

CARL H. COLEMAN
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EDUCATION

HARVARD UNIVERSITY LAW SCHOOL, J.D., *magna cum laude*, June 1990; Supervising Editor, *Harvard Law Review*

HARVARD UNIVERSITY, A.M., East Asian Studies, June 1990

GEORGETOWN UNIVERSITY, B.S.F.S., *cum laude*, International Affairs, Certificate in Asian Studies, May 1986

NATIONAL TAIWAN NORMAL UNIVERSITY, Taipei, Taiwan, intensive Chinese language program, August 1984-May 1985

CURRENT EMPLOYMENT

SETON HALL UNIVERSITY SCHOOL OF LAW, Newark, NJ (Fall 2000-present)

I have been a full-time professor at Seton Hall Law School since 2000, where I have taught courses in Health Law, Public Health Law, Bioethics, International Human Rights Law, Torts, Business Law, Federal Income Taxation, and European Union Law. In 2005, I was awarded tenure and promoted to the rank of full Professor of Law. From 2002-2009 I served as the Director of Seton Hall's nationally ranked Health Law & Policy Program. Since 2009, I have been dividing my time between Seton Hall's Newark campus and my home in France.

In addition to my teaching and research, I serve as Academic Director of Seton Hall Law's Division of Online Learning. In that capacity, I oversee the development, teaching, and evaluation of approximately 15 online graduate courses for working professionals seeking to enhance their knowledge of legal, regulatory, and policy issues. I also work closely with Seton Hall's Center for Health & Pharmaceutical Law & Policy in producing white papers, organizing conferences, and providing executive education to professionals in the pharmaceutical and medical device industries (including a semi-annual 5-day training program co-sponsored with Sciences Po in Paris). In 2007, I was awarded the Andrea J. Catania Fellowship for Excellence in Teaching.

OTHER PROFESSIONAL EXPERIENCE

WORLD HEALTH ORGANIZATION, Geneva, Switzerland (September 2006-present)

During the 2006-07 academic year, I was seconded by Seton Hall to the World Health Organization to serve as Bioethics and Law Adviser. My work at WHO focused primarily on pandemic preparedness and research with human participants. I was the principal drafter of WHO's report *Ethical Considerations in Preparing for a Public Health Response to Pandemic Influenza*, which was the culmination of an extensive series of international consultations. I also collaborated on the development of training materials for African research ethics committees and led several workshops in Ibadan, Nigeria. During the 2007 WHO World Health Assembly, I was actively involved in developing position papers on the international community's obligations regarding the sharing of influenza virus samples.

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HARVARD UNIVERSITY LAW SCHOOL, J.D., magna cum laude, June 1990; Supervising Editor, Harvard Law Review

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I have been a full-time professor at Seton Hall Law School since 2000, where I have taught courses in Health Law, Public Health Law, Bioethics, International Human Rights Law, Torts, Business Law, Federal Income Taxation, and European Union Law. In 2005, I was awarded tenure and promoted to the rank of full Professor of Law. From 2002-2009 I served as the Director of Seton Hall's nationally ranked Health Law & Policy Program. Since 2009, I have been dividing my time between Seton Hall's Newark campus and my home in France.

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involved in developing position papers on the international community's obligations regarding the sharing of influenza virus samples.

Since my return to Seton Hall I have remained closely involved with WHO as a consultant to the Ethics and Health unit. I have served as rapporteur for a variety of international collaborative projects, including guidance on tuberculosis prevention, care, and control; standards and operational guidance for research ethics committees; ethical issues in patient safety activities; and ethical issues in international emergency response efforts. I also developed and served as director of a training program on clinical trials legislation for African drug regulatory authorities. I am currently working with WHO on two projects: one to develop quality indicators for research ethics systems, and another to assist African countries in coordinating the work of drug regulatory authorities and research ethics review.

NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, New York, NY (July 1993-July 2000)

The New York State Task Force on Life and the Law is an advisory commission appointed by the New York State Governor with a mandate to develop legislative and regulatory responses to issues raised by medical advances. From 1995 to 2000, I was Executive Director of the Task Force; from 1993 to 1995 I served as Counsel. My responsibilities included conceptualizing projects, overseeing the analytical and policy content of book-length reports and other publications, planning and running commission meetings, supervising professional staff, interacting with high-level governmental officials, soliciting stakeholder input, representing the Task Force in the media and before diverse public and professional audiences, and securing government and private grants to support the Task Force's work.

LEVENTHAL SLADE & KRANTZ, New York, NY (September 1991-June 1993)

From 1991 to 1993 I was an associate in this boutique litigation firm, where I was involved in all stages of trial and appellate litigation, including investigating facts, drafting pleadings, briefs and other documents, appearing in court, and counseling clients. My practice focused on employment discrimination and commercial litigation.

HON. JAMES L. OAKES, Chief Judge, U.S. Court of Appeals, 2d Circuit, New York, NY (July 1990-July 1991)

From 1990 to 1991, I served as law clerk to the chief judge of the federal appellate court for New York, Connecticut, and Vermont. My primary duties involved preparing the judge for oral arguments and drafting opinions.

PAUL, WEISS, RIFKIND, WHARTON & GARRISON, New York, NY (Summer 1988 and 1989)

In 1988, I was a Summer Associate at the Shanghai office of this international law firm. In 1989, I returned as a Summer Associate in the New York office.

PUBLICATIONS

BOOK

Carl H. Coleman, Jerry A. Menikoff, Jesse A. Goldner & Nancy N. Dubler, THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS (Lexis 2005) (with 2005-2012 cumulative update)

ARTICLES

Kate Greenwood, Carl H. Coleman, and Kathleen M. Boozang, Toward Evidence-Based Conflicts of Interest Training for Physician-Investigators, 40 J.L. MED. & ETHICS 500 (2012)

Carl H. Coleman, Michael J. Selgelid, Andreas Reis, Lee B. Reichman, & Ernesto Jaramillo, The Role of Informed Consent in Tuberculosis Testing and Screening, 39 EUROPEAN RESPIRATORY J. 1057-59 (2012)

- Kathleen M. Boozang, Carl H. Coleman, and Kate Greenwood, An Argument against Embedding Conflicts of Interest Disclosures in Informed Consent, J. HEALTH & LIFE SCIENCES L., 230-267 (June 2011)
- Carl H. Coleman, Do Physicians' Legal Duties Conflict with Public Health Values? The Case of Antibiotic Overprescription, 6 J. BIOETHICAL INQUIRY 181 (2009)
- Carl H. Coleman, Vulnerability as a Regulatory Category in Human Subject Research, 37 J.L. MED. & ETHICS 12 (2009)
- Carl H. Coleman, Beyond the Call of Duty: Compelling Health Care Professionals to Work During an Influenza Pandemic, 94 IOWA L. REV. 1 (2008)
- Carl H. Coleman, Research with Decisionally Incapacitated Human Subjects: An Argument for a Systemic Approach to Risk-Benefit Assessment, 83 IND. L.J. 743 (2008)
- Carl H. Coleman, Marie-Charlotte Bouésseau, and Andreas Reis, The Contribution of Ethics to Public Health, 86 BULLETIN OF THE WORLD HEALTH ORG. 578 (2008)
- Carl H. Coleman & Marie-Charlotte Bouésseau, How Do We Know That Research Ethics Committees Are Really Working? The Neglected Role of Outcomes Assessment in Research Ethics Review, 9 BMC MED. ETHICS 6 (2008)
- Carl H. Coleman & Andreas Reis, Potential Penalties for Health Care Professionals Who Refuse to Work During a Pandemic, 299 JAMA 1471 (2008)
- Carl H. Coleman, Duties to Subjects in Clinical Research, 58 VAND. L. REV. 387 (2005)
- Carl H. Coleman, Rationalizing Risk Assessment in Human Subject Research, 46 ARIZ. L. REV. 1 (2004)
- Carl H. Coleman, Why Have IRBs at All? A Reply to Noah, 25 J. LEGAL MED. (2004) (response to article by Lars Noah)
- Carl H. Coleman, HIV, ARTs, and the ADA, AM. J. BIOETHICS, Winter 2003, at 43 (short commentary on article by Mark Sauer)
- Carl H. Coleman, Conceiving Harm: Disability Discrimination in Assisted Reproductive Technologies, 50 UCLA L. REV. 17 (2002)
- Carl H. Coleman, Assisted Reproductive Technologies and the Constitution, 30 FORDHAM URB. L.J. 57 (2002) (part of symposium at Fordham Law School, "Religious Values and Legal Dilemmas in Bioethics")
- Carl H. Coleman, The "Disparate Impact" Argument Reconsidered: Making Room for Justice in the Assisted Suicide Debate, 30 J. L. MED. & ETHICS 17 (2002) (commentary on article by Ronald Lindsay)
- Ann M. Carroll & Carl H. Coleman, Closing the Gaps in Genetics Legislation and Policy: A Report by the New York State Task Force on Life and the Law, 5 GENETIC TESTING 275 (2001)
- Carl H. Coleman, Is There a Constitutional Right to Preconception Sex Selection? AM. J. BIOETHICS, Winter 2001, at 27 (commentary on article by John Robertson), excerpted in JUDITH DAAR, REPRODUCTIVE TECHNOLOGIES AND THE LAW (Lexis 2006)

Carl H. Coleman & Barbara A. DeBuono, Developing Public Policy on Assisted Reproductive Technologies: Reflections on the Work of the New York State Task Force on Life and the Law, 73 *FERTILITY & STERILITY* 21 (2000)

Carl H. Coleman, Procreative Liberty and Contemporaneous Choice: An Inalienable Rights Approach to Frozen Embryo Disputes, 84 *MINN. L. REV.* 55 (1999)

Tracy E. Miller, Carl H. Coleman, & Anna Maria Cugliari, Treatment Decisions for Patients without Surrogates: Rethinking Policies for a Vulnerable Population, 45 *J. AM. GERIATRICS SOC'Y* 369 (1997)

Carl H. Coleman & Alan R. Fleischman, Guidelines for Physician-Assisted Suicide: Can the Challenge Be Met? 24 *J. L. MED. & ETHICS* 217 (1996)

Carl H. Coleman & Tracy E. Miller, Stemming the Tide: Assisted Suicide and the Constitution, 23 *J. L. MED. & ETHICS* 389 (1995); reprinted in *PHYSICIAN-ASSISTED SUICIDE* (Greenhaven Press, 1997)

Developments in the Law — Sexual Orientation and the Law, 102 *HARV. L. REV.* 1508, 1554-84 (1989) (primary author of section on employment law); reprinted as a book, SEXUAL ORIENTATION AND THE LAW (Harvard University Press 1990)

BOOK CHAPTERS

Carl H. Coleman, End-of-Life Treatment Decisions in United States Law, in Stefania Negri ed., SELF-DETERMINATION, DIGNITY AND END-OF-LIFE CARE: REGULATING ADVANCE DIRECTIVES IN INTERNATIONAL AND COMPARATIVE PERSPECTIVE (2012)

Carl H. Coleman, Assisted Reproductive Technologies, in JAMES J. PONZETTI ET AL. ED., INTERNATIONAL ENCYCLOPEDIA OF MARRIAGE AND FAMILY 2D ED. (2002)

Carl H. Coleman & Michele Petruzzelli, Decision Making for Residents Without Surrogates, in MATHY D. MEZEY & NANCY NEVELOFF DUBLER EDs., VOICES OF DECISION IN NURSING HOMES: RESPECTING RESIDENTS' PREFERENCES FOR END-OF-LIFE CARE 65 (2001)

REPORTS OF THE SETON HALL CENTER FOR HEALTH & PHARMACEUTICAL LAW & POLICY
THE LIMITS OF DISCLOSURE AS A RESPONSE TO FINANCIAL CONFLICTS OF INTEREST IN CLINICAL RESEARCH (2010) (collaborator)

CONFLICTS OF INTEREST IN CLINICAL TRIAL RECRUITMENT & ENROLLMENT: A CALL FOR INCREASED OVERSIGHT (2009) (collaborator)

REPORTS OF THE NEW YORK STATE TASK FORCE ON LIFE AND THE LAW
GENETIC TESTING AND SCREENING IN THE AGE OF GENOMIC MEDICINE (2000) (editor-in-chief)

ASSISTED REPRODUCTIVE TECHNOLOGIES: ANALYSIS AND RECOMMENDATIONS FOR PUBLIC POLICY (1998) (editor-in-chief; primary author of selected chapters)

WHEN DEATH IS SOUGHT: ASSISTED SUICIDE AND EUTHANASIA IN THE MEDICAL CONTEXT, SUPPLEMENT TO REPORT (1997) (primary author); excerpts reprinted in JOHN D. ARRAS AND BONNIE STEINBOCK EDs., ETHICAL ISSUES IN MODERN MEDICINE, 5TH ED. (Mayfield Press, 1998)

WHEN DEATH IS SOUGHT: ASSISTED SUICIDE AND EUTHANASIA IN THE MEDICAL CONTEXT (1994) (primary author of chapter on legal issues)

ONLINE COMMENTARIES

Guest blogger, Healthlawprof Blog (February-March 2012)

Carl H. Coleman and Marie-Charlotte Bouèsseau, Strengthening Local Review of Research in Africa: Is The IRB Model Relevant? BIOETHICS FORUM, December 22, 2006

Carl H. Coleman, End-of-Life Decision-Making and the Politics of the Fetus, BIOETHICS FORUM, July 26, 2006

SELECTED PRESENTATIONS

European Healthcare Compliance Certification Program, Paris, France (June 2013), "An Ethical Framework for Compliance Professionals"

International Pharmaceutical Compliance Conference and Best Practices Forum, Madrid, Spain (May 2013), "Compliance as a Profession"

International Society of Healthcare Ethics and Compliance, Paris, France (September 2012), "Models of Ethical Compliance: Implications for Compliance Education"

Bocconi University School of Management, Milan, Italy (May 2012), "Ethics as a Global Health Challenge"

World Health Organization Workshops on the Ethics of Tuberculosis Prevention, Care, and Control, Baku, Azerbaijan, (December 2011) and Beijing, China (June 2011), "Ethical and Legal Aspects of Public Health Measures in TB Care and Control"

World Health Organization Task Force on Cholera Control, Geneva, Switzerland (May 2011), "Ethical Considerations Related to Oral Cholera Use in Large-Scale Humanitarian Crises"

Seton Hall Law School, Newark, New Jersey (March 2011), "Financial Conflicts of Interest in Medical Research" (March 2011)

European Healthcare Compliance Ethics and Regulation Program, Paris, France (February 2011), "Lessons from U.S. Healthcare Fraud and Abuse Enforcement and Compliance Programs"

Forum for Ethical Review Committees in Asia and the Western Pacific, Shanghai, China (November 2010), "Assessing the Outcomes of Research Ethics Review"

University of Heidelberg Institute of Public Health, Heidelberg, Germany (September 2010), "Ethics and Global Public Health"

World Health Organization Consultation on Norms and Standards for Research Ethics Committees, Geneva, Switzerland (November 2009), "Assessing the Outcomes of Research Ethics Review"; follow-up presentation at Brocher Foundation, Hermance, Switzerland (February 2010)

International Consultative Workshop on DR-TB and the HIV/AIDS Crisis in the Southern Africa Region, Manzini Swaziland (October 2009), "Ethical Issues in the Management of Drug-Resistant TB"

World Health Organization Guidelines Committee on Infant and Young Child Feeding the Context of HIV, Geneva, Switzerland (October 2009), "The Role of Directive Counseling in HIV Infant Feeding Programs"

Center for Health & Pharmaceutical Law & Policy, Seton Hall Law School, Newark NJ (March 2009), "Legal Issues in the Recruitment and Enrollment of Human Research Subjects"

American Society for Reproductive Medicine, San Francisco, CA (November 2008), "ART and the HIV-Discordant Couple"

American Public Health Association, San Diego, CA (October 2008), "Ethical Issues in Pandemic Influenza Planning and Response: The Activities of WHO" (with Andreas Reis)

International Association of Bioethics, Rijeka, Croatia (September 2008), "Addressing Ethical Issues in Pandemic Preparedness: National Efforts, WHO Guidance, and Future Directions" (with Andreas Reis)

Second International Pharmaceutical Regulatory and Compliance Congress, Paris, France (May 2008), "Ethical Issues in Clinical Trials in Developing Countries"

Columbia University Center for Women's Reproductive Care, Distinguished Guest Lecturer (April 2008), "Assisted Reproductive Technologies and Family Law"

Food and Drug Law Institute, Washington, D.C. (March 2008), "Ethical Issues in Representing Sponsors of Clinical Trials"

Ethics and Infectious Disease, Oxford University (July 2007), "The Role of Law in Limiting the Over-prescription of Antibiotics"

11th Futures Forum, Copenhagen, Denmark (June 2007), "Ethical Issues in Pandemic Preparedness"

9th Global Forum on Bioethics in Research, Vilnius, Lithuania (June 2007), "Quality Assurance for Research Ethics Committees"

University of Geneva, Institute of Graduate Studies (June 2007), "Ethics and Global Health Diplomacy"

European Network of Excellence Clinigene/Consert Think Tank (April 2007), "Overseeing Human Gene Therapy: Is The IRB Model Appropriate?"

University of Zurich Institute of Biomedical Ethics (March 2007), "Rethinking the Process of Research Ethics Review"

University of Ibadan, Nigeria (February 2007), "Strengthening Research Ethics Committees in Africa"

Brooklyn Law School, David G. Trager Public Policy Symposium (February 2007), "End-of-Life Decision-Making: U.S. Perspectives"

Italian Senate Health Law Committee (November 2006), Testimony on Proposed Legislation on End-of-Life Decision-Making

American Society of Law, Medicine & Ethics Health Law Teachers' Conference (June 2006), "Surrogate Decision-Making in Medical Research"

New York State Assembly Health Committee (December 2005), Testimony in Support of the Family Health Care Decisions Act

National Association of Women Judges (October 2004), "Frozen Embryos in the Courts"

New York State Judicial Institute (June 2004), "Human Subject Research and the Law"

Human Biotechnology Governance Forum, Johns Hopkins University School of Advanced International Studies (May 2004), "Regulatory Models for Reproductive Technologies"

Serono Symposia International (April 2004), "Legal and Ethical Issues Surrounding HIV and Women"

New York Academy of Medicine Conference on Dementia Research (March 2004), "Legal and Ethical Challenges in Dementia Research"

Albany Law School (November 2003), "Informed Consent to Clinical Trials"

American Society of Bioethics and the Humanities (October 2003), "Human Subject Research and the Courts"

Fordham Law School, Symposium on Religious Values and Legal Dilemmas in Bioethics (January 2002), "Assisted Reproductive Technologies and the Constitution"

National Academy of Sciences, Institute of Medicine, Board on Health Sciences Policy (June 2000), "Assisted Reproductive Technologies and Public Policy"

Fordham Law School (April 2000), "The Culture of Death in America"

Long Island University (November 1998), Keynote speaker at conference, "Good Dying: Is it Possible?"

American Society of Law, Medicine, & Ethics/Gerontological Society of America (November 1998), "The Person Who Lacks a Surrogate"

St. John's University School of Law (April 1997), "Assisted Suicide: Private Acts and Public Policy"

American Medical Association, Conference on State Legislation (January 1997), "Legislation on Assisted Suicide"

Association of the Bar of the City of New York (February 1996), "Confidentiality and Genetic Testing"

End-Stage Renal Disease Network (October 1995), "Starting and Stopping Dialysis: Ethical and Legal Considerations"

White House Conference on Aging and Developmental Disabilities (January 1995), "Treatment Decisions for Developmentally Disabled Patients"

OTHER PROFESSIONAL ACTIVITIES

Member, Secretary's Advisory Committee on Human Research Protections (SACHRP), U.S. Department of Health & Human Services (March 2010-March 2013)

Course director, World Health Organization Global Learning Opportunities for Vaccine Quality training program, Legislation for Clinical Trials (offered in Nairobi, Kenya, July 2012)

Rapporteur for a variety of World Health Organization projects, including Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, Ethics of Tuberculosis Prevention, Care, and Control, Research Ethics Committees: Basic Concepts for Capacity-Building, Research Ethics in International Epidemic Response, and Ethical Considerations in Developing a Public Health Response to Pandemic Influenza

Visiting Scholar, Brocher Foundation, Hermance, Switzerland (Winter 2010)

Peer reviewer for Yale University Press, Cambridge University Press, New England Journal of Medicine, Journal of Law, Medicine & Ethics, American Journal of Bioethics, Milbank Quarterly, IRB: Ethics and Human Research, Public Health Ethics, International Review of Law and Economics, Journal of Empirical Issues in Human Research Ethics, Kennedy Institute of Ethics Journal

Member, Institutional Review Board, Seton Hall University (Fall 2003-Spring 2006); University of Medicine and Dentistry of New Jersey (Fall 2001-Spring 2003)

Member, Steering Committee, Family Health Decisions Coalition (Fall 2001-Winter 2010)

Member, New York State Bar Association (Spring 2001-Spring 2004)

Member, Health Law Section Executive Committee (Fall 2002-Spring 2004)

Co-Chair, Committee on Ethical Issues in the Provision of Health Care (Fall 2002-Spring 2004)

Chair, Special Committee on Treatment Decisions (Spring 2001-Spring 2002)

Member, Association of the Bar of the City of New York (Fall 1993-Spring 2000)

Member, Committee on Health Law (Fall 1999-Spring 2000)

Member, Committee on Bioethical Issues (Fall 1996-Spring 1999); Legislative Liaison (Fall 1996-Spring 1998)

Member, Committee on Legal Problems of the Aging (Fall 1993-Spring 1996); Chair, Subcommittee on Patient Self-Determination (Fall 1993-Spring 1995)

Member, Lesbian & Gay Law Association of New York (Fall 2005-Spring 2009)

Core Faculty, Certificate Program in the Ethics and Regulation of Research with Human Subjects, Montefiore Medical Center/Albert Einstein College of Medicine and New York University Division of Nursing (Spring 2003)

Member, Advisory Committee, Initiative to Improve the Effectiveness of Health Care Agents (Fall 1998-Spring 2001)

Member, Attorney General's Commission on Quality Care at the End of Life (April 1997-August 1998)

Admitted to practice in New York State; U.S. Supreme Court; U.S. Court of Appeals, Second Circuit; U.S. District Court (SDNY, EDNY)

CERTIFICATIONS

Facilitation skills certificate, World Health Organization, Global Learning Opportunities for Vaccine Quality program (one-week intensive course on facilitating training programs in an intercultural environment)

Certified in use of Quality Matters assessment rubric for online education

LANGUAGES

English (native speaker); French (professional working proficiency); Mandarin (basic)