Emerging Sciences and Technologies: Law, Policy & Ethics
LAW 6037/PA 8790/BTHX 8000
Fall 2015
3 Credits

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Office hours by appointment

Room: Mondale Hall 65

Time: Thursdays, 4:05-7:00

SCOPE

Emerging sciences and technologies (ES&Ts)—including, but not limited to, nanoscience and nanotechnology, genetics and genomics, cognitive science, neurotechnology, synthetic biology, information technology, and social robotics—enable revolutionary innovation across almost all sectors including medicine, energy, food and agricultural, materials and chemicals manufacturing, electronics, computing, defense, and many other. At the same time, ES&Ts are defined by considerable uncertainties and, as such, there is growing concern about potential adverse impacts including environmental, health, and safety (EHS) risks, privacy concerns, and a range of ethical, legal, and social implications (ELSI). These concerns are heightened governance structures and tools that are perceived by many as outdated, inadequate, or poorly equipped for handling the unique challenges posed by ES&Ts.

This course will take an interdisciplinary approach to examining the legal, public policy, social, economic, and ethical implications of nanotechnology. The course will explore the need to develop public policies for nanotechnology from the perspective of different stakeholders (federal agencies, the public, industry, the environment, international organizations, etc.) and examine and contrast different statutory objectives and regulatory strategies. Students will explore different research methodologies used in the various disciplines that study ELSI issues. Because nanotechnology is also a uniquely interdisciplinary field, requiring collaboration between scientists and engineers in virtually all the science disciplines, as well as social scientists, ethicists, lawyers and policy analysts, enrollment by students with a broad range of interests is encouraged. This course satisfies the 3L writing requirement for law students.

This interdisciplinary course will examine issues at the nexus of law, ethics, public policy, society, and ES&Ts. As ES&Ts are both shaping and shaped by a range of social, political, and cultural factors, we will spend considerable time exploring ways in which to conceptualize and study past, present, and future techno-social relationships, systems, and impacts. Topics we will explore include the role of science and technology as both a tool for and the subject of law and policy; the legal, ethical, economic, and policy implications of ES&T research and development; environmental and human health risk analysis and regulation (e.g., EPA, FDA, OSHA, and state and local regulatory mechanisms); intellectual property issues; liability issues; and global impacts. Topics will be approached from the perspective of different stakeholders (e.g., federal agencies, industry, academic researchers, the environment, international organizations, and the public) and in the context of different application areas (e.g., drugs, devices, food, agriculture, energy, environmental remediation). We will examine and contrast different statutory objectives, regulatory strategies, and governance approaches. We will also explore different research methodologies used in the various disciplines that study ELSI issues. Because ES&Ts also uniquely interdisciplinary fields that require collaboration between scientists and engineers from virtually all disciplines, as well as social scientists, ethicists, lawyers and policy analysts, enrollment by students with a broad range of interests is encouraged. There are no science or law prerequisites. This course satisfies the 3L writing requirement for law students.
GOALS

- Enhance understanding of the role of ES&Ts, and of science and technology more generally, as both a tool for and the subject of law and policy

- Enhance ability to think and approach ES&T problems in inter- and multi-disciplinary ways
  - Appreciate different research methodologies for studying ELSI issues

- Enhance understanding and ability to discuss:
  - What different ELSI concerns are or should be
  - Which actors bear or should bear responsibility for ES&T ELSI concerns
  - What the scope and limits of each actor’s responsibilities are or should be
  - Whether and how these responsibilities are or should be individual, collective, or both

- Increase understanding of the governance implications of ES&Ts and their applications, with special emphasis on legal and policy issues emerging in regulatory contexts

COURSE REQUIREMENTS

Readings, Participation & Attendance (30% of final grade)
This course deals with novel, complex, and often controversial questions for which there are seldom “right answers.” Consequently, our classroom time will be spent parsing, debating, and crystallizing these complex challenges.

Each course session (once per week) will require reading approximately 50-75 pages of material. Course readings will be pulled from a range of sources and available online through the course website (TBD). Because this is a new and rapidly developing field, reading materials will change and be updated during the course of the semester. Consequently, I do not recommend printing all the readings at once or reading too far ahead. You will be given ample notice of changes to the syllabus.

Each student will be expected to come to class having done the required reading in preparation, and to participate actively, including debating the key questions for that class. Active learning exercises will be incorporated into the class. If you do not participate, either by not listening or not speaking or both (please contact me if you are shy about speaking), your participation score will drop. If you are absent from class for reasons other than personal emergencies, your discussion grade for that class session will be 0. Work, field trips for other classes, seminars, trips, etc. are not emergencies. If a student has more than one non-emergency absence in the semester, see me for additional assignments.

Brief-Outline of Final Paper (20% of final grade)
In preparation for the final paper on a topic related to ELSI issues and ES&T, students will choose their topics and develop outlines for their papers by mid-semester. Each student will turn in a 2-4 page outline for his or her paper, including a concise problem statement that the paper will address. Each student will be asked to integrate the course readings into their topic, making connections between what has been covered in class and what the paper will cover.

Each paper should be typed and double-spaced, 20-30 pages long including footnotes or endnotes, and carefully proofread. Law students should use Bluebook form and footnotes. Other students should follow the citation format of a leading journal in their field (which should be identified on the cover page of the paper). For Law students who are 3Ls, the paper can satisfy the senior writing requirement; we will ask you to clarify by Class 4 whether you are submitting the paper to satisfy this requirement. Each student should get the instructors' approval of a paper topic by Class 4 by meeting with Profs. Van Ness or Fatehi.
Peer Review (10% of final grade)
Each student will each be asked to peer review the paper outlines of 2 other students. Review sheets will be used as a guide to provide feedback to the author.

Final Paper & Paper Presentation (40% of final grade)
At the end of the semester, each student will work to author a paper analyzing a novel, pressing, or controversial ELSI problem in the context of ES&Ts and presenting recommendations for what the legal, ethical, or policy response should be. This paper is an opportunity for original thinking: while it is important to show your mastery of the relevant literature, the thrust of the paper should be your own analysis and argument. Papers should *clearly state and articulate a position* on an unresolved legal, ethical, social, or policy problem and deploy a clear method of analysis. Interdisciplinary or multidisciplinary approaches to analysis are encouraged. We will discuss potential topics in mid-Oct. Expected length is 20-40 pages.* Papers should be in Times New Roman, 12 point font, and double-spaced with no greater than 1.25 inch left and right margins, 1 inch top and bottom. Students should use the citation style most suitable for the type of paper they are writing (i.e., Bluebook for legal papers, CMOS for social science papers, etc.). Each student will present his or her paper in a “public meeting” format in class, playing the role of a scholar presenting to decision makers or other suitable audiences. Each student will have 10-15 minutes to state the findings from his or her research and potential implications for decision making.

* This class has been approved for fulfillment of the 3L writing requirement. Third year law students using this course to fulfill the 3L writing requirement must complete a substantive research paper satisfying the requirements of Scholastic Requirement Rule 5.4. Scholastic Rule 5.4(1) states that students will satisfy this requirement “by receiving a grade of C- or above (or a grade of P) in a seminar, course, independent research paper, or other credited exercise which is certified by the supervising professor as satisfying the writing requirement through a written product of no fewer than twenty (20) pages, that is based on the student’s original research, employs standard legal citation, and is of at least near-publishable quality.”

Overall Grade
Grades will be given on a 4.0-0.0 scale corresponding to the letter grades A-F. Students may elect to take the course S/N. For Law students who do an exceptional job, having a 3.9-4.0 average in the course, an A+ will be given. (note A+ is not an option for grading for other graduate students)

Course Website
Readings, syllabi, and other materials will be posted in the course Google Drive folder. Please email instructor if you need access.

POLICIES
For anyone who has a disability which may require some modification of seating, testing, or other class requirements, appropriate arrangements may be made. Please see me after class or schedule a time to meet with me. Disability Services is located at 16 Johnston Hall.

If you are unsure about your performance feedback (aka grades) or anything else about the class, do feel free to talk to me about it. I am available through email and usually respond quickly.

Academic Misconduct: Examples of inappropriate conduct include, but are not limited to plagiarism. Make sure you know what plagiarism is before submitting your final papers. It involves any text taken verbatim from other sources that is not in quotations, or the use of another’s ideas without appropriate citation. In cases of misconduct, I will take appropriate actions, which could include filing a report with the Office for Student Academic Integrity. Violations will elicit penalties such as failing the assignment or failing grade for the entire course, depending upon the nature and severity of the infraction. To review the Regent’s policy on academic conduct, please refer to http://www.fpd.finop.umn.edu/groups/ppd/documents/summary/nutshelldetail.cfm?id=29.
TOPICS & READINGS

Week 1: September 10, 2015
Overview of Course
What are ES&Ts?
Mapping the course themes

Week 2: September 17, 2015
Epistemological questions
The relationship between S&T, law, ethics, and public policy


Week 3: September 24, 2015
Risk, Risk Perception, and Risk Governance
Geoengineering


Week 4: October 1, 2015
The relationship between S&T, law, ethics, and public policy, cont.
ES&T Policy and Governance


**Week 5: October 8, 2015**

**Environmental Risk Assessment and Oversight**

**EPA; Toxicogenomics; Nanomaterials**

42 U.S. Code § 7408

42 U.S. Code § 7409

National Research Council (US) Committee on Applications of Toxicogenomic Technologies to Predictive Toxicology. *Applications of toxicogenomic technologies to predictive toxicology and risk assessment*. National Academies Press (US), 2007. [read Chapter 6—don’t worry too much about the technicalities—just get the rough idea of what toxicogenomics can be used for]

*American Lung Ass'n v. EPA*, 134 F.3d 388 (D.C. Cir. 1998)

*American Trucking Associations v. USEPA*, 175 F.3d 1027 (D.C. Cir. 1999) [read introduction and section IV]


**Week 6: October 15, 2015**

**Human Health Applications; Human Subjects Research**

**FDA/NIH**


- Only read 1449-1456 and 1458-1459

- Read 93-107; bottom of 121-126 (stop before C); 131-136 (stop before C); 188-192 (stop at notes and questions); and 283-298.

**Week 7: October 22, 2015**

**FDA, cont. or TBD**

**Week 8: October 29, 2015**

***Paper topic & draft outline (Brief) due; peer comments***

**Biotechnology in Food and Agriculture**

**GEOs**


**Week 9: November 4, 2015**

**Intellectual Property Rights**

**Genes, Nanomaterials**


- Skip *Laboratory Corp. v. Metabolite*
- Stop after *Prometheus v. Mayo*
- DO THIS READING BEFORE NARD

- READ ANDREWS BEFORE THIS READING
- Read p. 1-25
- Its fine to skip over the repeated case facts for *Prometheus v. Mayo*

The legal back-and-forth (decisions and remands and appeals) with *Prometheus* and *Myriad* can get kind of confusing—if you’re confused, look it up. There are lots of articles laying out the order of events (Wikipedia does a nice job of it too)

**Week 10: November 5, 2015**
Global Implications


**Week 11: November 12, 2015**

**Constitutional Issues & Human Enhancement**

**Broader Ethical Implications**


**Week 12: November 19, 2015**

TBD

**Week 13: December 3, 2015**

**Week 14: December 8, 2015**

***Student paper presentations***

Course summary and synthesis

**FINAL PAPERS DUE 12/23 AT 11:59PM**