

## SYLLABUS

**Book: Jerry Menikoff, Introduction to Law and Bioethics (listed pages)  
B-space will be regularly used to post additional readings**

**Week of May 23, 2011: Basics of Doctor-Patient Relationship**, pp. 151 - 184.  
**Distribution of Authority in Doctor-Patient Relationship:  
Consent, Refusal and Demand**,.

Plan for the Week

Initially, I will introduce core concepts of medical ethics and of law. We will then focus on one of the main building blocks of biomedical ethics: the doctor-patient relationship.

For Monday, May 23, please read pp. 151-154, pp. 170-175 and the posted article from BBC World News.

For Tuesday, May 24, please read pp. 154-170 and pp. 185-92. Also read the posted cases *Hidding v. Williams* and *Burton v. Brooklyn Doctors' Hospital*.

For Wednesday, May 25, please read pp. 192-207, pp. 356-376 and the posted case *In re Baby K*.

For Thursday, May 26, please read pp. 175-183

**Week of May 30, 2011: Meanings and Consequences of Death**, pp. 443 - 467.  
**Decision-making about Death**, pp. 241 - 355.  
**Pairs Problem #1**: Bring your Genes to Berkeley reading and essay assignment.

Plan for the week:

For Tuesday, May 31, please read pp. 443 – 467 (text). Please also read the N.J. statute section on death, and the articles by Greenberg and by Groopman, both from the *New Yorker*, both posted on b-space.

For Wednesday, June 1, see Stephen's posted reading assignment: excerpt from Shiffrin.

For Thursday, June 2, Read pp. 356 – 376. Continue on Greenberg and Groopman, both from the *New Yorker* and both posted on bspace. Also please read pp. 5-20 from Shah & Miller article also posted on bspace. Please print out and bring to class the CA Advanced Directive Form for Health Care posted on b-space.

**Week of June 5, 2011: Continuation of Death Decisions; Begin Issues in Genetics, Ownership and Transfer of Human Tissues/Organs,**

Plan for the week: a) Continuation of Death Decisions; b) Begin Genetic Issues and Ownership of tissues.

For Monday, June 6, please read the materials that are required for your first pairs essay (posted on b-space). Partners will meet during class on Monday. Please bring your blank California Advance Directive form to class again.

For Tuesday, June 7, please read pp. 256 - 271, 276 – 284.

For Wednesday, June 8, please read pp. 377 – 388 (*Katskee and Safer*). Please also read materials posted on b-space [Excerpts from Winickoff, excerpts from Iceland Activists.

For Thursday, June 9: Continuation of Winickoff, Iceland, and Beth Israel Hospital

**Week of June 12, 2011: Ownership of Tissue and Commodification.**

Plan for the Week of June 13 – June 16, 2011: Ownership of Body Tissue and Commodification:

For Monday, June 13, please read pp. 404 – 417. Please also read (1) excerpts from “Market Inalienability” by Peggy Radin in Harvard Law Review and 2) excerpts from two of my articles that comment on Radin’s work in Wisconsin Law Review and California Law Review. All are posted on b-space.

For Tuesday, June 14, please read Brotherton v. Cleveland, and Michele Goodwin’s article “Empires of the Flesh”, from U. Alabama Law Review, both posted on b-space.

For Wednesday, June 15, please read the article from the NYT on the Havasupai

For Thursday, June 16, Lecture on Reproductive Issues. pp. 417-38 (I have decided that it doesn’t make sense to spend several more days on reproductive issues when a sizable minority of the class has already studied these issues in detail and others of you may take a course in the future that is specialized on those questions. The issues we will deal with instead will involve Pharmaceutical Regulation.

**Week of June 19 - 23, 2011: Pharma Regulation,**

Plan for the Week of June 20 – 23

All readings for this coming week are on b-space unless otherwise noted; they are posted in the order assigned.

For Monday, June 20, please complete your reading for the second pairs problem and be ready to meet with your partner during Monday’s class. There is no additional reading for Monday’s class. In the second hour I will focus on filling in some holes in what we have covered in our work so far.

For Tuesday June 21, please read bspace Items #1 - #6 (you may skim item #2; it’s there for reference).

For Wednesday, June 22, please read Items #7 - #15. These are short pieces raising various issues in pharma regulation.

For Thursday, June 23, please read #16, the Abigail Alliance case.

**Week of June 26, 2011: Access to Care and the ACA. Racial disparities in access to health care.** Selection of readings will be posted on b-space.

Plan for the Week of June 27-30: Access to Care and Racial Disparities

For Monday, June 27, please read the materials numbered 1 – 6 (See assigned pages for Items 1 and 2 listed on the b-space file heading).

For Tuesday, June 28, please read materials numbered 7 – 9. (See assigned pages for item 7 on the b-space file heading).

For Wednesday, June 29, please read items 10 - 11. (See assigned pages for Item 10 on the b-space file heading).

There may be another reading or two added depending on our progress during the week.

## APPENDICES

### INSTRUCTIONS FOR PAIRS PROBLEMS

**Due Date:** Essays should be submitted by email. You will have 10 days to do the assignment with your partner and then write it up.

**Basic Arrangement:**

- Each pair should meet several times, as needed, to discuss the various aspects of the problem. These assignments are not mainly *research* problems; they are mainly *thinking* problems. No additional research is contemplated, nor is it likely to be helpful. The pair should discuss the relevant considerations, construct an analysis and an optimal resolution of the stated problem, and present it as well as possible, with points being supported by evidence and argument.
- You should depend mainly on readings assigned for this project; but you may also use any readings and class discussions that you wish. However, if you insist on doing some limited research beyond what has been assigned, *spend no more than two hours total for the pair*.
- One member of each pair will write up the pair's work on this first assignment; the other will be the writer for the second project. The author of the paper will have final responsibility for the product but must draw on and incorporate ideas and views of the other member. Building a quality work team is a major purpose of these assignments. Each of the pair members is responsible for the quality of the pair product, both its ideas and its presentation.

**Grading:** Grades for each project will be based on two elements.

- *First*, grades will depend on the quality of the product. Comprehensiveness (including consideration of counterarguments), depth and presentation matter. Be concrete rather than vague. *The particular view-point you present about the issue does not matter to your grade. There is no "right answer."*
- The grades for each paper will be assigned to each member of the pair; the score will count 20% of the overall grade for the non-writing member and 30% of overall grade for the writer; positions will be reversed on the second paper.

**Length and Form:** Papers should be no longer than 1500 words total (counting notes, subtitles, etc). State your word count at the end of the paper. Use font no smaller than 12 pt. No formal citations are required. If you use any, a simple form, (e.g. consent form, p. x; Text, p. x, Baby K, p. x) is fine for this purpose.

**Honor Code:** In addition to the requirements of the honor code generally, you affirm that you have honestly followed the instructions for this assignment. You can discuss the problem with your partner at any time; please do not discuss with others.

## SUBSTANTIVE PAIRS PROBLEM #1:

### The Berkeley Undergraduate Gene Test Problem

The controversy about the Berkeley gene testing project of 2010 has quieted down. Assume you have been hired as an outside consultant to evaluate the merits of the original plan as well as the project as it was actually implemented. Consider the materials provided for Problem #1 and any personal knowledge you may have, and write a report about the Gene Test plan.

Your report should analyze and evaluate the 2010 plan (original and actual) and make recommendations – based on evidence and argument -- about *whether* and *how* any similar project should be developed in the future. Be sure to evaluate counter-arguments as well as presenting your own views. Be as concrete as possible in stating and explaining your evaluation and recommendation(s). Would you suggest that any legal, regulatory, or legislative action be taken to control whether such plans can be conducted in the future? Why or why not?

## SUBSTANTIVE PAIRS PROBLEM #2

The Kennedy Krieger Research Institute (KKI), affiliated with Johns Hopkins University, conducted research to determine the comparative effectiveness of various methods of abating children's exposure to lead in their homes.

Several families sued KKI claiming that the informed consent process for the experiment was inadequate, that KKI had a duty to provide better warnings about the risks of the experiment and that KKI should have informed them of the results of their children's blood tests in a timely fashion.

There was a major public outcry against the University and KKI, prompting academic and op ed articles, as well as amicus briefs, and a request for reconsideration of the Court's opinion. You have an edited version of the Court's opinion and several supplemental pieces that defend the University against the Court's criticism, as well as excerpts from the federal regulations regarding consent and risk in research on human subjects, especially children. The Regulations are discussed in the opinion and in the other substantive material as well, and the excerpts from the Code itself are mostly for reference if necessary.

After you read the materials, write an essay analyzing whether you think the KKI experiment was legally and ethically sound. Key points you should address include:

- Was the research therapeutic or nontherapeutic (i.e., did it benefit the children in the study?)
- Did the study harm the children enrolled in it? If so, was there more than "minimal risk" of harm (see 45 CFR 46.102i)?
- In case the study was determined to present more than minimal risk, was it in your view nonetheless permissible under SubPart D Special Protections for Children set forth in 45 CFR 46.405, 45 CFR 46.406 or 45 CFR 46.407?

- Insofar as you can tell, did the consent process satisfy the general federal requirements for protecting subjects' autonomy through informed consent?
- Did the study contribute to or detract from just distribution of the benefits and burdens of research within society?

You may interweave your answers to the above questions or treat them separately. You may elect to answer all the above bullet questions or less than all, but you must address at least three.

Questions about legal terminology or procedure in the materials, please feel free to email me or Stephen.