

Milken Institute School of Public Health

THE GEORGE WASHINGTON UNIVERSITY

Department of Health Policy and Management

PUBH 6368, Fall 2017

Law, Medicine and Ethics, 2 credit hours

Tuesday, 4:10-6:00 p.m., GWSPH TBD

Residential Graduate Course

Instructor

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Office Hours: By appointment. Please e-mail or call to schedule a meeting.

Course Description

This course explores legal, ethical, and policy issues that arise in the biomedical arena. We address controversial and challenging questions concerning, *inter alia*, the definitions of life and death, the nature of personal identity, the requirements of justice, and the boundaries of liberty. We will draw on legal, medical, and ethical/philosophical literature in examining these issues.

Course Prerequisite(s):

Public Health and Law (PUBH 6335), Health Services and Law (PUBH 6330), or Instructor's Permission (if you have not taken either course, please contact the professor in advance of class)

Course Learning Objectives – Upon completion of the course, students will be able to:

- Establish a working knowledge of health policy issues in law, medicine and ethics.
- Participate in informed discussions, debate, and analytical writing regarding issues in law, medicine, and ethics.
- Develop the skills necessary for critical analysis of current and recurring bioethics issues.

Required Texts

(Readings should be completed before coming to class!)

Title	Author	Edition
Law, Science and Medicine ("Text")*	Gostin, et al.	3d ed., Foundation Press (2005)
*Because the text is now out of print, readings are available on Blackboard for students who are unable to find a used copy of the book. In addition, copies of the textbook are on reserve in Himmelfarb library.		
Additional Required Readings available on Blackboard or distributed in class		

Methods of Instruction (check all that apply)

<input checked="" type="checkbox"/>	Lectures	<input checked="" type="checkbox"/>	Class and Small Group Discussions
<input checked="" type="checkbox"/>	Case Studies	<input checked="" type="checkbox"/>	Student-led Discussions
<input checked="" type="checkbox"/>	Required Readings/Textbook		
<input checked="" type="checkbox"/>	Required Readings on Blackboard		

Methods of Evaluation

Percent of Grade

Class Participation [attendance, careful preparation, thoughtful and insightful contributions to discussion that demonstrate mastery of the course material, written discussion questions, and leadership in discussion question assignments]	25
Substantial paper: Topic (5%) Outline (10%) Draft (25%) Peer Review (10%) Final Draft (25%)	75 (total)

Students will be graded on their class participation and substantive writings.

Grading Scale and Standards

A: 94-100%	C+: 77-79%
A-: 90-93%	C: 73-76%
B+: 87-89%	C-: 70-72%
B: 84-86%	F: Below 70%
B-: 80-83%	

Workload:

In this course, you will be expected to spend approximately 4-6 hours per week in independent learning, which can include reviewing assigned material, preparing for class discussions, working on assignments, and group work. In addition, you will spend an average of 2 hours per week in direct instruction.

Class Policy: Expectations for individual contributions and acceptable levels of collaboration for assignments on which students may work together

Collaboration among students outside of class is strongly encouraged. Assignments must be written independently, although it is acceptable to seek the opinions of others on drafts. Comprehensive academic research in peer-reviewed sources and rigorous citation of all sources will be expected. These guidelines will be discussed in more detail in class.

Class Policy: Attendance/Participation, and Discussion

Class attendance is mandatory. Class discussions showing careful preparation, rigorous thought, and an informed understanding of the subject matter will be an integral part of the learning process. *Please read and analyze all of the assigned materials before class to facilitate discussions.* All students will be expected to participate actively in class discussions. Students will also be expected occasionally to lead discussion on discussion questions assigned in class. **Absences will only be excused in extraordinary circumstances and must be discussed with the professor prior to class.**

Law, Medicine, and Ethics is a demanding course that requires students to think critically and utilize high-level analytical skills regarding complex issues. The discipline requires such mastery not only in well-articulated written work, but also in thoughtful discussions between and among students and instructors. Receiving full points for participation is not simply a matter of showing up and turning work in on time. Outstanding participation grades require truly thoughtful, insightful, and well-argued contributions and leadership in class that demonstrate a high level of mastery of the course material.

Class Policy: Use of laptop computers/Internet/mobile phones/tablets/electronic devices. Laptop computers/tablets may be used in class only for taking notes with wifi disabled. The Internet, mobile phones, or any other electronic communication device should not be used during class except in the case of an emergency. The instructor reserves the right to ban the use of electronic devices altogether if these guidelines are not followed.

Class Policy: Assignments.

Substantial paper: A 10-12 page paper suitable for peer-reviewed publication will be developed in stages throughout the semester. Details on each stage of the paper will be discussed in class. All assignments should be **typed, double-spaced, and in 12-point type with 1-inch margins.**

- Topic: Due at 4:00 p.m. on Tuesday, September 19, 2017
- Outline: Due at 4:00 p.m. on Tuesday, October 17, 2017
- Draft: Due at 4:00 p.m. on Tuesday, November 14, 2017
- Peer Review: Due at 4:00 p.m. on Tuesday, November 21, 2017
- Final Draft: Due at 4:00 p.m. on Friday, December 15, 2017

Class Policy: Late Work

Students must meet the due dates for all assignments. **Extensions will be granted only in extraordinary circumstances and must be discussed with the professor in advance of the due date.** Grades for unexcused late assignments will be reduced one step for each day the assignment is late (A to A-, B+ to B, etc.).

Class Policy: Make-up Work

Any student who experiences significant family or personal illness or emergency after the final withdrawal date and is unable to complete course work should ask the instructor for an incomplete for the course. Each case will be managed on an individual basis.

University Policy on Religious Holidays

- Students should notify faculty during the first week of the semester of their intention to be absent from class on their day(s) of religious observance.
- Faculty should extend to these students the courtesy of absence without penalty on such occasions, including permission to make up examinations.
- Faculty who intend to observe a religious holiday should arrange at the beginning of the semester to reschedule missed classes or to make other provisions for their course-related activities.

Blackboard

Blackboard will be used for posting course files and assignments and for communicating with the class. You are already enrolled for this course on Blackboard if you have completed registration for the course. It is your responsibility to periodically check the course site (log in at <http://blackboard.gwu.edu/> Using your gwu.edu address) for updates to the syllabus/readings.

Academic Integrity

All Milken Institute School of Public Health Students are required to complete two (separate) online activities regarding academic integrity -- the GW Academic Integrity Activity and the Identifying and Avoiding Plagiarism Activity. Both activities must be completed within 2 weeks of starting your coursework at Milken Institute School of Public Health. - See more at: <https://publichealth.gwu.edu/integrity - sthash.FIIRdO5H.dpuf>

Academic dishonesty is defined as cheating of any kind, including misrepresenting one's own work, taking credit for the work of others without crediting them and without appropriate authorization, and the fabrication of information. Common examples of academically dishonest behavior include, but are not limited to, the following: cheating; fabrication; plagiarism; falsification and forgery of University academic documents; facilitating academic dishonesty. For the remainder of the code, see <https://studentconduct.gwu.edu/code-academic-integrity>.

NOTE: Please type out and sign the following honor pledge at the end of each assignment:

“On my honor as a student of the George Washington University, I have neither given nor received assistance on this assignment.

[Signed: Your name]”

Support for Students Outside the Classroom

Disabilities Support Services (DSS)

Any student who may need an accommodation based on the potential impact of a disability, should contact the Disability Support Services office at 202.994.8250 in the Rome Hall, Suite 102, to establish eligibility and to coordinate reasonable accommodations. For additional information please refer to: <https://disabilitysupport.gwu.edu/>

Mental Health Services- 202-994-5300

The University’s Mental Health Services offers 24/7 assistance and referral to address students’ personal, social, career, and study skills problems. Services for students include: crisis and emergency mental health consultations, confidential assessment, counseling services (individual and small group), and referrals. <https://counselingcenter.gwu.edu/>

Adverse Weather/Class Cancellation

In the advent of inclement weather or any other emergency, the Milken Institute School of Public Health will follow the decision of the University. Call the University hotline at 202.994.5050 or check the Human Resources status button at <http://hr.gwu.edu/adverse-weather-conditions-and-emergency-situations>. In the event of class cancellation, the professor will email you about rescheduling, assignments due, etc.

Emergency Preparedness and Response Procedures

The University has asked all faculty to inform students of these procedures, prepared by the GW Office of Public Safety and Emergency Management in collaboration with the Office of the Executive Vice President for Academic Affairs.

To Report an Emergency or Suspicious Activity

Call the University Police Department at 202-994-6111 (Foggy Bottom) or 202-242-6111 (Mount Vernon).

Shelter in Place – General Guidance

Although it is unlikely that we will ever need to shelter in place, it is helpful to know what to do just in case. No matter where you are, the basic steps of shelter in place will generally remain the same.

- If you are inside, stay where you are unless the building you are in is affected. If it is affected, you should evacuate. If you are outdoors, proceed into the closest building or follow instructions from emergency personnel on the scene.
- Locate an interior room to shelter inside. If possible, it should be above ground level and have the fewest number of windows. If sheltering in a room with windows, move away from the windows. If there is a large group of people inside a particular building, several rooms may be necessary.
- Shut and lock all windows (for a tighter seal) and close exterior doors.
- Turn off air conditioners, heaters, and fans. Close vents to ventilation systems as you are able. (University staff will turn off ventilation systems as quickly as possible).
- Make a list of the people with you and ask someone to call the list in to UPD so they know where you are sheltering and who is with you. If only students are present, one of the students should call in the list.
- Await further instructions. If possible, visit GW Campus Advisories for incident updates (<http://CampusAdvisories.gwu.edu>) or call the GW Information Line 202-994-5050.

- Make yourself comfortable and look after one other. You will get word as soon as it is safe to come out.

Evacuation

An evacuation will be considered if the building we are in is affected or we must move to a location of greater safety. We will always evacuate if the fire alarm sounds. In the event of an evacuation, please gather your personal belongings quickly (purse, keys, GWorld card, etc.) and proceed to the nearest exit. Every classroom has a map at the door designating both the shortest egress and an alternate egress. Anyone who is physically unable to walk down the stairs should wait in the stairwell, *behind the closed doors*. Firemen will check the stairwells upon entering the building.

- Once you have evacuated the building, proceed to our primary rendezvous location: the court yard area between the GW Hospital and Ross Hall. In the event that this location is unavailable, we will meet on the ground level of the Science & Engineering Hall (800 22nd Street NW). From our rendezvous location, we will await instructions to re-enter the School.

Alert DC

Alert DC provides free notification by e-mail or text message during an emergency. Visit GW Campus Advisories for a link and instructions on how to sign up for alerts pertaining to GW. If you receive an Alert DC notification during class, you are encouraged to share the information immediately.

GW Alert

GW Alert provides popup notification to desktop and laptop computers during an emergency. In the event that we receive an alert to the computer in our classroom, we will follow the instructions given. You are also encouraged to download this application to your personal computer. Visit GW Campus Advisories to learn how.

Additional Information

Additional information about emergency preparedness and response at GW or the University's operating status can be found on GW Campus Advisories (<http://CampusAdvisories.gwu.edu>) or by calling the GW Information Line at 202-994-5050.

Session Outline

Session 1

September 5

Course Overview and Introduction

- a. Introduction to bioethics literature and analysis.
- b. Introduction to legislative issues in bioethics.
- c. Case study: HR 3200, Sec. 1233
- d. Case study: Ethical considerations for using untested interventions for Ebola virus disease (EVD)

Required Readings:

- 1) Vaughn, L. (2013). *Bioethics: principles, issues, and cases*. New York: Oxford University Press, c2013, Ch. 1-2
- 2) HR 3200, Sec. 1233 — 111th Congress (2009-2010)
- 3) Nyhan, B. (2010). Why the "Death Panel" Myth Wouldn't Die: Misinformation in the Health Care Reform Debate. *The Forum*, 8(1), ISSN (Online) 1540-8884.
- 4) Luhby, T., *CNN Money* and Aleccia, J., *Kaiser Health News*, Fake Obamacare "death panels" are back, Feb. 14, 2017
- 5) Department of Health and Human Services, Centers for Medicare & Medicaid Services (2016), *Advance Care Planning*.
- 6) Gostin, L.O., Lucey, D., Phelan, A. (2014). The Ebola Epidemic: A Global Health Emergency. *Journal of The American Medical Association*, 312(11), 1095-1096.
- 7) World Health Organization, "Ethical considerations for use of unregistered interventions for Ebola virus disease (EVD)."
- 8) McNeil Jr., D. New Ebola Vaccine Gives 100 Percent Protection, *The New York Times*, Dec. 22, 2016

In addition, please review the slide presentation, "Introduction to U.S. Legal System."

Defining Death

- a. Introduction to legal cases in bioethics.
- b. Legal/Medical/Ethical definitions of death.

Required Readings:

- 1) *State v. Guess*, 244 Conn. 761, 715 A.2d 643 (1998), plus notes, Text, pp. 976-981
- 2) Karen Grandstrand Gervais, *Advancing the Definition of Death: A Philosophical Essay*, plus notes, Text pp. 981-991
- 3) Curfman, G., Morrissey, S., & Drazen, J. (2008). Cardiac transplantation in infants. *The New England Journal Of Medicine*, 359(7), 749-750.
- 4) Boucek, M. M., Mashburn, C., Dunn, S. M., Frizell, R., Edwards, L., Pietra, B., & Campbell, D. (2008). Pediatric heart transplantation after declaration of cardiocirculatory death. *The New England Journal Of Medicine*, 359(7), 709-714.
- 5) Truog, R., & Miller, F. (2008). The dead donor rule and organ transplantation. *The New England Journal Of Medicine*, 359(7), 674-675.
- 6) Bernat, J. (2008). The boundaries of organ donation after circulatory death. *The New England Journal Of Medicine*, 359(7), 669-671.
- 7) Veatch, R. M. (2008). Donating hearts after cardiac death--reversing the irreversible. *The New England Journal Of Medicine*, 359(7), 672-673.
- 8) Kevin G. Munjal, Stephen P. Wall, Lewis R. Goldfrank, Alexander Gilbert, Bradley J. Kaufman, and Nancy N. Dubler, on behalf of the New York City uDCDD Study Group, "A Rationale in Support of Uncontrolled Donation after Circulatory Determination of Death," *Hastings Center Report*, 43, no. 1 (2013): 19-26.
- 9) Magnus, D. C., Wilfond, B. S., & Caplan, A. L. (2014). Accepting brain death. *The New England Journal Of Medicine*, 370(10), 891-894.

Withholding and Withdrawal of Life-Sustaining Treatment

- a. Decision-making competence.
- b. Surrogate decision-making.
- c. The "right" to die.
- d. Legal standards of review.

Required Readings:

- 1) *Cruzan v. Director, Missouri Dept. of Health*, 497 U.S. 261 (1990), plus notes, Text, pp. 1001-1017
- 2) The Multi-Society Task Force on PVS (1994). Medical Aspects of the Persistent Vegetative State *New England Journal Of Medicine*, 330, 1572-1579, plus correction, *New England Journal Of Medicine*, 333, 130
- 3) *In re Conroy*, plus notes, Text, pp. 1072-1081
- 4) Gostin, L.O. (2005). Ethics, the Constitution, and the dying process: the case of Theresa Marie Schiavo. *Journal of the American Medical Association*, 293(19): 2403-7.
- 5) Vegetative Patient Shows Signs of Awareness, Study Says, *The New York Times*, September 7, 2006
- 6) Spontaneous Movements Often Occur After Brain Death, *Science Daily*, Jan. 13, 2000
- 7) Wilkinson, D. J. (2011). A Life Worth Giving? The Threshold for Permissible Withdrawal of Life Support From Disabled Newborn Infants. *American Journal Of Bioethics*, 11(2), 20-32.
- 8) Pew Research Center. Living to 120 and beyond: Americans' views on aging, medical advance, and radical life extension. Washington, DC 2013.
- 9) Fewing, R., Kirk, T. W., & Meisel, A. (2014). A Fading Decision. *Hastings Center Report*, 44(3), 14-16.

ASSIGNMENT DUE BEFORE CLASS: PAPER TOPIC

Physician-Assisted Suicide: Legal Issues

- a. Euthanasia v. physician-assisted suicide: Legal distinctions.
- b. Statutory Law.
- c. Evolution of common law regarding the "right" to die and physician-assisted suicide.

Required Readings:

- 1) Gostin, L.O. (1997). Health law and ethics. Deciding life and death in the courtroom: from Quinlan to Cruzan, Glucksberg, and Vacco -- a brief history and analysis of constitutional protection of the 'right to die'. *Journal of the American Medical Association*, 278(18), 1523-1528.
- 2) Gostin, L.O. (2006). Physician-assisted suicide: a legitimate medical practice? *Journal of the American Medical Association*, 295(16), 1941-1943
- 3) *Washington v. Glucksberg*, 521 U.S. 702 (1997), and *Vacco v. Quill*, 521 U.S. 793 (1997), Text pp. 1035-1050
- 4) The Oregon Death with Dignity Act, Text, pp. 1050-1055
- 5) Current Annual Report on Oregon's Death with Dignity Act
- 6) Notes, Text, pp. 1056-1058
- 7) Teitelbaum, J., & Rosenbaum, S. (2007). Gonzales V. Oregon: Implications for Public Health Policy and Practice. *Public Health Reports* (1974-), (1). 122.
- 8) Robinson, J. (2010). Baxter and the Return of Physician-Assisted Suicide. *Hastings Center Report*, 40(6), 15-17.
- 9) Loggers, E., Starks, H., Shannon-Dudley, M., Back, A., Appelbaum, F., & Stewart, F. (2013). Implementing a Death with Dignity program at a comprehensive cancer center. *The New England Journal Of Medicine*, 368(15), 1417-1424.

Physician-Assisted Suicide: Ethical and Social Issues

- a. Euthanasia v. physician-assisted suicide: Ethical/moral distinctions.
- b. The role of trade organizations/medical societies.
- c. Policy v. law v. ethics/morals.

Required Readings:

- 1) A piece of my mind. It's over, Debbie. (1988). *Journal of the American Medical Association*, 259(2), 272.
- 2) "Debbie" Case Helps Euthanasia Cause, *Chicago Tribune*, March 20, 1988.
- 3) Quill, T. (1991). Death and dignity. A case of individualized decision making. *The New England Journal Of Medicine*, 324(10), 691-694.
- 4) Rachels, J. *Active and Passive Euthanasia*, plus notes, Text, pp. 1059-1062
- 5) Emanuel, E. J. (2016). Attitudes and Practices of Euthanasia and Physician-Assisted Suicide in the United States, Canada, and Europe. *Journal of The American Medical Association*, 316(1), 79-90.
- 6) American Medical Association, Council on Ethical and Judicial Affairs, Policies (Excerpt)
- 7) Murphy, T. F. (2011). A Philosophical Obituary: Dr. Jack Kevorkian Dead at 83 Leaving End of Life Debate in the US Forever Changed. *American Journal Of Bioethics*, 11(7), 3-6.
- 8) Raus, K., Sterckx, S., & Mortier, F. (2011). Is Continuous Sedation at the End of Life an Ethically Preferable Alternative to Physician-Assisted Suicide?. *American Journal Of Bioethics*, 11(6), 32-40.
- 9) Menzel, P. T., & Steinbock, B. (2013). Advance Directives, Dementia, and Physician-Assisted Death. *Journal of Law, Medicine & Ethics*, 41(2), 484-500.

Maternal-Fetal Relations: Ethical and Social Issues

- a. Ethical/social debates regarding maternal-fetal relations and abortion.
- b. Autonomous decision-making.

Required Readings:

- 1) Thomson, J.J. (1971). A Defense of Abortion. *Philosophy & Public Affairs*, 1(1), 47-66.
- 2) *In re A.C.*, 573 A.2d 1235 (D.C. 1990) (Excerpt)
- 3) *In re: Baby Boy Doe, A Fetus*, 260 Ill.App.3d 392, 198 Ill.Dec. 267, 632 N.E.2d 326 (1997), plus Notes, Text, pp. 1226-1236
- 4) Rhoden, N. K. (1987). Cesareans and samaritans. *The Journal of Law, Medicine & Ethics*, 15, 118–125. (Excerpt)
- 5) Cantor, J. (2012). Court-ordered care--a complication of pregnancy to avoid. *The New England Journal Of Medicine*, 366(24), 2237-2240.
- 6) Amnesty International, Ltd. (2017). Criminalizing Pregnancy: Policing Pregnant Women Who Use Drugs in the USA. (Executive Summary)

ASSIGNMENT DUE BEFORE CLASS: OUTLINEAbortion: Legal Jurisprudence

- a. Legal debates regarding abortion.
- b. Evolution of the common law.

Required Readings:

- 1) *Griswold v. Connecticut*, 381 U.S. 497 (1965), plus notes, Text, pp. 1134-1138
- 2) *Roe v. Wade*, 410 U.S. 113 (1973), majority opinion, Stewart concurring opinion, and Rehnquist dissent
- 3) *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992), plus notes, Text, pp. 1143-1161
- 4) *Gonzales v. Carhart*, 548 U.S. 938 (2006) (all opinions)
- 5) Orentlicher, D. (2011). The Legislative Process Is Not Fit for the Abortion Debate. *Hastings Center Report*, 41(4), 13-14.
- 6) Rosenbaum, Sara. When Common Sense and Public Health Prevail: *Whole Woman's Health v. Hellerstedt*. *HealthAffairsBlog*. July 1, 2016.
- 7) *Whole Woman's Health v. Hellerstedt*, 579 U.S. ____ , No. 15-274 (2016), majority opinion and Ginsburg concurring opinion.
- 9) Presidential Memorandum Regarding the Mexico City Policy, Jan. 23, 2017
- 10) Lo, N. C., & Barry, M. (2017). The Perils of Trumping Science in Global Health - The Mexico City Policy and Beyond. *The New England Journal Of Medicine*, 376(15), 1399-1401

Assisted Reproduction

- a. The meaning and interpretation of parental rights.
- b. Surrogate motherhood.
- c. Ethics and assisted reproduction.

Required Readings:

- 1) *Davis v. Davis*, 842 S.W.2d 588 (TN 1992), cert. denied, 507 U.S. 911, plus note, Text, pp. 1115-1124.
- 2) *In re Baby M*, 109 N.J. 396, 537 A.2d 1227 (1988), plus note, Text, pp. 1188-1198.
- 3) Notes, Text, pp. 1209-1213
- 4) Purdy, L. M. (1989), Surrogate Mothering: Exploitation Or Empowerment?. *Bioethics*, 3: 18–34. (Excerpt)
- 5) Susan Sherwin (1987). Feminist Ethics and In Vitro Fertilization, *Canadian Journal of Philosophy*, 17(Sup1), 264-284.
- 6) Cohen, E. Surrogate Offered \$10,000 to Abort Baby, *CNN.com* (March 6, 2013).
- 7) Ravitsky, V. (2012). Conceived and deceived: the medical interests of donor-conceived individuals. *The Hastings Center Report*, 42(1), 17-22.
- 8) Cohen, I., & Adashi, E. (2013). Made-to-order embryos for sale--a brave new world?. *New England Journal Of Medicine*, 368(26), 2517-2519.
- 9) Hookway, James. 2014. Thailand targets surrogacy practices amid scandals; government threatens to close door on major international hub for infertile couples. *Wall Street Journal* (Online), Aug 27, 2014.
- 10) Macer, D. (2014). Ethical Conditions for Transnational Gestational Surrogacy in Asia. *American Journal Of Bioethics*, 14(5), 1-2.

Stem Cells & Cloning

- a. Review of bioethics advisory commissions' recommendations regarding cloning and research involving embryonic and adult stem cells.
- b. Discussion of proper role of advisory commissions in public policy-making.
- c. Discussion of ethical/legal/policy debates regarding cloning and research involving stem cells.

Required Readings:

- 1) National Bioethics Advisory Commission, Cloning Human Beings, Executive Summary.
- 2) Childress, J.F. (1997). The Challenges of Public Ethics: Reflections on NBAC's Report, *The Hastings Center Report*, 27(5), 9-11.
- 3) President's Council on Bioethics, Human Cloning and Human Dignity, plus notes, Text, pp. 1213-1222.
- 4) Fletcher, J.C., The National Bioethics Advisory Commission's Report on Stem Cell Research: A Review, *ASBH Exchange* (2000).
- 5) Bush Vetoes Measure on Stem Cell Research, *NYT*, June 21, 2007.
- 6) Executive Order 13505, March 9, 2009, Removing Barriers to Responsible Scientific Research Involving Human Stem Cells.
- 7) 2009 Guidelines on Human Stem Cell Research. In Stem Cell Information [World Wide Web site]. Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services, 2011.
- 8) Davis, D.S. (2013). Not with a bang, but a whimper: *Sherley v. Sebelius*. *Hastings Center Report* 43(1), 17-18.
- 9) Stein, R. Scientists report possibly crucial advance in human embryonic stem cell research, *The Washington Post*, Oct. 5, 2011
- 10) Baker, M. Stem Cells Made by Cloning Adult Humans, *Nature*, April 28, 2014.
- 11) With three first-in-human trials, therapeutic stem cell science takes a bold step, *ScienceDaily* (October 20, 2014).

Genetics

- a. Discussion of ethical/moral/legal issues raised by advances in genetics.
- b. Discussion of privacy implications and recent legislation involving genetics.
- c. Discussion of ethics cases in genetics.

Required Readings:

- 1) Text: Decoding the Structure of Life, Text, pp. 6-11; Katskee v. Blue Cross/Blue Shield, 245 Neb. 808, 515 N.W.2d 645 (1994), plus notes, Text, pp. 25-28; Genetic Enhancement, Text, pp. 39-46.
- 2) Hudson, K., Holohan, M., & Collins, F. (2008). Keeping pace with the times--the Genetic Information Nondiscrimination Act of 2008. *New England Journal Of Medicine*, 358(25), 2661-2663.
- 3) Genetics and Public Policy Center, The Genetic Information Nondiscrimination Act.
- 4) Genetics and Public Policy Center, Information on The Genetic Information Nondiscrimination Act.
- 5) Donley, et al. (2012). Prenatal whole genome sequencing: just because we can, should we? *The Hastings Center Report*, 42 (4), 28-40.
- 6) Presidential Commission for the Study of Bioethical Issues, Privacy and Progress in Whole Genome Sequencing, Executive Summary.
- 7) Conley, J. (2013). Myriad, finally: Supreme Court surprises by not surprising. *Genomics Law Report*.
- 8) Parens, E., Appelbaum, P., Chung, W. (2013). Incidental Findings in the Era of Whole Genome Sequencing. *Hastings Center Report*, 43(4),16-19.
- 9) The National Academy of Sciences and National Academy of Medicine, Committee on Human Gene Editing: Scientific, Medical, and Ethical Considerations. Human Genome Editing: Science, Ethics, and Governance, Executive Summary
- 10) Belluck, P. In Breakthrough, Scientists Edit a Dangerous Mutation From Genes in Human Embryos. *The New York Times* (Aug. 2, 2017).
- 11) Cha, A.E. FDA cracks down on company marketing 'three-parent' babies. *Washington Post* (Aug. 8, 2017).
- 12) Malarkey, M.A. Letter to John Zhang dated Aug. 4, 2017.

ASSIGNMENT DUE BEFORE CLASS: PAPER DRAFT

Research with Human Subjects

- a. The evolution of human subjects research policy
- b. The Nazi Experiments
- c. Tuskegee
- d. Informed consent in research trials
- e. Guidelines for international research trials
- f. Case studies in research with human subjects

Required Readings:

- 1) Overview and the Nazi War Crimes Trials, plus notes, Text, pp. 871-885
- 2) Henry Beecher, *Ethics and Clinical Research*, plus notes, Text, pp. 886-890
- 3) Testimony of Fred Gray, plus notes, Text, pp. 890-894
- 4) Patricia King, *The Dangers of Difference*, Text, pp. 894-898
- 5) *Government Regulations*, Text, pp. 904-907
- 6) Department of Health and Human Services, Regulations on Protection of Human Subjects, plus notes, Text, pp. 907-914
- 7) U.S. Department of Health and Human Services (Jan. 18, 2017), Final rule enhances protections for research participants, modernizes oversight system, available at: <https://www.hhs.gov/about/news/2017/01/18/final-rule-enhances-protections-research-participants-modernizes-oversight-system.html>
- 8) Federal Policy for the Protection of Human Subjects, Final Rule, Executive Summary, 82 Fed. Reg. 7149 (Jan. 19, 2017)
- 9) CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects, plus notes, Text, pp. 918-924
- 10) Lurie, P., & Wolfe, S. M. (1997). Unethical trials of interventions to reduce perinatal transmission of the human immunodeficiency virus in developing countries. *The New England Journal Of Medicine*, 337(12), 853-856.
- 11) Angell, M. (1997). The ethics of clinical research in the Third World. *The New England Journal Of Medicine*, 337(12), 847-849.
- 12) Levine, R. J. (1998). Editorial: The 'Best Proven Therapeutic Method' Standard in Clinical Trials in Technologically Developing Countries. *IRB: Ethics and Human Research*, 20(1), 5-9.
- 13) Bloom, B. R. (1998). The Highest Attainable Standard: Ethical Issues in AIDS Vaccines. *Science*, 279(5348), 186-188.
- 14) Lynch, H. (2012). Ethical Evasion Or Happenstance And Hubris? *Hastings Center Report*, 42(2), 30-38.
- 15) Hudson, K.L., & Collins, F.S. (2013). Family matters. *Nature*, 500(7461), 141-142.

ASSIGNMENT DUE BEFORE CLASS: PEER REVIEW

Distributive Justice

- a. Theories of justice
- b. Legal rights and human rights
- c. Justice and health reform

Readings:

- 1) Social Justice, Text, pp. 633-636
- 2) Fried, C. (1976). Equality and Rights in Medical Care, *The Hastings Center Report*, 6(1), 29-34.
- 3) Daniels, N. (1985). *Just health care / Norman Daniels*. Cambridge [Cambridgeshire]; New York: Cambridge University Press, 1985, pp. 6-7.
- 4) Veatch, R. (1976). What is a 'Just' Health Care Delivery, in *Ethics and Health Policy*, Veatch, R. M. and Branson, R., eds. Cambridge, Mass: Ballinger Publishing Co. 131-142.
- 5) President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. Securing Access to Health Care: A Report on the Ethical Implications of Differences in the Availability of Health Services, Vol. 1. Washington, D.C.: U.S. Government Printing Office, 1983. Excerpt.
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- 7) Bayer, R., Callahan, D., Caplan, A. L., & Jennings, B. (1988). Toward Justice in Health Care. *American Journal of Public Health*, 78(5), 583-588.
- 8) Mariner, W. K., Glantz, L. H., & Annas, G. J. (2012). Reframing Federalism - The Affordable Care Act (and Broccoli) in the Supreme Court. *New England Journal Of Medicine*, 367(12), 1154-1158.
- 9) Jost, T.S. (2012). A Mutual Aid Society? *The Hastings Center Report*, 42(5), 14-16.
- 10) Sage, W. M. (2012), How Many Justices Does It Take to Change the U.S. Health System?. *Hastings Center Report*, 42: 27-33.

The Allocation of Health Care Resources

- a. Rationing
- b. Futile Care
- c. Macroallocation & Microallocation
- d. Case study: Oregon

Readings:

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- 5) Callahan, D. (1991). Ethics and priority setting in Oregon. *Health Affairs (Project Hope)*, 10(2), 78-87.
- 6) Brown, L. (1991). The national politics of Oregon's rationing plan. *Health Affairs (Project Hope)*, 10(2), 28-51.
- 7) Alakeson, V. (2008). Why Oregon went wrong. *BMJ: British Medical Journal*, 337a2044.
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- 9) Singer, P. Why We Must Ration Health Care, *The New York Times*, July 19, 2009.
- 10) Callahan, D. (2011). Rationing: Theory, Politics, and Passions. *The Hastings Center Report*, (2). 23.
- 11) Klugman, C. M. and Bard, J. S. (2013), Futility on the Border. *The Hastings Center Report*, 43: 11–12.
- 12) Blumenthal, N. P., Mendez, J. D., Smith, M. L. and Hyland, B. (2013), A Second Chance. *The Hastings Center Report*, 43: 12–13.

REMINDER: FINAL PAPER DUE DECEMBER 15, 2017, 5:00 PM