

Life, Death, & Human Subjects

PUBH 292.10, CRN 56610 (Two Credits)

Spring Semester, 2006

Wednesdays 4:10-6:00 p.m.

Ross 323

Instructors

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Text

B. Furrow et. al., *Bioethics: Health Care Law and Ethics (5th edition)* (West);
Supplemental readings provided by instructors

Office Hours

Professor Rosenbaum: Tuesdays, 1-3 p.m. and by appointment

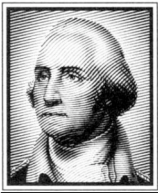
Professor Burke: Wednesdays, 1-3 p.m. and by appointment

Professor Singh: by appointment only

Professor Goldstein: by appointment only

Course Description

This course, structured to work in an intimate seminar style, is designed to address those issues in law, ethics and policy that focus on the scope and limits of individual autonomy within the health system. The issues covered in this course are highly related, and collectively they can be thought of as personhood issues. The specific foci of this course



are: reproductive health (abortion, family planning, and rights in pregnancy and childbearing); human sexual relations; refusal by both competent and non-competent persons of potentially lifesaving medical treatment; assisted suicide; research involving human subjects; and health care rationing.

Many of the materials covered in this course are sensitive, and this course aims to encourage searching, principled, and thoughtful discussion, grounded in law, ethics, and diversity of belief.

Course Objectives

- To learn about, explore, and better understand the complex legal and ethical considerations that flow from the interaction of individuals and the health system.
- To develop skills and analytic techniques for approaching sensitive health policy topics.
- To better understand all points of view in important debates such as abortion rights, human sexuality, individual patient autonomy, death and dying, assisted suicide, and health care rationing.
- To better understand the legal and ethical environment in which health research takes place.
- To read and interpret the laws and key judicial decisions governing the relationship between individuals and the health system, and to understand the evolution of these decisions and laws within a broader social, political, and cultural context.

Grading

Students will be tested on **both** their substantive writings **and** their ability to tackle and engage in classroom discussion. **The major work for the course will be a mid-term exam (take-home) and a final writing assignment (in-class) designed to measure your analytical ability to discuss the implications of the class topics.**

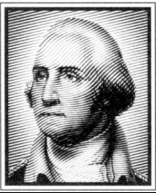
For each class, the syllabus includes “discussion points” for students to think about as they read. Please come to class prepared to comment on these points and contribute to general class discussion.

Mid-term exam.....35%
Final writing assignment (in-class)..... 45%
Class participation..... 20%

Academic Integrity

All students will be held to University Academic Integrity standards. Particularly important will be the avoidance of plagiarism in the preparation of analytic writing.

See <http://www.gwu.edu/~ntegrity/code.html#definition>.



Syllabus Spring 2006

INTRODUCTION

Class 1: January 18

Course Overview

Lead Professor: All

Objective:

- Review syllabus and course
- Explain US judicial system, the role of cases and case-law in the formation of the legal foundations of U.S. law
- Explain the process of legislation and the interaction of federal and state laws under the U.S. Constitution and in a health law context
- Review the major theories of bio-medical and legal ethics
- Overview of the ethical framework in which “personhood” legal decisions are made
- Examine the evolution of the legal concept of “privacy” and its roots

Readings:

- Text pp. 1-30

PART 1. HUMAN REPRODUCTION

Objective: to understand various aspects of the law of human reproduction, including abortion, sterilization, contraception, and birth; to read cases and statutory language

Class 2: January 25

Abortion

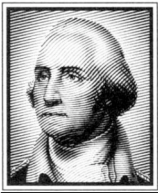
Lead Professor: Sara Rosenbaum

Readings:

- Text pp. 31-68 (Introduction; *Roe v Wade*; *Planned Parenthood v Casey*)
- Blackboard: *Planned Parenthood v Heed*

Discussion Points:

- In *Casey*, Justice O’Connor states that the Court is reaffirming *Roe*’s fundamental holding. Is this in fact true? If not, why not?
- Do *Roe* and *Casey* differ in how they balance the interests of the state against those of the woman? How?
- What differences if any do you see in how the role of physicians is dealt with in *Roe* and *Casey*?



- Should minors' right to *consent* to reproductive services equate with their right to *privacy* regarding the services they receive? If not, why not?

Class 3: February 1

Abortion

Lead Professor: Sara Rosenbaum

Assignment of teams/positions for Class 4 exercise

Readings:

- Text pp. 68-83 middle of the page (*Stenberg v. Carhart*)
- Blackboard: Public Law 108-105 (Partial Birth Abortion Ban Act of 2003); and *Carhart v Gonzales*

Discussion Points:

- The tragedy of mortally compromised fetuses is at issue in *Stenberg* and *Gonzales*. Think about the difference between an induced preterm delivery and a D&E or D&X procedure. Why might some parents prefer one procedure over the other? What role should the law play in shaping this choice?
- In reading the Partial Birth Abortion Ban Act and *Gonzales*, think about:
 - The name of the act
 - The potential reach of the act in terms application to first or second trimester abortions
 - The power of Congress to make decisions about whether certain medical procedures are medically necessary
- Why is the distinction between facts and law so critical to the outcome of *Gonzales*? How does this distinction help you understand the difference between courts and legislatures in the legal system? Why is it so crucial that the "health of the mother" exception is considered a Constitutional rule rather than a standard arrived at after Congressional fact-finding?

Class 4: February 8

In Class Exercise: The Case of the Morning-After Pill: Two Rapid Debates

The class will be divided into 5 teams, and each team will have a specific task as follows:

Team 1: prepare and present an overview of the Morning-After Pill issue (15 mins)

Team 2: debate the "pros" of question #1 (20 mins)

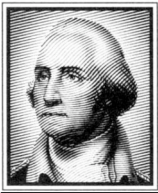
Team 3: debate the "cons" of question #1 (20 mins)

Team 4: debate the "pros" of question #2 (20 mins)

Team 5: debate the "cons" of question #2 (20 mins)

1. Should licensed pharmacists and pharmacies be able to exercise a "conscience clause"?

2. Should religious hospitals be able to exercise a "conscience clause" and not prescribe the morning after pill for victims of rape?



Teams must conduct their own outside research for this assignment in preparation for the in-class presentations.

Class 5: February 15

Abortion wrap-up/State Interest in Life

Lead Professors: Sara Rosenbaum & Taylor Burke

Readings:

- Text pp. 159-173 (Introduction; *In Re A.C.*)
- Blackboard: *State v. McKnight*

Discussion Points:

- Think about the state's interest in *In re A.C.* and *McKnight* versus the state's interest in the abortion cases. Does it make sense to you that depending on the circumstances, the state's interest in protecting life could outweigh other interests such as those of third parties or mothers?
- If the state intervenes in fetal-maternal decision making, what are the implications for extensions to the State's interests in ensuring prenatal care?
- What are the implications of genetic testing as they relate to:
 - Privacy and confidentiality? Physician duty to inform?
- Do you see any connections/differences in selective abortions versus genetic abortions?

PART 2. HUMAN SEXUALITY

Objective: to understand the legal context for human sexual intimacy not related to reproduction

Class 6: February 22

Human Sexuality; Same-gender marriage

Lead Professors: Taylor Burke & Tasmeen Singh

Readings:

Human Sexuality:

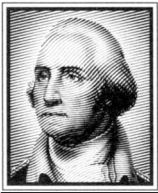
- Blackboard: *Lawrence v. Texas*; *State v. Limon*; Rosenbaum S., Burke T., "Lawrence v. Texas: Implications for Public Health Policy and Practice" Public Health Reports, August 2003.

Same-gender marriage:

- Blackboard: *Goodridge v. Massachusetts Dept. of Public Health*; Graglia, L. "Single-sex 'Marriage': The role of the courts" 2001 B.Y.U. L. Rev. 1013.

Discussion Points:

- Is/should human sexuality be related to reproduction in the eyes of the law?
 - Does the legal framework for human reproduction differ from social realities?
 - What implications does *Lawrence* have on the status of abortion law?
- What distinction does *Lawrence* make regarding the ability of the state to criminalize same gender sexual conduct? What precedent does this set for *Goodridge*?
- What is the state's interest in regulating marriage?



- How do these interests differ by same gender versus opposite gender marriage?
- Are they reflective of social norms?

PART 3: ENDING MEDICAL TREATMENT AND ASSISTED SUICIDE

Objective: to understand the legal and ethical context for decisions related to the refusal of treatment, as well as affirmative decisions to end life.

Class 7: March 1

Defining Death/Decisions by Competent Patients

Lead Professor: Taylor Burke

Readings:

- Text pp. 209-219 (Introduction; Uniform Determination of Death Act)
- Text pp. 238-243; 256-268 (Introduction; *Bowia v. Superior Court*)
- Blackboard: Rieff, D. “Illness as More Than a Metaphor”, New York Times Magazine, December 4, 2005; Kalkut, G., Dubler, N. “The Line Between Life and Death” The New York Times, May 10, 2005; Definition of Death Criteria Table.

Discussion Points:

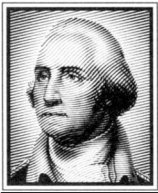
- What are the ethical principals that conflict when talking about death?
- What is the difference between higher and whole brain death? Why does it make a difference?
- In *Bowia*, who did the court decide should determine whether a competent adult can make a decision to forgo life threatening conditions—physicians/state or the person?
 - What special arguments present when someone once had decision making capacity and then lost it?
- What are the implications for organ donations?
- Should there be special considerations for anencephalic infants? Why or Why not?
- Do we have a right to die?
 - What is the conflict between a state’s interest in a person’s life and a self/guardian’s interest?
 - How are these decisions different in the case of a living person versus a fetus?
 - Where is the balance between protecting life and taking away liberty?

Class 8: March 8

Decisions by Incompetent Patients

Lead Professor: Taylor Burke

Assignment of take-home mid-term examination



Readings:

- Text pp. 243-256 (*Cruzan v. Director, Missouri Dept. of Health*)
- Text pp. 273-297 (Roth et al.; Uniform Health Care Decisions Act)
- Text pp. 327-336 (*Guardianship of Schiavo*)
- Blackboard: Schwartz, J “For End of Life, Hospital Pairs Ethics and Medicine”, New York Times, July 4, 2005; Bloche, M. “Managing Conflict at the End of Life” New England Journal of Medicine, June 9, 2005; Gostin, L. “Ethics, the Constitution, and the Dying Process” Journal of the American Medical Association, May 19, 2005; Death Decision Hierarchy Chart.

Discussion Points:

- In *Cruzan*, does the court recognize a constitutional right to die?
- What legal effect does an advanced directive have?
- How do you determine if someone has the competence to make decisions? Consider the criteria presented in the readings. Do they seem reasonable to you?
- Does the Uniform Health-care Decisions Act take into account all possible scenarios?
- What is the difference between a guardian, surrogate, or power of attorney?
- Did the legal structure for ending medical treatment work well in *Schiavo*? Why not?

No class March 15 – Spring Break

Class 9: March 22

Assisted Suicide

Lead Professor: Sara Rosenbaum

Due: Mid-term examination handed in at the beginning of class

Readings:

- Text pp. 365-398 (*Washington v. Glucksberg*; *Vacco v. Quill*; Oregon Death with Dignity Act; Report on Oregon Death with Dignity Act)

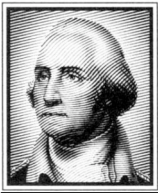
Discussion points:

- What is the fundamental interest presented in *Glucksberg*?
- What is the legal framework in the distinction between active and passive euthanasia?
- Do we have a right to commit suicide? Does the Constitution protect it? Do the courts recognize it?
- Is there a difference between the right to commit suicide and the right to ask assistance in doing so?
- If you could rewrite the Oregon Death with Dignity Act, how would you do so? Would you broaden it or make it narrower?

PART 4: RESEARCH ON HUMAN SUBJECTS

Class 10: March 29

Human Subject Research Overview/Ethics and Regulations



Lead Professor: Tasmeen Singh

Readings:

- Text: pp 408-422, 440-449
- Blackboard: Brandon, D. et al. "The Legacy of Tuskegee and Trust in Medical Care: Is Tuskegee Responsible for Race Differences in Mistrust of Medical Care?" Journal of the American Medical Association, July 2005; Wendler, D. et al. "Quantifying the Federal Minimal Risk Standard" Journal of the American Medical Association, August 17, 2005.

Discussion points:

- What constitutes research?
- Who is a human subject?
- Who is responsible for protecting human subjects?
- What role does the Nuremberg code play in regulating human subjects research today?

Class 11: April 5

Therapeutic and Non-therapeutic Trials

Lead Professor: Tasmeen Singh

Readings:

- Text: pp. 422-437 (*Grimes v. Kennedy Krieger Institute, Inc.*)
- Blackboard: The Case of Jesse Gelsinger; Meier, B. "Contracts Keep Drug Research Out of Reach" The New York Times, November 29, 2004; Montori, V. et al. "Randomized Trials Stopped Early for Benefit" Journal of the American Medical Association, November 2, 2005; Associated Press "AIDS Drug Tests On Foster Children Violated Rules" June 16, 2005

Discussion points:

- What is the difference between therapeutic and non-therapeutic research?
- What constitutes a vulnerable population?
- What special considerations do special populations present in conducting research?
- What are the implications of doing non-therapeutic research in vulnerable populations?
 - Is this research necessary? If so, how can vulnerable populations be protected?
- What is the role of the individual institution versus the federal government in protecting human subjects?

PART 5. ALLOCATION OF HEALTH CARE RESOURCES

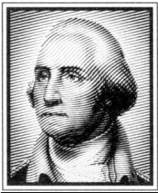
Class 12: April 12

Health Insurance as an Ethical Matter

Lead Professor: Sara Rosenbaum

Readings:

- Blackboard: Institute of Medicine, *Insuring America's Health*, Chapters 2, 4 and 5.



Discussion Points:

- In your view, what are the strengths and limitations of linking individual and community public health to the presence of universal health insurance coverage? Why do you think the IOM made this link an explicit basis of its recommendations? What are the ethical implications of such a link? Was all the fact finding really necessary?
- How would you characterize differences in the coverage models?
- Does universal coverage necessarily mean compulsory coverage?

Class 13: April 19

Macro Question of Coverage and Access: The Oregon Health Plan

Lead Professor: Melissa Goldstein

Readings:

- Blackboard: Callahan, D., "Ethics and Priority Setting in Oregon" Health Affairs 1991; Brown, L. "The National Politics of Oregon's Rationing Plan" Health Affairs 1991; 3 Web Links.

Discussion Points:

- Do you agree with the process Oregon used to develop the Oregon Health Plan? Why or why not? How, if at all, would you have designed the process differently?
- Do you believe that the Oregon Health Plan involves rationing? Why or why not? Explain your definition of rationing.
- What population(s) does the Oregon Health Plan apply to? Do you believe that those populations are fairly represented in the development of the Oregon Health Plan's Prioritized List of Health Services? Why or why not?
- Discuss the ethical principle of justice as applicable to the Oregon Health Plan.

Class 14: April 26

In-class final exam