harm to desperate individuals.

11. Even if the question is not one of inappropriate access to a clinical trial but "only" the opportunity to obtain an experimental treatment without meeting eligibility criteria (a matter that I will discuss in detail below), the policy implications are immense. Individual patients would understandably prefer to avoid randomization and the rigors of review to qualify for a study, therefore they would seek every opportunity to obtain a hoped-for remedy in other ways. There are too many tragic stories about U.S citizens traveling abroad for the latest unproven remedy, from peach seeds in the 1980s to stem cells today. The threats to science and future patients as well as current patients are grave.

12. Many observers believe that delays in improvements in the treatment of many adult cancers, for example, can be ascribed to the fact that only about five percent of adults with cancer are being treated on protocols, due in part to the ability of many patients to obtain approved drugs from their doctors "off label" without systematic study. By contrast, pediatric cancer treatment has advanced much more rapidly, thanks in part to the more disciplined nature of pediatric recruitment practices. In general, unrecorded off-label uses due to resistance to randomization are depriving the medical system of vast quantities of information. Policies that could aggravate this problem without strong justification in terms of individual patient benefit should be avoided.

<u>What are special exceptions for access to experimental treatments outside the formal clinical trial context that are sometimes granted and why are they not justifiable in this case?</u>

13. A patient's voluntary informed consent is a necessary *but not a sufficient* condition for ethical study participation or access to an experimental treatment. There is a strong public policy presumption that the public interest in valid and reliable data in the

testing of new drugs and devices should be protected and that exceptions to this presumption should be limited and well justified.

14. As an expression of society's care and concern for persons with serious diseases, in the past 20 years the clinical trials system has developed alternate pathways for access to experimental treatments. These expanded access mechanisms are sometimes referred to as "compassionate use" exceptions, though the term compassionate use is misleading. It tends to assume exactly what the clinical trial is designed to determine, namely, whether providing a certain treatment is an act of compassion or not because it could expose the patient to undue risks. In fact, expanded access mechanisms originated in the efforts of the HIV advocacy community in the 1980s. However, since then even many HIV-AIDS activists have reconsidered the wisdom of expanded access in certain instances.

15. Two forms of expanded access are being sought in this case. The first is a protocol exception which the plaintiffs claim would make it possible for Jacob to receive PTC124 without efficacy data being reported to the FDA. Here the critical ethical questions have to do with the implications of such an arrangement for Jacob, for possible future patients, and for those patients who have already been randomized and are in a controlled trial. As has been said, there is a strong public policy presumption that access to experimental treatments should be limited and well justified. Protocol exceptions may be justifiable for particular patients who are ineligible for a trial if the available data indicate safety and potential efficacy. Strong justification for a protocol exception based on safety and efficacy data is important because without it the public policy implications of a permissive approach to such exceptions must be given great weight. The expert

physician-scientists in the PTC124 trials have not reached the conclusion that the data are sufficient to determine that the drug is safe and effective. I have not seen an alternative analysis of the data that could overcome the presumption that those who are most expert concerning this trial are in the best position to make this judgment. A protocol exception must also meet the problems of recruitment and avoidance of randomization discussed above, problems that could easily compromise the scientific process and the ability of a field of study to produce reliable and valid information that could benefit future patients.

16. Protocol exceptions also raise questions of fairness concerning other similarly situated patients who may not have the wherewithal to petition for an exception. The company asserts there could be as many as a thousand in this country alone. This equity consideration is another element of the public policy presumption that requires a strong justification for an individual protocol exception. Moreover, were other patients in a position to petition for an exception they would surely do so in order to avoid randomization but that would jeopardize the trial and, again, be unfair to those who agreed to be randomized.

17. Thus the critical question in this case is whether the justification for a protocol exception based on the available data is strong enough to overcome the public policy presumption favoring a clinical trial's ability to enroll sufficient numbers of subjects for the sake of the public interest in valid and reliable data and in equity considerations. It is important to note that the expert physicians who are responsible for this study and are most familiar with the disease and the experimental treatment have not concluded that the potential benefit to Jacob is strong enough to overcome the public policy presumption. Absent refuting evidence and arguments their judgment should be

respected. Based on the materials I have reviewed I have not noted adequate refutation in this case.

18. Just as there are ethical and policy considerations relating to a protocol exception, so there are ethical and policy considerations relating to a single-patient IND. A single-patient IND is a clinical trial. The goal of a clinical trial is to increase knowledge about a disease and any intervention. Patient-subject benefit is desirable but not the goal of a clinical trial. However, individuals may not be exploited in clinical trials simply for the sake of gaining knowledge. Therefore, like any clinical trial, a single-patient IND has to satisfy risk-benefit considerations. The ethical requirements for a single-patient IND include sufficient knowledge of the drug's safety and some evidence of clinical effectiveness. A core problem with the wish for a single-patient IND in this case is that the expert scientific investigators apparently do not believe that either of these conditions has been met so far in the study of PTC124. The U.S. Food and Drug Administration grants discretion to the trial sponsor to make this judgment. I have not seen an alternative analysis that would serve as a justification for overcoming the recommendations of the expert investigators.

19. Just as equity considerations apply to protocol exceptions, so they also apply to the opportunity to obtain a physician's cooperation for a single-patient IND. Similarly situated individuals may not have the wherewithal to be in contact with a physician-scientist who is in a position to develop and execute a proper protocol. Fairness considerations are an element in my conclusion that a single-patient IND should not be granted in this case.

20. I note that an independent data monitoring committee (DMC) has been established for the PTC124 2b trial now enrolling. At such time when the DMC has unblinded access to data from the rigorously designed study, they have the responsibility to decide whether the trial should be stopped. For example, interim data from that trial may indicate that the experimental treatment shows benefit and should be offered to all patient-subjects, or that the experimental treatment appears to show harm and the trial should be stopped for that reason. Obviously no such conclusion has been reached by a DMC as yet in this case.

21. One physician has stated that he is prepared to take responsibility for a single-patient IND study involving Jacob. Again, a single-patient IND is a clinical trial, the purpose of which is to gain knowledge and not necessarily to benefit the patient-subject. Therefore all the conditions of a clinical trial would have to be satisfied, including the design of a protocol with suitable study endpoints (i.e., markers of efficacy for this patient-subject), FDA approval and IRB review. I have not seen any indication that a protocol has been developed for a single-patient trial in this case.

22. The purpose of all clinical trials is to increase knowledge that can be generalized to future patients; benefit to those who are participants in the trial, though obviously desirable, is secondary and is often not achievable or intended. Contrary to assertions that have been made in this case, there is little justification for a single-patient IND in terms of increased societal knowledge. Any results of what are sometimes pejoratively called "n of 1" studies are simply too individualized to be generalizable to other patients. This is precisely why a number of patients with a specific set of qualifications are recruited into controlled clinical trials, especially in Phase 2 studies.

23. Of course, single-patient INDs are sometimes justifiable. Phase 2 or Phase 3 trials may reach a point where data on safety and efficacy in a number of individuals with at least somewhat varied manifestations and stages of disease permit reasonable inferences about safety and possible efficacy that might justify a single-patient IND. But these judgments must be made on a case-by-case basis. For all the reasons I have elaborated, I do not believe the case for a single-patient IND has been established in this case, either in terms of safety and efficacy or fairness to future patients.

What would be the effect on the roles and relationships of disease advocacy groups, industry, and the scientific community if legal petition for special access to experimental treatment became a familiar practice?

24. The regulatory system for clinical trials is a fragile one that requires the support of numerous stakeholders in the public health, including the courts. The loss of such support would have many unintended detrimental effects on medical science and countless future patients. One of these unintended effects would be a distortion of the relationships between disease advocacy groups, industry, and the scientific community. Patients and their families should not have reason to believe that their advocacy would help them achieve special access to experimental treatments. Traditionally advocates have helped to educate legislators, funding sources, and the general public about the need for more investment into research on a particular disease. The integrity of their appeals rests heavily on the public's confidence that advocates may not directly benefit but that their situation provides them with unique insight into the needs and possibilities for more research.

I declare under penalty of perjury that the foregoing is true and correct.

Jonathan D. Moreno, Ph.D.

Executed this 12th day of August, 2008.

JONATHAN D. MORENO

David and Lyn Silfen University Professor of Ethics
University of Pennsylvania

CONTACT INFORMATION:

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EDUCATION:

Ph.D., Washington University, 1977 (Philosophy)
Dissertation: The Development of the Theory of Signs in the American Philosophical Tradition.
B.A., Hofstra University, 1973 (Highest Honors in philosophy and psychology)

ELECTED HONORARY MEMBERSHIPS:

Institute of Medicine of the National Academies	Member
The Hastings Center, Garrison, NY	Fellow
Kennedy Institute of Ethics, Georgetown University	Faculty Affiliate
The New York Academy of Medicine	Fellow
World Technology Network	Fellow

HONORS AND AWARDS:

Benjamin Rush Medal, College of William and Mary Law School, 2008.
Nominee, Virginia Literary Award for *Mind Wars*, 2007.
Alumnus of the Month, Hofstra University, May 2007.
Nominee, Los Angeles Times Book Prize for *Undue Risk*, 1999
Nominee, Virginia Literary Award for *Undue Risk*, 1999.

Honorary Doctorate of Humane Letters, Hofstra University, 1998
Board of Trustees Alumni Achievement Award, Hofstra University, 1993
Andrew W. Mellon Post-Doctoral Fellow in association with the Aspen Institute for Humanistic Studies, 1984-85.
Dilthey Fellow, George Washington University, June 1983
Douglas Greenlee Prize, Society for the Advancement of American Philosophy, 1982
Faculty research grant, George Washington University, July-August 1981
Teaching Fellowship in Philosophy, Washington University, 1976-77
University Fellowship in Philosophy, Washington University, 1975-76

ENDOWED LECTURESHIPS:

Mielke Lecturer, Program in Neuroscience, University of Wisconsin, Madison, 2007.
Berry Lecturer, Department of Philosophy, Vanderbilt University, 2007.
Stevenson College Alumni Distinguished Lecturer, University of California at Santa Cruz, 2007
Conley Ethics Lecturer, American College of Surgeons, 2007.
Cowan Lecturer, Division of Medical Ethics, University of Utah College of Medicine, 2006.
John R. Hogness Symposium Speaker, Warren G. Magnuson Health Sciences Center in Seattle,
University of Washington, Seattle, WA. 2003.
Inaugural Distinguished Lecturer, Center for Health Care Ethics, St. Louis University, St. Louis, Mo., 2003.
Samuel G. Dunn Lecturer in Medicine and the Humanities, University of Texas Medical Branch,
Galveston, Tx., 2003.
John T. Conley Lecturer, American Head and Neck Society, 2003.
Reynolds Lecturer, Emory & Henry College, Emory, Va., 2003
Donovan Lecturer, St. Agnes Health Care Center, Baltimore, Md., 2002
Sanders Lecturer, University of Kentucky Medical School, Lexington, Ky., 2002
Leikin Lecturer, Children's National Medical Center, 2002
Melissa A. Warfield Visiting Professor, Children's Hospital of the King's Daughters, Norfolk,
Va., 2001
Dunlop Lecturer, University of Massachusetts Medical Center at Worcester, 2000
John T. Conley Distinguished Lecturer in the Medical Humanities, SUNY Health Science Center
at Brooklyn, 2000
Iago Galdston Memorial Lecturer, New York Academy of Medicine, 1995
George M. Estabrook Distinguished Service Award, Hofstra University Alumni Association,
1992
Edward J. Arida Memorial Lecturer, Lutheran Medical Center, Brooklyn, New York,
1992

Irene Lefton Memorial Lecturer, North Shore University Hospital, Manhasset, New York, 1991

CURRENT ACADEMIC PROFESSIONAL APPOINTMENTS:

University of Pennsylvania	David and Lyn Silfen University Professor of Ethics, Professor of Medical Ethics and Professor of History and Sociology of Science in the Standing Faculty
	Professor of Philosophy (Secondary Appointment)
	Senior Fellow, Center for Bioethics

OTHER PROFESSIONAL APPOINTMENTS:

Howard Hughes Medical Institute, Chevy Chase, Md. (2000)	Bioethics Advisory Board
Center for American Progress, Washington, DC (2005)	Senior Fellow, Editor of *Science Progress* (www.scienceprogress.org)
National Academy of Sciences/Institute of Medicine (2005)	Advisory Committee on Human Embryonic Stem Cell Research
National Academies (2006)	Board on Life Sciences
Bill and Melinda Gates Foundation (2006)	Bioethics Advisory Board for Grand Challenges in Global Health Initiative, Beijing, China
GlaxoSmithKline (2007)	Chief Medical Officer's Advisory Board
National Research Council (2007)	Committee on Military and Intelligence Methodology for Emergent Physiological and Cognitive/Neural Science Research in the Next Two

Decades

Institute of Medicine (2007)	Membership Committee, Section 11 Vice Chair
The IHEU-Appignani Center for Bioethics (2007)	Advisory Board
Hofstra College of Liberal Arts and Sciences (2008)	Advisory Board

PREVIOUS ACADEMIC APPOINTMENTS:

University of Virginia, 1998-2006	Emily Davie and Joseph S. Kornfeld Professor of Biomedical Ethics and Director of the Center for Biomedical Ethics
State University of New York, Health Science Center at Brooklyn, 1989-98	Professor of Pediatrics and of Medicine Director, Division of Humanities in Medicine
George Washington University, 1985-89	Associate Professor of Philosophy, Health Care Sciences, and Child Health and Development
George Washington University, 1978-1985	Assistant Professor of Philosophy
University of Texas at Austin, 1978-1979	Assistant Professor of Philosophy
Swarthmore College, Swarthmore, Pa, Spring 1978	Visiting Assistant Professor of Philosophy

PREVIOUS PROFESSIONAL APPOINTMENTS:

National Research Council 2006-07	Committee on Biodefense Analysis and Countermeasures

Institute of Medicine 2005-06	Committee on Ethical Considerations for Revisions to DHHS Regulations for Protection of Prisoners Involved in Research
Association for the Accreditation of of Human Research Protection Programs 2000-06	Council on Accreditation
National Research Council, 2004-05	Co-Chair, Committee on Guidelines for Human Embryonic Stem Cell Research
Genomics Collaborative, Inc. Cambridge, Ma., 2001-04.	Bioethics Advisory Board
Office of the Secretary, U.S. Department of Health and Human Services, 2003	Secretary's Advisory Committee on Human Research Protections (declined)
Office of the Secretary, U.S. Department of Health and Human Services, 2001-2002	National Human Research Protections Advisory Committee
National Research Council Program 2002-03	Panel to Review the Dose Reconstruction of the Defense Threat Reduction Agency
Institute of Medicine 2001-2007	Board on Health Sciences Policy
National Bioethics Advisory Commission, 1998-2000.	Senior Consultant
Department of Clinical Bioethics, National Institutes of Health, Spring 1998	Special Expert
University of Pennsylvania, Center for Bioethics, 1995-1997	Faculty Associate Director, Project on Human Research Ethics
President's Advisory Committee on	Senior Policy and Research Analyst

Human Radiation Experiments, 1994-1995	
Department of Health, State of New York Council 1993-97	Organ Procurement and Transplant Policy
University of Maryland, Institute of Philosophy and Public Policy, 1990-1991	Visiting Scholar
Children's National Medical Center, Washington, DC, 1987-1988	Philosopher-in-Residence
The Hastings Center, 1984-1985	Associate for Social and Behavioral Studies
The Hastings Center, Summer 1983	Visiting Scholar

OFFICES IN ORGANIZATIONS AND PROFESSIONAL SOCIETIES:

Chair, American Society for Bioethics and Humanities Task Force on Promotion and Tenure, 2007.
President, American Society for Bioethics and Humanities, 2003-04
Board of Directors, American Society of Law, Medicine, and Ethics, 1997-2000
Committee on Medicine in Society, New York Academy of Medicine, 1995-1998.
Committee on Bioethical Issues, Association of the Bar of the City of New York, 1991-95
Member ex officio, Committee on Philosophy and Medicine, American Philosophical Association, Eastern Division, 1987-89.
Forum on Bioethics chairperson, 1988-89; program chair, 1987-88; membership coordinator, 1986-87, American Public Health Association.
Executive Council, American Society of Group Psychotherapy and Psychodrama,1985-91
Executive Council, Society for the Advancement of American Philosophy, 1986-88; Eastern Division Chairperson, 1983-85

EDITORIAL BOARDS:

Accountability in Research
American Journal of Bioethics

Bioethics and *Developing World Bioethics*
Cambridge Quarterly of Healthcare Ethics
HEC (HealthCare Ethics Committee) Forum
Journal of Clinical Ethics
Journal of Law, Medicine, and Ethics
Neuroethics

CONSULTATION (SELECTED):

Chair, External Review Committee, Institute for Philosophy and Public Policy, University of Maryland at College Park, 2008.
External Consultant, Center for Bioethics and Center for Genetics and Public Policy, Vanderbilt University, 2005.
External Consultant, Department of Bioethics, Case Western Research University, 2005.
External Reviewer, Assessment of the Scientific Information for the Radiation Exposure Screening and Education Program, National Research Council, 2005.
External Consultant, Center for Bioethics, Columbia University, 2005.
Summer Institute on Randomized Clinical Trials Involving Behavioral Interventions, National Institutes of Health, 2004, 2005.
A2ALL Live Liver Donor Advisory Group, 2002-present.
External Review Committee, Center for Bioethics, University of Minnesota, 2004.
External Reviewer, Report on Testosterone and Aging, Institute of Medicine, 2004.
Data Safety Monitoring Boards, National Heart, Lung and Blood Institute, 2001-2004.
Data Safety Monitoring Board, Maryland Psychiatric Research Center, 2001-present.
External Reviewer, Report on Human Research Protection Program Accreditation, Institute of Medicine, 2001.
Task Force on Research Ethics, American Psychiatric Association, 2000-2002.
External Review Committee, Center for Bioethics, University of Pennsylvania, Philadelphia, Pennsylvania, 2000.
Ethics Task Force, Indiana University School of Medicine, Indianapolis, Indiana, 1999.
Neonatal Research Network, Data Safety and Monitoring Committee, National Institute of Child Health and Development, National Institutes of Health, 1989.
Center for Scientific Review, National Institutes of Health, 1998.
Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, 1996.
Department of Health, State of New York, Workgroup on IRB Guidelines, 1997-98. Department of H 1997-98.
Human Genome Project, National Institutes of Health, 1994.
Humanities, Science and Technology Program, National Endowment for the Humanities, 1993.
New York State AIDS Advisory Council, Subcommittee on Newborn Screening

(Executive
Secretary), 1993-94.
Joint Commission for the Accreditation of Health Care Organizations, External Standards Development Workgroup, 1993-1994.
Committee on Recruitment and Retention of Women in Clinical Trials, Institute of Medicine,
National Academy of Sciences, 1993.
Maimonides Medical Center, Office of Academic Affairs, Brooklyn, New York, 1992-1998.
American Association of Blood Banks Ethics Committee, 1990-91.
Brookdale Hospital, Medical Staff Ethics Committee, Brooklyn, New York, 1989.

GRANT SUPPORT (SELECTED):

National Bioethics Commissions, Greenwall Foundation, $13,000. Principal Investigator, 2007-08.

Ethics and Data Monitoring Committees, Greenwall Foundation, $80,000. Co-Principal Investigator, 2006-08.

Research Integrity and Financial Conflicts of Interest, National Institutes of Health, $296,000. Co-Investigator, 2003-2005.

Regulating Innovative Surgery: Recommendations for National Policy and an Education Program, Greenwall Foundation, $180,000. Co-Principal Investigator, 2002-2004.

Research Ethics Course for Research Nurse Coordinators, National Institutes of Health, $554, 839. Faculty, 2002-2005.

Divided Loyalties: Conflicts of Interest in Medicine, National Library of Medicine, $222,000. Co-Principal Investigator, 2002-2005.

Standards of Risk Disclosure by Surgeons, Rockefeller Brothers Fund, $178,000. Co-Chair, 2001-2003.

Ethics and Public Health, Greenwall Foundation, $15,000. Principal Investigator, 2000-2001.

Effects of Breast Cancer Diagnosis on First Degree Relatives. Arthur Vining Davis Foundation, $188,000. Faculty, 2000-2001.

Racial Categories in Health Care. Pettus Crowe Foundation, $10,000. Principal Investigator, 1999-2001.

Project on Informed Consent, Human Research Ethics Group. University of Pennsylvania Center for Bioethics/Annenberg Public Policy Center, $75,000. Principal Investigator, 1995-97.

Reassessing Health, Normality, and Confidentiality. National Institutes of Health, Human Genome Initiative. Consultant, 1994-95.

Educating HealthCare Ethics Committees. U.S. Department of Education, Fund for the Improvement of Post-Secondary Education. Faculty, 1993-95.

Organization of the Metropolitan New York Ethics Committee Network. Greenwall Foundation, $25,000. Principal Investigator, 1992-93.

Education and Consultation on Ethical and Legal Issues in Adolescent AIDS. New York State AIDS Institute (sub-contract, $5,000). Principal Investigator, 1992.

Program Development in Basic Introductions to the Humanities. National Endowment for the Humanities, $25,000. Co-Principal Investigator, 1983-85.

BOOKS:

Under Review: Moreno J.D. and Berger S. (eds.) Progress in Bioethics (Cambridge, Ma.: MIT Press, 2009).

In Press: Moreno J.D. and Weiss R. (eds.) Science Next: Big Ideas for the American Future (Bellevue Literary Press, 2009).

Moreno J.D. Mind Wars: Brain Research and National Defense (Washington, D.C.: Dana Press, 2006); Japanese translation: ASCII Corporation, 2008.

Reitsma A.R. and Moreno J.D. (eds.) Ethical Guidelines for Innovative Surgery (Frederick, Md.: University Publishing Group, 2006).

Moreno J.D. Is There an Ethicist in the House? On the Cutting Edge of Bioethics (Bloomington, Indiana: Indiana University Press, 2005).

Emanuel E., Crouch R., Arras J., Moreno J.D. and Grady C. (eds.) Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary (Baltimore, Md.: The Johns Hopkins University Press, 2003).

Shamoo A.E. and Moreno J.D. (eds.) National Defense and Human Research Protections. New York: Taylor & Francis, 2003.

Moreno J.D. (ed.) In the Wake of Terror: Medicine and Morality in a Time of Crisis. Cambridge, Ma.: MIT Press, 2003; paperback edition, 2004.

Shamoo A.E. and Moreno J.D. (eds.) Business and Research: Proceedings of the Third National Conference on the Business of Human Experiments: Ethical, Legal, and Regulatory Issues. New York: Taylor & Francis, 2002.

Moreno J.D. Undue Risk: Secret State Experiments on Humans. New York: W.H.Freeman Publishers, 1999; New York: Routledge Publishers, 2001.

Ahronheim J., Moreno J.D. and Zuckerman C. Ethics in Clinical Practice (paperback edition), Sudbury, Ma.: Jones and Bartlett Publishers, 2005. (First edition: Little, Brown and Company, 1994; second edition: Aspen Publishers, 2000)

Moreno J.D. (ed.) Arguing Euthanasia: The Controversy Over Mercy Killing, Assisted Suicide and the "Right to Die". New York: Touchstone/Simon & Schuster, 1995; Japanese translation: Mita Industries, Ltd., 1997.

Moreno J.D., Deciding Together: Bioethics and Moral Consensus. New York: Oxford University Press, 1995.

Moreno J.D. (ed.) Jacob L. Moreno: Auszuge aus der Autobiographie. Koln: InScenario, 1995.

Moreno J.D. (ed.) Paying the Doctor: Health Policy and Physician Reimbursement. Dover,
Massachusetts: Auburn House, 1991.

Glassner B. and Moreno J.D. (eds.) The Qualitative-Quantitative Distinction in the Social Sciences. (Vol.112, Boston Studies in the Philosophy of Science.) Dordrecht, The Netherlands: Kluwer Academic Publishers, 1989.

French R. S. and Moreno J.D. (eds.). The Public Humanities: An Old Role in Contemporary Perspective. Washington, DC: George Washington University, 1984.

Moreno J.D. and Glassner B. Discourse in the Social Sciences: Translating Models of Mental Illness. Westport, Connecticut: Greenwood Press, 1982.

BOOK CHAPTERS:

In press: Moreno J.D. "Bioethics and Bioweapons," Robert B. Baker and Laurence B. McCullough, eds. The Cambridge World History of Medical Ethics. Cambridge: Cambridge University Press, 2008.

Blacksher E. and Moreno J.D. "The History of Informed Consent in Research." The Oxford Textbook of Clinical Research Ethics. New York: Oxford University Press, 2008.

Hurt V. and Moreno J.D. "Captive Populations: Prisoners, Students and Soldiers." The Oxford Textbook of Clinical Research Ethics. New York: Oxford University Press, 2008

Moreno J.D. "Helsinki Into the Future: An Epilogue." In: U. Schmidt and A. Frewer (eds.) History and Theory of Human Experimentation. Stuttgart: Fran Steiner Verlag, 2007.

Moreno J.D. "Stumbling Toward Bioethics: Human Experiments and the Early Cold War." In: LaFleur W.R., Bohme G., and Shimazono S. (eds.) Dark Medicine: Rationalizing Unethical Medical Research. Bloomington: Indiana University Press, 2007.

Moreno J.D., "Bioethics and Bioterrorism." In B. Steinbock (ed.), The Oxford Handbook of Bioethics. New York: Oxford University Press, 2007.

Blacksher E. and Moreno J.D. "Research Ethics." In: Fletcher's Introduction to Clinical Ethics, third edition. Hagerstown, Md.: University Publishing Group, 2005.

Moreno J.D. "Secret State Experiments and Medical Ethics." In: A.W. Galston and C.Z. Peppard, eds., Expanding Horizons in Bioethics. Dordrecht, The Netherlands: Springer, 2005.

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Mather J. and Moreno J.D., "Veterans as Human Subjects: Are They Uniquely Vulnerable?" BNA Medical Research Law and Policy, August 7, 2002.

Moreno J.D. "Fiduciary Knowledge and Moral Consensus in Bioethics," Janus Head 5(1):87-97, 2002.

Guyer, R.L. and Moreno, J.D. "Bioterror," Social Education 66(2):80-89, 2002.

Moreno J.D. Commentary, "Physicians and Firearms:Do Clinicians Have a Role in Gun Safety Ownership?" Medical Crossfire 4(2):25, 2002.

Moreno J.D. "Fatal Cost of Gene Therapy Study Should Give Rise to Regulations," The Cavalier Daily, February 22, 2000.

Moreno J.D. "Without Consent. Interview by Charles Seife," New Scientist 13;164(2212):48-51, 1999.

Moreno J.D. "Lessons Learned -- A Half-Century of Experimenting on Humans," The Humanist September/October 1999.

Moreno J.D. "The Dilemmas of Experimenting on People," Technology Review 100(5):31-36, 1997.

Moreno J.D. "Do Bioethics Commissions Hijack Public Debate?" Hastings Center Report 26(3):47, 1996.

Schwarz R.H. and Moreno J.D. "HIV Testing: The Evolution of a Policy" (Editorial). Women's Health Issues 6(2):109-111, 1996.

Povar G. and Moreno J.D. "Hipocrates y las HMOs." Cemar 1(2):4-5, February 1996 (Argentina); synopsis of "Hippocrates and the Health Maintenance Organization." Annals of Internal Medicine 109(5), 1988.

Moreno J.D. "The Ethics of Medical Futility." Case Management News. 1994.

Moreno J.D. and Zuckerman C., "The Metropolitan New York Ethics Committee Network," HEC (Healthcare Ethics Committee) Forum 4(6):340-341, 1992.

Moreno J.D. "Organizing Bioethics." Society for Bioethics Consultation Newsletter, Spring 1992.

Moreno J.D. "Perinatal Screening for HIV Infection." Ethicscope. Washington, DC: Children's National Medical Center, Fall 1991.

Moreno J.D. "Ethics Consultation as Moral Engagement." Bioethics News 10(1), 1991 (Australia); reprinted from Bioethics 5(1), 1991.

Moreno J.D. "Bioethics." In: Health and Medical Horizons. New York: MacMillan Publishing Company, 1990.

Moreno J.D. "Intervista a Jonathan D. Moreno", Es-Se' Psicodinamica 5(9):13-15, 1989.

Moreno J.D. "Patients' Rights" (case comment). PA 89 6(2):42-3, March/April 1989.

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Moreno J.D. "Is Pediatrics Special?" Ethicscope. Washington, DC: Children's Hospital National Medical Center, Fall 1988.

Moreno J.D. "To Intubate or Not?" (case comment). PA 88 5(7):239, August 1988.

Moreno J.D. "Bioethics." Health and Medical Horizons. New York: MacMillan, 1988.

Moreno J.D. "Why Caring Counts." Ethicscope. Washington, DC: Children's Hospital National Medical Center, Spring 1988.

Moreno J.D. "To Tell the Truth." Ethicscope. Washington, DC: Children's Hospital National Medical Center, Winter 1988.

Moreno J.D. "A Philosopher? In a Children's Hospital?" and "AIDS and the Caregiver: Balancing Risks and Duties." Ethicscope. Washington, DC: Children's Hospital National Medical Center, Fall 1987.

Moreno J.D. "Bioethics." Health and Medical Horizons. New York: MacMillan, 1987.

Moreno J.D. "Diaper Dilemma: Prescription for a Friend" (case comment). PA 87 4(6):164, 1987.

Moreno J.D. "Environmental Ethics and the Problem of Posterity." Washington, DC: George Washington University Graduate Institute for Policy Education and Research, 2(4), 1986.

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Moreno J.D. "Stop All the Implants: Suffering is Too Great." USA Today. February 11, 1986.

Moreno J.D. "Handicapped Infants." The New Physician 35(1):42-4, 1986.

Moreno J.D. "It's Time for Restraint in Reporting on Reagan's Health." Washington Post. July 31, 1985.

Moreno J.D. "What Do We Want Doctors to Be?" USA Today. May 15, 1985.

Moreno J.D. "An American Paradox: The Value of Liberal Education." GW Forum 26(4):13-15, 1984.

REVIEWS:

Vaccine A: The Covert Government Experiment That's Killing Our Soldiers -- and Why GI's Are Only the First Victims, by Gary Matsumoto. In: Washington Post Book World, November 7, 2004, BW05.

Freedom Evolves by Daniel Dennett. In: Cerebrum 5(2):81-87, 2003.

The Birth of Bioethics, by Albert R. Jonsen. In: Hastings Center Report 29(4):42-43, 1999.

Informed Consent: Patient Autonomy and Physician Beneficence Within Clinical Medicine, by Stephen Wear. In: HEC Forum 6(5):323-25, 1994.

Bioethics in a Liberal Society, by Max Charlesworth. In: Academic Medicine 69(7):553-54, 1994.

Just Doctoring: Medical Ethics in the Liberal State, by Troyen Brennan. In: Ethics 103(4):832-34, 1993.

Balancing Act: The New Medical Ethics of Medicine's New Economics, by E. Haavi Morreim. In: Medical Humanities Review 6(2):38-40, 1992.

Deciding for Others: The Ethics of Surrogate Decision Making, by Allen E. Buchanan and Dan W. Brock. In: Ethics 103(1):172-75, October 1992.

Classic Cases in Medical Ethics, by Gregory Pence. In: The Hastings Center Report 21(5):42-3, 1991.

Splitting the Difference: Compromise and Integrity in Politics and Ethics, by Martin Benjamin. In: Bioethics Books 2(2):41-43, 1991.

Private Acts, Social Consequences, by Ronald Bayer. In: Medical Humanities Review 3(2):69-71, July 1989.

William James: His Life and Thought, by Gerald Myers. In: Journal of the History of Philosophy 26(3):500-2, 1988.

Streams of Experience: Essays in the History and Philosophy of American Culture, by John J. McDermott. In: New England Quarterly 59(4):566-9, 1986.

The Insanity Defense and the Trial of John W. Hinckley, Jr., by Lincoln Caplan. In: The Hastings Center Report 15(1):45-6, 1985.

The Formative Essays of Justice Holmes, by Frederic R. Kellogg. In: Transactions of the Charles S. Peirce Society 20(4):147-52, 1985.

Role Playing and Identity, by Bruce Wilshire. In: Cross Currents 33(4):505-7, 1983-4.

Philosophy in Medicine, by Charles M. Culver and Bernard Gert. In: APA Newsletter on Philosophy and Medicine, pp. 2-3, 1983.

Troubled Philosopher: John Dewey and the Struggle for World Peace, by Charles F. Howlett. In: Journal of the History of Philosophy 19(1):129-32, 1981.

A Poetic for Sociology, by Richard Brown. In: Qualitative Sociology 1(3):134-6, 1979.

The Culture of Experience, by John J. McDermott. In: Human Studies 1(1):217-20, 1978.

GUEST EDITORSHIPS:

"Consensus in Bioethics," Bioethics 17(4), 2003. Co-editor: Eric Meslin.

"Consensus Decision-Making in Panels and Committees." Journal of Medicine and Philosophy 16(4), 1991. Co-editor: Robert Veatch.

"The Autobiography of J.L. Moreno, MD" (Abridged; with an Introduction). Journal of Psychodrama, Group Psychotherapy and Sociometry 42(1-2), 1989.

INTERVIEWS ON THE WORLD-WIDE WEB:

"The Three-Parent Embryo: Ethical Implications," ReachMD,

http://www.reachmd.com/xmsegment.aspx?sid=2587.

"Ethics and War," *Penn Current*, March 6, 2008.
http://www.upenn.edu/pennnews/current/interviews/090607-1.html

"Neuroscience at War: Mind Wars Trans-Atlantic Discussion," Dana Foundation, September 26, 2007. http://www.dana.org/events/detail.aspx?id=9244

"Neuroscience and the Next Generation of War," Center for American Progress, December 7, 2006. http://www.youtube.com/watch?v=RFPxMtwZB6M

"Jonathan Moreno on 'Mind Wars,'" Dana Press, on "Neurophilosophy," November 23, 2006. http://neurophilosophy.wordpress.com/2006/11/23/podcast-jonathan-moreno-on-mind-wars/

"Neurosecurity and Scientists," New York Academy of Sciences, November 22, 2006.
http://www.nyas.org/publications/readersReport.asp?articleID=65

PREVIOUS EDITORIAL POSITIONS:

Regional Correspondent, Society for Bioethics Consultation Newsletter, 1991-3.
Editorial Board:The International Journal of Action Methods: Psychodrama, Skill Training and
Role Playing, 1980-present.
Board of Scientific Advisors: Psychodrama: Zeitschrift fur Theorie und Praxis, 1989-present.
Consulting Editor, Medical Ethics for the Physician, 1990-93.
Scientific Advisory Board: AIDS Treatment Resources, Inc., 1990-1992.
Editor: American Philosophical Association Newsletter on Philosophy and Medicine, 1987-89.
Editor: American Society of Group Psychotherapy and Psychodrama Newsletter, 1985-1988.
Consulting Editor: Qualitative Sociology, 1977-83.
Co-editor: Tales (recipient of grants from Coordinating Council of Literary Magazines and
National Endowment for the Arts), 1975-79.
Editorial staff: Telos, 1975-76.

MANUSCRIPT REVIEW (SELECTED):

ASAIO Journal
Accountability in Research
American Journal of Public Health
Archives of Internal Medicine
Bioethics/Developing World Bioethics
Biosecurity and Bioterrorism

British Medical Journal
Cambridge University Press
Duke University Press
Hastings Center Report
HEC Forum
JAMA
Journal of Clinical Ethics
Journal of Health Politics, Policy and Law
Journal of Health Psychology
Journal of Medicine and Philosophy
Journal of Preventive Medicine
Kluwer Academic Publishers
The Lancet
Medical Ethics for the Pediatrician
Nature Medicine
Neurology
New England Journal of Medicine
Oxford University Press
Journal of Action Methods: Psychodrama, Group Psychotherapy and Sociometry
Psychopharmacology
Qualitative Sociology
Science
Social Science and Medicine
Sociological Quarterly
Stem Cells
SUNY Press
Temple University Press

INVITED LECTURES AND OTHER PROFESSIONAL ACTIVITIES (SELECTED):

Plenary, "Achieving Excellence in DoD Human Research Protection Programs: Training Program," Crystal City, Va. June 26, 2008.

"Research and Neuroethics," Forum on Neuroscience and Nervous System Disorders, "From Molecules to Mind: Challenges for the 21st Century, Institute of Medicine, Washington, D.C. June 25, 2008.

"Neuroethics," Capitol Hill science policy briefing, *Seed Magazine*, Washington, D.C. March 20, 2008.

"Mind Wars: Brain Research and National Defense," Hofstra University, Hempstead, N.Y. March 12, 2008.

Panel on Neuroscience, Ethics and Law, Association of American Law Schools, New York, N.Y. January 5, 2008.

"Mind Wars: Brain Research and National Defense," Department of Psychiatry Grand Rounds, University of Texas Southwestern Medical School, Dallas. December 12, 2007.

"Mind Wars: Brain Research and National Defense," University of Texas at Dallas Public Forum, December 11, 2007.

"The Ethics of Human Embryonic Stem Cell Research," Ethics Grand Rounds, University of Texas Southwestern Medical School, Dallas. December 11, 2007.

"Mind Wars: Brain Research and National Defense," Stevenson College, University of California at Santa Cruz. November 30, 2007.

"The Ethics of Human Experimentation for National Security Purposes," Stevenson College, University of California at Santa Cruz. November 29, 2007.

"Informed Consent," Secretary's Advisory Committee on Human Research Protections, Arlington, Va. July 31, 2007.

Organizing committee and session chair, ESCRO Committee Workshop, Stanford University. July 19, 2007.

"Progressive Bioethics," President's Council on Bioethics staff lunch speaker, Washington, DC. July 12, 2007.

Panelist, "From Abigail to Penelope: Individual to Corporate Rights," Food and Drug Law Institute, Washington, DC. June 28, 2007.

Co-organizer and Speaker, International Stem Cell Workshop, Embassy of France/European Council on Science and Technology/Center for American Progress, Washington, DC. June 15, 2007.

Panelist, Embryonic Stem Cell Research Controversy, Second Federal Circuit Judicial Conference, Lake George, New York. June 8, 2007.

"Stem Cell Ethics and Policy," GCRC Forum, Wake Forest University Medical School, Winston-Salem, N.C. May 16, 2007.

Panel, "Emerging Technologies in Stem Cells: the Science, the Ethics and the Opportunities," Biotech 2007, Durham, N.C. May 15, 2007.

"Mind Wars: Brain Research and National Defense," Keynote address, IHEU Appignani Bioethics Center, New York, N.Y. May 11, 2007.

"Mind Wars: Brain Research and National Defense," Philadelphia Veterans Affairs Hospital, May 3, 2007.

Community Acceptance Panel on Riot Control Agents, National Institute of Justice, Washington, D.C. April 30, 2007

"Mind Wars: Brain Research and National Defense," Edward F. Mielke Lecture, Program in Neuroscience, University of Wisconsin, Madison, WI. March 28, 2007.

"Mind Wars: Brain Research and National Defense," Keynote address, *The Deal* Annual Symposium, New York, N.Y. March 21, 2007

"Mind Wars: Brain Research and National Defense," Berry Lecture, Department of Philosophy, Vanderbilt University, Nashville, TN. March 26, 2007.

"Mind Wars: Brain Research and National Defense," Potomac Institute Center for Neurotechnology and Society, Ballston, VA. March 16, 2007.

"When Policy Affects Innovation: At the Crossroads of Academia and Industry," American Institute for Medical and Biological Engineering, Washington, D.C. February 28, 2007.

"Emerging Issues in the Ethics of Biodefense," John Hopkins University and Duke University Workshop on Ethics and Biodefense, Washington, D.C. February 5, 2007.

"Ethical Guidelines for Human Embryonic Stem Cell Research," University of California at Davis Medical School, Davis, CA, December 13, 2006.

"Mind Wars: Brain Research and National Defense," Simpson Center for the Humanities, University of Washington, Seattle, WA, October 12, 2006.

"Mind Wars: Brain Research and National Defense," Honors Program, Wichita State University, Wichita, KA. September 31, 2006.

"Lessons of the Advisory Committee on Human Radiation Experiments," Division of Medical Ethics, University of Chicago, Chicago, IL. September 27, 2006.

"Ethical Guidelines for Human Embryonic Stem Cell Research," New York State Task Force on Life and the Law, New York, N.Y. September 19, 2006.

"Ethical Guidelines for Human Embryonic Stem Cell Research," American College of Research Physicians, Phoenix, AZ. May 1, 2006.

"Ethics of Clinical Research," George Washington University Medical School, Washington, D.C. April 28, 2006.

"Neuroscience and National Defense," Department of Bioethics, Cleveland Clinic, Cleveland, OH. April 18, 2006.

"Ethical Guidelines for Human Embryonic Stem Cell Research," Conference on The New Medicine, University of Virginia, Charlottesville, VA. March 16, 2006.

"Progressive Bioethics," New York University Law School, New York, N.Y. March 10, 2006.

"Conflicts of Interest in Bioethics," Division of Medical Ethics, Harvard Medical School, Boston, MA. February 17, 2006.

"Ethical Guidelines for Human Embryonic Stem Cell Research," Institute for Ethics and Public Affairs, Old Dominion University, Norfolk, VA. February 9, 2006.

"Ethical Guidelines for Human Embryonic Stem Cell Research," Center for Biodesign, Arizona State University, Tempe, AZ. January 31, 2006.

"Let's Think Small," Inaugural Keynote Lecture for Center for Nanotechnology in Society, Arizona State University, Tempe, AZ. January 30, 2006.

"Mind Wars: National Security and the Brain," Division of Medical Ethics, University of Utah, Salt Lake City, UT. January 18, 2006.

"Ethical Guidelines for Human Embryonic Stem Cell Research," America's Health Insurance Plans Convention, Las Vegas, NV. June 10, 2005.

"Neuroscience, Dual Use, and National Security," Inter-Institute Bioethics Group, National Institutes of Health, Bethesda, MD. June 6, 2005.

"Ethics and Genetics," Introduction to Bioethics and Culture, Centre for Biomedical Ethics and Culture, Sindh Institute of Urology and Transplantation, Karachi, Pakistan. April 8, 2005.

"The History of Human Research Protections: Where Does Accreditation Fit In?" Annual Meeting Keynote, American Association of Human Research Protection Programs, Atlanta, GA. March 14, 2005.

"Consensus in Public Bioethics Commissions," Conference on Public Bioethics Commissions, Yale University, New Haven, CT. January 21, 2005.

"Seeking Consensus and Information on Stem Cell Research," Center for Practical Bioethics, Kansas City, MO. January 14, 2005.

"Secret State Experiments on Humans," Ethics Grand Rounds, University of Texas Southwestern Medical Center, Dallas, TX. December 14, 2004.

"Ethical and Policy Issues in Human Embryonic Stem Cell Research," Workshop on Human Embryonic Stem Cell Research, National Academy of Sciences, Irvine, CA. December 1, 2004.

Harvard University Medical School, Division of Medical Ethics Stem Cell Forum, Boston, MA. November 23, 2004.

"Why the Helsinki Declaration is Still Relevant,' Conference on the 40th Anniversary of the Declaration of Helsinki, Hanover, Germany. October 2, 2004.

"Secret State Experiments on Humans," Emory University IRB Retreat, Atlanta, GA. September 10, 2004.

"Brave New World: What's the Price?" Memphis Public Libraries, Memphis, TN. May 3, 2004.

"A Practical Primer on Research Ethics," American Association for the Study of Liver Disease, New Orleans, La. May 15, 2004.

"Bioethics and the National Security State," Institute for Philosophy and Public Policy, University of Maryland, College Park, MD. February 6, 2004.

Invited testimony on ethics and internet file-sharing, U.S. Senate Permanent Subcommittee on Investigations, Washington, D.C. September 30, 2003.

"History and Ethics of Human Experiments," Institute of Genomics and Informatics, University of California, Irvine. December 10, 2003.

"Ethics of Innovative Surgery," Berman Bioethics Institute, Johns Hopkins University, Baltimore, MD. November 17, 2003.

"Bioethics and the National Security State," Presidential Address, American Society for Bioethics and Humanities, Montreal, Canada. October 25, 2003.

"Human Research Protections: How We Got Here, Where We Are, and Where We're Going,"
Grand Rounds, Department of Dermatology, Indiana University Medical School, Indianapolis, IN. September 17, 2003.

"Must Surgeons be Samaritans?" American Head and Neck Society, Nashville, TN. May 6, 2003.

"History and Ethics of Biowarfare Research," Haverford College, Haverford, PA. April 15, 2003.

"Bioterrorism and the Ethics of Research Design," Royal Society of Medicine, London, England. April 5, 2003.

"What Do Doctors Owe to Research Subjects?" Grand Rounds, Department of Clinical Bioethics, Warren G. Magnuson Clinical Center, National Institutes of Health, Bethesda, MD. April 2, 2003.

"Ethics and the Blood Supply," Advisory Committee on Blood Safety and Availability, Department of Health and Human Services, Washington, D.C. January 23, 2003.

"Informed Consent and Disaster-Related Research," NIMH Workshop on Disaster-Related Research, New York Academy of Medicine. January 13-14, 2003.

"Bioethics and Bioterrorism," American Public Health Association, Philadelphia, PA. November 11, 2002.

"Neuroscience and Ethics," Canadian Institute of Health Research, Toronto, Canada. November 9, 2002.

"Bioethics and National Security" (keynote), Conference on Bioethics and National Security, Friends Research Institute, Washington, D.C. October 21, 2002.

"The Ethics of Stem Cell Research," Carillion Health System Annual Ethics Conference, Richmond, VA. September 19, 2002.

"Undue Risk: Secret State Experiments on Humans," St. Agnes Medical Center, Baltimore, MD. June 6, 2002.

"Gaging Ethics," Neuroethics: Mapping the Field, Charles W. Dana Foundation, Stanford University and University of California at San Francisco, San Francisco, CA. May 13-14, 2002.

"Brave New World: What's the Price?" Blue Cross/Blue Shield of Minnesota Major Accounts Summit, Minneapolis, MN. April 23, 2002.

"Undue Risk: Secret State Experiments on Humans," University of Maryland School of Medicine, Baltimore, MD. March 21, 2002.

"Undue Risk: Secret State Experiments on Humans," University of Kentucky School of Medicine, Lexington, KY. March 20, 2002.

"Bioethics and Bioterrorism," Association of The Bar of North Carolina, Raleigh, NC. February 15, 2002.

"Human Experiments and National Security," Center for Bioethics and Humanities, Duke University, Durham, NC. February 14, 2002.

"Human Experiments and National Security," American Association for the Advancement of Science, Washington, D.C. December 18, 2001.

"Bioethics and National Security," Human Subjects Research Subcommittee, Committee on Science, National Science and Technology Council, Washington, D.C. November 7, 2001.

"Can It Happen Here? Secret State Experiments on Humans," Cedars Sinai Medical Center, Los Angeles, CA. October 21, 2001.

"Deciding for Others Together: Moral Consensus in the Midst of Uncertainty," Center for Clinical Ethics, SUNY at Buffalo, Buffalo, NY. September 21, 2000

"Ethical Issues in Research Involving Persons at Risk for Suicide," National Institutes of Mental Health Workshop, Washington, D.C. June 7-8, 2001.

"Fiduciary Knowledge and Moral Consensus in Bioethics," Annual Conference on the Human Sciences, George Washington University, Washington, D.C. April 20, 2001.

"Secret State Experiments on Humans," Institution for Social Policy Studies, Yale University, New Haven, CT. April 18, 2001.

"Bioethics and Moral Consensus," Department of Philosophy, Carnegie-Mellon University, Pittsburgh, PA. March 15, 2001.

"Ethical Issues and the Minimal Genome" (panel), American Association for the Advancement of Science, San Francisco, CA. February 19, 2001.

"How Much Progress Have We Made in Human Experimentation Ethics," Division of Cardiology Grand Rounds, University of Virginia. January 23, 2001.

"Protectionism in Human Subjects Research," Maryland Psychiatric Research Center, Towson, MD. January 8, 2001.

"More Ethical Issues in Clinical Trials," Janssen Pharmaceuticals, Princeton, NJ. September 6, 2000.

"The NBAC Report on Research Involving Persons with Mental Disorders," Baylor College of Medicine Department of Psychiatry, Houston, TX. October 6, 2000.

"Undue Risk: Secret State Experiments on Humans," Dunlop Lecture, University of Massachsetts at Worcester, Worcester, MAassachusetts. June 7, 2000.

"Ethical Issues in Psychiatric Research" and "Undue Risk: Secret State Experiments on Humans,"Center for Biomedical Ethics, University of Minnesota, Minneapolis. May 3-4,

2000.

"Undue Risk: Secret State Experiments on Humans," Health Law and Ethics Program, Seton Hall University Law School, Newark, NJ. March 28, 2000.

"Human Experiment Policy in the National Security Establishment in the Early Cold War," Chembioweapons Forum, Kennedy School of Government, Harvard University, Cambridge, MA. February 22, 2000.

"Undue Risk: Secret State Experiments on Humans," Division of Humanities in Medicine, SUNY Health Science Center at Brooklyn. January 27, 2000.

"Current Issues in Psychiatric Research Ethics," Department of Psychiatry Grand Rounds, University of Virginia. August 30, 1999.

"Cultural Differences -- Ethics in Clinical Trials," Drug Industry Association, Baltimore, MD. June 30, 1999.

"Consensus and Ethics Committees," Carilion Health System, Roanoke, VA. May 25, 1999.

"Commentary," Belmont Revisited: Twenty Years after the National Commission, University of Virginia. April 16-18, 1999.

"The Future of Biomedical Ethics," Annual Medical Alumni Retreat, University of Virginia. January 29, 1999.

"Ethics of Research Design," Ethics in Neurobiological Research, Friends Research Institute, Baltimore, MD. November 13, 1998.

"Doing Human Reproduction Ethics in Public: A Tale of Two Ethics Commissions," Conference on Human Cloning, Hofstra University School of Law, Hempstead, NY. October 1, 1998.

"The Pentagon Meets the Nuremberg Code: A Case Study in Organization Ethics," Conference on Organization Ethics, University of Virginia. September 26, 1998.

"The Advisory Committee on Human Radiation Experiments and the New York State Workgroup on Research Involving Persons from the Protected Classes," Northeast regional meeting of the Food and Drug Administration/NIH Office for Protection from Research Risks, Rochester, NY. August 6, 1998.

"Research Involving Persons with Mental Disorders that May Affect Decisionmaking Capacity," Southwest regional meeting of the Food and Drug Administration/NIH Office for Protection from Research Risks, Albuquerque, NM. April 29, 1998.

"Regulation of Research on the Decisionally Impaired: History and Gaps in the Current Regulatory System," Keynote Lecture for conference on "Conducting Medical Research on the Decisionally Impaired," University of Maryland School of Law, Baltimore, MD. May 28, 1997.

"The Nuremberg Code and the Ethics of Research," Clinical Investigators Training Program, Harvard University Medical School/Beth Israel-Deaconess Medical Center, Boston, MA. April 22, 1997.

"Ethical Issues in the Care of Children and Adolescents," Academy of Medicine in Richmond, Staten Island, NY. February 26, 1997.

"Research with Cognitively Impaired Subjects," National Bioethics Advisory Commission, Bethesda, MD. February 24, 1997.

"Research in the Emergency Setting: A Debate," Ronald Reagan Institute of Emergency Medicine, National Press Club, Washington, D.C., December 19, 1996.

"The Lessons of History for Bioethics," American Association of Bioethics Annual Meetings, San Francisco, CA. November 22, 1996.

"Current Ethical Issues in Pediatrics," Grand Rounds, Department of Pediatrics, Nassau County Medical Center, East Meadow, NY. October 24, 1996.

Keynote, "Fruits of the Tree of Knowledge: Ethics and Genetic Testing," National Cancer Institute Patient Educators' Network Annual Meeting, Memorial Sloan-Kettering Cancer Center, New York, NY. September 27, 1996.

"Managed Care," Grand Rounds, Department of Medicine, Maimonides Medical Center, Brooklyn, NY. March 13, 1996.

"Research Ethics," National Institutes of Health General Clinical Research Centers Annual Meeting, Crystal City, VA. March 9, 1996.

"A Legacy of Mistrust: The Human Radiation Experiments," Wednesday Lecture Series, University of Virginia College of Medicine.. January 31, 1996.

"The Roles and Functions of Hospital Ethics Committees," Conference on "Current Issues in Bioethics," East Carolina University School of Medicine, Greenville, NC. December 1, 1995.

"The Report of the President's Advisory Committee on Human Radiation Experiments," Symposium on the Ethical Considerations of the Use of Human Subjects in Research," University of Michigan Medical School, Ann Arbor,MI. November 28, 1995.

"Ethical Issues in Managed Care," Conference on the Ethics of Managed Care, Long

Beach Memorial Hospital, Long Beach, NY. November 1, 1995.

"The Report of the Advisory Committee on Human Radiation Experiments and IRB Review of Research Involving Risks of Radiation," Panel, PRIM&R, Boston, MA. October 19, 1995.

"The Report of the President's Advisory Committee on Human Radiation Experiments," Ethics Colloquium, New York University School of Medicine, New York, NY. September 27, 1995.

"Is Ethics Consultation an Elegant Distraction?" Society for Bioethics Consultation, Cleveland, OH. September 16, 1995.

"Current Issues in Pediatric Ethics," Department of Pediatrics Grand Rounds, Duke University Medical Center, Durham, NC. September 12, 1995.

"Informed Consent and Risk," Blood Forum, National Academy of Sciences Institute of Medicine, Washington, D.C. January 23, 1995.

"The Human Radiation Experiments Controversy," American Association of Bioethics, Pittsburgh, PA. October 9, 1994.

"Ethics of Precluding Women From Clinical Trials with Teratogens," Ethics Rounds, Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA. March 2, 1994.

"Issues in Pediatric Ethics," Department of Pediatrics Grand Rounds, Maimonides Medical Center, NY. January 4, 1994.

"Current Issues in Medical Ethics," Department of Otolaryngology Grand Rounds, Long Island College Hospital, NY. November 11, 1993.

"Clinical Ethics" (annual course for members of ethics committees), Latin American School of Bioethics, La Plata, Argentina. October 8-15, 1993.

"HIV Disease in Women," Dartmouth Medical School, Hanover, NH. April 15, 1993.

"Ethical Issues in Managed Care," National Managed Health Care Congress, Washington, D.C. April 13, 1993.

Moderator, "Bioethics: Hard Choices in a New Era," Staff Training for Extramural Professionals, National Institutes of Health, Bethesda, MD. December 9-10, 1992.

"Growth Hormone Therapy in Children and Adults: Who Should or Should Not Be Treated?" Endocrine Society Annual Meetings, San Antonio, TX. June 25, 1992.

"Current Issues in Medical Ethics," Annual Housestaff Orientation, Maimonides Medical

Center, Brooklyn, NY. June 24, 1992.

"Ethical Reflections on Physician-Assisted Suicide," Association of the Bar of the City of New York. March 4, 1992.

"Ethics of Managed Health Care," American Society of Addiction Medicine, Orlando, FL October 25, 1991.

Testimony before U.S. House of Representatives Committee on Ways and Means concerning proposed legislation for national health insurance, Washington, DC. October 24, 1991.

"Ethical Implications," HIV Perinatal Screening Workshop, District of Columbia Commission of Public Health, Washington, DC. September 20, 1991.

"Moral Consensus and Reconstruction in Bioethics," Society for Bioethics Consultation, Toronto, Canada. September 6, 1991.

"DNR: Do We Have a Choice?" Medicine Grand Rounds, Harlem Hospital, New York, NY. May 22, 1991.

"Physician-Assisted Suicide," New York Academy of Medicine, May 20, 1991.

"Current Bioethical Issues," Office of the Medical Examiner of the City of New York. May 9, 1991.

"The State of Institutional Ethics Committees," Annual Meeting, Bioethics Resources Group, Ltd., Charlotte, NC. April 17, 1991.

"Making Health Care Decisions: Should Adolescents Decide?" Medical Humanities Program, Davidson College, Davidson, NC. April 16, 1991.

"Families' Role in Decision Making," Ethics Rounds, The Jewish Home and Hospital, New York, NY. January 28, 1991.

"DNR and Surgery," Surgery Grand Rounds, Sloan-Kettering Memorial Cancer Center, New York, NY. January 23, 1991.

"Ethical Issues in Pediatrics," Pediatric Grand Rounds, Sloan-Kettering Memorial Cancer Center, New York, NY. November 8, 1990.

"Ethical Issues in the Prevention, Testing and Treatment of AIDS in Adolescents," Ad Hoc Group on Adolescents and AIDS of the New York State AIDS Advisory Council, New York, NY. September 24, 1990.

"Private Acts, Social Consequences," Empire Blue Cross and Blue Shield Board of

Directors Seminar, Tarrytown, NY. September 7, 1990.

"Institutional Ethics Committees: Proceed With Caution," University of Maryland Conference on Hospital Ethics Committees and the Law, Baltimore, MD. June 25, 1990.

"DNR Orders in the Informed Consent Framework," Medicine Grand Rounds, Methodist Hospital, Brooklyn, NY. May 25, 1990.

"Health Care Decision Making for Patients Lacking Capacity," Ethics Conference, Millard Fillmore Hospitals, Buffalo, NY. May 10, 1990.

"Glasnost and Perestroika in Doctor-Patient Relations," Medicine Grand Rounds, University Hospital of Brooklyn. April 26, 1990.

"Allocation of Scarce Resources," Tulane University Medical Center Ethics Conference, New Orleans, LA. March 17, 1990.

"Making Decisions for Children," Mt. Sinai Medical Center Ethics Conference, New York, NY. March 9, 1990.

"The Role of Competence in the Informed Consent Framework," Psychiatry Grand Rounds, University Hospital of Brooklyn. October 11, 1989.

"Justice and Health Care," National Institutes of Health Bioethics Course, Bethesda, MD. May 1, 1989.

"The New York State DNR Law in the Framework of Medical Ethics," Medicine Grand Rounds, Long Island College Hospital, Brooklyn, NY. April 20, 1989.

"Ethical Issues in Maternal-Fetal Relations," Obstetrics Grand Rounds, University Hospital of Brooklyn. March 20, 1989.

"Informed Consent for Blood Transfusions," American Association of Blood Banks, Miami, FL.February 24, 1989.

"Baby Doe: Retrospect and Prospect," Pediatric Grand Rounds, University Hospital of Brooklyn. February 8, 1989.

"Consensus Decision-Making in Bioethics," Kennedy Institute Intensive Bioethics Course, Washington, DC. June 10, 1988.

"Surrogate Decision Making," State of Maryland Department of Human Resources, Westminster, MD. May 19, 1988.

"The Patient with Carcinoma - Quality of Life," American Urological Association, Washington, D.C. May 13, 1988.

"Ethical Issues in Cancer Care," Adelphi University School of Social Work, Garden City, NY. April 30, 1987.

"Ethical Issues in the Care of Children with Handicapping Conditions," Association for Crippled Children's Services and Maternal/Fetal Health, Washington, DC. March 30, 1987.

"Ethics in Nursing: An Overview," Nursing Leadership Workshop, Children's Hospital National Medical Center, Washington, DC. January 14, 1987.

"Ethics Committees and Community Hospitals," Howard County General Hospital, Columbia, MD. April 10, 1986.

"Ethical Issues in Psychiatric Practice," Hospital and Institute of the Athletes' Union, Budapest, Hungary. March 10, 1986.

"Ethical Issues in Death and Dying," Concern for Dying, Inc., San Francisco, CA. January 3, 1986.

"The Moral Paradox of Deinstitutionalization," The Hutchings Psychiatric Center, Syracuse, NY. December 6, 1985.

"Environmental Ethics and the Problem of Posterity," Long Island Colloquium on Environmental Risk Assessment, Greenvale, NY. November 6, 1985.

"Hospital Ethics Committees," Department of Pediatrics Grand Rounds, Mt. Sinai Hospital, New York, NY. March 28, 1985.

"Ethical Issues in Neonatology," St. Joseph's Hospital and Medical Center, Paterson, NJ. March 21, 1985.

"The Dewey-Trotsky Debate," Department of Philosophy, SUNY at Buffalo, Buffalo, NY. March 1, 1985.

"Pragmatists and Pluralists: An American Way of Metaphysics," Department of Philosophy, SUNY at Stony Brook, Stony Brook, NY. March 5, 1982.

"Model Translation in the Social Sciences," American Association for the Advancement of Science - Pacific Division, Davis, CA. June 23, 1980.

"Model Translation in Psychiatry," Department of Psychiatry Grand Rounds, George Washington University School of Medicine. March 12, 1980.

INTERDISCIPLINARY RESEARCH GROUPS:

Racial Categories in Health, Center for Biomedical Ethics, University of Virginia. Director,
1999-2000.
Human Research Ethics Group, Center for Bioethics, University of Pennsylvania. Director, 1995-97.
Research Group on the Care of Imperiled Newborns, The Hastings Center. Co-director, 1984-85;
member, 1984-87.
Research Group on the Diagnosis and Treatment of Infants at Risk for HIV, The Hastings Center. Member, 1988-89.

UNIVERSITY OF PENNSYLVANIA COMMITTEE SERVICE:

Member, Advisory Board, Center for the Integration of Genetic Health Information, 2008-present.

Member, Committee on the Undergraduate Experience, 2008-present.

Member, Advisory Board, Institute for Regenerative Medicine, 2007-present.

Chair, Committee on Appointments and Promotions, Department of Medical Ethics, 2007-present.

Member, Committee on the Undergraduate Experience, College of Arts and Sciences, 2007-present.

Member, Committee on Academic Freedom and Responsibility, Faculty Senate, October 2007-May 2008.

PREVIOUS ADMINISTRATIVE AND COMMITTEE EXPERIENCE:

Advisory Council, Auto Safety Laboratory, University of Virginia, 2000-2006.
Advisory Council, General Clinical Research Center, University of Virginia School of Medicine, 1999-2002.
Medical Advisory Council, University of Virginia School of Medicine, 1998-2002.
Medical Policy Council, University of Virginia Health Sciences Center, 1998-2002.
Chair, Task Force on Student Appeals, College of Health Related Professions, SUNY Health
Science Center at Brooklyn, 1996-97.
President's Task Force on the Future of the Relationship with Sophie Davis Medical School,
SUNY Health Science Center at Brooklyn, 1995.
Subcommittee on Objectives, Liaison Committee on Medical Education, SUNY Health Science
Center at Brooklyn, 1992.
Chair, Search Committee for Assistant Provost for Student Affairs, SUNY Health

Science
Center at Brooklyn, 1992.
Search Committee for Director of Medical Research Library of Brooklyn, SUNY Health Science
Center at Brooklyn, 1991.
Director of the Division of Humanities in Medicine, SUNY Health Science Center at Brooklyn.
1989-1998.
Course director, "Health and Society," Master of Public Health Program, George Washington
University, 1986-88.
Executive Secretary, Middle States Association Accreditation Steering Committee, George
Washington University, 1986-87.
Oncology Unit Advisory Council, George Washington University Hospital, 1986-88.
Chair, Committee on Health Care, Society, and Ethics, George Washington University, 1985-88.
Director of Study Programs, The Hastings Center, 1984-85.
Co-director, Current Issues in Bioethics, George Washington University, 1982.
Coordinator, Humanities Course Program, George Washington University, 1983-84.
Faculty Coordinator for National Fellowship Awards, George Washington University, 1983-85.
University and college committees, George Washington University, 1980-88.

INSTITUTIONAL ETHICS COMMITTEE SERVICE:

Consultant, Hospital Ethics Committee, University of Virginia, 1998-2006.
Consultant, Human Investigation Committee, University of Virginia, 1998-2006.
Research Ethics Committee, University of Virginia, 1998-2006.
Ethics Committee, University Hospital at Brooklyn/Kings County Hospital Center, 1991-98.
Institutional Review Board, SUNY Health Science Center at Brooklyn, 1990-94.
Animal Care and Use Committee, SUNY Health Science Center at Brooklyn, 1989-90.
AIDS Policy Committee, George Washington University, 1986-88.
Ad Hoc Surrogate Uterus Committee, George Washington University Hospital, 1986.
Ethics Committee, George Washington University Hospital, 1985-88.
Hospital Ethics Forum, Children's National Medical Center, Washington, DC, 1985-88.

PERSONAL:

Born June 11, 1952, Poughkeepsie, New York.
Married in 1980 to Leslye S. Fenton
Son, Jarrett Alexander, born June 28, 1986.
Daughter, Jillian Alea, born December 20, 1989.

Previous legal matters in which I have consulted as an expert

2007

James Baird et al. v. Community Blood Center of Greater Kansas City, Inc.
Missouri

Bernie W. Holland v. Automatic Elevator Company, Inc., Cardinal Health 200, Inc., Duke University Health Systems, Inc., d/b/a Durham Regional Hospital, and Duke University Health Systems, Inc., d/b/a Duke Raleigh Hospital
North Carolina

2005

Werner matter
Maryland

Blanton v. Lucas
South Carolina

Baycol litigation
National

Stolle matter
Ohio

Castro v. NYT Television
New Jersey

2004

Vasquez v. Weisbrod
Colorado

Ashton v. Blythe
District of Columbia